

SCOLR Pharma, Inc.
Form 10-Q
August 07, 2009

UNITED STATES

SECURITIES AND EXCHANGE COMMISSION
Washington, D.C. 20549

FORM 10-Q

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

For the quarterly period ended June 30, 2009

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
(State or other jurisdiction of
incorporation or organization)

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

19204 North Creek Parkway, Suite 100, Bothell, Washington 98011
(Address of principal executive offices)

425-368-1051
(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 No ..

Indicate by check mark whether the registrant has submitted electronically and posted on its corporate Web site, if any, every Interactive Data File required to be submitted and posted pursuant to Rule 405 of Regulation S-T (§232.405 of this chapter) during the preceding 12 months (or for such shorter period that the registrant was required to submit and post such files). Yes .. No ..

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Indicate by check mark whether the registrant is a large accelerated filer, an accelerated filer, or a non-accelerated filer, or a smaller reporting company (as defined in Rule 12b-2 of the Exchange Act).

Large accelerated filer Accelerated filer
Non-accelerated filer (Do not check if a smaller reporting company) Smaller reporting company

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 August 3, 2009 |
|---------------------------------|---|
| Common Stock, par value \$0.001 | 41,098,270 |

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FORM 10-Q

For the Quarterly Period Ended June 30, 2009

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PART I: FINANCIAL INFORMATION

Item 1. Financial Statements

SCOLR Pharma, Inc.

CONDENSED BALANCE SHEETS
(Unaudited)

| | June 30, 2009 | December 31, 2008 |
|---|------------------|----------------------|
| ASSETS | | |
| Current Assets | | |
| Cash and cash equivalents | \$ 3,128,839 | \$ 6,363,243 |
| Accounts receivable | 203,072 | 177,253 |
| Interest and other receivables | 4,822 | 1,157 |
| Prepaid expenses and other assets | 350,631 | 286,359 |
| Total current assets | 3,687,364 | 6,828,192 |
| Property and Equipment — net of accumulated amortization of \$1,594,032 and \$1,289,844, respectively | 682,806 | 790,947 |
| Intangible assets — net of accumulated amortization of \$473,307 and \$465,724, respectively | 560,046 | 557,639 |
| Restricted cash | 473,711 | 473,711 |
| | \$ 5,403,927 | \$ 8,650,489 |
| LIABILITIES AND STOCKHOLDERS' EQUITY | | |
| Current Liabilities | | |
| Accounts payable | \$ 75,949 | \$ 238,701 |
| Accrued liabilities | 660,179 | 668,694 |
| Current portion of term loan | — | 87,850 |
| Total current liabilities | 736,128 | 995,245 |
| Deferred rent | 284,530 | 310,010 |
| Long-term portion of term loan | — | 23,269 |
| Total liabilities | 1,020,658 | 1,328,524 |
| Commitments and Contingencies | | |
| 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 41,098,270 and 41,130,270 issued and outstanding as of June 30, 2009, and December 31, 2008, respectively | 41,098 | 41,130 |
| Additional paid-in capital | 71,795,099 | 71,255,901 |
| Accumulated deficit | (67,452,928) | (63,975,066) |
| Total stockholders' equity | 4,383,269 | 7,321,965 |

\$ 5,403,927 \$ 8,650,489

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 June 30, | | Six months ended June 30, | |
|---|--------------------------------|----------------|------------------------------|----------------|
| | 2009 | 2008 | 2009 | 2008 |
| Revenues | | | | |
| Royalty income | \$ 230,789 | \$ 279,571 | \$ 402,561 | \$ 545,126 |
| Total revenues | 230,789 | 279,571 | 402,561 | 545,126 |
| Operating expenses | | | | |
| Marketing and selling | 39,468 | 191,047 | 146,051 | 428,739 |
| Research and development | 793,503 | 1,197,321 | 1,615,437 | 2,080,533 |
| General and administrative | 972,884 | 1,062,646 | 2,126,535 | 2,294,930 |
| Total operating expenses | 1,805,855 | 2,451,014 | 3,888,023 | 4,804,202 |
| Loss from operations | (1,575,066) | (2,171,443) | (3,485,462) | (4,259,076) |
| Other income (expense) | | | | |
| Interest income | 2,040 | 59,353 | 11,112 | 159,671 |
| Interest expense | (1,082) | (3,859) | (3,512) | (8,172) |
| Other | - | 1,238 | - | 1,238 |
| Total other income | 958 | 56,732 | 7,600 | 152,737 |
| Net loss | \$ (1,574,108) | \$ (2,114,711) | \$ (3,477,862) | \$ (4,106,339) |
| Net loss per share, basic and diluted | \$ (0.04) | \$ (0.05) | \$ (0.08) | \$ (0.10) |
| Shares used in computing basic and diluted net loss per share | 41,098,270 | 41,128,590 | 41,098,270 | 41,100,676 |

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

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SCOLR Pharma, Inc.

