

SCOLR Pharma, Inc.  
Form 10-K  
March 29, 2011  
Table of Contents

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

Washington, D.C. 20549

**Form 10-K**

x **ANNUAL REPORT PURSUANT TO SECTION 13 OR 15(d) OF THE SECURITIES EXCHANGE ACT OF 1934**

For the fiscal year ended December 31, 2010

.. **TRANSITION REPORT UNDER 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)

91-1689591  
(IRS Employer Identification No.)

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

of incorporation or organization)  
19204 North Creek Parkway, Suite 100

98011

Bothell, WA  
(Address of principal executive offices)

(Zip Code)

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

Securities registered under Section 12(b) of the

Name of each exchange on which registered:

Exchange Act:

None

Securities registered under Section 12(g) of the Exchange Act:

Common Stock, \$0.001 par value per share

Series A Junior Participating Preferred Share Purchase Rights

(Title of each class)

Indicate by check mark if the registrant is a well-known seasoned issuer, as defined in Rule 405 of the Securities Act. Yes  No

Indicate by check mark if the registrant is not required to file reports pursuant to Section 13 or Section 15(d) of the Act. Yes  No

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 if disclosure of delinquent filers pursuant to Item 405 of Regulation S-K (§229.405 of this chapter) is not contained herein, and will not be contained, to the best of registrant's knowledge, in definitive proxy or information statements incorporated by reference in Part III of this Form 10-K or any amendment to this Form 10-K.

Indicate by check mark whether the registrant is a large accelerated filer, an accelerated filer, 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  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

The aggregate market value of the registrant's common stock held by non-affiliates of the registrant as of June 30, 2010, was approximately \$21.0 million, based upon the closing sale price on the NYSE Amex Exchange reported for such date. The number of shares outstanding of the registrant's common stock was 49,816,073 as of March 10, 2011.

**DOCUMENTS INCORPORATED BY REFERENCE**

Certain information required by Item 5 of this report and the information required by Part III of this annual report, to the extent not set forth herein, is incorporated herein by reference from the registrant's definitive proxy statement relating to the registrant's 2011 annual meeting of stockholders.



**Table of Contents****Explanatory Note**

In this Form 10-K as of and for the year ended December 31, 2010, we are restating in Item 8 Financial Statements and Supplementary Data, our balance sheets and the related statements of operations for the first three quarters of 2010. This restatement is more fully described in Note 2,

Restatement of 2009 Financial Statements for an Immaterial Error and Note 17. Restatement of Quarterly Financial Information, in the financial statements. The Company does not intend to restate separately its quarterly reports on Form 10-Q for the first three quarters of 2010. The financial statements included in such reports should not be relied on.

The restatement results from our review during the fourth quarter of 2010 of guidance relating to 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. EITF 07-5 provides guidance as to assessing equity versus liability treatment and classification for equity-linked financial instruments, including stock purchase warrants. The Company adopted EITF 07-5 on January 1, 2009, but did not properly assess the impact of an anti-dilution provision contained in an outstanding stock purchase warrant issued by the Company in 2002. Because of the anti-dilution feature, the warrant would not be considered indexed to the Company's own stock, and is therefore required under EITF 07-5 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.

This error resulted in an understatement of the Company's liabilities at each of its balance sheet dates in the prior seven quarters. Additionally, the change in fair market value of the liability was not included in reported net loss in each of the prior seven quarters. Based on the qualitative and quantitative analysis, the effect of the error was considered to be immaterial to reported results of operations as well as the Company's financial position as of and for the period ended December 31, 2009 and for each of the three quarters reported in 2009. This error had no impact on previously reported cash flows from operating, financing or investing activities. As permitted by SAB 108, codified as Topic 1N, the balance sheet and related statements of operations, stockholder's equity and cash flows as of December 31, 2009 and for the period then ended were corrected by recording the fair value of the warrant liability of \$172,000 as of December 31, 2009 and a charge to unrealized loss in the statement of operations for the year then ended. The effect of the correction of the error is included in the accumulated deficit as of December 31, 2009 in the accompanying balance sheet.

The effect of the correction of the error on our consolidated balance sheet as of December 31, 2009 is as follows (in thousands):

	Liabilities			Accumulated Deficit		
	Reported	Adjustment	Revised	Reported	Adjustment	Revised
<b>December 31, 2009</b>	\$ 910	\$ 172	\$ 1,082	\$ (70,672)	\$ (172)	\$ (70,844)

The effect of the correction of the error on our statement of operations for the year ended December 31, 2009 is as follows (in thousands):

Year ended	Unrealized Gain/(Loss) on Fair Value of Warrants			Net Loss			Basic and Diluted Net Loss Per Share		
	Reported	Adjustment	Revised	Reported	Adjustment	Revised	Reported	Adjustment	Revised
<b>December 31, 2009</b>	\$	\$ (172)	\$ (172)	\$ (6,697)	\$ (172)	\$ (6,869)	\$ (0.16)	\$ (0.01)	\$ (0.17)

We have not separately amended our quarterly Reports on Form 10-Q as of March 31, 2010, June 30, 2010, and September 30, 2010 and for the periods then ended; the periods affected by the restatement, and therefore the financial statements and related financial information for these affected periods should no longer be relied upon. All financial and other information included in this Form 10-K reflects the correction of the immaterial error as of December 31, 2009 and for the period then ended, and the restatement of the first three quarters of 2010.

**Table of Contents**

We have reported 2010 and 2009 balance sheets to account for the value of the warrant to purchase shares of our common stock as a liability, and have restated prior consolidated statements of operations for the quarterly change in fair value of the warrants for each of the first three quarters of 2010. This restatement had no impact on previously reported revenues, operating expenses, total assets or cash position.

The following table presents the cumulative adjustments for each affected component of liabilities and stockholders' equity at the end of each restated period (in thousands):

(Unaudited)	Liabilities			Accumulated Deficit		
	Reported	Adjustment	Restated	Reported	Adjustment	Restated
<b>March 31, 2010</b>	\$ 701	\$ 390	\$ 1,091	\$ (71,505)	\$ (390)	\$ (71,895)
<b>June 30, 2010</b>	569	165	734	(72,211)	(165)	(72,376)
<b>September 30, 2010</b>	526	255	781	(73,080)	(255)	(73,335)

Upon exercise or expiration of the warrant, the fair value of the warrant at that time will be reclassified to equity from liabilities. Until that time, the fair value of the warrant is recorded as a current liability at each financial reporting date and the associated unrealized gain (loss) is recorded in the statements of operations. The incremental impact for the unrealized gain (loss) from the valuation of warrants to purchase common stock for each of the restated quarters in 2010 is as follows (in thousands):

(Unaudited)	Unrealized Gain/(Loss) on Fair Value of Warrants			Net Loss			Basic and Diluted Net Loss Per Share		
	Reported	Adjustment	Restated	Reported	Adjustment	Restated	Reported	Adjustment	Restated
<b>Three months ended March 31, 2010</b>	\$	\$	(218)	\$ (218)	\$ (833)	\$ (218)	\$ (1,051)	\$ (0.02)	\$ (0.02)
<b>Three months ended June 30, 2010</b>			225	225	(706)	225	(481)	(0.01)	(0.01)
<b>Six months ended June 30, 2010</b>			7	7	(1,539)	7	(1,532)	(0.03)	(0.03)
<b>Three months ended September 30, 2010</b>			(90)	(90)	(869)	(90)	(959)	(0.02)	(0.02)
<b>Nine months ended September 30, 2010</b>	\$	\$	(83)	(83)	\$ (2,408)	\$ (83)	\$ (2,491)	(0.05)	(0.05)

**Table of Contents**

**SCOLR Pharma, Inc.**

**FORM 10-K**

**TABLE OF CONTENTS**

	<b>Page</b>
<b>PART I</b>	
Item 1. <u>Business</u>	5
Item 1A. <u>Risk Factors</u>	21
Item 1B. <u>Unresolved Staff Comments</u>	31
Item 2. <u>Properties</u>	31
Item 3. <u>Legal Proceedings</u>	31
Item 4. <u>Reserved</u>	31
<b>PART II</b>	
Item 5. <u>Market for the Registrant's Common Equity, Related Stockholder Matters and Issuer Purchases of Equity Securities</u>	32
Item 7. <u>Management's Discussion and Analysis of Financial Condition and Results of Operations</u>	33
Item 8. <u>Financial Statements and Supplementary Data</u>	42
Item 9. <u>Changes in and Disagreements With Accountants on Accounting and Financial Disclosure</u>	70
Item 9A. <u>Controls and Procedures</u>	70
<b>PART III</b>	
Item 10. <u>Directors and Executive Officers of the Registrant</u>	72
Item 11. <u>Executive Compensation</u>	72
Item 12. <u>Security Ownership of Certain Beneficial Owners and Management</u>	72
Item 13. <u>Certain Relationships and Related Transactions</u>	72
Item 14. <u>Principal Accountant Fees and Services</u>	72
<b>PART IV</b>	
Item 15. <u>Exhibits and Financial Statement Schedules</u>	73

---

**Table of Contents**

**PART I**

In this Annual Report, the words we, our, ours, and us refer only to SCOLR Pharma, Inc. and not to any other person or entity.

