

SCOLR Pharma, Inc.  
Form 10-Q  
November 06, 2009

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UNITED STATES

SECURITIES AND EXCHANGE COMMISSION  
Washington, D.C. 20549

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FORM 10-Q

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

For the quarterly period ended September 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

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SCOLR Pharma, Inc.  
(Exact name of registrant as specified in its charter)

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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)

425-368-1050  
(Registrant's telephone number, including area code)

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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 November 2, 2009 |
|---------------------------------|---|
| Common Stock, par value \$0.001 | 41,098,270                                |

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SCOLR Pharma, Inc.

FORM 10-Q

For the Quarterly Period Ended September 30, 2009

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## PART I: FINANCIAL INFORMATION

Item 1. Financial Statements  
SCOLR Pharma, Inc.CONDENSED BALANCE SHEETS  
(Unaudited)

|  | September<br>30,<br>2009 | December 31,<br>2008 |
|--|--------------------------|----------------------|
| <b>ASSETS</b>  |                          |                      |
| Current Assets   |                          |                      |
| Cash and cash equivalents  | \$ 1,946,908             | \$ 6,363,243         |
| Accounts receivable  | 240,363                  | 177,253              |
| Interest and other receivables   | 6,282                    | 1,157                |
| Prepaid expenses and other assets  | 285,807                  | 286,539              |
| Total current assets   | 2,479,360                | 6,828,192            |
| Property and Equipment — net of accumulated depreciation of \$1,245,400 and \$1,289,844, respectively  | 555,364                  | 790,947              |
| Intangible assets — net of accumulated amortization of \$493,671 and \$465,724, respectively   | 564,359                  | 557,639              |
| Restricted cash  | 473,711                  | 473,711              |
|  | \$ 4,072,794             | \$ 8,650,489         |
| <b>LIABILITIES AND STOCKHOLDERS' EQUITY</b>  |                          |                      |
| Current Liabilities  |                          |                      |
| Accounts payable   | \$ 26,102                | \$ 238,701           |
| Accrued liabilities  | 633,277                  | 668,694              |
| Current portion of term loan   | —                        | 87,850               |
| Total current liabilities  | 659,379                  | 995,245              |
| Deferred rent  | 271,790                  | 310,010              |
| Long-term portion of term loan   | —                        | 23,269               |
| Total liabilities  | 931,169                  | 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 September 30, 2009, and December 31, 2008, respectively | 41,098                   | 41,130               |
| Additional paid-in capital   | 72,138,140               | 71,255,901           |
| Accumulated deficit  | (69,037,613)             | (63,975,066)         |
| Total stockholders' equity   | 3,141,625                | 7,321,965            |
|  | \$ 4,072,794             | \$ 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<br>September 30, |             | Nine months ended<br>September 30, |                |
|--|-------------------------------------|-------------|------------------------------------|----------------|
|  | 2009                                | 2008        | 2009                               | 2008           |
| <b>Revenues</b>  |                                     |             |                                    |                |
| Royalty income   | \$ 261,651                          | \$ 236,308  | \$ 664,212                         | \$ 781,435     |
| Total revenues   | 261,651                             | 236,308     | 664,212                            | 781,435        |
| <b>Operating expenses</b>                              |                                     |             |                                    |                |
| Marketing and selling                                  | 54,351                              | 116,840     | 200,402                            | 545,579        |
| Research and development                               | 572,189                             | 2,307,103   | 2,187,626                          | 4,387,636      |
| General and administrative                             | 1,220,745                           | 947,684     | 3,347,279                          | 3,242,614      |
|  | 1,847,285                           | 3,371,627   | 5,735,307                          | 8,175,829      |
| <b>Facility lease termination</b>                      |                                     |             |                                    |                |
| Gain from lease buyout                                 | —                                   | (4,100,000) | —                                  | (4,100,000)    |
| <b>Expenses related to relocation and lease buyout</b> |                                     |             |                                    |                |
|  | —                                   | 116,867     | —                                  | 116,867        |
| Total facility lease buyout                            | —                                   | (3,983,133) | —                                  | (3,983,133)    |
| Total operating (revenue) expenses                     | 1,847,285                           | (611,506)   | 5,735,307                          | 4,192,696      |
| Income (loss) from operations                          | (1,585,634)                         | 847,814     | (5,071,095)                        | (3,411,261)    |
| <b>Other income (expense)</b>                          |                                     |             |                                    |                |
| Interest income  | 948                                 | 45,858      | 12,060                             | 205,530        |
| Interest expense                                       | —                                   | (3,393)     | (3,512)                            | (11,565)       |
| Other  | —                                   | 91          | —                                  | 1,329          |
| Total other income                                     | 948                                 | 42,556      | 8,548                              | 195,294        |
| Net (loss) income                                      | \$ (1,584,686)                      | \$ 890,370  | \$ (5,062,547)                     | \$ (3,215,967) |
| Net (loss) income per share, basic and diluted         | \$ (0.04)                           | \$ .02      | \$ (0.12)                          | \$ (0.08)      |
| <b>Shares used in computing basic net</b>              |                                     |             |                                    |                |
| (loss) income per share                                | 41,098,270                          | 41,130,270  | 41,098,270                         | 41,110,684     |
| <b>Shares used in computing diluted net (loss)</b>     |                                     |             |                                    |                |
| income per share                                       | 41,098,270                          | 41,561,623  | 41,098,270                         | 41,110,684     |

