

SCOLR Pharma, Inc.
Form 10-Q
August 10, 2010

UNITED STATES
SECURITIES AND EXCHANGE COMMISSION
Washington, D.C. 20549

FORM 10-Q

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

For the quarterly period ended June 30, 2010

OR

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

For the transition period from to .

Commission File Number: 001-31982

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

Delaware
(State or other jurisdiction of
incorporation or organization)

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

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

425-368-1050
(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

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. See the definitions of "large accelerated filer," "accelerated filer" and "smaller reporting company" in Rule 12b-2 of the Exchange Act).

Large accelerated filer	<input type="checkbox"/>	Accelerated filer	<input type="checkbox"/>
Non-accelerated filer	<input type="checkbox"/>	Smaller reporting company	<input checked="" type="checkbox"/>

(Do not check if a 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

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

Title	Shares outstanding as of August 2, 2010
Common Stock, par value \$0.001	49,816,073

SCOLR Pharma, Inc.
FORM 10-Q

For the Quarterly Period Ended June 30, 2010

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PART I: FINANCIAL INFORMATION

Item 1. Financial Statements
SCOLR Pharma, Inc.

CONDENSED BALANCE SHEETS
(In thousands, except par values and number of shares)
(Unaudited)

	June 30, 2010	December 31, 2009
ASSETS		
Current Assets		
Cash and cash equivalents	\$ 3,270	\$ 1,176
Accounts receivable	124	269
Prepaid expenses and other assets	412	228
Total current assets	3,806	1,673
Property and Equipment — net of accumulated depreciation of \$1,347 and \$1,272, respectively		
	361	435
Intangible assets — net of accumulated amortization of \$556 and \$514, respectively	741	565
Restricted cash	383	438
	\$ 5,291	\$ 3,111
LIABILITIES AND STOCKHOLDERS' EQUITY		
Current Liabilities		
Accounts payable	\$ 39	\$ 47
Accrued liabilities	352	640
Deferred revenue	—	25
Total current liabilities	391	712
Deferred rent	178	198
Total liabilities	569	910
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 and 41,098,270 issued and outstanding as of June 30, 2010, and December 31, 2009, respectively	50	41
Additional paid-in capital	76,883	72,832
Accumulated deficit	(72,211)	(70,672)
Total stockholders' equity	4,722	2,201
	\$ 5,291	\$ 3,111

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

SCOLR Pharma, Inc.

CONDENSED STATEMENTS OF OPERATIONS
(In thousands, except per share amounts)
(Unaudited)

	Three months ended June 30,		Six months ended June 30,	
	2010	2009	2010	2009
Revenues				
Licensing fees	\$ 100	\$ —	\$ 125	\$ —
Royalty income	123	231	264	403
Total revenues	223	231	389	403
Operating expenses				
Marketing and selling	63	39	99	146
Research and development	256	794	596	1,615
General and administrative	595	973	1,219	2,127
Total operating expenses	914	1,806	1,914	3,888
Loss from operations	(691)	(1,575)	(1,525)	(3,485)
Other income (expense)				
Interest income	—	2	1	11
Interest expense	—	(1)	—	(4)
Other	(15)	—	(15)	—
Total other income (expense)	(15)	1	(14)	7
Net loss	\$ (706)	\$ (1,574)	\$ (1,539)	\$ (3,478)
Net loss per share, basic and diluted	\$ (0.01)	\$ (0.04)	\$ (0.03)	\$ (0.08)
Shares used in computing basic and diluted net loss per share	49,684	41,098	46,430	41,098

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

SCOLR Pharma, Inc.