This Annual 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 annual report. Forward looking statements, including statements concerning the sufficiency of our liquidity and capital resources to continue our operations for a period of time, expectations related to the development of our nutritional products business, expectations and intentions related to the conduct of the regulatory trials for our ibuprofen and pseudoephedrine products, beliefs in the capabilities of our technology and anticipated contribution to our margins of sales of our nutritional products, are subject to important factors that could cause actual results to differ materially from our forward-looking statements. Such factors include unanticipated scheduling of shipments of our nutritional products, litigation, regulatory concerns related to the conduct of our clinical trials, inadequacy of our human resources to accomplish our strategic and operational goals and each of the Risk Factors identified in Item 1A of this Annual Report, as well as those discussed elsewhere in this Annual Report and others detailed from time-to-time in our periodic and current 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.

**Item 1. Business  
Overview**

We are a specialty pharmaceutical company that combines formulation experience and knowledge with our proprietary and patented Controlled Delivery Technology (CDT<sup>®</sup>) platforms to develop and commercialize novel prescription, over-the-counter (OTC), and nutritional products. Our CDT platforms are based on multiple issued and pending patents and other intellectual property for custom designed extended release and/or enhanced performance of active pharmaceutical ingredients and nutritional products.

Our innovative drug delivery technologies enable us to customize the formulations of tablets or capsules in order to release their active ingredients predictably over a specified timeframe of up to 24 hours. Our platforms are designed to offer a cost effective means to reduce the frequency of drug administration, improve the effectiveness of the drug treatment, ensure greater patient compliance with a treatment program, reduce side effects, and/or increase drug safety.

We have developed multiple private label extended release nutritional products incorporating our formulation technology for commercialization in the United States and Canada. Historically, we have generated revenues as a percentage of profits on select products sold by our partner Perrigo Company. During the fourth quarter of 2010, we were informed by Perrigo Company, 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 anticipate revenues in 2011 through our own direct sales efforts.

We have put a significant amount of effort into introducing novel extended release dietary supplements directly to numerous national retail and pharmacy outlets. In addition, we have engaged the Emerson Group to provide sales and logistical support to our products. We have introduced more than 10 different extended release

---

**Table of Contents**

dietary supplements to numerous US retailers and pharmacy outlets and continue to develop new formulations. We believe these products have the potential to generate contribution margins that are significantly greater than the margins we have historically realized with our royalty arrangements.

Our lead drug product candidate is a 12 hour extended release formulation of ibuprofen, an analgesic typically used for the treatment of pain, fever and inflammation. We completed our pivotal Phase III trial demonstrating safety and efficacy of our 12 hour 600 mg extended release ibuprofen for the OTC market. We are currently working with the U.S. Food and Drug Administration, or FDA, as we seek to complete the remaining activities required in our New Drug Application, or NDA, on the product formulation. The FDA will require completion of an actual use study (AUS) meant to simulate how consumers use the product in an OTC environment, prior to submission of our NDA. The information gathered will be utilized to assess safety and compliance. There are currently no extended release formulations of ibuprofen approved for use in North America.

We have also developed a 12 hour extended release formulation of pseudoephedrine, a decongestant that is widely used to relieve sinus pressure related to allergies and the common cold. In August 2008, we submitted an Abbreviated New Drug Application, or ANDA, on our 12 hour pseudoephedrine product. In January 2009 the FDA issued a Complete Response Letter detailing deficiencies in the ANDA. We submitted our first amendment to our ANDA in response to the identified deficiencies in August 2009. Throughout the course of the FDA's review, we have submitted additional amendments in response to questions raised from divisions of the FDA, including our most recent amendment which was submitted in August 2010. 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 deficiencies cited relate to the conduct of the study, trial design and other related quality concerns. The issues raised do not relate to the product formulation. 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 or partnership support to initiate clinical activities in response to the FDA's action.

We have completed initial development activities on various pharmaceutical compounds. Several of these compounds, including ondansetron and raloxifene, have been evaluated in clinical trials, while others including rivastigmine and risperidone have been evaluated in the laboratory. With the exception of ondansetron, which is the subject of a Manufacture, License and Distribution Agreement with RedHill Biopharma, Inc. discussed below, all of the compounds included in the portfolio are available for license. We have deferred further external development activities pending additional funding or partnership support.

On March 12, 2010, we completed a private placement of units consisting of an aggregate of 8,260,000 shares of our common stock and warrants to purchase an aggregate of 1,652,000 shares of our common stock. The units were sold at a purchase price of \$0.50 per unit. The warrants have an exercise price of \$0.75 per share, which exercise price is not subject to adjustment on the basis of future issuances of securities at a price lower than the exercise price, or any other event other than split, combination or reclassification of our common stock. Taglich Brothers, Inc. acted as placement agent for the offering. Mr. Michael N. Taglich, a member of our board of directors, is the president and a principal shareholder of Taglich Brothers. Net proceeds of the offering were approximately \$3.6 million after placement agent fees of \$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 our common stock. The warrants sold in the offering, and those issued to Taglich Brothers are identical, have an exercise period of five years, and are valued 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.

We had approximately \$1.9 million in cash and cash equivalents, and approximately \$257,000 in restricted cash as of December 31, 2010. We anticipate that our existing cash and cash equivalents will be sufficient to fund



---

**Table of Contents**

our operations under our current operating plan into the second quarter of 2011 unless the timing of inventory purchases necessary to fulfill any orders for our nutritional products places additional constraint on our liquidity prior to that time, or unforeseen events impact our liquidity.

On December 22, 2010, we notified the NYSE Amex Exchange (the Exchange) of our intent to file a Form 25 with the Securities and Exchange Commission (the Commission) to effect the voluntary withdrawal of our common stock from listing on the Exchange, after concluding that we could not reasonably expect to regain compliance with the continued listing requirements of the Exchange within the extension period afforded to us. We filed the Form 25 with the Commission on January 3, 2011 and our common stock ceased trading on the Exchange on January 13, 2011. On January 13, 2011 our common stock began trading on the OTC Bulletin Board under our new ticker symbol SCLR.

We were incorporated on October 12, 1994, in Delaware under the name Caddy Systems, Inc. From April 1995 to July 2002, we operated under the name Nutraceutix, Inc. In July 2002, we changed our name to SCOLR, Inc. and to SCOLR Pharma, Inc. in July 2004. SCOLR is an acronym for Self-Correcting Oral Linear Release, an important feature of our lead technology.

Our principal executive offices are located at 19204 North Creek Parkway, Suite 100, Bothell, Washington 98011. Our general telephone number is (425) 368-1050. Our website is [www.scolr.com](http://www.scolr.com). Information contained on our website is not part of, and is not incorporated into, this annual report. Our filings with the SEC are available without charge on our website.

**Corporate Strategy**

Our strategy is to develop and commercialize prescription, OTC, and nutritional products utilizing our innovative oral drug delivery technologies. We plan to commercialize products that are feasible to accomplish, given our limited resources, and partner with others in order to maximize the value of the assets in our portfolio. Our technologies enable us to develop custom formulations of tablets or capsules that release their active ingredients predictably over a specified timeframe of up to 24 hours. We believe that our technologies are capable of significantly improving the delivery of many prescription, OTC, and nutritional products. We leverage the advantages of our formulation technology (i.e. simplicity and breadth of application) and outsource the manufacturing, distribution and clinical testing in order to maximize the return on our intellectual property. We believe this formulation process enables us to leverage the available capacity in existing contract manufacturing and research organizations, and manage the cost of development efforts against our existing and anticipated revenues. We spent \$1.2 million on product research and development in 2010 and \$2.4 million in 2009.

Our current operating plan related to product development and commercialization includes activities relating to (i) launching direct sales of our line of extended release nutritional products, (ii) initiation of the actual use study required as a condition to approval of our lead ibuprofen product, (iii) evaluation of the deficiencies identified by the FDA with respect to the ANDA application for our pseudoephedrine product and (iv) efforts to secure development and/or commercialization support for our lead drug products through strategic partnerships. We have deferred all other product development and commercialization activities pending additional revenue, financing or partnership support.

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

In addition to our direct sales efforts on nutritional products, we continue to seek collaborative arrangements, acquisitions and alliances with corporate partners, licensors, and licensees to provide options for

---

## **Table of Contents**

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 brand Nuprin<sup>®</sup> (excluding Canada) is anticipated to provide additional opportunities for our extended release ibuprofen product.

Extended release drug delivery technologies such as our CDT platforms can in some circumstances be applied to reformulate existing drugs and extend the patent protection, thereby improving product release profiles and enhancing important revenue streams for pharmaceutical companies. Many pharmaceutical and specialty pharmaceutical companies have also successfully utilized extended release technologies to develop product line extensions.

We expect to seek collaborations in order to advance the manufacturing, selling, and marketing of our potential products. However, based on an evaluation of each product opportunity and available funding, we may consider establishing limited manufacturing or sales and marketing capabilities to better maintain control over product development timelines and to capture more of the economic value of the opportunity. We do not currently have commercialization or manufacturing capabilities.

### **Commercial Relationships**

An important part of our strategy is to seek collaborations and strategic partnerships to develop or market some of our products. We have entered into collaborations and currently plan to enter into additional collaborations with established third parties to manufacture and commercialize our existing and potential products. From time to time, we are engaged in discussions with pharmaceutical companies regarding development of products incorporating our CDT platforms and other types of marketing, manufacturing, or distribution opportunities. Following is a summary of our recent collaborations.

