

SCOLR Pharma, Inc.  
Form 10-Q  
May 09, 2011  
Table of Contents

**UNITED STATES**  
**SECURITIES AND EXCHANGE COMMISSION**

Washington, D.C. 20549

**FORM 10-Q**

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

For the quarterly period ended March 31, 2011

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)

Edgar Filing: SCOLR Pharma, Inc. - Form 10-Q

**Delaware** **91-1689591**  
(State or other jurisdiction of **(I.R.S. Employer**  
**incorporation or organization)** **Identification No.)**  
**19204 North Creek Parkway, Suite 100, Bothell, Washington 98011**  
**(Address of principal executive offices, including zip code)**  
**425-368-1050**  
**(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

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 by check mark whether the registrant is a shell company (as defined in Rule 12b-2 of the Exchange Act) Yes  No

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

Title	Shares outstanding as of May 5, 2011
Common Stock, par value \$0.001	49,816,073

**Table of Contents**

**SCOLR Pharma, Inc.**

**FORM 10-Q**

**For the Quarterly Period Ended March 31, 2011**

**Table of Contents**

**PART I: Financial Information**

<u>Item 1. Financial Statements</u>	1
<u>Unaudited Condensed Balance Sheets at March 31, 2011 and December 31, 2010</u>	1
<u>Unaudited Condensed Statements of Operations for the three-month periods ended March 31, 2011, and March 31, 2010</u>	2
<u>Unaudited Condensed Statements of Cash Flows for the three-month periods ended March 31, 2011, and March 31, 2010</u>	3
<u>Notes to Unaudited Condensed Financial Statements</u>	4
<u>Item 2. Management's Discussion and Analysis of Financial Condition and Results of Operations</u>	8
<u>Item 4. Controls and Procedures</u>	12
<b><u>PART II: Other Information</u></b>	13
<u>Item 1. Legal Proceedings</u>	13
<u>Item 1A. Risk Factors</u>	13
<u>Item 2. Unregistered Sales of Equity Securities and Use of Proceeds</u>	14
<u>Item 6. Exhibits</u>	14
<b><u>Signatures</u></b>	15

**Table of Contents****PART I: FINANCIAL INFORMATION****Item 1. Financial Statements****SCOLR Pharma, Inc.****CONDENSED BALANCE SHEETS**

(In thousands, except par values and number of shares)

	March 31, 2011 (Unaudited)	December 31, 2010
<b>ASSETS</b>		
Current Assets		
Cash and cash equivalents	\$ 822	\$ 1,891
Accounts receivable and other receivables	67	103
Inventory	323	324
Prepaid expenses and other assets	145	270
Total current assets	1,357	2,588
Property and Equipment net of accumulated depreciation of \$242 and \$217, respectively	303	327
Intangible assets net of accumulated amortization of \$382 and \$354, respectively	672	686
Restricted cash	257	257
	\$ 2,589	\$ 3,858
<b>LIABILITIES AND STOCKHOLDERS EQUITY</b>		
Current Liabilities		
Accounts payable	\$ 183	\$ 145
Accrued liabilities	319	307
Deferred revenue		56
Fair value of warrant	45	150
Total current liabilities	547	658
Deferred rent	149	159
Total liabilities	696	817
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 49,816,073 issued and outstanding as of March 31, 2011, and December 31, 2010	49	49
Additional paid-in capital	77,115	77,041
Accumulated deficit	(75,271)	(74,049)
Total stockholders equity	1,893	3,041
	\$ 2,589	\$ 3,858

Edgar Filing: SCOLR Pharma, Inc. - Form 10-Q

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

**Table of Contents****SCOLR Pharma, Inc.****UNAUDITED CONDENSED STATEMENTS OF OPERATIONS****(In thousands, except per share amounts and number of shares)**

	<b>Three months ended March 31,</b>	
	<b>2011</b>	<b>2010<sup>1</sup></b>
<b>Revenues</b>		
Licensing fees	\$	\$ 25
Royalty income	66	141
Research and development	118	
<b>Total revenues</b>	<b>184</b>	<b>166</b>
<b>Operating expenses</b>		
Marketing and selling	125	59
Research and development	647	340
General and administrative	740	601
<b>Total operating expenses</b>	<b>1,512</b>	<b>1,000</b>
<b>Loss from operations</b>	<b>(1,328 )</b>	<b>(834 )</b>
<b>Other income (expense)</b>		
Interest income	1	1
Unrealized gain (loss) on fair value of warrant	105	(218)
<b>Total other income (expense)</b>	<b>106</b>	<b>(217)</b>
<b>Net loss</b>	<b>\$ (1,222)</b>	<b>\$ (1,051)</b>
<b>Net loss per share, basic and diluted</b>	<b>\$ (0.02)</b>	<b>\$ (0.02)</b>
<b>Shares used in computing basic and diluted net loss per share</b>	<b>49,816,073</b>	<b>43,140,968</b>