CONDENSED STATEMENTS OF CASH FLOWS
(Unaudited)

| | Six months ended June 30, | |
|--|------------------------------|----------------|
| | 2009 | 2008 |
| Cash flows from operating activities: | | |
| Net loss | \$ (3,477,862) | \$ (4,106,339) |
| Reconciliation of net loss to net cash used in operating activities | | |
| Depreciation and amortization | 248,092 | 209,614 |
| Write-off of intangible assets | 79,859 | 36,073 |
| Share-based compensation for employee services | 575,626 | 615,876 |
| Increase (decrease) in cash resulting from changes in assets and liabilities | | |
| Accounts and other receivables | (29,484) | (52,227) |
| Prepaid expenses and other current assets | (64,092) | (152,963) |
| Accounts payable and accrued expenses | (318,442) | (658,993) |
| Deferred gain on lease termination | — | 1,000,000 |
| Net (cash used) in operating activities | (2,986,303) | (3,108,959) |
| Cash flows from investing activities: | | |
| Purchase of equipment and furniture | (95,419) | — |
| Proceeds from insurance settlement | 85,267 | — |
| Patent and technology rights payments | (126,798) | (129,354) |
| Restricted cash | — | (564,000) |
| Net (cash used) by investing activities | (136,950) | (693,354) |
| Cash flows from financing activities: | | |
| Payments on term loan | (111,119) | (39,092) |
| Proceeds from exercise of common stock options and warrants | (32) | 40,086 |
| Net (cash used) provided by financing activities | (111,151) | 994 |
| Net (decrease) in cash | (3,234,404) | (3,801,319) |
| Cash at beginning of period | 6,363,243 | 11,825,371 |
| Cash at end of period | \$ 3,128,839 | \$ 8,024,052 |
| Cash paid during the period for interest | \$ 2,786 | \$ 7,414 |

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, 2008 has been derived from the audited financial 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, 2009. 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, 2008.

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 December 2007, the FASB issued SFAS No 141(R), Business Combinations (SFAS No. 141(R)). SFAS No. 141(R) replaces SFAS No. 141, Business Combinations (“SFAS No. 141”), however retains the fundamental requirements that the acquisition method of accounting be used for all business combinations and for an acquirer to be identified for each business combination. SFAS No. 141(R) requires an acquirer to recognize the assets acquired, liabilities assumed, and any noncontrolling interest in the acquiree at the acquisition date, at their fair values as of that date, with specified limited exceptions. Changes subsequent to that date are to be recognized in earnings, not goodwill. Additionally, SFAS No. 141(R) requires costs incurred in connection with an acquisition be expensed as incurred. Restructuring costs, if any, are to be recognized separately from the acquisition. The acquirer in a business combination achieved in stages must also recognize the identifiable assets and liabilities, as well as the noncontrolling interests in the acquiree, at the full amounts of their fair values. SFAS No. 141(R) is effective for business combinations occurring in fiscal years 2009 or after.

In May 2009, the FASB issued SFAS No. 165, "Subsequent Events." SFAS No. 165 defines subsequent events as transactions that occur after the balance sheet date but before financial statements are issued or are available to be issued. SFAS No. 165 defines two types of subsequent events: (i) events or transactions that provide additional evidence about conditions that existed at the date of the balance sheet, including the estimates inherent in the process of preparing financial statements (that is, recognized subsequent events); and (ii) events that provide evidence about conditions that did not exist at the date of the balance sheet but arose after that date (that is, nonrecognized subsequent events). In addition, SFAS No. 165 requires an entity to disclose the date through which subsequent events have been evaluated, as well as whether that date is the date the financial statements were issued or the date the financial statements were available to be issued. SFAS No. 165 is effective for periods ending after June 15, 2009. The adoption of SFAS No. 165 effective June 30, 2009 did not have any effect on our financial position, results of operations or cash flows.

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In June 2009, the Financial Accounting Standards Board (“FASB”) issued SFAS No. 168 “FASB Accounting Standards Codification™ and the Hierarchy of Generally Accepted Accounting Principles—a replacement of FASB Statement No. 162.” SFAS No. 168 will become the source of authoritative U.S. generally accepted accounting principles (“GAAP”) recognized by the FASB to be applied by nongovernmental entities. Rules and interpretive releases of the Securities and Exchange Commission (“SEC”) under authority of federal securities laws are also sources of authoritative GAAP for SEC registrants. This Statement is effective for financial statements issued for interim and annual periods ending after September 15, 2009. On the effective date, the Codification will supersede all then-existing non-SEC accounting and reporting standards. All other non-grandfathered, non-SEC accounting literature not included in the Codification will become non-authoritative. As we believe that our accounting practices are consistent with the Codification, we do not believe that the adoption of SFAS No. 168 will have a material effect on our financial position, results of operations or cash flows.

In June 2008, the FASB issued FASB Staff Position EITF 03-6-1, “Determining Whether Instruments Granted in Share-Based Payment Transactions Are Participating Securities.” This position states that unvested share-based payment awards that contain nonforfeitable rights to dividends (whether paid or unpaid) are participating securities and shall be included in the computation of earnings per share (EPS) under the two-class method described in paragraphs 60 and 61 of FASB Statement No. 128, “Earnings per Share.” FSP EITF 03-6-1 is effective for financial statements issued for fiscal years beginning after December 15, 2008. The adoption of EITF 03-6-1 in the current year did not have an effect on the Company’s calculation of EPS for the three and six months ended June 30, 2009 and 2008.

Note 3 – Accounts Receivable

At June 30, 2009, accounts receivable consisted of royalty receivables from Controller Delivery Technology (CDT)-based product sales.

