SCOLR Pharma, Inc.
Form 10-Q
May 02, 2008

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, 2008
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 o	Accelerated filer x
Non-accelerated filer o (Do not check if a smaller	Smaller reporting company o

reporting company)

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, 2008
Common Stock, par value $0.001	41,128,359

SCOLR Pharma, Inc.
FORM 10-Q

For the Three Months Ended March 31, 2008

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PART I: FINANCIAL INFORMATION

Item 1. Financial Statements

SCOLR Pharma, Inc.

CONDENSED BALANCE SHEETS

	March 31, 2008 (Unaudited)	December 31, 2007
ASSETS		
Current Assets		
Cash and cash equivalents	$ 9,459,276	$ 11,825,371
Accounts receivable	264,038	225,900
Interest and other receivables	185	16
Prepaid expenses	382,008	423,213
Total current assets	10,105,507	12,474,500
Property and Equipment — net of accumulated depreciation of $1,048,943 and $964,738, respectively	664,726	748,931
Intangible assets — net of accumulated amortization of $404,668 and $385,452, respectively	507,051	464,023
	$ 11,277,284	$ 13,687,454
LIABILITIES AND STOCKHOLDERS' EQUITY		
Current Liabilities		
Accounts payable	$ 214,300	$ 757,420
Accrued liabilities	348,437	586,849
Current portion of term loan	81,930	80,047
Total current liabilities	644,667	1,424,316
Long-term portion of term loan	89,917	111,119
Total liabilities	734,584	1,535,435
Commitments and Contingencies (Note 8)		
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 41,128,359 and 40,991,385 issued and outstanding as of March 31, 2008 and December 31, 2007, respectively	41,128	40,991
Additional paid-in capital	70,327,838	69,945,666
Accumulated deficit	(59,826,266)	(57,834,638)
Total stockholders' equity	10,542,700	12,152,019
	$ 11,277,284	$ 13,687,454

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,	
	2008	2007
Revenues		
Licensing fees	$ —	$ 173,077
Royalty	265,555	325,620
Research and development	—	621,222
Total revenues	265,555	1,119,919
Operating expenses		
Marketing and selling	237,693	249,882
Research and development	883,212	1,795,874
General and administrative	1,232,284	1,176,498
Total operating expenses	2,353,189	3,222,254
Loss from operations	(2,087,634)	(2,102,335)
Other income (expense)		
Interest income	100,319	204,976
Interest expense	(4,313)	(161)
Other	—	2,941
	96,006	207,756
Net Loss	$ (1,991,628)	$ (1,894,579)
Net loss per share, basic and diluted	$ (0.05)	$ (0.05)
Shares used in computing basic and diluted net loss per share	41,025,450	38,084,501

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,	
	2008	2007
Cash flows from operating activities:		
Net loss	$ (1,991,628)	$ (1,894,579)
Reconciliation of net loss to net cash used in operating activities		
Depreciation and amortization	104,863	92,262
Write-off of intangible assets	19,043	6,571
Loss on the disposal of equipment	—	5,700
Share-based compensation for non-employee services	—	25,742
Share-based compensation for employee services	342,222	404,655
Increase (decrease) in cash resulting from changes in assets and liabilities		
Accounts and other receivables	(38,307)	414,034
Prepaid expenses and other current assets	41,205	(16,545)
Accounts payable and accrued expenses	(781,532)	426,042
Deferred revenue	—	(185,577)
Net cash used in operating activities	(2,304,134)	(721,695)
Cash flows from investing activities:		
Purchase of equipment and furniture	—	(282,496)
Patent and technology rights payments	(82,729)	(110,783)
Purchase of short-term investments	—	(438,111)
Maturities and sales of short-term investments	—	985,939
Net cash (used) provided by investing activities	(82,729)	154,549
Cash flows from financing activities:		
Proceeds from term loan	—	246,500
Payments on term loan	(19,319)	—
Proceeds from exercise of common stock options and warrants	40,087	61,969
Net cash provided by financing activities	20,768	308,469
Net (decrease) in cash	(2,366,095)	(258,677)
Cash at beginning of period	11,825,371	15,217,946
Cash at end of period	$ 9,459,276	$ 14,959,269
Cash paid during the period for interest	$ 3,897	$ —
Non-cash investing and financing activities:		
Unrealized loss on short-term investments	$ —	$ (56)
Reclassification of fair value of warrant liability to equity	$ —	$ 1,171,045

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. (the "Company") 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. The balance sheet at December 31, 2007, 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, 2008. 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, 2007.