<sup>1</sup> See Note 1 to financial statements

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

**Table of Contents****SCOLR Pharma, Inc.****UNAUDITED CONDENSED STATEMENTS OF CASH FLOWS****(In thousands)**

	<b>Three months ended March 31,</b>	
	<b>2011</b>	<b>2010<sup>1</sup></b>
<b>Cash flows from operating activities:</b>		
Net loss	\$ (1,222)	\$ (1,051)
Reconciliation of net loss to net cash used in operating activities		
Depreciation and amortization	51	64
Write-off of intangible assets		11
Unrealized (gain) loss on fair value of warrant	(105)	218
Share-based compensation for employee services	74	64
Increase (decrease) in cash resulting from changes in assets and liabilities		
Accounts and other receivables	35	125
Prepaid expenses and other current assets	125	(73)
Accounts payable and accrued expenses	41	(82)
Deferred revenue	(56)	(25)
<b>Net cash used in operating activities</b>	<b>(1,057)</b>	<b>(749)</b>
<b>Cash flows from investing activities:</b>		
Purchase of equipment and furniture		(3)
Patent and technology rights payments	(12)	(226)
Restricted cash		54
<b>Net cash used by investing activities</b>	<b>(12)</b>	<b>(175)</b>
<b>Cash flows from financing activities:</b>		
Net proceeds from issuance of common stock options and warrants		3,713
<b>Net provided by financing activities</b>		<b>3,713</b>
Net increase (decrease) in cash	(1,069)	2,789
Cash at beginning of period	1,891	1,176
Cash at end of period	\$ 822	\$ 3,965
Issuance of warrants in connection with equity offering	\$	\$ 689

<sup>1</sup> See Note 1 to financial statements

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

---

**Table of Contents**

**SCOLR Pharma, Inc.**

**NOTES TO UNAUDITED CONDENSED FINANCIAL STATEMENTS**

**Note 1 Financial Statements**

The unaudited financial statements of SCOLR Pharma, Inc. (the Company, we or our ) 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 ( SEC ). 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, 2010 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 securities 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, 2011. The accompanying unaudited financial statements and related notes should be read in conjunction with the audited financial statements and the Annual Report on Form 10-K for the fiscal year ended December 31, 2010.

*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 and assumptions are used for several purposes, including, but not limited to, those used in revenue recognition, determination of the allowance for doubtful accounts, depreciable lives of assets, determination of fair value of stock options and warrants, including share-based compensation expense, and deferred tax valuation allowances. Future events and their effect on the Company s reported financial results 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.

*Reclassifications*

Certain prior period amounts have been reclassified from general and administrative expenses to marketing and selling expenses on the Statements of Operations to conform to the current period presentation. These reclassifications did not change the prior year s net cash flows from operating, investing and financing activities.

*Restatement of Prior Period Information*

Financial results for the three months ended March 31, 2010 have been restated to account for an outstanding stock purchase warrant issued by the Company in 2002 with an anti-dilution provision as a liability. Because of the anti-dilution feature, the warrant [is] not considered indexed to the Company s own stock in accordance with Emerging Issues Task Force Issue 07-5 Determining Whether an Instrument (or Embedded Feature) Is Indexed to an Entity s Own Stock (EITF 07-5), codified as ASC 815-40-15 and therefore is required to be classified as a liability and re-measured at fair value at each reporting period, with changes in fair value recognized in operating results. Refer to our Annual Report on Form 10-K for the year ended December 31, 2010 for a detailed discussion of the restatement, including Note 2 to our financial statements in Form 10-K.

**Note 2 New Accounting Pronouncements**

Effective January 1, 2011, the Company adopted Accounting Standard Update ( ASU ) 2009-13, Revenue Arrangements with Multiple Deliverables and ASU 2010-17, Milestone Method of Revenue Recognition. These ASUs revise and clarify accounting for the milestone method and arrangements with multiple deliverables, including how to separate deliverables into units of accounting determining the allocation of revenue to the units of accounting. There are also expanded disclosure requirements for significant judgments made in the application of these standards, if material. The adoption of these pronouncements did not have a material effect on the Company s financial statements.



---

## **Table of Contents**

### **Note 3 Liquidity**

The Company incurred a net loss of approximately \$1,222,000 for the three months ended March 31, 2011, and used cash from operations of approximately \$1,057,000. Cash flows used in investing activities during the three months ended March 31, 2011 of \$12,000 represent patent and trademark related expenditures. Cash flows from investing activities for the period ended March 31, 2010 represent payments for legal expenses associated with our patents, off-set by a decrease in restricted cash of \$54,000 used as payment for rent. Cash flows provided by financing activities for the period ended March 31, 2010, reflects \$3.7 million in proceeds from issuance of common stock and warrants to purchase common stock.

The Company had approximately \$822,000 in cash and cash equivalents, and \$257,000 in restricted cash, related to its facility lease, as of March 31, 2011. The Company is investing its cash and cash equivalents in government-backed securities. These securities have quoted prices in active markets. Based on our existing cash and cash equivalents, and absent additional funding, we will be unable to fund our operations through the second quarter of 2011.

The Company is seeking to take advantage of an opportunity to provide its novel extended release dietary supplements to the market via direct sales efforts to numerous national retailers. The Company will require substantial working capital to source product from third parties for later sale. The Company has not yet secured the additional sources of working capital it anticipates will be needed to fund inventory. The Company may raise additional capital to fund inventory through equity or debt financing, factoring of accounts receivables or other sources. If the Company is unable to obtain necessary additional financing to fund inventory, the Company's ability to provide its extended release dietary supplements to the market via direct sales efforts will be adversely affected and the Company will be required to reduce the scope of its business or discontinue its business operations.