Note 4 — Liquidity

The Company incurred a net loss of approximately \$3.5 million for the six months ended June 30, 2009, and used cash from operations of approximately \$3.0 million. Cash flows of \$136,950 used by investing activities during the six months ended June 30, 2009, represents \$95,419 for equipment purchases plus \$126,798 in patent and trademark related expenditures. These amounts were offset by \$85,267 in proceeds from an insurance settlement. Cash flows used by financing activities for the period ended June 30, 2009, reflects payments on term loan of \$111,119 through April 2009, at which time the loan was paid off.

The Company had approximately \$3.1 million in cash and cash equivalents, and \$473,711 in restricted cash, related to our facility lease, as of June 30, 2009. The Company is investing its cash and cash equivalents in government-backed securities. These securities are considered level 1 securities in accordance with FASB 157 “Fair Value Measurements” as the securities have quoted prices in active markets. Based on our current operating plan, the Company anticipates that its existing cash and cash equivalents, together with expected royalties from third parties, will be able to fund its operations until late 2009, assuming the Company does not trigger additional obligations, including contractual severance or lease obligations, and unless unforeseen events arise that negatively impact its liquidity.

The Company’s current operating strategy is to actively manage liquidity by limiting clinical and development expenses to its ibuprofen and pseudoephedrine lead products while supporting existing alliances and collaborations. The Company has deferred all significant expenditures on development projects, including the actual use study required by the FDA as a prerequisite to submission of its regulatory application for ibuprofen, pending additional

financing or partnership support. Without additional revenues or funding the Company does not expect to be able to complete development of its current projects. The Company continues to evaluate opportunities to reduce operating expenses, including renegotiating the lease of its corporate facility and restructuring management (including renegotiating employment agreements and reducing the number of executives). The Company did not pay the full lease payment due on its facility in July and August 2009 (although the full amount due was accrued) and the landlord may claim a default and seek to accelerate payments or exercise other rights (including drawing on the letter of credit collateralized by \$473,711 in restricted cash) provided in the lease.

The Company expects its operating losses and negative cash flow to continue as it advances preclinical research and related work to support applications for regulatory approvals and commercialization of its product candidates. We need to generate additional revenues or raise additional capital to fund operations, continue research and development projects, and commercialize our products. In April 2009, the Company engaged HealthPro BioVentures LLC, a life science investment bank and strategic advisory firm, as its financial advisor in connection with the evaluation of various prospective transactions, and identifying and evaluating potential strategic partners. In addition, in May 2009, the Company engaged an additional investment bank to explore the opportunity to seek additional financing and strategic partners. The Company may not be able to secure additional financing on favorable terms, or at all. If the Company is unable to obtain necessary additional financing, its business will be adversely affected and it may be required to reduce the scope of its development activities or discontinue operations.

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The Company's capital resources are very limited and operations to date have been funded primarily with the proceeds from public equity financings, royalty payments, and collaborative research agreements. The Company is pursuing additional sources of financing that could involve strategic transactions, including mergers and business combinations, new partnerships as well as opportunities to expand product sales and other options. However, there are significant uncertainties as to the Company's ability to access potential sources of capital. The Company may not be able to enter any strategic transaction or collaboration on terms acceptable, or at all, due to conditions in the pharmaceutical industry or in the economy in general. Competition for such arrangements is intense, with many specialty pharmaceutical companies attempting to secure alliances with more established pharmaceutical or consumer products companies. Although the Company has been engaged in discussions with potential partners, there is no assurance that any agreements will result from these discussions in a timely manner, or at all, or that revenues generated by such agreements will offset operating expenses sufficiently to reduce its short term funding requirements.

In addition to efforts to enter into collaboration and licensing agreements, the Company plans to continue to seek access to the capital markets to fund its operations. The Company filed a shelf registration statement in the amount of \$40 million which was declared effective by the Securities and Exchange Commission on November 25, 2008 under which it may offer from time-to-time, one or more offerings of securities up to an aggregate public offering price of \$40 million. However, the financial markets have been very difficult for entities in the Company's development stage and financial condition and there can be no assurance that financing will be available on favorable terms or at all. Additionally, as described below, the Company has received notice from the NYSE Amex that it is not in compliance with continued listing requirements. While the Company has provided the NYSE Amex with a plan to regain compliance with applicable listing standards, its inability to maintain listing of its common stock on the NYSE Amex may further limit its ability to access the capital markets. Any issuance of additional securities would be extremely dilutive to the Company's existing stockholders.

The Company's failure to raise capital, including financial support from partnerships or other collaborations, in 2009 would materially adversely affect its business, financial condition and results of operations, and could force it to reduce or cease operations. If the Company is forced to reduce or cease operations it may trigger additional obligations, including contractual severance obligations aggregating as much as \$1.5 million. In addition, the Company may be forced to liquidate assets at reduced levels due to its immediate liquidity requirements. These conditions raise substantial doubt about the Company's ability to continue as a going concern. Consequently, the audit report prepared by the Company's independent registered public accounting firm relating to its financial statements for the year ended December 31, 2008 included a going concern explanatory paragraph.

On June 25, 2009 the Company received notice from the NYSE Amex LLC that it was not in compliance with Section 1003(a)(iii) of the NYSE Amex Company Guide with stockholders' equity of less than \$6,000,000 and losses from continuing operations and net losses in its five most recent fiscal years. As allowed by Exchange rules, the Company submitted a plan of compliance on July 29, 2009, advising the Exchange of action it has taken and will take, to regain compliance with Section 1003(a)(iii) of the Company Guide by December 27, 2010. The Exchange will evaluate the submitted plan and determine whether the plan includes a reasonable demonstration of an ability to regain compliance with the continued listing standards within the specified timeframes, in which case the plan will be accepted. However, there can be no assurance that such plan will be accepted by the Exchange. If the submitted plan is not accepted by NYSE Amex, or if the plan is accepted but the Company is not in compliance with the continued listing standards within the appropriate time period, or if the Company does not make progress consistent with the plan during the plan period, the Company may become subject to delisting proceedings.