CONDENSED STATEMENTS OF CASH FLOWS
(In thousands, unaudited)

	Six months ended June 30,	
	2010	2009
Cash flows from operating activities:		
Net loss	\$ (1,539)	\$ (3,478)
Reconciliation of net loss to net cash used in operating activities		
Depreciation and amortization	129	248
Write-off of intangible assets	19	80
Share-based compensation for employee services	126	576
Increase (decrease) in cash resulting from changes in assets and liabilities		
Accounts receivable	145	(29)
Prepaid expenses and other current assets	(188)	(65)
Accounts payable and accrued expenses	(212)	(318)
Deferred revenue	(25)	—
Net cash used in operating activities	(1,545)	(2,986)
Cash flows from investing activities:		
Purchase of equipment and furniture	(4)	(95)
Proceeds from insurance settlement	—	85
Patent and technology rights payments	(246)	(127)
Restricted cash	55	—
Net cash used in investing activities	(195)	(137)
Cash flows from financing activities:		
Payments on term loan	—	(111)
Proceeds from exercise of options	121	—
Net proceeds from issuance of common stock and warrants	3,713	—
Net cash provided by (used in) financing activities	3,834	(111)
Net increase (decrease) in cash	2,094	(3,234)
Cash at beginning of period	1,176	6,363
Cash at end of period	\$ 3,270	\$ 3,129
Cash paid during the period for interest	\$ —	\$ 3
Supplemental disclosure of noncash financing activities:		
Issuance of warrants in connection with equity offering	\$ 689	\$ —
Issuance of common stock to employee	\$ 103	\$ —

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

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 (“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, 2009 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, 2010. 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, 2009.

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 October 2009, the Financial Accounting Standards Board (“FASB”) issued ASU 2010-13, Multiple Deliverable Revenue Arrangements. ASU 2009-13 provides principles and application guidance on whether multiple deliverables exist, how the arrangement should be separated, and the consideration allocated. This standard shall be applied prospectively for revenue arrangements entered into or materially modified in fiscal years beginning on or after June 15, 2010, with earlier application permitted. Alternatively, an entity may elect to adopt this standard on a retrospective basis. The Company is currently assessing the impact of ASU 2010-13 on its financial statements. Adoption of this standard is not expected to have a material impact on the financial statements.

In March 2010, the FASB ratified Emerging Issues Task Force (EITF) Issue No. 08-9, “Milestone Method of Revenue Recognition” (Issue 08-9). The Accounting Standards Update resulting from Issue 08-9 amends ASC 605-28.1. The

Task Force concluded that the milestone method is a valid application of the proportional performance model when applied to research or development arrangements. Accordingly, the consensus states that an entity can make an accounting policy election to recognize a payment that is contingent upon the achievement of a substantive milestone in its entirety in the period in which the milestone is achieved. The milestone method is not required and is not the only acceptable method of revenue recognition for milestone payments. The guidance in Issue 08-9 is effective for fiscal years, and interim periods within those years, beginning on or after June 15, 2010, and may be applied: prospectively to milestones achieved after the adoption date, or retrospectively for all periods presented. The Company is currently assessing the impact of this guidance on its financial statements. Adoption of this standard is not expected to have a material impact on the financial statements.

Note 3 – Accounts Receivable

At June 30, 2010, accounts receivable consisted of royalty receivables from Controlled Delivery Technology (CDT)-based product sales.

Note 4 – Financing

On March 12, 2010, the Company completed a private placement of units consisting of one share of the Company's common stock and a warrant to purchase one-fifth of one share of common stock. An aggregate of 8,260,000 shares of common stock and warrants to purchase an aggregate of 1,652,000 shares of common stock were sold at a purchase price of \$0.50 per unit. Taglich Brothers, Inc. acted as placement agent for the offering. Mr. Michael N. Taglich, Chairman of the Company's board of directors, is the president and a principal shareholder of Taglich Brothers. Net proceeds of the offering were approximately \$3.7 million after placement agent fees of approximately \$289,100, expenses of registration, and other direct and incremental offering costs. Taglich Brothers was also issued a warrant to purchase 578,200 shares of the Company's common stock. The warrants sold in the offering and those issued to Taglich Brothers are identical, have an exercise price of \$0.75 per full share of common stock, and are exercisable beginning six months from the warrant issuance date for a period of five years. The fair value of the warrants was estimated at \$0.31 using the Black-Scholes option-pricing model. The Black-Scholes valuation was based on the following assumptions: volatility of 86.57%; term of five years; risk-free interest rate of 2.39%; and 0% dividend yield.