The Company has actively managed its liquidity by limiting clinical and development expenses to its ibuprofen product, and reducing the cash expenses related to its general administrative activities. The Company stopped activities related to its pseudoephedrine product following receipt of an FDA deficiency letter in March, 2011 and ceased substantially all activities related to the actual use study required by the FDA as a prerequisite to submission of its regulatory application for ibuprofen during the second quarter of 2011. The Company requires additional financing, revenue or partnership support in order to fund the remaining activities necessary to complete the study and move forward with its regulatory application. The Company has deferred all significant expenditures on new projects pending additional financing or partnership support. Without additional funding the Company does not expect to be able to complete development of its current projects and anticipates it would be forced to discontinue its operations during the second quarter of 2011.

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 has also sought to generate revenue from product sales and to access capital through strategic transactions and collaborative agreements as opportunities to expand product sales. However, there are significant uncertainties as to the Company's ability to increase revenues or access potential sources of capital. The Company may not be able to obtain financing or enter any collaboration on terms acceptable to it, 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.

The Company's failure to increase revenues or raise capital, including financial support from partnerships or other collaborations would force the Company to reduce or cease operations. If the Company is forced to reduce or cease our operations, it may trigger additional obligations, including contractual severance obligations aggregating as much as \$150,000. In addition, the Company may be forced to liquidate assets at reduced levels due to our immediate liquidity requirements.

### **Note 4 Accounts Receivable**

At March 31, 2011, accounts receivable consisted of royalty receivables. The Company did not have any write-offs or bad debt expense in three months ended March 31, 2011 and 2010. In addition, the Company did not have an allowance for doubtful accounts as of March 31, 2011 or December 31, 2010, as all accounts receivable were considered collectible.

### **Note 5 Income Taxes**

The Company continues to maintain a valuation allowance for the full amount of the net deferred tax asset balance associated with its net operating losses as sufficient uncertainty exists regarding its ability to realize such tax assets in the future. The Company expects the amount of the net deferred tax asset balance and full valuation allowance to increase in future periods as it incurs future net operating losses. There were no unrecognized tax benefits as of March 31, 2011 or December 31, 2010. The Company does not anticipate any significant changes to its

unrecognized tax benefits within the next twelve months.

**Table of Contents****Note 6 Technical Rights, Patent License and Royalty Agreements**RedHill Biopharma Ltd.

On May 2, 2010, the Company entered into an Exclusive License Agreement (the Agreement) with RedHill Biopharma Ltd., an Israeli company (RedHill). Under the Agreement, SCOLR granted to RedHill the exclusive, worldwide, and perpetual rights to produce, market, and sell Ondansetron tablet formulations based on SCOLR's proprietary CDT platforms. Under the terms of the Agreement, the Company received the initial licensing fee of \$100,000 in May 2010. Additionally, RedHill is obligated to make milestone payments to SCOLR of \$250,000 each upon (i) final marketing approval by the FDA of the Ondansetron product and (ii) the first commercial sale of the product by RedHill. SCOLR will receive an 8% royalty on direct and sublicense sales royalties actually received by RedHill, net of RedHill's reasonable marketing and distribution expenses. The Agreement specifies a maximum payment to SCOLR, including royalties and all other fees, of \$30 million.

On November 3, 2010, RedHill engaged SCOLR Pharma to perform certain research services related to an extended release formulation of Ondansetron. Under the agreement, RedHill is to pay SCOLR \$100,000 in total fees. RedHill paid \$50,000 of the total fee upon signing the agreement and paid the remaining \$50,000 in the first quarter of 2011. The full \$100,000 was recorded as revenue in the first quarter of 2011.

Perrigo Company of South Carolina, Inc

On October 20, 2005, the Company entered into a Manufacture, License and Distribution Agreement with a subsidiary of Perrigo Company (Perrigo). Perrigo is a leading global healthcare supplier and one of the world's largest manufacturers of OTC pharmaceutical and nutritional products for the store brand and contract manufacturing markets. Under the agreement, the Company granted a license to its CDT technology to Perrigo for the manufacture, marketing, distribution, and sale of specific dietary supplements in the United States. The Company receives royalty payments based on Perrigo's net profits derived from the sales of products subject to the agreement. On January 24, 2010, the Company amended the Perrigo agreement to provide for a reduction in the royalty rate due to it on sales by Perrigo of products licensed under the Agreement. The amendment also modified the methodology for calculation of net profits for determining the amount of such royalties, removed Perrigo's exclusivity rights with respect to three out of the five categories of products licensed under the agreement and eliminated Perrigo's right to request that it develop additional dietary supplement products for sale under the agreement.

The term of the agreement is determined on a product-by-product basis and, unless earlier terminated, ends with respect to particular products on the tenth anniversary of the first commercial sale of that product. Two principal products are sold by Perrigo under the Agreement, one of which, glucosamine chondroitin, began commercial sales in 2005, and the other, a calcium supplement, began commercial sale in August 2007. In addition, under certain conditions, the Company may terminate the agreement with respect to individual products covered thereby at any time after the fifth (5th) anniversary of the first commercial sale of that product. The agreement is otherwise terminable by mutual consent, for material breach, or in circumstances of bankruptcy, insolvency or liquidation.