#### **Emerson Sales/Services Agreement**

On August 27, 2010, we entered into a Sales Agency Agreement (the "Sales Agreement") with S. Emerson Group, Inc. ("Emerson Group"), effective August 1, 2010. Also on August 27, 2010, we entered into an Account Services Agreement (the "Services Agreement") with Emerson Healthcare LLC ("Emerson Health"), an affiliate of Emerson Group.

Pursuant to the Sales Agreement, Emerson Group acts as our non-exclusive agent to provide strategy consulting, sales, marketing and account management services in support of our new line of extended-release nutritional products. The initial term of the Sales Agreement is 36 months, followed by successive 12-month renewal terms. The Sales Agreement may be terminated by either party upon 12 months' written notice to the other party, or upon 10 days' written notice to the other party for "good cause" as defined in the Sales Agreement. In consideration of the services to be provided by Emerson Group under the Sales Agreement, Emerson Group will receive a monthly retainer of \$4,000 and commissions based on the net sales of our products. As further consideration for the services performed under the Sales Agreement, we issued to Emerson Group a warrant to purchase 100,000 shares of our common stock at an exercise price of \$0.50 per share. The fair value of the warrants was estimated at \$0.33 per share using the Black-Scholes option-pricing model. The Black-Scholes valuation was based on the following assumptions: volatility of 88.35%; contractual term of ten years; risk-free interest rate of 2.66%; and 0% dividend yield. Total value of issued warrants, which approximated \$32,000, was expensed as a part of our selling expenses.

Under the Services Agreement, Emerson Health will act as our non-exclusive agent to perform warehousing, distribution, logistics, fulfillment, accounts receivable management, invoicing, collections, cash management and other operational services in support of sales of our extended-release nutritional products. The initial term of the Services Agreement is 12 months, followed by successive 12-month renewal terms. The Services Agreement may be terminated by either party for any reason upon 12 months' written notice to the other

---

**Table of Contents**

party, or upon 10 days written notice to the other party for good cause, as defined in the Services Agreement. As consideration for the services to be provided by Emerson Health under the Services Agreement, Emerson Health will receive a monthly fee equal to a specified percentage of the gross sales of our nutritional products covered under the Sales Agreement. In addition, scheduled fees will be payable to Emerson Health for warehouse, freight, and certain other itemized services rendered at Emerson Health's distribution center and warehouse facility.

**RedHill Biopharma Ltd.**

On May 2, 2010, we entered into an Exclusive License Agreement (the Agreement) with RedHill Biopharma Ltd., an Israeli company (RedHill). Under the Agreement, we granted to RedHill the exclusive, worldwide, and perpetual rights to produce, market, and sell Ondansetron tablet formulations based on our proprietary CDT platforms. Per the terms of the Agreement, we received an initial licensing fee of \$100,000 in May 2010. Additionally, RedHill is obligated to make milestone payments to us 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. We 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 us, including royalties and all other fees, of \$30 million. In addition, from time to time we have been, and may continue to be engaged by RedHill to assist with research and development activities in exchange for separately negotiated fees.

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 will pay the remaining \$50,000 when services performed by SCOLR are complete. The estimated term of the study and agreement is four to five months. As of December 31, 2010, the initial up-front fee of \$50,000 was recorded as deferred revenue. We have substantially completed the services to be performed by us under the agreement, and anticipate recognizing revenue of \$100,000 including the \$50,000 that was previously deferred upon full completion.

**NUPRIN® Trademark**

On March 11, 2010, we purchased from Advanced Healthcare Distributors, LLC all of its right, title, and interest in and to the NUPRIN® trademark worldwide, excluding Canada. We paid \$180,000 in cash for these rights to the NUPRIN® trademark. The trademark asset is being amortized over ten years. The purchase of the right, title and interest provide us the opportunity and option to utilize the NUPRIN® brand in conjunction with commercialization of ibuprofen.

**Perrigo Company of South Carolina, Inc**

On October 20, 2005, we 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, we granted a license to our CDT technology to Perrigo for the manufacture, marketing, distribution, and sale of specific dietary supplements in the United States. We receive royalty payments based on Perrigo's net profits derived from the sales of products subject to the agreement. On January 24, 2010, we amended the Perrigo agreement to provide for a reduction in the royalty rate due to us 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 we 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

## **Table of Contents**

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, we 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 years ended December 31, 2010 and 2009, the Company recorded royalty revenues earned under the Perrigo agreement of approximately \$493,000 and \$919,000, respectively. During the fourth quarter of 2010, we were informed by Perrigo Company, 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.

### **Chrono Nutraceuticals, LLC.**

On November 20, 2009, we entered into a license agreement with Chrono Nutraceuticals LLC, a newly formed Arizona limited liability company ( Chrono ), providing Chrono with exclusive rights in Canada to manufacture and sell four extended release dietary supplements using our proprietary CDT drug delivery platform. In addition, we granted Chrono the rights to manufacture and sell two of such products in the United States on a nonexclusive basis.

Under the terms of the license agreement, Chrono paid an initial fee of \$25,000 and agreed to pay an additional \$87,500 that became due on January 31, 2010. Chrono failed to deliver the additional payment of \$87,500 and we terminated the license agreement. The initial \$25,000 fee is not refundable and was recorded as revenue in March 2010.

### **Temple University**

We have agreements with Temple University ( Temple ) providing us with exclusive worldwide rights for certain patents related to our CDT, with the right to sublicense. Under the terms of the agreements with Temple we are required to make a minimum annual royalty payment of approximately \$49,000, which is recorded in general and administrative expense. The total amount expensed was \$81,000 and \$95,000 for 2010 and 2009, respectively.

### **Customers**

In 2010, two customers, Perrigo and RedHill, accounted for 95% of total revenue. In 2009, one customer, Perrigo, accounted for 98% of total revenue. These revenues relate to the royalty income from the sale of products using our CDT technologies, licensing fees and research and development income.

## **Our CDT Platforms**

We believe that our proprietary CDT platforms have the potential to significantly improve a large number of oral prescription, OTC, and nutritional products. Under certain circumstances, our proprietary CDT technologies can be used in solid oral dosage formulations to yield tablets or capsules that release their active agents in a custom designed, controlled manner over a specified timeframe of up to 24 hours.

Under most circumstances, oral administration is the preferred route for drug delivery due to its convenience and widely accepted use. However, many orally-administered, immediate release drug products are rapidly utilized by the body, thereby requiring more frequent administration throughout the day. Consequently, patient non-compliance can be a significant problem for many of these products. Our oral extended release technologies

## **Table of Contents**

can eliminate the need for multiple daily dosing by extending the release of the active drug component so that the product maintains its therapeutic usefulness over a longer period of time. In addition, lowering the peak levels of certain drugs in the blood by extending their release profile may reduce the adverse effects associated with peak levels of these drugs.

Our CDT technology represents a robust, simple and cost effective approach to drug tablet and capsule formulation that employs simplified manufacturing processes using conventional granulation, blending, and compression equipment in a two or three-step process. Our extended release tablet and capsule formulations contain readily available and generally-regarded-as-safe (GRAS) excipients (i.e., non-drug ingredients such as hydrophilic polymers, amino acids, or electrolytes). These excipients are used to modulate the release rate of the drug in order to provide a wide variety of delivery profiles.

Our CDT technologies can accommodate comparatively high volumes of an active ingredient while being adaptable to deliver these active ingredients over a wide range of release profiles and timeframes. We believe that our tablet and capsule formulations are capable of generating the extended release profiles required for reproducible, cost-effective, and optimized oral delivery of drugs for up to 24 hours.

In addition, our formulation technologies can be combined with active ingredients in order to enhance the solubility characteristics. Our formulation technologies are designed to allow the successful manufacture of complex drugs without employing costly micro-milling, nano-particulate, coated-particle, or other solubility enhancing technologies.

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. In the aggregate, our formulation technologies offer a range of alternatives capable of addressing some of the most challenging hurdles in oral drug delivery, including challenging release profiles, poorly soluble active ingredients, and compounds that are difficult to tablet. We have also done preliminary work on formulations that could provide enhanced bioavailability for selected drug targets. Our issued patents are summarized below.

*Dual Polymer Patent* (U.S. Patent No. 6,337,091 issued 2002 and expiring in 2017). This first generation of our technology is based on hydrophilic matrices which allow for the controlled diffusion of active ingredients from the matrix through progressive swelling and erosion of the tablets. The resulting CDT tablets or capsules employ combinations of conventional tableting materials selected specifically for the active ingredient(s) and the desired release profile. Various release patterns and rates can be achieved.

*Salt Patent* (U.S. Patent No. 6,090,411 issued July 18, 2000 and expiring in 2018). This technology provides for the controlled and programmable release of the active pharmaceutical ingredient (API) through dry blending and direct compression of a salt, a polymer, and the API. We believe that this salt-based technology provides several advantages over comparable extended release technologies.

*Amino Acid Patents* (U.S. Patent No. 6,517,868 issued February 11, 2003, U.S. Patent No. 6,936,275 issued August 30, 2005, and U.S. Patent 7,229,642 issued June 12, 2007, all expiring in 2021). These technologies employ an extended release matrix system based on the application of amino acids, gums and polymers which may improve drug solubility within the dosage form via hydrophobic/polar interaction. Our amino acid technologies are designed to offer simpler solutions to certain difficult formulation challenges.