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

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SCOLR Pharma, Inc.

CONDENSED STATEMENTS OF CASH FLOWS  
(Unaudited)

|   | Nine months ended<br>September 30, |                |
|---|------------------------------------|----------------|
|   | 2009                               | 2008           |
| <b>Cash flows from operating activities:</b>  |                                    |                |
| Net loss  | \$ (5,062,547)                     | \$ (3,215,967) |
| <b>Reconciliation of net loss to net cash used in operating activities</b>          |                                    |                |
| Depreciation and amortization   | 330,529                            | 312,064        |
| Write-off of intangible assets  | 86,681                             | 38,424         |
| (Gain) on sale of equipment   | (14,016)                           | —              |
| Share-based compensation for employee services                                      | 962,596                            | 894,327        |
| <b>Increase (decrease) in cash resulting from changes in assets and liabilities</b> |                                    |                |
| Accounts and other receivables  | (68,235)                           | (18,298)       |
| Prepaid expenses and other current assets   | 732                                | 99,806         |
| Accounts payable and accrued expenses   | (451,860)                          | (281,049)      |
| Net (cash used) in operating activities   | (4,216,120)                        | (2,170,693)    |
| <b>Cash flows from investing activities:</b>  |                                    |                |
| Purchase of equipment and furniture   | (95,419)                           | (2,615)        |
| Proceeds from insurance settlement  | 85,267                             | —              |
| Proceeds from sale of fixed assets  | 80,000                             | —              |
| Patent and technology rights payments   | (158,912)                          | (159,832)      |
| Restricted cash   | —                                  | (564,000)      |
| Net (cash used) by investing activities   | (89,064)                           | (726,447)      |
| <b>Cash flows from financing activities:</b>  |                                    |                |
| Payments on term loan   | (111,119)                          | (59,331)       |
| Proceeds from exercise of common stock options and warrants                         | (32)                               | 40,086         |
| Net (cash used) by financing activities   | (111,151)                          | (19,245)       |
| Net (decrease) in cash  | (4,416,335)                        | (2,916,385)    |
| Cash at beginning of period   | 6,363,243                          | 11,825,371     |
| Cash at end of period   | \$ 1,946,908                       | \$ 8,908,986   |
| Cash paid during the period for interest  | \$ 2,165                           | \$ 10,502      |

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 May 2009, the FASB issued Accounting Standards Codification (ASC) 855, previously known as SFAS No. 165, “Subsequent Events.” ASC 855 defines subsequent events as transactions that occur after the balance sheet date but before financial statements are issued or are available to be issued. ASC 855 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, ASC 855 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. ASC 855 is effective for periods ending after June 15, 2009. The adoption of ASC 855, effective June 30, 2009 did not have any effect on our financial position, results of operations or cash flows.



In June 2009, the FASB issued Accounting Standards Codification (ASC) 105, previously known as SFAS No. 168, “FASB Accounting Standards Codification™ and the Hierarchy of Generally Accepted Accounting Principles—a replacement of FASB Statement No. 162.” ASC 105 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 ASC 105 had a material effect on our financial position, results of operations or cash flows.

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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 nine months ended September 30, 2009 and 2008.