During the fourth quarter of 2010, the Company was informed by Perrigo, that certain retail accounts will no longer carry certain of Perrigo's products. The Company expects revenues from Perrigo to continue to decrease substantially as a result of such discontinuance as remaining product is sold through during the first half of 2011.

**Note 7 Warrants**

During the three months ended March 31, 2011, there were no warrants exercised. The Company had the following warrants to purchase common stock outstanding at March 31, 2011:

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
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
March 12, 2010	2,230,200	0.75	5 years	2,230,200	March 11, 2015
August 27, 2010	100,000	0.50	10 years	100,000	August 26, 2020
Grand Total	4,481,750			4,481,750	



**Table of Contents**

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

The 2002 warrant had a fair value of \$45,000 as of March 31, 2011. The \$105,000 unrealized gain for the change in fair value for the quarter ending March 31, 2011 has been recognized in other income in the statement of operations.

**Note 8 Share-Based Compensation**

During the three-month period ended March 31, 2011, the Company granted 10,000 options to purchase shares of its common stock pursuant to the Company's 2004 Equity Incentive Plan. The fair value of the stock options awarded was \$2,000. Additionally, in February 2011, 26,500 restricted stock shares vested at a grant price of \$1.29. These shares vested over a three year period.

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 (in thousands):

Functions	Three Months Ended	
	March 31,	
	2011	2010
Research and development	6	15
General and administrative	68	49
<b>Total</b>	<b>\$ 74</b>	<b>\$ 64</b>

**Note 9 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 were 49,816,073 and 43,140,968 for the three months ended March 31, 2011 and 2010 respectively.

For the three month period ending March 31, 2011, 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 2011 and 2010 as the effect would have been anti-dilutive.

	2011	2010
Assumed exercise of stock options	3,410,401	4,946,419
Assumed conversion of warrants	4,481,750	4,381,750
<b>Total</b>	<b>7,892,151</b>	<b>9,328,169</b>

**Note 10 Subsequent Events**

On April 26, 2011, we executed a Second Amendment to Lease Agreement (the Lease Amendment) with the landlord of the Company's principal office in Bothell, Washington under the Standard Multi-Tenant Lease dated June 19, 2008 between the Company and the landlord, as amended (the Lease). Pursuant to the terms of the Lease Amendment, the Company and the landlord agreed to (1) reduce the term of the Lease such that it will expire on March 31, 2012 rather than January 31, 2016, (2) reduce the amount of monthly rent and common area maintenance (CAM) charges from



---

## **Table of Contents**

approximately \$38,756 to \$11,050 (a portion of which the Company collects from existing subtenants), and (3) forgive all past due amounts in respect of unpaid rent and CAM charges. In consideration for the landlord's agreement to the Lease Amendment, the landlord is entitled to retain the cash security deposit paid by the Company to the landlord under the Lease and to fully draw down and retain a Letter of Credit issued by Silicon Valley Bank in favor of the landlord. The Lease Amendment also provides for termination of the Lease by the landlord upon 75 days written notice to the Company and provides the landlord with certain rights to re-market the premises.

On April 26, 2011, each of Stephen J. Turner, President and Chief Executive Officer, and Richard M. Levy, Executive Vice President and Chief Financial Officer, entered into amendments to their employment agreements with the Company pursuant to which Messrs. Turner and Levy agreed to accept a reduction in their severance benefits. Under the existing employment agreements, Mr. Turner and Mr. Levy were separately entitled, upon termination of their employment by the Company without cause, or upon their resignation for good reason in connection with or within 12 months following a change of control (as such terms are defined in the agreements), to severance benefits consisting of (1) cash payments of \$316,665 and \$282,830, respectively, (2) continuation of medical coverage for up to 12 months following termination and (3) acceleration of vesting of the unvested portion of stock options outstanding as of the date of termination. Under the amended employment agreements, each of Mr. Turner and Mr. Levy are separately entitled to receive cash severance of \$75,000 upon the termination of their employment by the Company without cause, or \$150,000 upon their resignation for good reason in connection with or within 12 months following a change of control. Messrs. Turner and Levy continue to be eligible for acceleration of vesting on any unvested options outstanding upon termination in either circumstance. The Company will no longer be obligated to provide continued medical coverage benefits upon termination of their employment.

### **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 unaudited financial statements, including the notes thereto, appearing in Item 1 of Part I of this quarterly report and the audited financial statements for the year ended December 31, 2010 in our annual report on Form 10-K for the year ended December 31, 2010 (2010 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 results, performance or achievements could differ materially from historical results or those contemplated, expressed or implied by the forward-looking statements contained in this report.

Important factors that could cause actual results to differ materially from our forward-looking statements are set forth under the heading Risk Factors in our 2010 Form 10-K, as supplemented and modified in our quarterly reports on Form 10-Q, including in Item 1A of Part II herein, 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.