*Method of forming a tablet* (U.S. Patent No. 7,749,537 issued July 6, 2010 and expiring in 2027.) This patent covers the process of pre-blending an active pharmaceutical ingredient that is susceptible to tackiness, with a suitable additive that enables improved processing for tablet production. The method allows for improved manufacturing of a blend via direct compression without the need for a granulation step or roller compaction. This is our newest patent and was approved in July, 2010.

**Table of Contents**

**Product Development**

Our proprietary drug delivery technologies are applicable to a wide range of drugs with different physical and chemical properties, including water soluble and insoluble drugs, as well as high dose and low dose drugs. Using our CDT platforms, we can formulate drugs with precise release profiles. In selecting product candidates for development, we generally focus on the applicability of our platforms to a particular compound and benefits to patients, as well as market size, patent protection, competition and other factors.

Our CDT technologies have been used to develop several dietary supplement products that are currently manufactured and distributed by third parties. We currently receive royalties and other payments from the sale of products that incorporate our CDT technology, including combinations of glucosamine and chondroitin, calcium and other dietary products. These revenues have been generated through our alliance with Perrigo. We have been 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 have also applied our CDT platforms to a portfolio of more than twenty pharmaceutical targets on a developmental basis. These target candidates include existing analgesic, cardiovascular, diabetes, anti-nausea, and pulmonary products. We continue to advance ibuprofen towards commercialization and we are deferring significant external development expenditures on new projects until additional financial resources or partnership support becomes available.

**Table of Contents**

The following tables summarize information regarding our current product formulations, clinical experience with other drugs, and the dietary supplements we have brought to market in the past, or are currently seeking to sell directly to retailers. These tables are qualified in their entirety by reference to the more detailed descriptions contained elsewhere in this annual report.

**Current Development Targets**

<b>Product</b>	<b>Application</b>	<b>Potential Advantages</b>	<b>Comments</b>
12 hr Ibuprofen	OTC Analgesic	- 1st extended release OTC ibuprofen  - 1 tablet vs. 3 every 12 hrs.  - Lower cost  - Patent protected	Successful Pivotal Phase III completed  Actual Use Study required prior to submission of NDA
12 hr Pseudoephedrine	OTC Decongestant	- 1/3rd size of current OTC products  - Lower cost  - Patent protected	ANDA submitted August 2008  FDA deficiency letter received March 2011

**Clinical Experience**

Following are additional targets with completed clinical work pending additional financing or partnerships.

<b>Product</b>	<b>Application</b>	<b>Comments</b>
IR Raloxifene	Rx Osteoporosis	Two pilot pharmacokinetic trials completed
ER Ondansetron	Rx Anti-Nausea	Two pilot pharmacokinetic trials completed
ER Phenylephrine	OTC Decongestant	Initial pilot pharmacokinetic trial completed
ER Niacin Niaspan® is a trademark of Abbott Laboratories.	Cardiovascular	<i>In-vivo</i> performance comparable to Niaspan®

**Table of Contents****Formulation Experience**

<b>Product</b>	<b>Application</b>	<b>Features</b>
Guaiifenesin	Expectorant	12 hour tablet formulation
Ibuprofen/Diphenhydramine	Analgesic, Sleep Aid	12 hour combination tablet formulation
Ibuprofen/Pseudoephedrine	Cough-Cold	12 hour combination tablet formulation
Naproxen sodium	Analgesic	24 hour tablet formulation
Pseudoephedrine/Loratadine	Decongestant, Antihistamine	12 hour combination tablet formulation
Fenofibrate (Tricor®)	Hypercholesterolemia,	Immediate release tablet
	Hypertriglyceridemia	Solid dispersion formulation
Gabapentin (Lyrica®)	Pain Management	12 hour extended release tablets
Tramadol (Ultram®)	Pain Management	12 and 24 hour extended release tablets
Propranolol (Inderal LA®)	Beta-Blocker	Comparable to reference listed drug
Metoprolol (Toprol XL®)	Beta-Blocker	Comparable to reference listed drug
Diltiazem HCl (Dilacor®)	Ca Channel Blocker	Comparable to reference listed drug
Nifedipine (Procardia®)	Ca Channel Blocker	Comparable to reference listed drug
Verapamil (Covera-HS®)	Ca Channel Blocker	Comparable to reference listed drug
Rivastigmine (Exelon®)	Alzheimer's Disease	24 hour extended release tablets
Risperidone (Risperdal®)	Schizophrenia/Bi-Polar	24 hour extended release tablets
Glipizide (Glucotrol® XL)	Diabetes	Comparable to reference listed drug
Metformin (Glucophage® XR)	Diabetes	Comparable to reference listed drug
Dimenhydrinate (Dramamine®)	Motion Sickness	24 hour extended release tablets
Theophylline (Theo-Dur®)	Asthma, Bronchodilator	12 hour extended release tablets

Tricor® is a trademark of Abbott Laboratories; Lyrica®, Procardia®, Glucotrol®, Dramamine® and Covera-HS® are trademarks of Pfizer; Ultram® and Risperdal® are trademarks of J&J; Inderal LA® is a trademark of Wyeth; Toprol® is a trademark of AstraZeneca; Dilacor® is a trademark of Watson; Exelon® is a trademark of Novartis; Glucophage® is a trademark of Bristol-Myers Squibb.



**Table of Contents****Dietary Supplements**

<b>Product</b>	<b>Features</b>	<b>Status</b>
Glucosamine Chondroitin 500/400 (mg)	24 hour once daily tablets	- On Market
Glucosamine Chondroitin MSM 500/400/200 (mg)	12 hour extended release tablets	- On Market
Glucosamine Chondroitin (Sodium Free) 500/400 (mg)	12 hour extended release tablets	- On Market
Glucosamine Sulfate 750 (mg)	12 hour extended release tablets	- On Market
Glucosamine HCl 750 (mg)	12 hour extended release tablets	- Available
Glucosamine HCl 1500 (mg)	12 hour extended release tablets	- Available
Glucosamine, Chondroitin, , MSM, Boswellia, HLA	12 hour extended release tablets	- Available
Calcium with Vitamin D 600/500 (mg/IU)	24 hour once daily tablets	- On Market
Vitamin C 500 (mg)	12 hour extended release tablets (ascorbic acid delivered over 12 hrs)	- Available
Vitamin C 1000 (mg)	12 hour extended release tablets	- Available
Mineral Ascorbates 500 (mg)	12 hour extended release tablets	- Available
Niacin 250/500 (mg)	12 and 24 hour extended release tablets	- Available
B-Vitamin Stress* Complex	12 and 24 hour extended release tablets	- Available
Caffeine 200 (mg)	10 hour extended release tablets (for 12 hours of energy)	- Available
Guarana, Green Tea (200 mg Caffeine eq.)	10 hour extended release tablets (for 12 hours of energy)	- Available
Cold Formula* (Echinacea, Zinc, Vitamin C, Andrographis)	12 hour extended release tablets	- Available
Echinacea 400 (mg)	12 hour extended release tablets	- Available
Ginkgo Biloba 120 (mg)	12 hour extended release tablets	- Available
St. John s Wort 300 (mg)	12 hour extended release tablets	- Available

\*These statements have not been evaluated by the FDA and are not intended to diagnose, treat or prevent any disease.



---

## **Table of Contents**

### ***Development Status of Lead Products***

***Ibuprofen*** We developed an extended release formulation of ibuprofen based on our CDT platforms and continue preparations for submission of a NDA, for a 12-hour CDT-based ibuprofen product. Our completed Phase III clinical trial to evaluate the safety and efficacy of our formulation achieved all endpoints at statistically significant levels with no significant adverse events. We have initiated the actual use study required by the FDA as a pre-requisite to submission of our regulatory application for ibuprofen, but anticipate the need for additional financing or partnership support to fund certain significant cost items necessary to complete the study. There are currently no extended release formulations of ibuprofen approved for use in North America.

***Pseudoephedrine*** We filed our first ANDA submission in August 2008. In January 2009 the FDA issued a Complete Response Letter detailing deficiencies in the ANDA. We submitted the first amendment to our ANDA in response to the identified deficiencies in August 2009. Throughout the course of the FDA's review, we have submitted additional amendments in response to questions raised from divisions of the FDA, including our most recent amendment submitted in August 2010. 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 deficiencies cited relate to the conduct of the study, trial design and other related quality concerns. The issues raised do not relate to the product formulation. 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 or partnership support to initiate clinical activities in response to the FDA's action. If approved, we anticipate seeking a strategic partnership or additional financing to fund the commercialization of the product. Our strategy is to contract with third-parties for manufacture of the product and to distribute the product under both the SCOLR name and under 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.

### ***Nutritional Products***

We have developed multiple private label extended release nutritional products incorporating our CDT technology for commercialization in the United States and Canada. We have historically generated a significant portion of our revenues as a percentage of profits on select products sold by our partner Perrigo. During 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.