ASU 2009-04, Accounting for Redeemable Equity Instruments—Amendment to Section 480-10-S99, updates the SEC staff’s guidance on the classification and measurement of redeemable securities that was originally issued as EITF Topic D-98, “Classification and Measurement of Redeemable Securities.” In addition to updating the guidance for Codification references, the revision reorganizes Topic D-98’s guidance. Instruments with nontraditional redemption features discussed throughout Topic D-98 are now grouped in an expanded scope section that explains whether or not each instrument is subject to the temporary equity classification of SEC Accounting Series Release 268, Presentation in Financial Statements of “Redeemable Preferred Stocks,” and related SEC staff guidance. The revised guidance also groups securities with specific contractual provisions that would require classification in temporary equity, and similarly organizes securities with contractual provisions for which permanent equity classification is appropriate. In addition, disclosure guidance throughout Topic D-98 is combined in a new section on disclosures. The issuance of ASU 2009-04 did not have a significant effect on the Company’s financial statements.

The FASB issued Statement 167, Amendments to FASB Interpretation No. 46(R) (not yet included in the Codification), to improve how enterprises account for and disclose their involvement with variable interest entities (VIEs), which are special-purpose entities and other entities whose equity at risk is insufficient or lacks certain characteristics. The issuance of Statement 167 did not have a significant effect on the Company’s financial statements.

### Note 3 – Accounts Receivable

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

### Note 4 — Facility Lease Termination

In May 2008, the Company entered into a Lease Termination and Surrender Agreement, under which the Company agreed to terminate the lease for its corporate facility for consideration of \$4.1 million. Under the terms of the agreement, the Company received \$1.0 million upon execution of the agreement and the remaining \$3.1 million in September 2008, at the time the Company vacated the premises. The \$4.1 million cash settlement and \$116,867 in costs that were incurred related to the lease and relocation to the new space were recognized in operating expense in September 2008.

### Note 5 — Liquidity

The Company incurred a net loss of approximately \$5.1 million for the nine months ended September 30, 2009, and used cash from operations of approximately \$4.2 million. Cash flows of \$89,064 used by investing activities during the nine months ended September 30, 2009, represents \$95,419 for equipment purchases plus \$158,912 in patent and trademark related expenditures. These amounts were offset by \$85,267 in proceeds from an insurance settlement and \$80,000 from the sale of research and development equipment. Cash flows used by financing activities for the period ended September 30, 2009, reflects payments on term loan of \$111,119 through April 2009, at which time the loan

was paid off.

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The Company had approximately \$1.9 million in cash and cash equivalents, and \$473,711 in restricted cash, related to our facility lease, as of September 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 through February 2010, assuming the Company does not trigger additional obligations, and unless unforeseen events arise that negatively impact its liquidity.

Our current operating strategy is to actively manage our liquidity by limiting clinical and development expenses to our ibuprofen and pseudoephedrine lead products, and reducing our marketing and general administrative and other operating expenses. 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. In addition, the Company has reduced its marketing and general and administrative expenses and continues to evaluate opportunities to reduce operating expenses. As described below in footnote 12 – Subsequent Events, the Company renegotiated the lease of its corporate facility to reduce the rent and leased space. In addition, in accordance with the amended lease agreement, the Company reduced its monthly cash lease payment by \$18,000 for a period of one year commencing November 1, 2009. During this one year period, \$18,000 of the Company's monthly rent will be paid through draw downs on the letter of credit collateralized by \$473,711 of restricted cash. The letter of credit secures the Company's lease obligation. In August 2009, the Company paid the rent due for July, August and September 2009. In addition to renegotiating the lease, in August 2009 the Company eliminated one executive position and in October 2009 reduced the annual cash compensation for two executive officers effective November 2009.

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. 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.

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 acceptable terms, 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, 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 LLC (“Exchange”) that it is not in compliance with continued listing requirements. While the Company has provided the Exchange with a plan to regain compliance with applicable listing standards, its inability to maintain listing of its common stock on the Exchange may further limit its ability to access the capital markets. Delisting from NYSE Amex could also have other negative results, including the potential loss of confidence by suppliers and employees, the loss of institutional investors interest and fewer business development opportunities. 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 \$975,000. 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.

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On June 25, 2009 the Company received notice from the Exchange 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. In September 2009, the Exchange approved the Company's plan to regain compliance with the continued listing standard set forth in Section 1003(a) (iii) of the NYSE Amex Company Guide within the specified timeframes indicated by the Exchange. However NYSE Amex LLC simultaneously issued a notice that the Company does not meet the continued listing standard set forth in Section 1003(a)(iv) of the NYSE Amex Company Guide because, based on the Exchange's a review of the Company's Form 10-Q for the period ending June 30, 2009, the Company has sustained losses which are so substantial in relation to its overall operations or its existing financial resources, or its financial condition has become so impaired that it appears questionable, in the opinion of the Exchange, as to whether the Company will be able to continue operations and/or meet its obligations as they mature.