The shares sold in the offering and shares underlying the warrants were registered with the SEC on a registration statement that became effective on May 21, 2010.

Note 5 — Liquidity

The Company incurred a net loss of approximately \$1,539,000 for the six months ended June 30, 2010, and used cash from operations of approximately \$1,545,000. Cash flows used by investing activities during the six months ended June 30, 2010 of \$195,000 include \$246,000 in patent and trademark related expenditures, offset by a \$55,000 decrease in restricted cash which was used to reduce the monthly rent obligation for the Company's headquarters in Bothell, Washington. Cash flows from investing activities for the six months ended June 30, 2009 represent proceeds of \$85,000 from an insurance settlement, and \$95,000 used to purchase research and development equipment. Cash flows provided by financing activities for the six months ended June 30, 2010, consist of net proceeds of \$3.7 million from the March 2010 private placement and \$121,000 of proceeds from the exercise of previously issued stock options. Cash flows used by financing activities for the six months ended June 30, 2009 reflect payment on a term loan of \$111,000 through April 2009, at which time the loan was paid off.

As of June 30, 2010 the Company had approximately \$3.3 million in cash and cash equivalents, and \$383,000 in restricted cash related to its facility lease. The Company invests its cash and cash equivalents in government-backed securities. These securities have quoted prices in active markets. At times, the balances in the Company's cash and cash equivalent accounts exceed federal insured limits. The Company has not experienced any losses related to these balances and believes there is limited credit risk.

The Company has deferred all significant expenditures on its development projects, including the actual use study required by the Food and Drug Administration (the "FDA") as a prerequisite to submission of its regulatory application for its ibuprofen product, pending additional financing, revenues or partnership support. Without additional financing, revenues or funding from a partnership or collaboration agreement, the Company may not be able to complete development and commercialization of its lead product candidates, including its ibuprofen and pseudoephedrine products.

The Company's capital resources are limited and operations to date have been funded primarily with the proceeds from equity financings, royalty payments, and collaborative research agreements. The Company is pursuing additional sources of financing that could involve strategic transactions, including additional debt or equity financing, mergers and business combinations, new partnerships, revenue growth from expansion of 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 obtain financing or enter any strategic transaction or collaboration on terms acceptable to it, or at all, due to conditions in the pharmaceutical industry, capital markets or the economy in general. Competition for such strategic partnerships is intense, with many specialty pharmaceutical companies attempting to secure alliances with more established pharmaceutical or consumer products companies.

The financial statements have been prepared assuming the Company will continue as a going concern and do not include any adjustments to reflect the possible future effects on the recoverability and classification of assets and liabilities that may result from the outcome of this uncertainty. If unforeseen events arise that negatively impact the Company's liquidity and the Company is unsuccessful in generating additional revenues or raising additional funds, it will be necessary to substantially reduce the Company's operations to preserve capital or otherwise wind up its business. If the Company is forced to reduce or cease operations it may trigger additional obligations, including contractual severance obligations aggregating as much as \$690,000. In addition, the Company may be forced to liquidate assets at

reduced levels should it develop immediate liquidity requirements. There can be no assurance that additional financing will be available on favorable terms or at all.

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 June 30, 2010 or December 31, 2009. The Company does not anticipate any significant changes to its unrecognized tax benefits within the next twelve months.

Note 7—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 exclusive, worldwide, and perpetual rights to produce, market, and sell Ondansetron tablet formulations based on SCOLR’s proprietary controlled delivery technology (CDT®). Per the terms of the Agreement, the Company received the 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.