Note 5 — Bank Term Loan

In April 2009, the Company paid off the term loan relating to research and development equipment purchased by the Company. Under the terms of the loan, there was no prepayment penalty.

Note 6 — 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, 2008, or June 30, 2009. The Company does not anticipate any significant changes to its unrecognized tax benefits within the next twelve months.

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Note 7 — Share-Based Compensation

In June, at the annual meeting, the shareholders approved an amendment to our 2004 Equity Incentive Plan (the “Plan”) to increase by 3,000,000 the maximum number of shares of common stock that may be issued under that Plan.

During the three-month period ended June 30, 2009, and 2008, the Company granted 92,500 and 905,000 stock options, respectively, with a fair value of \$25,900 and \$642,492, respectively, to purchase shares of its common stock. No restricted stock was issued during the three month period ended June 30, 2009.

The following tables set forth the aggregate share-based compensation expense resulting from equity incentive awards issued to the Company’s employees and to non-employees for services rendered that is recorded in the Company’s results of operations for the period ended:

| Functions | Three Months Ended June 30, | | Six Months Ended June 30, | |
|----------------------------|--------------------------------|------------|------------------------------|------------|
| | 2009 | 2008 | 2009 | 2008 |
| Marketing and selling | \$ 5,127 | \$ 17,690 | \$ 12,671 | \$ 43,080 |
| Research and development | 64,546 | 84,827 | 146,421 | 171,720 |
| General and administrative | 151,120 | 171,137 | 416,535 | 401,076 |
| Total | \$ 220,793 | \$ 273,654 | \$ 575,627 | \$ 615,876 |

Note 8 — 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 41,098,270 and 41,100,676 for the six months ended June 30, 2009, and 2008 respectively.

At June 30, 2009, and 2008, the weighted average number of diluted shares does not include potential common shares which are anti-dilutive. 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: | 2009 | 2008 |
|-----------------------------------|-----------|-----------|
| Assumed exercise of stock options | 4,700,999 | 4,379,179 |
| Assumed conversion of warrants | 2,226,550 | 3,171,399 |
| Total | 6,927,549 | 7,550,578 |

Note 9 — 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 10 — Warrants

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During the three months ended June 30, 2009, there were no new warrants issued or exercised. The Company had the following warrants to purchase common stock outstanding at June 30, 2009:

| 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 |
| 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 | 2,226,550 | | | 2,226,550 | |

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

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Note 11 – Subsequent Events

We have considered all events that have occurred subsequent to June 30, 2009 and through August 7, 2009, the date the financial statements as of and for the period ended June 30, 2009 were available to be issued.

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 2008 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 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®) platforms to develop novel pharmaceutical, OTC, and nutritional products. Our CDT platforms are 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.

We have developed multiple private label controlled release nutritional products incorporating our CDT platforms 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. We have developed additional nutritional products and are seeking to expand sales of nutritional products in other markets.

Our lead product candidate is a CDT-based controlled release formulation of ibuprofen, an analgesic typically used for the treatment of pain, fever and inflammation. In November 2008, we successfully completed our pivotal phase III trial to evaluate the safety and efficacy of our 12 hour CDT 600 mg controlled release ibuprofen for the OTC market. There are currently no controlled release formulations of ibuprofen approved for use in North America. In addition, our first Abbreviated New Drug Application, or ANDA, for our 12 hour pseudoephedrine product was accepted by the FDA in September 2008. In January 2009, we received a complete response letter from the FDA which requests additional information in the area of chemical manufacturing and controls, all of which was identified by the FDA as “minor.” We expect to be in a position to amend our submission and provide the requested information by the end of August 2009. We believe our formulation will offer attractive tablet size and cost saving opportunities when compared to similar tablets already on the market.

In July 2009, Dr Reddy's terminated our collaboration and license agreement to pursue commercialization of an undisclosed oral prescription drug for the cardiopulmonary market. Dr Reddy's informed us that it had decided not to pursue the cardiovascular product based on its assessment of the financial opportunity, including competition for the particular product candidate.

We expect our operating losses and negative cash flow to continue as we advance preclinical research and related work to support applications for regulatory approvals and commercialization of our product candidates. We need to raise additional capital to fund operations, continue research and development projects, and commercialize our products. In April 2009, the Company engaged HealthPro BioVentures LLC, a life science investment bank and strategic advisory firm, as its financial advisor in connection with the evaluation of various prospective transactions, and identifying and evaluating potential strategic partners. In May 2009, we engaged an additional investment bank to explore the opportunity to seek additional financing and strategic partners. We may not be able to secure additional financing on favorable terms, or at all. If we are unable to obtain necessary additional financing, our business will be adversely affected and we may be required to reduce the scope of our development activities, discontinue operations, or seek bankruptcy protection.