On October 15, 2009 the Company submitted additional information to the Exchange to address how it plans to regain compliance with section 1003(a) (iv) of the Company Guide by March 15, 2010. If the Exchange does not accept the plan, or even if accepted, if the Company is not in compliance with the continued listing standards at the end of the plan period, or the Company does not make progress consistent with the plan during such period, then the Exchange may initiate delisting proceedings.

## 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 September 30, 2009. The Company does not anticipate any significant changes to its unrecognized tax benefits within the next twelve months.

## Note 7 — Share-Based Compensation

During the three-month period ended September 30, 2009, the Company granted 400,000 options to purchase shares of its common stock with a fair value of \$163,542. No restricted stock was issued during the three-month period ended September 30, 2009, and no stock options or restricted stock was issued during the three month period ended September 30, 2008. During the nine month periods ended September 30, 2009 and 2008, the Company granted stock options and shares of restricted stock for 992,500 and 996,500 shares of common stock, respectively, with a fair value of \$407,077 and \$757,416.

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 |           | Nine Months Ended |           |
|----------------------------|--------------------|-----------|-------------------|-----------|
|                            | September 30,      |           | September 30,     |           |
|                            | 2009               | 2008      | 2009              | 2008      |
| Marketing and selling      | \$ 36,426          | \$ 10,139 | \$ 49,097         | \$ 53,219 |
| Research and development   | 210,751            | 95,731    | 357,172           | 267,451   |
| General and administrative | 139,791            | 172,580   | 556,327           | 573,657   |

|       |            |            |            |            |
|-------|------------|------------|------------|------------|
| Total | \$ 386,968 | \$ 278,450 | \$ 962,596 | \$ 894,327 |
|-------|------------|------------|------------|------------|

Note 8 — Net Loss Per Share Applicable to Common Stockholders

Basic net income (loss) per common share is calculated based on the weighted-average number of shares of the Company's common stock outstanding during the period. Diluted net income (loss) per common share is calculated based on the weighted-average number of shares of our common stock outstanding and other dilutive securities outstanding during the period. The potential dilutive shares of the Company's common stock resulting from the assumed exercise of outstanding stock options, and the assumed exercise of the warrants are determined under the treasury stock method. Diluted net income (loss) per share includes the effect of potential issuances of common stock, except when the effect is anti-dilutive. Shares used in the computation of net income (loss) per common share are as follows:

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|  | Three months ended |            | Nine months ended |            |
|--|--------------------|------------|-------------------|------------|
|  | September 30,      |            | September 30,     |            |
|  | 2009               | 2008       | 2009              | 2008       |
| Weighted-average number shares – basic | 41,098,270         | 41,130,270 | 41,098,270        | 41,110,684 |
| Effect of dilutive securities:         |                    |            |                   |            |
| Stock options                          | —                  | 83,431     | —                 | —          |
| Warrants                               | —                  | 347,922    | —                 | —          |
| Weighted-average shares - diluted      | 41,098,270         | 41,561,623 | 41,098,270        | 41,110,684 |

For the three month period ending September 30, 2009, and the nine month periods ending September 30, 2009, and 2008, the weighted average number of diluted shares does not include potential issuances of common shares which are anti-dilutive. The following potential common shares were not included in the calculation of diluted net loss per share for these periods in 2009 and 2008 as the effect would have been anti-dilutive.

|                                   | 2009      | 2008      |
|-----------------------------------|-----------|-----------|
| Assumed exercise of stock options | 5,148,193 | 4,352,512 |
| Assumed conversion of warrants    | 2,226,550 | 3,171,399 |
| Total                             | 7,374,743 | 7,523,911 |

## 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

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

## Note 11 – Related Party Transactions

On August 28, 2009, Dr. Bruce S. Morra resigned as President and Chief Executive Officer of the Company. In connection with Dr. Morra's resignation the Company entered into a Separation and Release Agreement with Dr. Morra which provided for an immediate lump-sum cash payment of \$230,093, and six monthly cash payments of \$35,529 commencing January 1, 2010. The six monthly cash payments were accrued at September 30, 2009 and are included in the results of operations. In addition, the Agreement provided for the acceleration of vesting of 125,000



outstanding stock options granted to Dr. Morra on January 30, 2009, the issuance of 214,285 shares of common stock to Dr. Morra on January 4, 2010, and payment of medical benefits for one year. The Separation and Release Agreement includes a waiver and release of certain claims by the parties. Dr. Morra continues to serve as a director of the Company.