NUPRIN® Trademark

On March 11, 2010, the Company purchased from Advanced Healthcare Distributors, LLC (“ADC”) all of ADC’s right, title, and interest in and to the NUPRIN® trademark worldwide, excluding Canada. The Company paid \$180,000 in cash for these rights to the NUPRIN® trademark. The trademark asset is being amortized over ten years.

Note 8— NYSE Amex Equities Exchange Listing

On June 25, 2009 the Company received notice from the NYSE AMEX Equities (the "Exchange") that it was not in compliance with Section 1003(a)(iii) of the NYSE Amex Company Guide (the “Company Guide”) with stockholders' equity of less than \$6 million and losses from continuing operations and net losses in its five most recent fiscal years. As permitted by Exchange rules, the Company submitted a plan of compliance on July 29, 2009, advising the Exchange of action it had taken and will take to regain compliance with Section 1003(a)(iii) of the Company Guide by December 27, 2010. On September 15, 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 Company Guide within the specified timeframes indicated by the Exchange.

Simultaneously with its approval of the compliance plan, the Exchange notified the Company that it does 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 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 planned to regain compliance with section 1003(a)(iv) of the Company Guide by March 15, 2010. On November 25, 2009, the Company received notice that the Exchange had accepted the Company's plan of compliance with respect to its noncompliance with the Exchange's continued listing standard set forth in Section 1003(a)(iv) of the Company Guide. On April 13, 2010, the Company received notice from the Exchange that the Company had resolved the continued listing deficiency with respect to Section 1003(a)(iv) of the Company Guide referenced in the September 15, 2009 notice from the Exchange. The Exchange noted that its staff will continue to monitor the Company for compliance. If the Company is able to demonstrate compliance for two consecutive quarters, the Exchange will deem the monitoring period with respect to Section 1003(a)(iv) of the Company Guide to be ended.

On November 23, 2009, the Company received a separate notice from the Exchange stating that the Company does not meet the continued listing standard set forth in Section 1003(a)(ii) of the Company Guide because it had stockholders' equity of less than \$4 million and losses from continuing operations in three of its four most recent fiscal

years. By the aforementioned letter dated June 25, 2009, the Exchange had previously advised the Company that it was not in compliance with Section 1003(a)(iii) of the Company Guide because it had stockholders' equity of less than \$6 million and losses from continuing operations and net losses in its five most recent fiscal years. On September 15, 2009, the Exchange notified the Company that it had accepted the Company's plan that would bring it into compliance with the continued listing requirements and granted the Company an extension until December 27, 2010 to regain compliance with Section 1003(a)(iii) of the Company Guide. Due to the higher stockholders' equity requirement of Section 1003(a)(iii), the Company was not required to submit an additional plan of compliance in connection with the deficiency relating to the \$4,000,000 stockholders' equity standard contained in Section 1003(a)(ii) of the Company Guide.

The Company may be subject to delisting proceedings if the Company is not in compliance with the continued listing standards within the period contemplated by the plan of compliance, or if the Company does not make progress consistent with its plan of compliance during the plan period.

The Company's stock trading symbol will remain DDD on the Exchange but will continue to include an indicator (.BC) as an extension to signify noncompliance with the continued listing standards. The .BC indicator will remain as an extension on the trading symbol until the Company has regained compliance with all applicable continued listing standards.

Note 9 — Warrants

During the six months ended June 30, 2010, there were no warrants exercised. The Company had the following warrants to purchase common stock outstanding at June 30, 2010:

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
Grand Total	4,381,750			4,381,750	

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

Note 10 — Share-Based Compensation

During the three-month periods ended June 30, 2010 and June 30, 2009, the Company granted 253,000 and 92,500 options to purchase shares of its common stock, respectively, with aggregate fair values of \$94,300 and \$25,900, respectively. No restricted stock was issued during the three month periods ended June 30, 2010 and June 30, 2009.