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Critical Accounting Policies and Estimates

Since December 31, 2008, 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, 2008, 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 December 2007, the FASB issued SFAS No. 141(R), Business Combinations (SFAS No. 141(R)). SFAS No. 141(R) replaces SFAS No. 141, Business Combinations (“SFAS No. 141”), however retains the fundamental requirements that the acquisition method of accounting be used for all business combinations and for an acquirer to be identified for each business combination. SFAS No. 141(R) requires an acquirer to recognize the assets acquired, liabilities assumed, and any noncontrolling interest in the acquiree at the acquisition date, at their fair values as of that date, with specified limited exceptions. Changes subsequent to that date are to be recognized in earnings, not goodwill. Additionally, SFAS No. 141(R) requires costs incurred in connection with an acquisition be expensed as incurred. Restructuring costs, if any, are to be recognized separately from the acquisition. The acquirer in a business combination achieved in stages must also recognize the identifiable assets and liabilities, as well as the noncontrolling interests in the acquiree, at the full amounts of their fair values. SFAS No. 141(R) is effective for business combinations occurring in fiscal years 2009 or after.

In May 2009, the FASB issued SFAS No. 165, “Subsequent Events.” SFAS No. 165 defines subsequent events as transactions that occur after the balance sheet date but before financial statements are issued or are available to be issued. SFAS No. 165 defines two types of subsequent events: (i) events or transactions that provide additional evidence about conditions that existed at the date of the balance sheet, including the estimates inherent in the process of preparing financial statements (that is, recognized subsequent events); and (ii) events that provide evidence about conditions that did not exist at the date of the balance sheet but arose after that date (that is, nonrecognized subsequent events). In addition, SFAS No. 165 requires an entity to disclose the date through which subsequent events have been evaluated, as well as whether that date is the date the financial statements were issued or the date the financial statements were available to be issued. SFAS No. 165 is effective for periods ending after June 15, 2009. The adoption of SFAS No. 165 effective June 30, 2009 did not have any effect on our financial position, results of operations or cash flows.

In June 2009, the Financial Accounting Standards Board (“FASB”) issued SFAS No. 168 “FASB Accounting Standards Codification™ and the Hierarchy of Generally Accepted Accounting Principles—a replacement of FASB Statement No. 162.” SFAS No. 168 will become the source of authoritative U.S. generally accepted accounting principles (“GAAP”) recognized by the FASB to be applied by nongovernmental entities. Rules and interpretive releases of the Securities and Exchange Commission (“SEC”) under authority of federal securities laws are also sources of authoritative GAAP for SEC registrants. This Statement is effective for financial statements issued for interim and annual periods ending after September 15, 2009. On the effective date, the Codification will supersede all then-existing non-SEC accounting and reporting standards. All other non-grandfathered, non-SEC accounting literature not included in the Codification will become non-authoritative. As we believe that our accounting practices are consistent with the Codification, we do not believe that the adoption of SFAS No. 168 will have a material effect on our financial position, results of operations or cash flows.

In June 2008, the FASB issued FASB Staff Position EITF 03-6-1, "Determining Whether Instruments Granted in Share-Based Payment Transactions Are Participating Securities." This position states that unvested share-based payment awards that contain nonforfeitable rights to dividends (whether paid or unpaid) are participating securities and shall be included in the computation of earnings per share (EPS) under the two-class method described in paragraphs 60 and 61 of FASB Statement No. 128, "Earnings per Share." FSP EITF 03-6-1 is effective for financial statements issued for fiscal years beginning after December 15, 2008. The adoption of EITF 03-6-1 in the current year did not have an effect on the Company's calculation of EPS for the three and six months ended June 30, 2009 and 2008.

Results of Operations

Comparison of the Three Months Ended June 30, 2009 and 2008

Revenues

Total revenues, which consist of royalty revenue from our collaboration agreements, decreased 17%, or \$48,782 to \$230,789 for the three months ended June 30, 2009, compared to \$279,571 for the same period in 2008. This decrease is primarily due to lower royalty income from our relationship with Perrigo.

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Royalty income increased 34%, or \$59,017 to \$230,789 in the three months ended June 30, 2009, compared to \$171,772 for the first quarter of 2009. This increase is a result of higher sales activities of our nutritional products by Perrigo. Royalty payments are based on Perrigo's net profits from the sale of CDT-based products which involve uncertainties and are difficult to predict.

Operating Expenses

Marketing and Selling Expenses

Marketing and selling expenses decreased 79%, or \$151,579 to \$39,468 for the three months ended June 30, 2009, compared to \$191,047 for the same period in 2008. This decrease was primarily due to a \$67,712 reduction in personnel related expenses due to reduction in personnel and lower advertising and tradeshow expenses of \$23,673. In addition, commission expense decreased \$10,292 due to lower royalty income.

Research and Development Expenses

Research and development expenses decreased 34%, or \$403,818 to \$793,503 for the three months ended June 30, 2009, compared to \$1.2 million for the same period in 2008. The decrease of \$254,567 is primarily due to our decision to defer development activities on certain projects pending additional funding and a reduction in personnel related expenses of \$188,060 due to personnel reductions. These decreases were offset by a \$130,000 expense related to settlement of claims by a former employee.

General and Administrative Expenses

General and administrative expenses decreased 8%, or \$89,762 to \$972,884 for the three months ended June 30, 2009, compared to \$1.1 million for the same period in 2008, primarily due to a decrease of \$87,654 in personnel related expenses through personnel reductions, a decrease of \$20,129 in travel expenses and a reduction in insurance premium expense of \$32,330. These decreases were offset by an increase in outside services of \$33,955 related to investment banking activities and an increase in legal expenses of \$45,532.