The Company appointed Stephen J. Turner as Chief Executive Officer and President as of August 31, 2009. Mr. Turner has been the Company's Chief Technical Officer since November 2003, and joined the Company in October 1999.

#### Note 12 – Subsequent Events

We have considered all events that have occurred subsequent to September 30, 2009 and through November 6, 2009, the date the financial statements as of and for the period ended September 30, 2009 were available to be issued.

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On November 2, 2009, the Company entered into an agreement with its Chief Executive and Chief Financial Officers to accept a reduction in cash compensation to a rate of \$175,000 per year effective November 1, 2009. In connection with this agreement, the Board of Directors granted each such officer fully vested options to purchase 500,000 shares of the Company's common stock at \$.48 per share. The options are exercisable for up to two years after termination of employment, for any reason. In addition, the Company granted its Senior Vice President Business and Legal Affairs options to purchase 200,000 shares of the Company's common stock at \$.48 per share. One-third of such options shall vest on October 29, 2010 with monthly vesting thereafter for 24 months until all options are fully vested. Such options are exercisable for one year after termination of employment.

On November 5, 2009, the Company entered into an agreement with Arden Realty Limited Partnership amending its lease dated June 20, 2008 of office and laboratory space at 19204 North Creek Parkway, Bothell, Washington. Under the terms of the amended lease, the Company reduced the amount of leased space to 15,615 square feet from 20,468 square feet and reduced the rental payments to the amounts set forth below. In addition, effective November 1, 2009, the Company will be allowed to pay up to \$18,000 of its monthly rent for twelve months through draw downs on the letter of credit which secures the lease. The remaining letter of credit (estimated to be \$256,820 after such reductions) shall remain in place through the lease termination date of January 31, 2016.

The remaining monthly rent is as follows:

| Period                               | Monthly Basic Rental - Total Premises |
|--------------------------------------|---------------------------------------|
| November 1, 2009 – August 31, 2010   | \$25,684.60                           |
| September 1, 2010 – October 31, 2010 | \$26,444.60                           |
| November 1, 2010 – August 31, 2011   | \$26,444.60                           |
| September 1, 2011 – August 31, 2012  | \$27,249.67                           |
| September 1, 2012 – August 31, 2013  | \$28,009.67                           |
| September 1, 2013 – August 31, 2014  | \$28,904.13                           |
| September 1, 2014 – August 31, 2015  | \$29,775.21                           |
| September 1, 2015 – January 31, 2016 | \$30,669.67                           |

## 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 our Annual Report on form 10-K for the year ended December 31, 2008, as updated by Item 1A of Part II of this Quarterly Report on Form 10-Q, and as otherwise detailed in our periodic reports filed with the SEC. We undertake no obligation to update any forward-looking statements, whether as a result of new information, future events or otherwise.

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 result of new information, future events or otherwise.

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### 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 through additional channels in the United States, as well as in Canada, Europe and 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 requested additional information in the area of chemical manufacturing and controls, all of which was identified by the FDA as "minor." In August 2009, we amended our submission and provided the requested information to the FDA. We believe our formulation will offer attractive tablet size and cost saving opportunities when compared to similar tablets already on the market.

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. 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.

### 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 May 2009, the FASB issued Accounting Standards Codification (ASC) 855, previously known as SFAS No. 165, "Subsequent Events." ASC 855 defines subsequent events as transactions that occur after the balance sheet date but before financial statements are issued or are available to be issued. ASC 855 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, ASC 855 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. ASC 855 is effective for periods ending after June 15, 2009. The adoption of ASC 855, 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 FASB issued Accounting Standards Codification (ASC) 105, previously known as SFAS No. 168, “FASB Accounting Standards Codification™ and the Hierarchy of Generally Accepted Accounting Principles—a replacement of FASB Statement No. 162.” ASC 105 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 ASC 105 had 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 nine months ended September 30, 2009 and 2008.

ASU 2009-04, Accounting for Redeemable Equity Instruments—Amendment to Section 480-10-S99, updates the SEC staff’s guidance on the classification and measurement of redeemable securities that was originally issued as EITF Topic D-98, “Classification and Measurement of Redeemable Securities.” In addition to updating the guidance for Codification references, the revision reorganizes Topic D-98’s guidance. Instruments with nontraditional redemption features discussed throughout Topic D-98 are now grouped in an expanded scope section that explains whether or not each instrument is subject to the temporary equity classification of SEC Accounting Series Release 268, Presentation in Financial Statements of “Redeemable Preferred Stocks,” and related SEC staff guidance. The revised guidance also groups securities with specific contractual provisions that would require classification in temporary equity, and similarly organizes securities with contractual provisions for which permanent equity classification is appropriate. In addition, disclosure guidance throughout Topic D-98 is combined in a new section on disclosures. The issuance of ASU 2009-04 did not have a significant effect on the Company’s financial statements.