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 Pronouncements

In February 2007, the Financial Accounting Standards Board issued SFAS No. 159, "The Fair Value Option for Financial Assets and Financial Liabilities." SFAS 159 permits companies to fair value certain financial assets and liabilities on an instrument-by-instrument basis with changes in fair value recognized in earnings as they occur. The election to fair value a financial asset or liability is generally irrevocable. SFAS 159 is effective for fiscal years beginning after November 15, 2007. Adoption of this statement did not have a material impact on the Company's financial position or results of operations.

In September 2006, the FASB issued SFAS No. 157, "Fair Value Measurement" ("SFAS 157"). The Statement provides guidance for using fair value to measure assets and liabilities. The Statement also expands disclosures about the extent to which companies measure assets and liabilities at fair value, the information used to measure fair value, and the effect of fair value measurement on earnings. This Statement applies under other accounting pronouncements that require or permit fair value measurements. This Statement does not expand the use of fair value measurements in any new circumstances. Under this Statement, fair value refers to the price that would be received to sell an asset or

paid to transfer a liability in an orderly transaction between market participants in the market in which the entity transacts. SFAS 157 is effective for fiscal years beginning after November 15, 2007. The adoption of SFAS 157 did not have a material impact on the Company's financial position, results of operation or cash flows.

Note 3 – Accounts Receivable

At March 31, 2008, accounts receivable consisted of royalty receivables from CDT-based product sales.

Note 4 — Liquidity

The Company incurred a net loss of approximately $2.0 million for the three months ended March 31, 2008, and used cash from operations of approximately $2.3 million. Cash flows of $82,729 used by investing activities during the three months ended March 31, 2008, primarily represented patent and trademark related expenditures. Cash flow provided by

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financing activities of $20,768 for the three months ended March 31, 2008, primarily reflected net proceeds from the exercise of stock options and warrants during the quarter.

The Company had approximately $9.5 million in cash, and cash equivalents at March 31, 2008. The Company has a history of recurring losses and expects such net losses to continue as the Company proceeds with clinical trials and preclinical development for multiple product candidates and applies for regulatory approvals of product candidates. 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 December 4, 2007, and April 21, 2006, for approximately $4.2 million and $11.9 million respectively, 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, 2008, approximately $21.1 million remained available for issuance under this shelf registration statement which expires in November 2008. 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 5 — Income Taxes

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. 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. There were no unrecognized tax benefits as of December 31, 2007, or March 31, 2008. The Company does not anticipate any significant changes to its unrecognized tax benefits within the next twelve months.

Note 6 — Share-Based Compensation

During the three-month period ended March 31, 2008, the Company granted 86,500 shares of service-based, restricted stock awards. The fair value of these awards was $1.29 per share based on the fair market value at the grant date. The restrictions on the grants lapse at the end of the required three year service period. Stock compensation expense of $4,818 was included in the Company's results for the three months ended March 31, 2008.

Note 7 — 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 were 41,025,450 for the three months ended March 31, 2008, and 38,084,501 for the three months ended March 31, 2007.

At March 31, 2008, and 2007, the weighted average number of diluted shares does not include potential common shares which are anti-dilutive, nor does it include restricted stock awards if the measurement has not been met. The following potential common shares were not included in the calculation of diluted net loss per share as the effect would have been anti-dilutive.

Common shares from:	2008	2007
Assumed exercise of stock options	3,554,321	3,188,665
Assumed conversion of warrants	3,624,342	2,368,792
Assumed vesting of restricted stock	86,500	—
Total	7,265,163	5,557,457

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Note 8 — 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 9 — Warrants

During the three months ended March 31, 2008, 50,000 warrants with an exercise price of $1.00 were exercised. There were no new warrants issued during the quarter. The Company had the following warrants to purchase common stock outstanding at March 31, 2008:

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
June 25, 2003	476,191	1.16	5 years	452,943	June 25, 2008
February 24, 2004	1,046,773	4.75	5 years	944,849	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
December 4, 2007	1,390,550	2.10	5 years	1,390,550	December 3, 2012
Grand Total	3,749,514			3,624,342	

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

Note 10 – Subsequent Event

On April 30, 2008, the Company executed an agreement to terminate the existing lease for its corporate facility for consideration of $4.1 million. Under the terms of the agreement, $1.0 million was paid upon execution of the agreement and the remaining $3.1 million is due at the time the Company vacates the premises. The Agreement requires the Company to vacate the premises no later than October 31, 2008.

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 2007 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 expres identify certain of such forward-looking statements. Although we believe that our plans, intentions and expectations reflected in such forward-looking statements are reasonable, we can give no assurance that such plans, intentions or expectations will be achieved. Actual 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.