### **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, over-the-counter (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 extended release nutritional products incorporating our CDT platforms that are sold by national retailers through our licensed partner, Perrigo. In October 2005, we entered into a strategic alliance with a subsidiary of Perrigo 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 and such royalty payments have historically been our primary source of revenue. In the fourth quarter of 2010, we were informed by Perrigo that certain retail accounts will no longer carry certain of Perrigo's products. We expect revenues from Perrigo to decrease substantially as a result of such discontinuance as remaining product is sold through during the first half of 2011. However, we anticipate introduction of improved formulations of similar products into the retail channel via our direct sales efforts in the United States.

We are seeking to provide our novel extended release dietary supplements to the market via direct sales efforts to numerous national retailers. This distribution channel is anticipated to provide higher contribution margins as compared





---

**Table of Contents**

to royalty revenues from a partnership. We have commercial relationships with contract manufacturing and distribution firms, sales and marketing brokers and business process services providers in place in order to support these direct sales efforts.

Our lead product candidate is a CDT-based extended 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 extended release ibuprofen for the OTC market. We have ceased substantially all activities on the actual use study required by the FDA as a prerequisite to submission of our regulatory application for ibuprofen prior to enrollment in that study. We will require additional financing, revenue or partnership support in order to fund the remaining activities necessary to complete the study and move forward with our regulatory application on the product. There are currently no extended 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. We submitted several amendments to our ANDA based upon comments from the FDA. On March 8, 2011, the FDA Division of Bioequivalence (Bioequivalence) identified further deficiencies related to our clinical study and requested additional information in order to continue the Bioequivalence review on our pending ANDA application. The FDA is unable to approve the ANDA application until the deficiencies are resolved. The FDA's action prevents us from receiving approval of the ANDA in 2011. We will need to obtain additional funding, revenue or partnership support to address the deficiencies. If approved, we believe our formulation will offer attractive tablet size and cost saving opportunities when compared to similar tablets already on the market.

In addition to cost saving measures implemented in 2010, in an effort to further reduce the Company's expenses, on April 26, 2011, we executed a Second Amendment to Lease Agreement (the Lease Amendment) with the landlord of the Company's principal office in Bothell, Washington under the Standard Multi-Tenant Lease dated June 19, 2008 between the Company and Arden, as amended (the Lease). Pursuant to the terms of the Lease Amendment, the Company and the landlord agreed to (1) reduce the term of the Lease such that it will expire on March 31, 2012 rather than January 31, 2016, (2) reduce the amount of monthly rent and common area maintenance (CAM) charges from approximately \$38,756 to \$11,050 (a portion of which the Company collects from existing subtenants), and (3) forgive all past due amounts in respect of unpaid rent and CAM charges. In consideration for the landlord's agreement to the Lease Amendment, the landlord is entitled to retain the cash security deposit paid by the Company to the landlord under the Lease and to fully draw down and retain a Letter of Credit issued by Silicon Valley Bank in favor of the landlord. The Lease Amendment also provides for termination of the Lease by the landlord upon 75 days written notice to the Company and provides the landlord with certain rights to re-market the premises.

Additionally, on April 26, 2011, each of Stephen J. Turner, President and Chief Executive Officer, and Richard M. Levy, Executive Vice President and Chief Financial Officer, entered into amendments to their employment agreements with the Company pursuant to which Messrs. Turner and Levy agreed to accept a reduction in their severance benefits. Under the existing employment agreements, Mr. Turner and Mr. Levy were separately entitled, upon termination of their employment by the Company without cause, or upon their resignation for good reason in connection with or within 12 months following a change of control (as such terms are defined in the agreements), to severance benefits consisting of (i) cash payments of \$316,665 and \$282,830, respectively, (ii) continuation of medical coverage for up to 12 months following termination and (iii) acceleration of vesting of the unvested portion of stock options outstanding as of the date of termination. Under the amended employment agreements, each of Mr. Turner and Mr. Levy are separately entitled to receive cash severance of \$75,000 upon the termination of their employment by the Company without cause, or \$150,000 upon their resignation for good reason in connection with or within 12 months following a change of control. Messrs. Turner and Levy continue to be eligible for acceleration of vesting on any unvested options outstanding upon termination in either circumstance. The Company will no longer be obligated to provide continued medical coverage benefits upon termination of their employment.

We expect our operating losses to decline and cash flows to improve as we advance direct sales of our nutritional products. However, we will need to raise additional capital to fund operations in the short-term, advance our nutritional products business, 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, we will be required to reduce the scope of our business, or discontinue operations.

---

## **Table of Contents**

### **Critical Accounting Policies and Estimates**

Since December 31, 2010, none of our critical accounting policies, or our application thereof, as more fully described in the 2010 Form 10-K, 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**

Effective January 1, 2011, the Company adopted Accounting Standard Update ( ASU ) 2009-13, Revenue Arrangements with Multiple Deliverables and ASU 2010-17, Milestone Method of Revenue Recognition. These ASUs revise and clarify accounting for the milestone method and arrangements with multiple deliverables, including how to separate deliverables into units of accounting determining the allocation of revenue to the units of accounting. There are also expanded disclosure requirements for significant judgments made in the application of these standards, if material. The adoption of these pronouncements did not have a material effect on the Company's financial statements.