The FASB issued Statement 167, Amendments to FASB Interpretation No. 46(R) (not yet included in the Codification), to improve how enterprises account for and disclose their involvement with variable interest entities (VIEs), which are special-purpose entities and other entities whose equity at risk is insufficient or lacks certain characteristics. The issuance of Statement 167 did not have a significant effect on the Company’s financial statements.

Results of Operations

### Comparison of the Three Months Ended September 30, 2009 and 2008

#### Revenues

Total revenues, which consist of royalty revenue from our collaboration agreements, increased 11%, or \$25,343 to \$261,651 for the three months ended September 30, 2009, compared to \$236,308 for the same period in 2008. This increase is a result of increased sales of our nutritional products by Perrigo. Royalty payments are based on Perrigo’s net profits from the sale of CDT-based products.



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### Operating Expenses

#### Marketing and Selling Expenses

Marketing and selling expenses decreased 53%, or \$62,489 to \$54,351 for the three months ended September 30, 2009, compared to \$116,840 for the same period in 2008. Of this reduction in expense, \$29,961 is due to a reduction in personnel and \$53,714 reflects the impact of lower advertising and tradeshow expenses.

#### Research and Development Expenses

Research and development expenses decreased 75%, or \$1.7 million to \$572,189 for the three months ended September 30, 2009, compared to \$2.3 million for the same period in 2008. Our deferral of development activities on certain projects pending additional funding resulted in a \$1.6 million reduction in expenses. In addition, personnel related expenses decreased \$48,969 due to personnel reductions. These decreases were offset by an increase of \$93,791 in non-cash share based compensation expense related to stock options granted during the year.

#### General and Administrative Expenses

General and administrative expenses increased 29%, or \$273,061 to \$1.2 million for the three months ended September 30, 2009, compared to \$947,684 for the same period in 2008, primarily due to higher personnel related costs, offset by lower non-cash share based compensation expense, insurance premiums, and director and shareholder relations expense. Personnel related expenses increased \$413,334 due to the recognition of severance costs associated with the resignation of our chief executive officer. Non-cash share based compensation expense decreased \$77,673 due to a lower number of stock options granted during the year. Insurance premiums decreased \$29,630 due to lower rates, and director and shareholder relations expense decreased \$28,788 due to a decrease in the number of directors.

#### Facility Lease Termination

In May 2008, we entered an agreement to terminate the lease for our former corporate facility for consideration of \$4.1 million which was recognized as a reduction to operating expense in September 2008. Under the terms of the agreement, we received \$1.0 million upon execution of the agreement and the remaining \$3.1 million in September 2008, at the time we vacated the premises. We incurred costs of \$116,867 related to relocation to our new facility and the lease buyout which were recognized in operating expense in September 2008.

#### Other Income (Expense), Net

Other income decreased 98%, or \$41,608 to \$948 for the three months ended September 30, 2009, compared to \$42,556 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 increased \$2.5 million to \$1.6 million for the three months ended September 30, 2009, compared to \$890,370 of net income for the same period in 2008. The increased net loss reflects the net impact of the non-recurring \$4.0 million income recognized in the prior year for the facility lease buyout.

#### Comparison of the Nine Months Ended September 30, 2009, and 2008



## Revenues

Total revenues decreased 15%, or \$117,223 to \$664,212 for the nine months ended September 30, 2009, compared to \$781,435 for the same period in 2008. This decrease is primarily due to lower royalty income from our strategic alliance with Perrigo.

## Operating Expenses

### Marketing and Selling Expenses

Marketing and selling expenses decreased 63%, or \$345,177 to \$200,402 for the nine months ended September 30, 2009, compared to \$545,579 for the same period in 2008. This decrease was primarily due to a decrease of \$189,339 in personnel related expenses through personnel reductions, a decrease of \$107,500 in advertising and tradeshow expense, and lower commission expense of \$21,106 associated with lower revenues.