### ***Intellectual Property***

We believe that patent and trade secret protection of our CDT platforms are important to our business and that our success will depend in part on our ability to maintain existing patent protection, obtain additional patents, maintain trade secret protection, and operate without infringing the proprietary rights of others. We have rights to six U.S. patents and three federal trademark registrations. Our policy is to pursue registrations for all of the trademarks associated with our key products and technologies. Our registered trademarks include: CDT, the CDT logo and design, SCOLR and the recently acquired Nuprin.

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. Our intellectual property includes two U.S. patents licensed exclusively to us by Temple University and three patent rights assigned to us by Dr. Reza Fassihi, a Professor of Biopharmaceutics and Industrial Pharmacy at Temple

## **Table of Contents**

University School of Pharmacy. Dr. Fassihi currently serves as a consultant to the Company. We are obligated to share in some up-front payments from licensees (to the extent that the costs of our development efforts on a licensed product do not exceed the amount of such up-front fees), and pay royalties based on product sales with respect to the CDT patents assigned to us by Dr. Fassihi. We are obligated to pay annual license maintenance fees and royalties based on product sales with respect to the CDT patents licensed to us by Temple. Royalties under these agreements are dependent on the product category involved. Royalties related to sales of nutritional and OTC products are paid based on a fixed dollar amount per number of units sold. We do not anticipate these payments to have a material impact on the margins we are able to achieve through sale of our nutritional or OTC products. Royalties related to sales of prescription drugs are paid based on a low single digit percentage of net sales of such products. The licenses are perpetual in duration, unless terminated for material breach, upon the occurrence of certain events of bankruptcy, insolvency or liquidation, or upon written notice delivered by SCOLR. The duration of the fee, royalty and other payments associated with these agreements generally coincides with the duration of the associated patents.

According to the United States Patent and Trademark Office (USPTO) a patent for an invention is the grant of a property right to the inventor, issued by the USPTO. The typical term for a new patent is 20 years from the date on which the application was filed with the USPTO. U.S. patent grants are effective only within the United States, U.S. territories, and U.S. possessions. The oldest patent in SCOLR's intellectual property (IP) estate, is the dual polymer patent was filed on October 27, 1997, and issued in 2002, will expire on October 27, 2017. United States patents expire based on their earliest effective filing date. The majority of our patents were filed on, or after, November 30, 2001 and expect to have full patent life to 2021 and beyond.

Our newest patent was approved in July, 2010 and expires in 2027. This patent covers the process of pre-blending an active pharmaceutical ingredient that is susceptible to tackiness, with a suitable additive that enables improved processing for tablet production. The method allows for improved manufacturing of a blend via direct compression without the need for a granulation step or roller compaction.

We have sought to protect our intellectual property through patent registration in many jurisdictions throughout the world based on a number of factors, including the possibility of future sales to those markets, or the anticipated introduction of similar products into those markets. Patent applications and patent issuances in large international markets such as the European Union may, in the future, be important to our ability to expand the geographic distribution of our products, particularly our lead ibuprofen product. In the future, we plan to file further U.S. and potentially foreign patent applications directed to new or improved products or processes.

In general, each of the patents described herein have the potential to be applied to nutritional, OTC and prescription products. With respect to our ibuprofen product, we have filed two patent applications relating to technologies which optimize the release profile of ibuprofen in order to achieve particular blood level concentrations of this active ingredient and/or to obtain specific therapeutic benefits.

We attempt to protect our proprietary position by filing U.S. and foreign patent applications related to our proprietary technology inventions and improvements that are important to the development of our business. Our success will depend in part on our ability to obtain and maintain patent protection for our technologies, preserve our trade secrets, and operate without infringing the proprietary rights of others. However, the issuance of a patent is not conclusive as to its validity or as to the enforceable scope of the claims of the patent. Our competitors may challenge or circumvent any of our issued patents and the patents may not provide us proprietary protection or a commercial advantage. Furthermore, we cannot assure you that any of our future processes or products will be patentable or will not infringe upon the patents of third parties.

## **Competition**

Our business is highly competitive and is affected by new technologies, government regulations, availability of financing, and other factors. In the drug delivery field, examples of our major competitors include, Valeant

## **Table of Contents**

International, Inc., Endo Pharmaceuticals, SkyePharma PLC, Depomed, Elan Corporation, PLC, Flamel Technologies, Inc., Impax Laboratories, Inc., Labopharm, Inc., and KV Pharmaceutical Company, as well as internal programs within many of the large pharmaceutical companies. The successful development and commercialization of major extended delivery prescription drugs can take five or more years and millions of dollars of research and clinical trials. These major competitors generally are better funded and equipped to fully realize the potential from new and unique patented drug delivery systems and are in possession of significantly stronger financial and research and development resources.

## **Manufacturing**

We currently have no internal commercial scale manufacturing, sales or distribution capabilities. Generally, either our collaborators manufacture the pharmaceutical products or we use a contract manufacturer. Accordingly, we must rely on third party manufacturers for all of our products or prototypes currently in development. In addition, we must rely on third party suppliers to provide sales and logistics support for our products we are currently introducing into the retail marketplace. We currently have agreements with several outside manufacturers and suppliers to support our efforts. Our dependence on third parties for manufacturing, sales and distribution may adversely affect our ability to deliver such products in a timely or competitive basis.

## **Environmental Matters**

Compliance with federal, state and local requirements which have been enacted or adopted regulating the discharge of materials into the environment, or otherwise relating to the protection of the environment have not had, nor are they anticipated to have in the future, a material effect on our capital expenditures, earnings or competitive position.

## **Sources and Availability of Raw Materials and Principal Suppliers**

Our technology allows for the use of conventional, readily available, GRAS excipients. A wide variety of materials can be used for our extended delivery formulation development and are available from a large number of manufacturers and distributors. The core chemical raw materials essential to our business are generally readily available from multiple sources in the United States and throughout the world. Certain other raw materials used in the manufacture of our products are, however, available from limited sources. We have no internal commercial scale manufacturing capabilities and generally have relied on our strategic partners or contract manufacturers to source the larger quantities of raw materials necessary for the manufacture of our products for commercial distribution. Our direct purchases of raw materials are generally of small quantities used for internal research and development purposes. Such purchases are typically made on the basis of individual purchase orders.

## **Government Regulation**

Government authorities in the United States and other countries extensively regulate the research, development, manufacture, labeling, promotion, advertising, distribution, and marketing of drug products. We must receive separate regulatory approval for each of our product candidates before we or our collaborators can sell them in the United States or internationally. In the United States, the FDA regulates drug products under the Federal Food, Drug, and Cosmetic Act, or FDCA, and implements regulations and other laws. Failure to comply with applicable U.S. requirements, both before and after approval, may subject us to administrative and judicial sanctions, such as a delay in approving or refusal by the FDA to approve pending applications, warning letters, product recalls, product seizures, total or partial suspension of production or distribution, injunctions, and/or criminal prosecutions.

The approval process requires substantial time, effort and financial resources, and we cannot be sure that any approval will be granted on a timely basis, or at all. There are several kinds of new drug applications, or NDAs, that may be submitted to obtain FDA approval of our or our collaborators' drugs, including full NDAs;

---

**Table of Contents**

section 505(b)(2) NDAs; and abbreviated new drug applications, or ANDAs. A full NDA is an NDA in which the information required for approval, including investigations of safety and effectiveness, comes from studies conducted by or for the sponsor or for which the sponsor has obtained a right of reference. A section 505(b)(2) NDA is an NDA in which at least some of the information required for approval comes from studies not conducted by or for the sponsor and for which the sponsor has not obtained a right of reference. An abbreviated new drug application, or ANDA, usually utilizes for proof of safety and effectiveness data demonstrating that the drug is bioequivalent to a drug which the FDA has previously approved.

*NDAs:* Approval of a full NDA by the FDA requires pre-clinical laboratory and animal tests and formulation studies; submission to the FDA of an Investigational New Drug Application for human clinical testing, which must be in effect before clinical trials can begin; and adequate and well-controlled clinical trials to establish safety and effectiveness of the product candidate for each indication for which approval is sought. To obtain approval an applicant must submit their application to the FDA; the FDA must complete a pre-approval inspection of manufacturing, analytical, and clinical research facilities to ensure that they are in compliance with local, state, and federal rules and regulations; and the FDA must deem the product safe and effective.

*505(b)(2) NDAs:* Section 505(b)(2) applications contain the full reports of investigations of safety and effectiveness as a traditional NDA, but where at least some of the information required for approval comes from studies not conducted by or for the applicant and for which the applicant has not obtained the right to reference. To obtain approval an applicant must submit its application to the FDA; the FDA must complete a pre-approval inspection of manufacturing, analytical, and clinical research facilities to ensure that they are in compliance with local, state, and federal rules and regulations; and the FDA must deem the product safe and effective. Preparing a 505(b) (2) NDA is generally less costly and time-consuming than preparing a full NDA.

*ANDAs:* The FDA may approve an ANDA if the product is the same in important respects as an already approved drug, or if the FDA has declared the drug suitable for an ANDA submission. An ANDA contains information to show that the proposed product is identical in active ingredient, dosage form, strength, route of administration, labeling, quality, performance characteristics, and intended use to a previously approved product. To obtain approval an applicant must submit their application to the FDA; the FDA must complete a pre-approval inspection of manufacturing, analytical, and clinical research facilities to ensure that they are in compliance with local, state, and federal rules and regulations; and the FDA must deem the product safe and effective. Conducting bioequivalence studies is less time-consuming and costly than conducting pre-clinical and clinical studies necessary to support an NDA.