Other Income (Expense), Net

Other income decreased 98%, or \$55,774 to \$958 for the three months ended June 30, 2009, compared to \$56,732 for the comparable period in 2008. This decrease was due to a decrease in interest income due to lower cash balances.

Net Loss

Net loss decreased 26%, or \$540,603 to \$1.6 million for the three months ended June 30, 2009, compared to \$2.1 million for the same period in 2008. The decrease was primarily due to lower operating expenses offset by lower revenues and other income.

Comparison of the Six Months Ended June 30, 2009, and 2008

Revenues

Total revenues decreased 26%, or \$142,565 to \$402,561 for the six months ended June 30, 2009, compared to \$545,126 for the same period in 2008. This decrease is primarily due to lower royalty income from our relationship

with Perrigo.

Operating Expenses

Marketing and Selling Expenses

Marketing and selling expenses decreased 66%, or \$282,688 to \$146,051 for the six months ended June 30, 2009, compared to \$428,739 for the same period in 2008. This decrease was primarily due to a decrease of \$208,562 in personnel related expenses through personnel reduction, a decrease of \$41,579 in advertising and tradeshow expense, and lower commission expense of \$18,069.

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Research and Development Expenses

Research and development expenses decreased 22%, or \$465,096 to \$1.6 million for the six months ended June 30, 2009, compared to \$2.1 million for the same period in 2008. The decrease is primarily due to a reduction in personnel related expenses of \$343,286 through reductions in personnel and a decrease of \$208,267 in clinical trial and outside manufacturing, and repairs and maintenance expenses as a result of our decision to defer development activities on certain projects pending additional funding. These decreases were offset by a \$130,000 expense related to settlement of claims by a former employee.

General and Administrative Expenses

General and administrative expenses decreased 7%, or \$168,395, to \$2.1 million for the six months ended June 30, 2009, compared to \$2.3 million for the same period in 2008, primarily due to a decrease of \$108,170 related to a reduction in personnel expense due to personnel reductions, a decrease in insurance premiums of \$55,324, and a decrease in travel related expenses of \$32,751. These decreases were offset by an increase in outside services of \$55,503 associated with investment banking activities and an increase in outside legal expenses of \$46,551.

Other Income (Expense), Net

Other income (expense) decreased 95%, or \$145,137 to \$7,600 for the six months ended June 30, 2009, compared to \$152,737 for the same period in 2008. This decrease was due to a decrease in interest income due to lower cash balances.

Net Loss

The net loss for the six months ended June 30, 2009, decreased 15%, or \$628,477 to \$3.5 million, compared with a net loss of \$4.1 million for the same period in 2008. This decrease was primarily due to lower operating expenses offset by lower revenues.

Liquidity and Capital Resources

We had approximately \$3.1 million in cash and cash equivalents, and \$473,711 in restricted cash as of June 30, 2009. Based on our current operating plan, we anticipate that our existing cash and cash equivalents, together with expected royalties from third parties, will be sufficient to fund our operations until late 2009, assuming we do not trigger additional obligations, including contractual severance or lease obligations described below, and unless unforeseen events arise that negatively impact our liquidity. In the event we are unsuccessful generating additional revenues or raising additional funds, it will be necessary to substantially reduce our operations to preserve capital or seek bankruptcy protection or otherwise wind up our business.

Our current operating strategy is to actively manage our liquidity by limiting clinical and development expenses to our ibuprofen and pseudoephedrine lead products while also supporting existing alliances and collaborations. We have deferred all significant expenditures on our development projects, including the actual use study required by the FDA as a prerequisite to submission of our regulatory application for ibuprofen, pending additional financing or partnership support. Without increased revenues or additional funding we do not expect to be able to complete development of our current projects. We continue to evaluate opportunities to reduce operating expenses, including renegotiating the lease of our facility and restructuring management (including renegotiating employment agreements and reducing the

number of executives). We did not pay the full lease payment due on our facility in July and August 2009 and the landlord may claim a default and seek to accelerate payments or exercise other rights (including drawing on the letter of credit collateralized by \$473,711 of our restricted cash) provided in the lease. Additional information concerning our lease obligations is included in our “Risk Factors” in Part II, Item 1A.

Our capital resources are very limited and operations to date have been funded primarily with the proceeds from public equity financings, royalty payments, and collaborative research agreements. We are pursuing additional sources of financing that could involve strategic transactions, including mergers and business combinations, new collaborations, as well as opportunities to expand product sales and other options. However, there are significant uncertainties as to our ability to increase revenues or access potential sources of capital. We may not be able to enter any collaboration on terms acceptable to us, or at all, due to conditions in the pharmaceutical industry or in the economy in general. Competition for such arrangements is intense, with many biopharmaceutical companies attempting to secure alliances with more established pharmaceutical or consumer products companies. Although we have been engaged in discussions with potential partners, there is no assurance that any agreements will result from these discussions in a timely manner, or at all, or that revenues generated from such an agreement will offset operating expenses to enable us to meet our short term funding requirements.