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### Research and Development Expenses

Research and development expenses decreased 50%, or \$2.2 million to \$2.2 million for the nine months ended September 30, 2009, compared to \$4.4 million for the same period in 2008. The decrease is primarily due to a reduction in personnel related expenses of \$342,951 through reductions in personnel and a decrease of \$2.0 million 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 an increase of \$89,721 in non-cash share based compensation expense related to options granted in the current year.

### General and Administrative Expenses

General and administrative expenses increased 3%, or \$104,665, to \$3.3 million for the nine months ended September 30, 2009, compared to \$3.2 million for the same period in 2008, primarily due to an increase of \$305,164 in personnel related expenses. Personnel related expenses increased due to the recognition of severance costs associated with the resignation of our chief executive officer. In addition, other outside service expenses increased \$94,632 due to investment banking activities. These increases were offset by lower insurance premium expense of \$84,954, a decrease in director and shareholder relations expense of \$78,274 due to a reduced number of directors, and a decrease of \$55,342 in travel expenses.

### Facility Lease Termination

In May 2008, we entered an agreement to terminate the lease for our former corporate facility for consideration of \$4.1 million, which was recognized as a reduction to operating expense in September 2008. Under the terms of the agreement, we received \$1.0 million upon execution of the agreement and the remaining \$3.1 million in September 2008, at the time we vacated the premises. We incurred costs of \$116,867 related to relocation to our new facility and the lease buyout which were recognized in operating expense in September 2008.

### Other Income (Expense), Net

Other income (expense) decreased 96%, or \$186,746 to \$8,548 for the nine months ended September 30, 2009, compared to \$195,294 of net income for the same period in 2008. This change was due to a decrease in interest income from lower cash balances.

### Net Loss

The net loss for the nine months ended September 30, 2009, increased 57%, or \$1.8 million to \$5.1 million, compared with a net loss of \$3.2 million for the same period in 2008. This change was primarily due to the net impact of the non-recurring \$4.0 million income recognized in the prior year for the facility lease buyout.

### Liquidity and Capital Resources

We had approximately \$1.9 million in cash and cash equivalents, and \$473,711 in restricted cash as of September 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 through February 2010, assuming we do not trigger additional obligations, and unless unforeseen events arise that negatively impact our liquidity. In the event we are unsuccessful in 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, and reducing our general administrative and other operating expenses while also supporting additional marketing and distribution of our nutritional products. 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. In addition, we have reduced our marketing and general and administrative expenses and continue to evaluate opportunities to reduce operating expenses. As described in Item 5 of Part II of this Quarterly Report, we renegotiated the lease of our corporate facility to reduce our rent and leased space. In addition, in accordance with the amended lease agreement, we reduced our monthly cash lease payment by \$18,000 for a period of one year commencing November 1, 2009. During this one year period, the \$18,000 of our monthly rent will be paid through draw downs on the letter of credit collateralized by \$473,711 of our restricted cash. The letter of credit secures our lease obligation. In August 2009, we paid the rent due for July, August and September 2009. In addition to renegotiating our lease, in August 2009 we eliminated one executive position and in October 2009 reduced the annual cash compensation for two executive officers effective November 2009.

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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.

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 the shelf registration statement 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 our common stock on the NYSE Amex may further limit our ability to access the capital markets. 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. Any issuance of additional securities would be extremely dilutive to the Company's existing stockholders.

Our failure to increase revenues or raise capital, including financial support from partnerships or other collaborations prior to February 2010 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 \$975,000. 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 nine months ended September 30, 2009 was approximately \$4.2 million compared to \$2.2 million for the nine months ended September 30, 2008. The nine months ended September 30, 2008 include a \$4.0 million gain on our lease termination. Expenditures for the nine months ended September 30, 2009 decreased substantially and operating revenues decreased due to lower income.

Cash flows from investing activities—Cash flows used in investing activities of \$89,064 during the nine months ended September 30, 2009 primarily represent 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 \$726,447 during the nine months ended September 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 used by financing activities for the nine months ended September 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 nine months ended September 30, 2008 cash flows used by financing activities primarily represented payments made on our term loan offset by the proceeds from the exercise of options and warrants.

As of September 30, 2009, we had \$1.8 million of working capital compared to \$5.8 million as of December 31, 2008. We have accumulated net losses of approximately \$69.0 million from our inception through September 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.

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Item 4. Controls and Procedures

Evaluation of Disclosure Controls and Procedures

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

Changes in Internal Control Over Financial Reporting

There have been no changes in our internal control over financial reporting during the third quarter of fiscal 2009 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

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 by February 2010, 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 through February 2010. 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 February 2010 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. In addition, we have reduced marketing and general and administrative costs and continue to evaluate opportunities to reduce operating expenses. If we are forced to reduce or cease our operations we may trigger additional obligations, including executive 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. In addition, the reduction in our marketing and business development activities will make it more difficult to complete a strategic alliance. 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 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.