The testing and approval process requires substantial time, effort and financial resources, and each may take several years to complete. The FDA may not grant approval on a timely basis, or at all. We may encounter difficulties or unanticipated costs in our efforts to secure necessary government approvals, which could delay or preclude us from marketing our product candidates. The FDA may limit the indications for use or place other conditions on any approvals that could restrict the commercial application of our product candidates.

We use third party manufacturers to produce our product candidates in clinical and commercial quantities. Future inspections by the FDA may identify compliance issues at the facilities of our contract manufacturers or collaborators that may disrupt production on distribution, or require substantial resources to correct. Also, new government requirements may be established that could delay or prevent regulatory approval of our product candidates under development.

*Other FDA Requirements:*

We and our collaborators are required to comply with a number of FDA requirements both before and after approval, regardless of the type of application submitted. For example, we are required to report certain adverse reactions and production problems, if any, to the FDA, and to comply with certain requirements concerning advertising and promotion for our products. Also, quality control and manufacturing procedures must continue to

**Table of Contents**

conform to regulations after approval, and the FDA periodically inspects manufacturing facilities to assess compliance. Accordingly, manufacturers must continue to expend time, money and effort in all areas of regulatory compliance, including production and quality control. In addition, discovery of issues such as safety problems may result in changes in labeling or restrictions on a product manufacturer or NDA holder, including removal of the product from the market. After approval, certain changes to the approved product, such as adding new indications, manufacturing changes, or additional labeling claims are subject to further FDA review and approval. In addition, the FDA may require post-approval studies.

**Employees**

As of December 31, 2010 we had 6 employees, all of whom are full time. None of our employees are represented by labor unions. We believe our relationship with employees is good.

**Executive Officers**

Our executive officers are generally elected annually at the meeting of our board of directors held in conjunction with the annual meeting of stockholders. The following are our current executive officers and their ages as of March 15, 2011:

<b>Name</b>	<b>Age</b>	<b>Office</b>	<b>Position Since</b>
Stephen J. Turner	40	President and CEO	2009
Richard M. Levy	52	Executive Vice President and Chief Financial Officer	2005

The following sets forth the business experience, principal occupations and employment of each of our current executive officers.

*Stephen J. Turner* is our President and Chief Executive Officer. Mr. Turner was appointed President and Chief Executive Officer in August 2009 and has worked for us since the fall of 1999 when he was primarily responsible for the commercialization and application of our CDT platforms. In 2003, Mr. Turner was promoted to our Vice President and Chief Technical Officer. In addition to Mr. Turner's involvement in our growth and the application of our technology platforms, he is named on one issued patent, has contributed to numerous additional patent filings, has published articles in industry related publications, and has presented his research findings at numerous academic seminars and symposia. Mr. Turner holds a BS in biology with a minor in geochemistry from Western Washington University and a MBA from the University of Washington.

*Richard M. Levy* has been our Chief Financial Officer since joining the Company in December 2005 and an Executive Vice President since 2009. Mr. Levy has experience as a chief financial officer, controller, consultant and auditor. Before joining us, Mr. Levy served as a consultant for two years to several companies including SCOLR Pharma. Prior to that, he served as the CFO for a major business unit and as corporate controller for Washington Mutual Bank. Mr. Levy worked for Bank of America in various capacities for seven years. His experience at Bank of America included serving as the senior vice president and controller of Bank of America Texas, and coordinating all accounting activities and acting as chief financial officer for newly acquired businesses from the Resolution Trust Corporation (RTC). His work at Bank of America also included international financial management experience in its international private banking and world banking divisions. His corporate financial duties also included serving as director and as chief financial officer of various Bank of America subsidiaries. Mr. Levy earned his B.A. in business economics and accounting from the University of California, Santa Barbara and he is licensed as a C.P.A.

## **Table of Contents**

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

*This annual report on Form 10-K contains forward looking statements that involve risks and uncertainties. Our business, operating results, financial performance, and share price may be materially adversely affected by a number of factors, including, but not limited, to the following risk factors, any one of which could cause actual results to vary materially from anticipated results or from those expressed in any forward-looking statements made by us in this annual report on Form 10-K or in other reports, press releases or other statements issued from time to time. Additional factors that may cause such a difference are set forth elsewhere in this annual report on Form 10-K.*

***We do not have sufficient cash to fund the operation of our business.***

We anticipate that our existing cash and cash equivalents will be sufficient to fund our operations under our current operating plan into the second quarter of 2011 unless the timing of inventory purchases necessary to fulfill any orders for our nutritional products places additional constraint on our liquidity prior to that time, or unforeseen events impact our liquidity.

Our current operating expenses reflect reductions in personnel, and other operating expenses implemented during 2010. However, our marketing, personnel and working capital requirements are expected to increase through 2011 as we expand our direct sales of nutritional products. We are actively managing our liquidity by limiting our clinical and development expenses to our lead products and supporting our existing alliances and collaborations. We have deferred all significant expenditures on new projects as well as major expenditures for our lead products pending additional financing or partnership support. We plan to continue efforts to enter into collaboration and licensing agreements for our product candidates, including extended release ibuprofen, that may provide additional funding for our operations. If we are unsuccessful with these efforts, we may have to significantly curtail or cease operations.

If we cannot generate revenues sufficient to sustain our operations we will need to raise additional capital to fund operations, conduct clinical trials, continue research and development projects, and commercialize our product candidates. The timing and amount of our need for additional financing will depend on a number of factors, including:

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;

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.

## **Table of Contents**

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 \$599,000. 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, 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.

***We have a history of substantial operating losses, may continue to incur substantial losses in the future and will require multiple financings to continue our operations, which would negatively impact our ability to run our business.***

We have a history of operating losses and we may continue to incur significant losses in the future unless our direct nutritional sales efforts are successful. We do not plan to continue the costly process of simultaneously conducting clinical trials and preclinical research for multiple product candidates without a partner. Our product development program may not lead to commercial products, either because our product candidates fail to be effective, are not attractive to the market, or because we lack the necessary financial or other resources relationships to pursue our programs through FDA approval and commercialization. Our net losses are likely to continue as we advance preclinical research and clinical trials, apply for regulatory approvals, develop our product candidates, and support commercialization of our potential products.

We have funded our operations primarily through the issuance of equity securities and we may not be able to generate positive cash flow in the future. We will need to seek additional funds through the issuance of equity securities or other sources of financing. If we fail to obtain necessary financing, our ability to run our business will be adversely affected and we may be required to reduce the scope of our research and business activity or cease operations.

***A significant number of shares of our common stock are or will be eligible for sale in the open market, which could drive down the market price for our common stock and make it difficult for us to raise capital.***

As of December 31, 2010, 49,816,073 shares of our common stock were outstanding, and there were 8,082,165 shares of our common stock issuable upon the exercise of outstanding options and warrants. If we raise additional funds through the sale of equity securities, our stockholders may experience substantial dilution and sales of a large number of shares by us or by existing stockholders could materially decrease the market price of our common stock and make it more difficult for us to raise additional capital through the sale of equity securities. The risk of dilution and the resulting downward pressure on our stock price could also encourage stockholders to engage in short sales of our common stock. By increasing the number of shares offered for sale, material amounts of short selling could further contribute to progressive price declines in our common stock.

***Our efforts to sell nutritional products directly to retailers may not be successful.***

Our revenue strategy involves direct sales of nutritional products, primarily through retail channels. We do not own manufacturing facilities necessary to support these sales and will be dependent on third party

---

**Table of Contents**

manufacturers to produce and in some cases distribute and otherwise administrate to the operation of our nutritional products business. Our direct sales efforts in the nutritional market will not be successful if, among other factors, we are unsuccessful in completing sales of our nutritional products or our manufacturing partners cannot manufacture the products in a quality, timely and cost effective manner. Additionally, our revenues may not support the substantial increase in working capital required to source and inventory product from third party manufacturers for later sale, and we do not have a credit facility to draw upon to support our working capital requirements.

***We lack experience selling products directly in the retail market and our level of staffing may be insufficient to effectively manage our nutritional business.***

The nutritional business involves multiple sales, manufacturing, logistics and account management functions. We have limited resources for performing these functions and limited experience in the retail market in which we are seeking to sell our nutritional products. Our lack of resources and inexperience may lead to failure of our strategy to sell our line of extended release nutritional products directly to retailers. We may fail to generate interest in our products from retailers, may be unable to conclude sales on favorable terms or may be unable to commit to the shipment volumes or delivery timeframes required by retailers. We have outsourced many of these functions to a third-party, but anticipate that to be successful we will need to additional staff-level personnel to manage the operations of our nutritional business. We may lack the financing to adequately staff our nutritional business, or may be unable to attract qualified employees on favorable terms. As a result we may be unable to obtain significant sales of our nutritional products, or may fail to meet the expectations of our retail customers, all of which would negatively affect our ability to generate revenue from our nutritional business.