On January 4, 2010, the Company issued 214,285 shares of common stock to Dr. Bruce Morra, the Company's former President and Chief Executive Officer, in accordance with the terms of Dr. Morra's employment agreement with the Company dated as of January 30, 2009. A liability of approximately \$103,000 was recorded at December 31, 2009 for the fair value of these shares as the award was subject to the availability of a sufficient number of shares under the Company's 2004 Equity Incentive Plan, as amended, at the date the shares were to be issued. During the three-month period ended March 31, 2010, additional compensation expense for these shares of approximately \$3,200 was recorded in general and administrative expense, reflecting the change in fair value of these shares from December 31, 2009 to the date of issuance.

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 June 30,		Six Months Ended June 30,	
	2010	2009	2010	2009
Marketing and selling	\$ —	\$ 5	\$ —	\$ 13
Research and development	8	65	24	146
General and administrative	54	151	102	417
Total	\$ 62	\$ 221	\$ 126	\$ 576

Note 11 — 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 the Company's 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 49,683,564 and 41,098,270 for the six months ended June 30, 2010 and 2009, respectively.

For the six month period ending June 30, 2010, 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 2010 and 2009 as the effect would have been anti-dilutive.

	2010	2009
Assumed exercise of stock options	4,780,412	4,700,999
Assumed conversion of warrants	4,381,750	2,226,550
Total	9,162,162	6,927,549

Note 12 — Subsequent Events – Purchase Commitments

In July 2010, the Company entered into a purchase agreement with a contract manufacturer, wherein the Company committed to purchase \$364,000 of finished goods inventory as needed and advanced approximately \$182,000 to the manufacturer as prepayment for the orders. The Company does not anticipate any losses resulting from this purchase commitment.

Item 2. Management's Discussion and Analysis of Financial Condition and Results of Operations.

SCOLR Pharma, Inc. is referred to as "we," "us," or "our" in this report. 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 annual report on Form 10-K for the year ended December 31, 2009.

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 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.

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.

Nutritional Products

We have developed multiple private label extended 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.

We are seeking to provide our novel extended release dietary supplements to the market via direct sales 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 sales and marketing brokers, contract manufacturers and distribution firms, in order to support these direct sales efforts.

We have submitted a number of nutritional products to national grocery, pharmacy and supplement retailers and received favorable indications of intention to purchase our products. However, these large retailers place orders three times a year based on a shelf planning cycle. Due to delays in product availability we missed the midyear shelf planning cycle for certain large accounts and, as a result, we did not take any orders in the second quarter of 2010. We expect to resubmit our products to the large retailers at the third shelf planning cycle in the third and fourth quarters of 2010. Orders placed in the fourth quarter of 2010 would be expected to reach retail stores in early 2011.

Ibuprofen

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. There are currently no extended release formulations of ibuprofen approved for use in North America. In March 2010, we acquired the NUPRIN® trademark worldwide, excluding Canada. We continue to evaluate the opportunities to generate revenues utilizing this trademark through sales of an immediate release ibuprofen product as well as other future opportunities utilizing our extended release ibuprofen formulations.

Pseudoephedrine

We filed our first Abbreviated New Drug Application (“ANDA”) submission in August 2008. Our submission was accepted by the Food and Drug Administration (“FDA”) in September 2008 and is currently under review. We anticipate approval in late 2010 and will seek to commercialize the product, pending additional revenues, financing or partnership support. Our strategy will be to manufacture and distribute the product with a partner or manufacture and distribute the product with the help of contract manufacturing companies. We seek to sell the product under the SCOLR name and private label to US retail outlets, with eventual expansion to foreign markets. We believe our formulation offers attractive tablet size and cost savings when compared to similar tablets currently on the market. Our ability to commercialize products containing pseudoephedrine may be adversely impacted by legislative and market changes relating to drug diversion.

Critical Accounting Policies and Estimates

Since December 31, 2009, 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, 2009, 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 October 2009, the FASB issued ASU 2010-13, Multiple Deliverable Revenue Arrangements. ASU 2009-13 provides principles and application guidance on whether multiple deliverables exist, how the arrangement should be separated, and the consideration allocated. This standard shall be applied prospectively for revenue arrangements entered into or materially modified in fiscal years beginning on or after June 15, 2010, with earlier application permitted. Alternatively, an entity may elect to adopt this standard on a retrospective basis. We are currently assessing the impact of ASU 2010-13 on our financial statements. Adoption of this standard is not expected to have a material

impact on our financial statements.