### **Results of Operations**

#### ***Comparison of the Three Months Ended March 31, 2011 and 2010***

##### ***Revenues***

Total revenues, which consist of licensing fees, research and development revenues, and royalty revenue from our collaboration agreements, increased 11%, or \$18,000 to \$184,000 for the three months ended March 31, 2011, compared to \$166,000 for the same period in 2010. This increase is due to recognition of \$100,000 in revenue attributable to our contract with RedHill Biopharma Ltd. ( RedHill ) for certain development services in connection with the license by RedHill of our CDT platforms for use in Ondansetron tablet formulations. Off-setting this increase is a \$75,000 reduction in royalty revenue from sales of our nutritional products by Perrigo compared to the prior period. Royalty payments are based on Perrigo's net profits from the sale of CDT-based products. During the fourth quarter of 2010, the Company was informed by Perrigo, that certain retail accounts will no longer carry certain of Perrigo's products. The Company expects revenues from Perrigo to continue to decrease substantially as a result of such discontinuance as remaining product is sold through during the first half of 2011.

##### ***Operating Expenses***

##### **Marketing and Selling Expenses**

Marketing and selling expenses increased 112%, or \$66,000 to \$125,000 for the three months ended March 31, 2011, compared to \$59,000 for the same period in 2010. This increase is primarily due to minimum annual royalty expense for the fee due to Temple University associated with our patents. The amount was amortized over the full year in 2010.

##### **Research and Development Expenses**

Research and development expenses increased 90%, or \$307,000 to \$647,000 for the three months ended March 31, 2011, compared to \$340,000 for the same period in 2010. This increase is due primarily to the advancement of the actual use study on our ibuprofen lead product during the first quarter of 2011, research and development work for RedHill, and formulation work related to our nutritional products.

##### **General and Administrative Expenses**

General and administrative expenses increased 23%, or \$139,000 to \$740,000 for the three months ended March 31, 2011, compared to approximately \$601,000 for the same period in 2010, primarily due to an increase in legal expense of \$93,000 related to business agreements and SEC reporting and corporate governance matters. In addition, personnel related expenses increased \$38,000 due to an increase in the number of employees and non-cash share based compensation expense. Insurance premiums decreased \$17,000 due to lower rates, and dues and seminars decreased \$13,000 as we eliminated activities.



## **Table of Contents**

### ***Other Income (Expense), Net***

Other income increased 148%, or \$323,000 to \$106,000 for the three months ended March 31, 2011, compared to \$217,000 other expense for the comparable period in 2010. This increase is due to the \$105,000 unrealized gain on fair value of warrant to purchase common stock for the three months ended March 31, 2011 as compared to the \$218,000 unrealized loss for the three months ended March 31, 2010.

### ***Net Loss***

Net loss increased 16%, or \$171,000 to \$1,222,000 for the three months ended March 31, 2011, compared to \$1,051,000 for the same period in 2010. The increase in net loss reflects higher research and development expenses.

### ***Liquidity and Capital Resources***

On March 31, 2011, we had approximately \$822,000 in cash and cash equivalents, and \$257,000 in restricted cash, related to our facility lease as of March 31, 2011. Based on our existing cash and cash equivalents, and absent additional funding, we will be unable to fund our operations through the second quarter of 2011.

Our current operating strategy is to actively manage our liquidity by limiting clinical and development expenses to our ibuprofen lead product, 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 remaining activities on the actual use study required by the FDA as a prerequisite to submission of our regulatory application for ibuprofen, pending additional financing, revenue or partnership support. Without continuing revenues or additional funding, we would not be able to continue our activities related to our nutritional products business, and complete development of our new products. In addition, we continue to evaluate opportunities to reduce operating expenses.

We are seeking to take advantage of an opportunity to market our novel extended release dietary supplements via direct sales efforts to numerous national retailers. This distribution channel is anticipated to provide higher contribution margins as compared to royalty revenues from a partnership. We have commercial relationships with contract manufacturing and distribution firms in addition to sales and marketing brokers in place, in order to support these direct sales efforts.

We will be required to fund inventory purchases necessary to fulfill any orders of our nutritional products, and we expect a delay in the conversion of such any such orders to cash. We have not yet secured the additional sources of working capital we anticipate will be needed to fund inventory. We may raise additional capital to fund inventory through equity or debt financing, factoring of accounts receivables or other sources. If we are unable to obtain the necessary additional financing to fund inventory, our ability to provide our extended release dietary supplements to the market via direct sales efforts will be adversely affected and we will be required to reduce the scope of our business or discontinue our business operations.

In addition to our direct sales efforts on consumer products, we continue to seek collaborative arrangements, acquisitions and alliances with corporate partners, licensors, and licensees to provide options for the research, development, clinical testing, manufacturing, marketing, and commercialization of our various product candidates in order to maximize the return on each development investment. Our acquisition of the global (excluding Canada) brand Nuprin® is expected to provide additional opportunities for our extended release ibuprofen product.

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 have also sought to generate revenue from product sales and to access capital through strategic transactions and collaborative agreements as opportunities to expand product sales. However, there are significant uncertainties as to our ability to increase revenues or access potential sources of capital. We may not be able to obtain financing or enter any collaboration on terms acceptable to it, 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.