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

Each OTC or pharmaceutical product we develop will require a separate costly and time consuming regulatory approval before we or our collaborators can manufacture and sell it in the United States or internationally. The regulatory process to obtain market approval for a new drug takes many years and requires the expenditure of substantial resources. We have had only limited experience in preparing applications and do not have experience in obtaining regulatory approvals. As a result, we believe we will rely primarily on third party contractors to help us prepare applications for regulatory approval, which means we will have less control over the timing and other aspects of the regulatory process than if we had our own expertise in this area. Our limited experience in preparing applications and obtaining regulatory approval could delay or prevent us from obtaining regulatory approval and could substantially increase the cost of applying for such approval.

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

We may encounter delays or rejections during any stage of the regulatory approval process based upon the failure of clinical data to demonstrate compliance with, or upon the failure of the product to meet the FDA's requirements for safety, efficacy, quality, and/or bioequivalence; and, those requirements may become more stringent due to changes in regulatory agency policy or the adoption of new regulations. For example, after submission of a marketing application, in the form of an NDA or ANDA, the FDA may deny the application, may require additional testing or data, and/or may require post marketing testing and surveillance to monitor the safety or efficacy of a product. In addition, the terms of approval of any marketing application, including the labeling content, may be more restrictive than we desire and could affect the marketability of products incorporating our extended release technology.

Certain products incorporating our technology will require the filing of an NDA. A full NDA must include complete reports of preclinical, clinical, and other studies to prove adequately that the product is safe and

## **Table of Contents**

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

***If we cannot establish collaborative arrangements with leading individuals, companies and research institutions, we may have to discontinue the development and commercialization of our products.***

We have limited experience in conducting full scale clinical trials, preparing and submitting regulatory applications, or manufacturing and selling pharmaceutical products. In addition, we do not have sufficient resources to fund the development, regulatory approval, and commercialization of our products. We expect to seek collaborative arrangements and alliances with corporate and academic partners, licensors and licensees to assist with funding research and development, to conduct clinical testing, and to provide manufacturing, marketing, and commercialization of our product candidates. We may rely on collaborative arrangements to obtain the regulatory approvals for our products.

For our collaboration efforts to be successful, we must identify partners whose competencies complement ours. We must also enter into collaboration agreements with them on terms that are favorable to us and integrate and coordinate their resources and capabilities with our own. We may be unsuccessful in entering into collaboration agreements with acceptable partners or negotiating favorable terms in these agreements.

If we cannot establish collaborative relationships, we will be required to find alternative sources of funding and to develop our own capabilities to manufacture, market, and sell our products. If we are not successful in finding funding and developing these capabilities, we will have to terminate the development and commercialization of our products.

***If our clinical trials are not successful or take longer to complete than we expect, we may not be able to develop and commercialize our products.***

In order to obtain regulatory approvals for the commercial sale of potential products utilizing our CDT platforms, we or our collaborators will be required to complete clinical trials in humans to demonstrate the safety and efficacy, or in certain cases, the bioequivalence, of the products. However, we or our collaborators may not be able to commence or complete these clinical trials in any specified time period, or at all, either because the appropriate regulatory agency objects or for other reasons, including:

lack of partnership or financing support necessary to fund clinical trials;

unexpected delays in the initiation of clinical sites;

slower than projected enrollment of eligible patients;

competition with other ongoing clinical trials for clinical investigators or eligible patients;

scheduling conflicts with participating clinicians;

limits on manufacturing capacity, including delays of clinical supplies; and,

the failure of our products to meet required standards.

## **Table of Contents**

We also rely on academic institutions and clinical research organizations to conduct, supervise or monitor some or all aspects of clinical trials involving our product candidates. We have less control over the timing and other aspects of these clinical trials than if we conducted the monitoring and supervision on our own. Third parties may not perform their responsibilities for our clinical trials on our anticipated schedule or consistent with a clinical trial protocol.

Even if we complete a clinical trial of one of our potential products, the clinical trial may not indicate that our product is safe or effective to the extent required by the FDA or other regulatory agency to approve the product. If clinical trials do not show any potential product to be safe, efficacious, or bioequivalent, or if we are required to conduct additional clinical trials or other testing of our products in development beyond those that we currently contemplate, we may be delayed in obtaining, or may not obtain, marketing approval for our products. Our product development costs may also increase if we experience delays in testing or approvals, which could allow our competitors to bring products to market before we do and would impair our ability to commercialize our products.

***We face intense competition in the drug delivery business, and our failure to compete effectively would decrease our ability to generate meaningful revenues from our products.***

The drug delivery business is highly competitive and is affected by new technologies, governmental regulations, health care legislation, availability of financing, litigation and other factors. Many of our competitors have longer operating histories and greater financial, research and development, marketing and other resources than we do. We are subject to competition from numerous other entities that currently operate or intend to operate in the industry. These include companies that are engaged in the development of extended release drug delivery technologies and products as well as other manufacturers that may decide to undertake in-house development of these products. Some of our direct competitors in the drug delivery industry include Valeant International, Inc., Endo Pharmaceuticals, SkyePharma PLC, Depomed, Elan Corporation, PLC, Flamel Technologies, Inc., Impax Laboratories, Inc., Labopharm, and KV Pharmaceutical Company. Many of the major pharmaceutical companies also have internal drug delivery programs that may compete directly with our business.

Many of our competitors have more extensive experience than we have in conducting preclinical studies and clinical trials, obtaining regulatory approvals, and manufacturing and marketing pharmaceutical products. Many competitors also have competing products that have already received regulatory approval or are in late-stage development, and may have collaborative arrangements in our target markets with leading companies and research institutions. Our competitors may develop or commercialize more effective, safer or more affordable products, or obtain more effective patent protection, than we are able to develop, commercialize or obtain. As a result, our competitors may commercialize products more rapidly or effectively than we do, which would adversely affect our competitive position, the likelihood that our products will achieve market acceptance, and our ability to generate meaningful revenues from our products.

***If we fail to comply with extensive government regulations covering the manufacture, distribution and labeling of our products, we may have to withdraw our products from the market, close our facilities or cease our operations.***

Our products, potential products, and manufacturing and research activities are subject to varying degrees of regulation by a number of government authorities in the United States (including the Drug Enforcement Agency, FDA, Federal Trade Commission, and Environmental Protection Agency) and in other countries. For example, our activities, including preclinical studies, clinical trials, manufacturing, distribution, and labeling are subject to extensive regulation by the FDA and comparable authorities outside the United States. Also, our statements and our customers' statements regarding dietary supplement products are subject to regulation by the FTC. The FTC enforces laws prohibiting unfair or deceptive trade practices, including false or misleading advertising. In recent years, the FTC has brought a number of actions challenging claims by nutritional companies.

---

## **Table of Contents**

Each OTC or pharmaceutical product we develop will require a separate costly and time consuming regulatory approval before we or our collaborators can manufacture and sell it in the United States or internationally. Even if regulatory approval is received, there may be limits imposed by regulators on a product's use or it may face subsequent regulatory difficulties. Approved products are subject to continuous review and the facilities that manufacture them are subject to periodic inspections. Furthermore, regulatory agencies may require additional and expensive post-approval studies. If previously unknown problems with a product candidate surface, or the manufacturing or laboratory facility is deemed non-compliant with applicable regulatory requirements, an agency may impose restrictions on that product or on us, including requiring us to withdraw the product from the market, close the facility, and/or pay substantial fines.

We also may incur significant costs in complying with environmental laws and regulations. We are subject to federal, state, local and other laws and regulations governing the use, manufacture, storage, handling, and disposal of materials and certain waste products. The risk of accidental contamination or injury from these materials cannot be completely eliminated. If an accident occurs, we could be held liable for any damages that result and these damages could exceed our resources.

***Our ability to commercialize products containing pseudoephedrine may be adversely impacted by retail sales controls, legislation, and other measures designed to counter diversion and misuse of pseudoephedrine in the production of methamphetamine, an illegal drug.***

We will require approval from the FDA prior to anticipated commercialization efforts of our extended release formulation of pseudoephedrine. On March 10, 2006, Congress enacted the Patriot Act, which included the Combat Methamphetamine Epidemic Act of 2005. Among its various provisions, this national legislation placed restrictions on the purchase and sale of all products containing pseudoephedrine and imposed quotas on manufacturers relating to the sale of products containing pseudoephedrine. Many states have also imposed statutory and regulatory restrictions on the manufacture, distribution and sale of pseudoephedrine products. Our ability to commercialize products containing pseudoephedrine and the market for such products may be adversely impacted by existing or new retail sales controls, legislation and market changes relating to diversion and misuse of pseudoephedrine in the production of methamphetamine.

***If our existing or new collaborations are not successful, we will have to establish our own commercialization capabilities, which would be expensive and time consuming and could delay the commercialization of the affected product.***

Extended release formulations of ondansetron are being developed for commercialization by a licensor of our technology and other products may in the future be developed and commercialized in collaboration with other corporate partners. Under these collaborations, we may be dependent on our collaborators to fund all or a portion of development, to conduct clinical trials, to obtain regulatory approvals for, and manufacture, market and sell products using our CDT platforms.

We have very limited experience in manufacturing, marketing and selling pharmaceutical products. There can be no assurance that we will be successful in developing these capabilities.

Our existing collaborations may be subject to termination on short notice. If any of our collaborations are terminated, we may be required to devote additional resources to the product covered by the collaboration, seek a new collaborator on short notice or abandon the product. The terms of any additional collaborations or other arrangements that we establish may not be favorable to us.