Overview

We are a specialty pharmaceutical company. Our corporate objective is to combine 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 based on multiple issued and pending patents and other intellectual property for the programmed release or enhanced performance of active pharmaceutical ingredients and nutritional products.

Our innovative drug delivery technologies enable us to formulate tablets or capsules that release their active agents predictably and programmably over a specified timeframe of up to 24 hours. Our platform is designed to reduce the frequency of drug administration, improve the effectiveness of the drug treatment, ensure greater patient compliance with a treatment program, reduce side effects, or increase drug safety. In addition, our technology can be incorporated into oral formulations to increase the solubility characteristics of previously non-soluble and sparingly-soluble drugs without employing costly or complex nano-crystalization, micro-milling or coated particle technologies.

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We have developed multiple private label extended-release nutritional products incorporating our CDT platform that are sold by national retailers. In October 2005, we entered into a strategic alliance with a subsidiary of Perrigo Company for the manufacture, marketing, distribution, sale and use of certain dietary supplement products in the United States. We receive royalty payments based on a percentage of Perrigo's net profits derived from the sales of products covered by our agreement.

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, 2007, 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, 2007, 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 February 2007, the Financial Accounting Standards Board issued SFAS No. 159, "The Fair Value Option for Financial Assets and Financial Liabilities." SFAS 159 permits companies to fair value certain financial assets and liabilities on an instrument-by-instrument basis with changes in fair value recognized in earnings as they occur. The election to fair value a financial asset or liability is generally irrevocable. SFAS 159 is effective for fiscal years beginning after November 15, 2007. Adoption of this statement did not have a material impact on the Company's financial position or results of operations.

In September 2006, the FASB issued SFAS No. 157, "Fair Value Measurement" ("SFAS 157"). The Statement provides guidance for using fair value to measure assets and liabilities. The Statement also expands disclosures about the extent to which companies measure assets and liabilities at fair value, the information used to measure fair value, and the effect of fair value measurement on earnings. This Statement applies under other accounting pronouncements that require or permit fair value measurements. This Statement does not expand the use of fair value measurements in any new circumstances. Under this Statement, fair value refers to the price that would be received to sell an asset or paid to transfer a liability in an orderly transaction between market participants in the market in which the entity transacts. SFAS 157 is effective for fiscal years beginning after November 15, 2007. The adoption of SFAS 157 did not have a material impact on the Company's financial position, results of operation or cash flows.

Results of Operations

Comparison of the Three Months Ended March 31, 2008 and 2007

Revenues

Total revenues decreased 76%, or $854,364 to $265,555 for the three months ended March 31, 2008, compared to $1.1 million for the same period in 2007. This decrease is primarily due to the higher level of research and development fees and licensing revenues in 2007 relating to a license agreement that was terminated in 2007.

Royalty income increased 19%, or $43,221 to $265,555 in the three months ended March 31, 2008 compared to the fourth quarter of 2007. This increase reflects the positive trend in sales of our nutritional products from our alliance with Perrigo. Royalty income decreased 18%, or $60,065 to $265,555 for the first quarter of 2008, compared to $325,620 for the same period in 2007. Royalty payments from Perrigo are based on Perrigo's net profits of CDT-based products which involve uncertainties and are difficult to predict. We expect these sales to increase during the remainder of 2008 as Perrigo expands sales at a large national retailer. Sales from our relationship with Nutraceutix remained substantially unchanged compared to the prior year. However, we expect these sales to decline as Nutraceutix sells through its inventory following termination of our license agreement as of December 31, 2007.

In the three months ended March 31, 2007, we received approximately $600,000 in research and development milestone payments, and we also recognized previously deferred licensing fee income of approximately $173,000 associated with our agreement with Wyeth. The December 2005 agreement with Wyeth provided for an upfront fee of $250,000 which

was recorded as deferred revenue and was being amortized over the development period until the contract was terminated in March 2007, at which time the remaining balance was recorded to income.

Operating Expenses

Marketing and Selling Expenses

Marketing and selling expenses decreased 5%, or $12,189 to $237,693 for the three months ended March 31, 2008, compared to $249,882 for the same period in 2007, primarily due to a reduction of $7,371 of non-cash, share-based compensation expense related to stock option grants. Additionally, advertising and tradeshow expense decreased $6,773 due a reduction in advertising, reduced participation in tradeshows, and commission expense decreased $4,363 due to lower royalty income. These expense decreases were offset by an increase in payroll related expenses due to annual increases.