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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 our drug delivery development programs, prosecution of our intellectual property, and the pursuit of licensing arrangements and strategic alliances. 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 September 15, 2009, we received notice that the NYSE Amex LLC (the “Exchange”) had accepted our plan of compliance with respect to the previously reported failure to comply with the Exchange’s continued listing standard set forth in Section 1003a)(iii) of the NYSE Amex Company Guide. Such deficiency relates to our failure to maintain stockholders’ equity of at least \$6,000,000 and because we have had losses from continuing operations and net losses in our five most recent fiscal years . If we are not in compliance with the continued listing standards within the appropriate time period, or if we do not make progress consistent with the plan during the plan period, we may become subject to delisting proceedings. Also on September 15, 2009, we received a separate notice from the Exchange stating that we did not meet the continued listing standard set forth in Section 1003(a)(iv) of the Company Guide because, based on the Exchange’s review of our Form 10-Q for the period ending June 30, 2009, we had sustained losses which are so substantial in relation to our overall operations or our financial resources, or our financial condition had become so impaired that it appeared questionable, in the opinion of the Exchange, as to whether we will be able to continue operations and/or meet our obligations as they mature. On October 15, 2009 we submitted additional information to the Exchange to address how we plan to regain compliance with section 1003(a)(iv) of the Company Guide by March 15, 2010. 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.

Item 5. Other Information

On November 5, 2009, we entered into an agreement with Arden Realty Limited Partnership amending its lease dated June 20, 2008 of office and laboratory space at 19204 North Creek Parkway, Bothell, Washington. Under the terms of the amended lease, we reduced the amount of leased space to 15,615 square feet from 20,468 square feet and reduced the rental payments to the amounts set forth below. In addition, effective November 1, 2009, we will be allowed to



pay up to \$18,000 of our monthly rent for twelve months through draw downs on the letter of credit which secures the lease. The remaining letter of credit (estimated to be \$256,820 after such reductions) shall remain in place through the lease termination date of January 31, 2016.

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The remaining monthly rent is as follows:

| Period                               | Monthly Basic Rental - Total Premises |
|--------------------------------------|---------------------------------------|
| November 1, 2009 – August 31, 2010   | \$25,684.60                           |
| September 1, 2010 – October 31, 2010 | \$26,444.60                           |
| November 1, 2010 – August 31, 2011   | \$26,444.60                           |
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| September 1, 2013 – August 31, 2014  | \$28,904.13                           |
| September 1, 2014 – August 31, 2015  | \$29,775.21                           |
| September 1, 2015 – January 31, 2016 | \$30,669.67                           |

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## Item 6. Exhibits

The following exhibits are filed herewith:

| Exhibit No. | Description  | Filed<br>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   |
| 10.3        | Separation and Release of Claims Agreement dated August 28, 2009, between Bruce S. Morra and the Company   | X                 |      |                           |           |             |
| 10.4        | Letter Agreement Regarding Separation and Release of Claims Agreement dated September 9, 2009, between Bruce S. Morra and the Company                | X                 |      |                           |           |             |
| 10.5        | Letter Agreement Regarding Employment dated October 28, 2009, between Stephen J. Turner and the Company, and between Richard M. Levy and the Company |                   | 8-K  | 10.1                      | 091152300 | 11/3/2009   |
| 10.6        | First Amendment to Lease dated November 5, 2009, between Arden Realty Limited Partnership and the Company  | X                 |      |                           |           |             |
| 31.1        | Certification of Chief Executive Officer pursuant to Section 302 of  | X                 |      |                           |           |             |

the Sarbanes-Oxley Act  
of 2002

Certification of Chief  
Financial Officer pursuant  
to Section 302 of the  
Sarbanes-Oxley Act of  
31.2 2002 X

Certification of Chief  
Executive Officer  
pursuant to Section 906 of  
the Sarbanes-Oxley Act of  
32.1 2002 X

Certification of Chief  
Financial Officer pursuant  
to Section 906 of the  
Sarbanes-Oxley Act of  
32.2 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/ STEPHEN J. TURNER  
Stephen J. Turner  
President and Chief Executive  
Officer  
(Principal Executive Officer)

Date: November 6, 2009

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

Date: November 6, 2009

## EXHIBIT INDEX

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