Our failure to increase revenues or raise capital, including financial support from partnerships or other collaborations would 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 \$150,000. In addition, we may be forced to liquidate assets at reduced levels due to our immediate liquidity requirements.

## Edgar Filing: SCOLR Pharma, Inc. - Form 10-Q

*Cash flows from operating activities* Net cash used in operating activities for the three months ended March 31, 2011 was approximately \$1,057,000 compared to \$749,000 for the three months ended March 31, 2010. The increase

---

## **Table of Contents**

in cash flows used in operating activities reflects our advancement of the actual use study for our lead ibuprofen product, research and development work for RedHill, and the formulation work related to our nutritional products for the three months ended March 31, 2011 compared with the same period in 2010.

*Cash flows from investing activities* Cash flows used in investing activities of \$12,000 during the three months ended March 31, 2010 primarily represent payments for patent rights. Cash flows used in investing activities for the three months ended March 31, 2010 primarily represent \$226,000 in payments for patent rights, and a \$54,000 reduction in our restricted cash balance used to reduce our lease obligation.

*Cash flows from financing activities* Cash flows from financing activities for the three months ended March 31, 2010 primarily represent net proceeds of \$3.7 million from issuance of common stock and stock warrants in our March 2010 equity transaction. There were no cash flows from financing activities for the three months ended March 31, 2011.

As of March 31, 2011, we had \$810,000 of working capital compared to \$1.9 million as of December 31, 2010. We have accumulated net losses of approximately \$75.3 million from our inception through March 31, 2011.

### **Item 4. Controls and Procedures** **Evaluation of Disclosure Controls and Procedures**

The Company's management, with the participation of its Chief Executive Officer and Chief Financial Officer, conducted an evaluation of the effectiveness of the design and operation of the Company's disclosure controls and procedures, as required by Rule 13a-15 of the Securities Exchange Act of 1934, as amended (the Exchange Act). Based on that evaluation and review of the material weakness in our controls over financial reporting identified below, the Chief Executive Officer and Chief Financial Officer have concluded that, as of the end of the period covered by this report, the Company's disclosure controls and procedures were not effective to ensure that information required to be disclosed by the Company in the reports that it files or submits under the Exchange Act is recorded, processed, summarized and reported within the time periods specified by the SEC's rules and forms and such information is accumulated and communicated to management, including the Company's Chief Executive Officer and Chief Financial Officer as appropriate to allow timely decisions regarding required disclosures.

### **Changes in Internal Control over Financial Reporting**

The Company's management is responsible for establishing and maintaining adequate internal control over financial reporting. The Company's internal control over financial reporting is a process designed under the supervision of its Chief Executive Officer and Chief Financial Officer to provide reasonable assurance regarding the reliability of financial reporting and the preparation of the Company's financial statements for external reporting in accordance with accounting principles generally accepted in the United States of America. Management evaluates the effectiveness of the Company's internal control over financial reporting using the criteria set forth by the Committee of Sponsoring Organizations of the Treadway Commission (COSO) in Internal Control Integrated Framework. During the fourth quarter of 2010, management, under the supervision and with the participation of the Company's Chief Executive Officer and Chief Financial Officer, assessed the effectiveness of the design and operation of the Company's internal control over financial reporting and identified a material weakness in internal control over financial reporting.

The material weakness pertains to controls relating to the process of accounting for warrants, specifically related to derivatives associated with issuance of warrants. Management concluded that the above control deficiency represents a material weakness in internal control over financial reporting. A material weakness is a control deficiency, or combination of control deficiencies, that results in a more than remote likelihood that a material misstatement of the annual or interim financial statements will not be prevented or detected.

During the course of assessing the effectiveness of both the design and operation of our internal control over financial reporting, we implemented a number of significant improvements in our internal control over financial reporting during the fourth quarter of 2010. We (i) hired a new Controller to provide additional experienced staff in our finance and accounting group, (ii) engaged outside contractors to ensure that accounting personnel with adequate experience, skills and knowledge relating to non-routine transactions are directly involved in the review and accounting evaluation of our non-routine transactions, and (iii) engaged an independent third party to assist our efforts to comply with Section 404 of the Sarbanes-Oxley Act of 2002.

During the fourth quarter of 2010, management identified additional steps necessary to address the material weakness described above. These measures included the implementation of procedures requiring more detailed



## **Table of Contents**

documentation of our complex, non-routine transactions and the application of generally accepted accounting principles to such transactions. During the first quarter of 2011, we implemented policies and procedures to assure timely involvement of specialized accounting resources, as needed in connection with the application of generally accepted accounting principles to complex, non-routine transactions. Additionally, we implemented a reorganization of our accounting and finance department in an effort to assure adequate review of non-routine transactions. We believe that the steps identified will improve the effectiveness of our internal controls over financial reporting as they relate to accounting for non-routine transactions.

Other than as described above, there was no change in our internal control over financial reporting (as defined in Rules 13a-15(f) and 15d-15(f) under the Exchange Act) occurred during the three month period ended March 31, 2011, that has materially affected, or is reasonably likely to materially affect, our internal control over financial reporting.