Research and Development Expenses

Research and development expenses decreased 51%, or $912,662 to $883,212 for the three months ended March 31, 2008, compared to approximately $1.8 million for the same period in 2007. This decrease of $854,242 was primarily due to our previously reported decision to defer development activities on certain projects pending additional funding, as well as the delayed commencement of our third ibuprofen trial while we waited for guidance from the FDA regarding our special protocol assessment. In addition, non-cash, share-based compensation expense related to stock option grants decreased $94,955. These decreases were offset by increases of $22,995 in outside consulting expense related to regulatory efforts on our projects, $23,057 of depreciation and amortization expense, and $19,043 related to the write-off of long-term intangible assets. While we expect to proceed with additional clinical activities for extended-release ibuprofen during 2008, we expect our research and development expenditures to decline unless we obtain additional financing.

General and Administrative Expenses

General and administrative expenses increased 5%, or $55,786 to $1.2 million for the three months ended March 31, 2008, compared to $1.2 million for the same period in 2007, primarily due to increases in payroll related expenses and the non-cash, share-based compensation expense related to stock option grants.

Other Income (Expense), Net

Other income decreased 54%, or $111,750 to $96,006 for the three months ended March 31, 2008, compared to $207,756 for the same period in 2007. The decrease in interest income was a result of lower interest rates and lower cash balances.

Net Loss

Net loss increased 5%, or $97,049, to $2.0 million for the three months ended March 31, 2008, compared to $1.9 million for the same period in 2007. The increase was primarily due to reduced research and development contract revenues.

Liquidity and Capital Resources

As of March 31, 2008, we had $9.5 million of working capital compared to $14.7 million as of March 31, 2007. We had approximately $9.5 million in cash and cash equivalents as of March 31, 2008. On April 30, 2008 we agreed to a buyout of our corporate facility in exchange for a payment from the landlord of $4.1 million. Under the agreement, we

received an upfront payment of $1.0 million and the remaining $3.1 million is due when we vacate the premises no later than October 31, 2008. With the additional funding provided from this transaction after payment of relocation costs, together with reductions in certain operating costs, we believe that our cash and cash equivalents will be sufficient to fund our operations at planned levels through the end of 2009.

Cash flows from operating activities—Net cash used in operating activities for the three months ended March 31, 2008, was approximately $2.3 million compared to $721,695 for the three months ended March 31, 2007. Expenditures for the three months ended March 31, 2008, decreased substantially and operating revenues decreased due to lower royalty income and the lack of research and development revenue.

Cash flows from investing activities—Cash flows used by investing activities of $82,729 primarily represent payments made for patent rights during the three months ended March 31, 2008. Cash flows provided by investing activities of $154,549 during the three months ended March 31, 2007, primarily represented the application of maturing short-term investments to fund operating activities, off-set by purchases of equipment.

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Cash flows from financing activities— Cash flows provided by financing activities of $20,768 primarily represent the exercise of stock options and warrants offset by payments made on our term loan during the three months ended March 31, 2008. In the three months ended March 31, 2007, cash flows from financing activities primarily represented the proceeds from a term loan to purchase a piece of equipment to be used in our research and development activities. We received cash of $61,969 in the first quarter of 2007 from the exercise of outstanding stock options and warrants.

We expect our operating losses and negative cash flow to continue as the Company advances preclinical research, applies for regulatory approvals and development of its product candidates. 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.

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, 2008, approximately $21.1 million remains available for issuance under this shelf registration statement which expires in November 2008. Additional funds may not be available on favorable terms or at all. If adequate funds are not available, we may curtail operations significantly including the delay, modification or cancellation of research and development projects. 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.

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 2008 that have materially affected, or are reasonably likely to materially affect, our internal control over financial reporting.

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.

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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 $2.0 million through March 31, 2008, $10.6 million in 2007, $10.7 million in 2006, and $8.9 million in 2005. We have accumulated net losses of approximately $59.8 million from our inception through March 31, 2008, 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 and we 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 2008. 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 and the proceeds from the buyout of our corporate facility lease, will be sufficient to fund our drug delivery business at planned levels through early 2009. 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.

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.

Our limited experience in preparing applications for regulatory approval of our products, and our lack of experience in obtaining such approval, may increase the cost of and extend the time required for preparation of necessary applications.

Each OTC or pharmaceutical product we develop 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 help us prepare applications for 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. Our limited experience in preparing applications and obtaining regulatory approval could delay or prevent us from obtaining regulatory approval and could substantially increase the cost of applying for such approval.

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

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. For example, after submission of a marketing application, in the form of an NDA or ANDA, the FDA may deny the application, may require additional testing or data, and/or may require post marketing testing and surveillance to monitor the safety or efficacy of a product. In addition, the terms of approval of any marketing application, including the labeling content, may be more restrictive than we desire and could affect the marketability of products incorporating our controlled release technology.