In March 2010, the FASB ratified Emerging Issues Task Force (EITF) Issue No. 08-9, “Milestone Method of Revenue Recognition” (Issue 08-9). The Accounting Standards Update resulting from Issue 08-9 amends ASC 605-28.1. The Task Force concluded that the milestone method is a valid application of the proportional performance model when applied to research or development arrangements. Accordingly, the consensus states that an entity can make an accounting policy election to recognize a payment that is contingent upon the achievement of a substantive milestone in its entirety in the period in which the milestone is achieved. The milestone method is not required and is not the only acceptable method of revenue recognition for milestone payments. The guidance in Issue 08-9 is effective for fiscal years, and interim periods within those years, beginning on or after June 15, 2010, and may be applied: prospectively to milestones achieved after the adoption date, or retrospectively for all periods presented. The Company is currently

assessing the impact of this guidance on its financial statements. Adoption of this standard is not expected to have a material impact on the financial statements.

Results of Operations

We expect our operating losses to decline and cash flows to improve as we advance the direct sales of nutritional products and the commercialization of our pseudoephedrine product. We actively manage our liquidity by sharply limiting the clinical and development expenses associated with our ibuprofen product and commercialization expenses to pseudoephedrine, our lead products. Our reduction of expenses is being partially offset by the addition and planned addition of resources including marketing, distribution, and administrative staffing to support the sale 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, revenues or partnership support. Without additional revenues or funding, we do not expect to be able to complete development or commercialization of our lead products.

Comparison of the Three Months Ended June 30, 2010 and 2009

Revenues

Total revenues consist of revenue for licensing fees and royalties from our collaborative agreements. Total revenues decreased 3%, or \$8,000 to \$223,000 for the three months ended June 30, 2010, compared to \$231,000 for the same period in 2009. This decrease is primarily due to a \$102,000 or 45% decrease in royalty revenues from our relationship with Perrigo. Effective January 1, 2010, commensurate with the amendment of our agreement with Perrigo, the royalty rate Perrigo pays us on sales of licensed products decreased from 50% of net profits to 20% of net profits, calculated in accordance with the amendment. The decrease in revenue attributable to the amendment of our agreement with Perrigo was offset by an increase in revenue resulting from the recognition of a \$100,000 licensing fee earned from RedHill Biopharma, Ltd. in connection with its license of our CDT platform for Ondansetron tablet formulations.

Operating Expenses

Marketing and Selling Expenses

Marketing and selling expenses increased 62%, or \$24,000 to \$63,000 for the three months ended June 30, 2010, compared to \$39,000 for the same period in 2009. This increase was primarily due to marketing and sales brokerage related expenses associated with the planned distribution of our nutritional products.

Research and Development Expenses

Research and development expenses decreased 68%, or \$538,000 to \$256,000 for the three months ended June 30, 2010, compared to \$794,000 for the same period in 2009. The decrease is attributable to a reduction of clinical and development expense of \$163,000 resulting from deferral of activities on certain projects, including our lead product candidates, pending additional revenue, financing or partnership support, and savings of \$375,000 as a result of lower personnel related expense due to headcount reductions, including a \$57,000 reduction in non-cash stock based compensation expense.

General and Administrative Expenses

General and administrative expenses decreased 39%, or \$378,000 to \$595,000 for the three months ended June 30, 2010, compared to \$973,000 for the same period in 2009, primarily due to a decrease of \$289,000 in personnel related expenses through headcount reductions, including a \$97,000 reduction in non-cash stock based compensation expense. Additional cost reductions included a decrease of \$66,000 in legal and outside support expenses compared to the prior period and a reduction in insurance premium