### **Limitations on the Effectiveness of Controls**

Because of its inherent limitations, internal control over financial reporting may not prevent or detect misstatements. Also, projections of any evaluation of effectiveness to future periods are subject to the risk that controls may become inadequate because of changes in conditions, or that the degree of compliance with the policies or procedures may deteriorate.

## **PART II: OTHER INFORMATION**

### **Item 1. Legal Proceedings**

We are not a party to any material litigation.

### **Item 1A. Risk Factors**

Other than as supplemented below there has been no change to the risk factors identified in our Annual Report on Form 10-K for the year ended December 31, 2010.

#### ***We do not have sufficient cash to fund the operation of our business through the second quarter of 2011.***

Our existing cash and cash equivalents are not expected to be sufficient to fund our operations through the second quarter of 2011.

We will need to raise additional capital to continue our operations over the short-term and will require additional financing, revenue or partnership support to conduct clinical trials, continue research and development projects, meet the working capital associated with our nutritional business and commercialize our product candidates. The timing and amount of our need for additional financing will depend on a number of factors, including:

our ability to raise needed capital quickly, at favorable pricing and on favorable terms;

the structure and timing of collaborations with strategic partners and licensees;

the timing of incurrence of the more significant costs items associated with the launch of the actual use study for our ibuprofen product;

the timing of an anticipated increase in our requirement for working capital related to any shipments of our nutritional products;





---

**Table of Contents**

our timetable and costs for the development of marketing operations and other activities related to the commercialization of our product candidates;

our ability to timely obtain any shareholder approvals necessary to complete a financing transaction;

the progress of our research and development programs and expansion of such programs;

the emergence of competing technologies and other adverse market developments; and,

the prosecution, defense and enforcement of potential patent claims and other intellectual property rights.

Additional equity or debt financing may not be available to us on acceptable terms, or at all. If we raise additional capital by issuing equity securities, substantial additional dilution to our existing stockholders may result which could decrease the market price of our common stock due to the sale of a large number of shares of our common stock in the market, or the perception that these sales could occur. These sales, or the perception of possible sales, could also impair our ability to raise capital in the future. In addition, the terms of any equity financing may adversely affect the rights of our existing stockholders. If we raise additional funds through strategic alliance or licensing arrangements, we may be required to relinquish rights to certain of our technologies or product candidates, or to grant licenses on terms that are unfavorable to us, which could substantially reduce the value of our business. If we are forced to reduce or cease our operations we may trigger additional obligations, including contractual severance obligations aggregating as much as \$150,000. In addition, we may be forced to liquidate assets at reduced levels due to our immediate liquidity requirements.

If we are unable to obtain sufficient additional financing to continue our near-term operations we may be forced to discontinue our operations during the second quarter of 2011. If we are unable to fulfill our future capital needs, we would be unable to meet our obligations and we would be required to delay, reduce or eliminate some or all of our business operations, including the pursuit of licensing, strategic alliances and development of drug delivery programs.

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

None

**Item 6. Exhibits**

The following exhibits are filed herewith:

<b>Exhibit No.</b>	<b>Description</b>
10.1	Second Amendment to Lease dated April 26, 2011 between Arden Realty Limited Partnership and Company
10.2	Amendment to Executive Employment Agreement dated April 26, 2011 between Stephen J. Turner and the Company
10.3	Amendment to Executive Employment Agreement dated April 26, 2011 between Richard M. Levy and the Company
31.1	Certification of Chief Executive Officer pursuant to Section 302 of the Sarbanes-Oxley Act of 2002
31.2	Certification of Chief Financial Officer pursuant to Section 302 of the Sarbanes-Oxley Act of 2002
32.1	Certification of Chief Executive Officer pursuant to Section 906 of the Sarbanes-Oxley Act of 2002
32.2	Certification of Chief Financial Officer pursuant to Section 906 of the Sarbanes-Oxley Act of 2002



**Table of Contents**

**SIGNATURES**

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

SCOLR Pharma, Inc.

Date: May 9, 2011

By: /s/ STEPHEN J. TURNER  
Stephen J. Turner  
President and Chief Executive Officer  
(Principal Executive Officer)

Date: May 9, 2011

By: /s/ RICHARD M. LEVY  
Richard M. Levy  
Executive Vice President and Chief

Financial Officer  
(Principal Financial Officer)

**Table of Contents**

EXHIBIT INDEX

<b>Exhibit No.</b>	<b>Description</b>
10.1	Second Amendment to Lease dated April 26, 2011 between Arden Realty Limited Partnership and Company
10.2	Amendment to Executive Employment Agreement dated April 26, 2011 between Stephen J. Turner and the Company
10.3	Amendment to Executive Employment Agreement dated April 26, 2011 between Richard M. Levy and the Company
31.1	Certification of Chief Executive Officer pursuant to Section 302 of the Sarbanes-Oxley Act of 2002
31.2	Certification of Chief Financial Officer pursuant to Section 302 of the Sarbanes-Oxley Act of 2002
32.1	Certification of Chief Executive Officer pursuant to Section 906 of the Sarbanes-Oxley Act of 2002
32.2	Certification of Chief Financial Officer pursuant to Section 906 of the Sarbanes-Oxley Act of 2002