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In addition to our efforts to enter into alliances and licensing agreements, we plan to continue to seek access to the capital markets to fund our operations. We filed a shelf registration statement in the amount of \$40 million which was declared effective by the Securities and Exchange Commission on November 25, 2008 under which we may offer from time-to-time, one or more offerings of securities up to an aggregate public offering price of \$40 million. However, the financial markets have been very difficult for companies at our development stage and financial condition and financing may not be available on favorable terms or at all. Additionally, we have received notice from the NYSE Amex that we are not in compliance with continued listing requirements. While we have provided the NYSE Amex with a plan to regain compliance with applicable listing standards, our inability to maintain listing of our common stock on the NYSE Amex may further limit our ability to access the capital markets. Any issuance of additional securities would be extremely dilutive to our existing stockholders.

Our failure to increase revenues or raise capital, including financial support from partnerships or other collaborations during the remainder of 2009 would materially adversely affect our business, financial condition and results of operations, and could force us to reduce or cease operations. If we are forced to reduce or cease our operations we may trigger additional obligations, including contractual severance obligations aggregating as much as \$1.5 million and obligations under our lease up to \$2.7 million, some of which we are attempting to reduce through negotiations. In addition, we may be forced to liquidate assets at reduced levels due to our immediate liquidity requirements. These conditions raise substantial doubt about our ability to continue as a going concern. Consequently, the audit report prepared by our independent registered public accounting firm relating to our financial statements for the year ended December 31, 2008 included a going concern explanatory paragraph.

Cash flows from operating activities—Net cash used in operating activities for the six months ended June 30, 2009 was approximately \$3.0 million compared to \$3.1 million for the six months ended June 30, 2008. The six months ended June 30, 2008 include a \$1 million deferred gain on our lease termination. Expenditures for the six months ended June 30, 2009 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 in investing activities of \$136,950 during the six months ended June 30, 2009, primarily represent the payments made for patent rights and the purchase of a new tablet press from an insurance settlement related to our facility move. Cash flows used in investing activities of \$693,354 during the six months ended June 30, 2008, primarily represented the payments made for patent rights and \$564,000 of restricted cash associated with our facility lease.

Cash flows from financing activities— Cash flows provided by financing activities for the six months ended June 30, 2009 primarily represent payments of \$111,119 made on our term loan through April 2009, at which time the loan was paid off. In the six months ended June 30, 2008, cash flows from financing activities primarily represented the proceeds from the exercise of options and warrants offset by payments made on our term loan.

As of June 30, 2009, we had \$3.0 million of working capital compared to \$5.8 million as of December 31, 2008. We have accumulated net losses of approximately \$67.4 million from our inception through June 30, 2009. We have funded our operations primarily through the issuance of equity securities, including \$3.6 million and \$10.9 million in net proceeds from our registered direct offerings in December 2007 and April 2006, respectively, and \$14.1 million from our private placement in February 2005.

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 second quarter of fiscal 2009 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

Other than the modification to the risk factors set forth below, there has not been a material change to the risk factors as set forth in our Annual Report on Form 10-K for the year ended December 31, 2008.

We do not have sufficient cash to fund the development of our product candidates or maintain our operations. If we are unable to obtain additional financing during 2009, we will be required to substantially curtail or cease operations, seek bankruptcy protection or otherwise wind up our business.

We anticipate that, based on our current operating plan, our existing cash and cash equivalents, together with expected royalties from third parties, we will be able to fund our operations until late 2009. We are actively managing our liquidity by limiting our clinical and development expenses to our ibuprofen and pseudoephedrine products and supporting our existing alliances and collaborations. If we are unable to increase revenues or raise additional capital by late 2009 we will be required to substantially curtail or cease operations, seek bankruptcy protection or otherwise wind up our business.

We have deferred all significant expenditures on new projects as well as major expenditures for our lead products pending additional financing or partnership support. We continue to evaluate opportunities to reduce operating expenses including renegotiating the lease of our current facility and reducing our continuing management expenses (including renegotiating employment agreements that include severance provisions of up \$1.5 million in the aggregate and reducing the number of executives). However, there can be no assurance that we will be successful in these efforts. If we are forced to reduce or cease our operations we may trigger additional obligations, including severance obligations, which would further negatively impact our liquidity and capital resources

We are pursuing new partnerships as well as opportunities to expand product sales and other options that will enable us to obtain financing for our operations. However, there are significant uncertainties as to our ability to be successful in these efforts or access potential sources of capital. We may not be able to enter any collaboration on terms acceptable to us, or at all, due to conditions in the pharmaceutical industry or in the economy in general. Competition for such arrangements is intense with many and specialty pharmaceutical companies attempting to secure alliances with more established pharmaceutical or consumer products companies. Although we have been engaged in discussions with potential partners there is no assurance that any agreements will result from these discussions in a timely manner, or at all, or that any revenues would be sufficient to address our capital needs. 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.

Additional equity or debt financing may not be available to us on acceptable terms, or at all. The capital markets have been experiencing extreme volatility and disruption for over a year, and the market has been very negative for companies in our industry and at our stage of development. The scope and extent of difficulties in the capital markets could make it difficult or impossible to raise capital and conditions may not improve in the amount of time left before we reach the end of our financial resources. 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 are unable to increase revenues or 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 delay or terminate our development programs, suspend prosecution of our intellectual property, the pursuit of licensing, strategic alliances and development of drug delivery programs.