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

If 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 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, FDA, Federal Trade Commission, 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 we develop 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 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 2008, 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 commercialization capabilities, which 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; or,

- 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. If any of our product candidates receive FDA or other regulatory authority approval, we will rely on third-party contractors to perform the manufacturing steps for our products on a commercial scale. We may be unable to identify manufacturers on acceptable terms or at all because the number of potential manufacturers is limited and the FDA and other regulatory authorities, as applicable, must approve any replacement manufacturer, including us, and we or any such third party manufacturer may be unable to formulate and manufacture our drug products in the volume and of the quality required to meet our clinical and commercial needs. We will be dependent upon these third parties to supply us in a timely manner with products manufactured in compliance with current good manufacturing practices (cGMPs) or similar manufacturing standards imposed by foreign regulatory authorities where our products will be tested and/or marketed. While the FDA and other regulatory authorities maintain oversight for cGMP compliance of drug manufacturers, contract manufacturers may at times violate cGMPs. The FDA and other regulatory authorities may take action against a contract manufacturer who violates cGMPs. We currently rely on Catalent Pharma Solutions, LLC (formerly Cardinal Health PTS, LLC) for the production of a number of our product candidates. If Catalent or other third party manufacturers are unable to provide adequate products and services to us, we could suffer a delay in our clinical trials and the development of or the submission of products for regulatory approval. In addition, we would not have the ability to commercialize products as planned and deliver products on a timely basis, and we may have higher product costs or we may be required to cease distribution or recall some or all batches of our products.

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.

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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. We do not carry key man 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.

If we fail to maintain an effective system of internal controls, we may not be able to accurately report our financial results or prevent fraud.

Effective internal controls are necessary for us to provide reliable financial reports and effectively prevent fraud. If we cannot provide reliable financial reports or prevent fraud, our operating results could be harmed.

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, 2008, 41,128,359 shares of our common stock were outstanding, and there were 7,265,163 shares of our common stock issuable upon outstanding options, restricted stock, and warrants. In addition, approximately $21.1 million in shares of our common stock will remain available for issuance under a shelf registration statement declared effective by the SEC in November 2005. Our stockholders may experience substantial dilution if we raise additional funds through the sale of equity securities, and sales of a large number of shares by us or by existing stockholders could materially decrease the market price of our common stock and make it more difficult for us to raise additional capital through the sale of equity securities. The risk of dilution and the resulting downward pressure on our stock price could also encourage stockholders 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.

Our stock price is subject to significant volatility.

The market price of our common stock could fluctuate significantly. Those fluctuations could be based on various factors in addition to those otherwise described in this report, including:

- general conditions in the healthcare industry;
- general conditions in the financial markets;
- our failure or the failure of our collaborative partners, for any reason, to obtain FDA approval for any of our products or products we license;
- for those products that are ultimately approved by the FDA, the failure of the FDA to approve such products in a timely manner consistent with the FDA's historical approval process;
- our failure, or the failure of our third-party partners, to successfully commercialize products approved by the FDA;
- our failure to generate product revenues anticipated by investors;
- problems with our sole contract manufacturer;
- the exercise of our right to redeem certain outstanding warrants to purchase our common stock;
- the sale of additional debt and/or equity securities by us;
-

announcements by us or others of the results of preclinical testing and clinical trials and regulatory actions, technological innovations or new commercial therapeutic products; and,

- developments or disputes concerning patent or any other proprietary rights.

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 special advance notice provisions for proposed business at annual meetings. In addition, Delaware and Washington law contain certain provisions that may have the effect of delaying, deferring or preventing a hostile takeover of our company. Further, we have a stockholder rights plan that is designed to cause substantial dilution to a person or group that attempts to acquire our company without approval of our board of directors, and thereby make a hostile takeover attempt prohibitively expensive for a potential acquiror. These

provisions, among others, may have the effect of making it more difficult for a third party to acquire, or discouraging a third party from attempting to acquire, control of our company, even if stockholders may consider such a change in control to be in their best interests, which may cause the price of our common stock to suffer.

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Item 6. Exhibits

The following exhibits are filed herewith:

Exhibit No.	Description	Filed Herewith	Incorporated by Reference 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 2, 2008	By:	/s/ Daniel O. Wilds Daniel O. Wilds Chief Executive Officer and President (Principal Executive Officer)
Date: May 2, 2008	By:	/s/ Richard M. Levy Richard M. Levy Chief Financial Officer and Vice President - Finance (Principal Financial Officer)

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