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In April 2009, the Company engaged HealthPro BioVentures LLC, a life science investment bank and strategic advisory firm, as its financial advisor in connection with the evaluation of various prospective transactions, and identifying and evaluating potential strategic partners. In addition, in May 2009, we engaged another investment bank to explore the opportunity to seek additional financing and strategic partners. There can be no assurance that these engagements will enable us to identify and implement strategic options that will benefit investors. In addition, if we are unable to meet our obligations to third parties as they become due, we may be subject to litigation claims and/or may seek bankruptcy protection.

We may be delisted from the NYSE Amex resulting in a more limited market for our common stock.

On June 25, 2009, we were notified of our failure to comply with the NYSE Amex continued listing standards under section 1003(a)(iii) of the Company Guide because our stockholders' equity was less than \$6,000,000 and we have had losses from continuing operations and net losses in our five most recent fiscal years. As of June 30, 2009, our stockholders' equity was approximately \$4.4 million. On July 28, 2009, we submitted a plan to the NYSE to regain compliance with its continued listing requirements. If the Exchange accepts the plan, then we may be able to continue our listing during the plan period up to December 27, 2010, during which time we will be subject to periodic review to determine whether we are making progress consistent with the plan. If the Exchange does not accept the plan, or even if accepted, if we are not in compliance with the continued listing standards at the end of the plan period or we do not make progress consistent with the plan during such period, then the Exchange may initiate delisting proceedings. If we are delisted from the NYSE Amex then our common stock will trade, if at all, only on the over-the-counter markets, such as the OTC Bulletin Board securities market, and then only if one or more registered broker-dealer market makers comply with quotation requirements. In addition, delisting of our common stock could further depress our stock price, substantially limit the liquidity of our common stock and materially adversely affect our ability to raise capital on terms acceptable to us, or at all. Delisting from NYSE Amex could also have other negative results, including the potential loss of confidence by suppliers and employees, the loss of institutional investor interest and fewer business development opportunities.

If we are unable to renegotiate terms of our facility lease, we may default and be forced to seek protection of the bankruptcy laws.

We are currently negotiating with the landlord of our corporate facility to restructure our lease to reduce our lease payments and include less space under the lease. We did not pay the full lease payment due in July and August 2009 while we continue discussions with the landlord. The lease for our facility provides for rental payments of \$31,379 per month, with annual increases commencing in late 2010, together with additional rental amounts based on our proportionate share of property taxes, insurance, utilities and common area maintenance expenses. Our failure to cure any default under the lease may provide the landlord with the right to accelerate the entire amount of the payments due under the lease, including past and future payments and to re-take possession of the leased premises. The total amount of the accelerated payments due under the lease would be approximately \$2.7 million. The landlord also has the right to apply our security deposit of \$38,629, together with the proceeds of an irrevocable, unconditional, standby letter of credit (secured by a restricted cash account) in the amount of \$473,711 provided to the landlord to secure our obligations under the lease. Additionally, the lease requires us to pay legal fees and other costs and expenses associated with the legal proceedings relating to a default under the lease. We are currently in settlement negotiations with the landlord but cannot provide any assurance as to whether a settlement agreement can be reached on acceptable terms, or at all.

Item 4.

Submission of Matters to a Vote of Security Holders

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We held our Annual Meeting of Stockholders on June 11, 2009, to elect six directors to hold office until the next annual meeting of stockholders, and until their successors are elected and qualified; and to ratify the selection of our independent registered public accounting firm for the 2009 fiscal year.

The tables below show the results of the stockholders' voting:

1. Election of Directors:

| | Yes | Withheld |
|-----------------------|------------|----------|
| Randall L-W Caudill | 34,523,724 | 890,888 |
| Herbert L. Lucas, Jr. | 35,438,667 | 890,888 |
| Wayne L. Pines | 35,324,851 | 890,888 |
| Bruce S. Morra | 35,218,017 | 890,928 |
| Jeffrey B. Reich | 35,750,200 | 890,928 |
| Michael N. Taglich | 35,271,672 | 892,270 |

2. Proposal to approve an increase in the maximum aggregate number of shares that may be issued under its 2004 Equity Incentive Plan by 3,000,000 shares, received the number of votes set below:

| For | Against | Abstain | Broker Non-Votes |
|-----------|-----------|---------|---------------------|
| 8,573,881 | 5,496,125 | 100,004 | 22,477,670 |

3. Proposal to ratify Grant Thornton LLP, the Company's independent registered public accounting firm for fiscal 2009, received the number of votes set below:

| For | Against | Abstain |
|------------|---------|---------|
| 36,173,973 | 402,336 | 71,371 |

Item 6. Exhibits

The following exhibits are filed herewith:

| Exhibit No. | Description | Filed Herewith | Form | Incorporated by Reference | | |
|-------------|--|-------------------|------|---------------------------|----------|-------------|
| | | | | Exhibit No. | File No. | Filing Date |
| 10.1 | Form of Director Indemnification Agreement dated May 26, 2009 | | 8-K | 10.1 | 09860027 | 5/29/2009 |
| 10.2 | Form of Officer Indemnification Agreement dated May 26, 2009 | | 8-K | 10.2 | 09860027 | 5/29/2009 |
| 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.

By: /s/ BRUCE S. MORRA
Bruce S. Morra
President and Chief Executive Officer
(Principal Executive Officer)

Date: August 7, 2009

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

Date: August 7, 2009

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EXHIBIT INDEX

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| 32.2 | Certification of Chief Financial Officer pursuant to Section 906 of the Sarbanes-Oxley Act of 2002 | X | | | | |