Our collaborations or other arrangements may not be successful because of factors such as:

our collaborators may have insufficient economic motivation to continue their funding, research, development, and commercialization activities;

## Table of Contents

our collaborators may discontinue funding any particular program, which could delay or halt the development or commercialization of any product candidates arising out of the program;

our collaborators may choose to pursue alternative technologies or products, either on their own or in collaboration with others, including our competitors;

our collaborators may lack sufficient financial, technical or other capabilities to develop these product candidates;

we may underestimate the length of time that it takes for our collaborators to achieve various clinical development and regulatory approval milestones; or,

our collaborators may be unable to successfully address any regulatory or technical challenges they may encounter.

***We have no manufacturing capabilities and will be dependent on third party manufacturers.***

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

***If we fail to protect and maintain the proprietary nature of our intellectual property, our business, financial condition and ability to compete would suffer.***

We principally rely on patent, trademark, copyright, trade secret and contract law to establish and protect our proprietary rights. We own or have exclusive rights to several U.S. patents and patent applications and we expect to apply for additional U.S. and foreign patents in the future. The patent positions of pharmaceutical, nutritional, and bio-pharmaceutical firms, including ours, are uncertain and involve complex legal and factual questions for which important legal issues are largely unresolved. The coverage claimed in our patent applications can be significantly reduced before a patent is issued, and the claims allowed on any patents or trademarks we hold may not be broad enough to protect our technology. In addition, our patents or trademarks may be challenged, invalidated or circumvented, or the patents of others may impede our collaborators' ability to commercialize the technology covered by our owned or licensed patents. Moreover, any current or future issued or licensed patents, or trademarks, or existing or future trade secrets or know-how, may not afford sufficient protection against competitors with similar technologies or processes, and the possibility exists that certain of our already issued patents or trademarks may infringe upon third party patents or trademarks or be designed around.



---

**Table of Contents**

by others. In addition, there is a risk that others may independently develop proprietary technologies and processes that are the same as, or substantially equivalent or superior to ours, or become available in the market at a lower price. There is a risk that we have infringed or in the future will infringe patents or trademarks owned by others, that we will need to acquire licenses under patents or trademarks belonging to others for technology potentially useful or necessary to us, and that licenses will not be available to us on acceptable terms, if at all. We cannot assure you that:

our patents or any future patents will prevent other companies from developing similar or functionally equivalent products or from successfully challenging the validity of our patents;

any of our future processes or products will be patentable;

any pending or additional patents will be issued in any or all appropriate jurisdictions;

our processes or products will not infringe upon the patents of third parties; or,

we will have the resources to defend against charges of patent infringement by third parties or to protect our own patent rights against infringement by third parties.

We may have to litigate to enforce our patents or trademarks or to determine the scope and validity of other parties' proprietary rights. Litigation could be very costly and divert management's attention. An adverse outcome in any litigation could adversely affect our financial results, stock price and ability to conduct business based on key technologies.

We also rely on trade secrets and proprietary know-how, which we seek to protect by confidentiality agreements with our employees, consultants, advisors, and collaborators. There is a risk that these agreements may be breached, and that the remedies available to us may not be adequate. In addition, our trade secrets and proprietary know-how may otherwise become known to or be independently discovered by others.

***Significant expenses in applying for patent protection and prosecuting our patent applications will increase our need for capital and could harm our business and financial condition.***

We intend to continue our substantial efforts in applying for patent protection and prosecuting pending and future patent applications both in the United States and internationally. These efforts have historically required the expenditure of considerable time and money, and we expect that they will continue to require significant expenditures. If future changes in United States or foreign patent laws complicate or hinder our efforts to obtain patent protection, the costs associated with patent prosecution may increase significantly.

***If we fail to attract and retain key executive and technical personnel we could experience a negative impact on our ability to develop and commercialize our products and our business will suffer.***

The success of our operations will depend to a great extent on the collective experience, abilities and continued service of relatively few individuals. We are dependent upon the continued availability of the services of our employees, many of whom are individually key to our future success. For example, if we lose the services of Stephen J. Turner, our President and Chief Executive Officer, or our Executive Vice President and Chief Financial Officer, Richard M. Levy, we could experience a negative impact on our ability to develop and commercialize our CDT technology, our financial results, and our stock price. We have been forced to terminate our research and development staff. The loss of the services of key members of this staff could substantially impair our ongoing research and development and our ability to obtain additional financing. We do not carry key man life insurance on any of our personnel.

## **Table of Contents**

Our success also significantly depends upon our ability to attract and retain highly qualified personnel. We face intense competition for personnel in the drug delivery industry. To compete for personnel, we may need to pay higher salaries and provide other incentives than those paid and provided by more established entities. Our limited financial resources may hinder our ability to provide such salaries and incentives. Our personnel may voluntarily terminate their relationship with us at any time, and the process of locating additional personnel with the combination of skills and attributes required to carry out our strategy could be lengthy, costly, and disruptive. If we lose the services of key personnel, or fail to replace the services of key personnel who depart, we could experience a severe negative impact on our financial results and stock price.

### ***Future laws or regulations may hinder or prohibit the production or sale of our products.***

We may be subject to additional laws or regulations in the future, such as those administered by the FDA or other federal, state or foreign regulatory authorities. Laws or regulations that we consider favorable, such as the Dietary Supplement Health and Education Act, DSHEA, may be repealed. Current laws or regulations may be interpreted more stringently. We are unable to predict the nature of such future laws, regulations or interpretations, nor can we predict what effect they may have on our business. Possible effects or requirements could include the following:

the reformulation of certain products to meet new standards;

the recall or discontinuance of certain products unable to be reformulated;

imposition of additional record keeping requirements;

change in the health coverage available to consumers, which may affect their buying habits;

expanded documentation of the properties of certain products; or,

expanded or different labeling, or scientific substantiation.

Any such requirement could have a material adverse effect on our results of operations and financial condition.

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

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

We have identified a material weakness in our internal control over financial reporting which pertains to controls relating to the process of accounting for warrants. See Item 9A Controls and Procedures Management's Report on Internal Control Over Financial Reporting. As of the date of this annual report on Form 10-K, we have implemented remedial measures related to the identified material weakness. The requirements of Section 404 of the Sarbanes-Oxley Act are ongoing and also apply to future years. We expect that our internal control over financial reporting will continue to evolve as our business develops. Although we are committed to continue to improve our internal control processes and we will continue to diligently and vigorously review our internal control over financial reporting in order to ensure compliance with the Section 404 requirements, any control system, regardless of how well designed, operated and evaluated, can provide only reasonable, not absolute, assurance that its objectives will be met. Therefore, we cannot be certain that in the future additional material weaknesses or significant deficiencies will not exist or otherwise be discovered. If our efforts to remediate the weakness identified are not successful or if other deficiencies occur, these weaknesses or deficiencies could result in misstatements of our results of operations, additional restatements of our consolidated financial statements, a decline in our stock price, or other material effects on our business, reputation, results of operations, financial condition or liquidity.



**Table of Contents**

*Our delisting from the NYSE Amex Exchange may adversely impact the liquidity and price of our common stock.*

In January 2011, we voluntarily delisted our common stock from the NYSE Amex Exchange after concluding that we could not reasonably expect to regain compliance with the continued listing requirements of the Exchange within the extensions period afforded to us. Our common stock is now quoted on the OTC Bulletin Board. The delisting of our common stock from NYSE Amex could further depress our stock price, substantially limit the liquidity of our common stock and materially adversely affect our ability to raise capital on terms acceptable to us, or at all. Delisting may also have other negative results, including the potential loss of confidence by suppliers and employees, the loss of institutional investor interest in our Company and fewer business development opportunities from strategic partners.

*Our stock price is subject to significant volatility.*

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

general conditions in the healthcare industry;

general conditions in the consumer products industry;

general conditions in the financial markets;

our failure or the failure of our collaborative partners, for any reason, to obtain FDA approval for any of our products or products we license;

for those products that are ultimately approved by the FDA, the failure of the FDA to approve such products in a timely manner consistent with the FDA's historical approval process;

our failure, or the failure of our third-party partners, to successfully commercialize products approved by the FDA;

our failure to generate product revenues and corresponding profits;

problems incurred by our primary third party suppliers/vendors;

our ability to exercise/redeem certain outstanding warrants to purchase our common stock;

the sale of additional debt and/or equity securities by us;

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

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

developments or disputes concerning patent or any other proprietary rights.

***Certain provisions in our charter documents and otherwise may discourage third parties from attempting to acquire control of our company, which may have an adverse effect on the price of our common stock.***

Our board of directors has the authority, without obtaining stockholder approval, to issue up to 5,000,000 shares of preferred stock and to fix the rights, preferences, privileges and restrictions of such shares without any further vote or action by our stockholders. Our certificate of incorporation and bylaws also provide for special advance notice provisions for proposed business at annual meetings. In addition, Delaware and Washington law

**Table of Contents**

contain certain provisions that may have the effect of delaying, deferring or preventing a hostile takeover of our company. Further, we have a stockholder rights plan that is designed to cause substantial dilution to a person or group that attempts to acquire our company without approval of our board of directors, and thereby make a hostile takeover attempt prohibitively expensive for a potential acquirer. These provisions, among others, may have the effect of making it more difficult for a third party to acquire, or discouraging a third party from attempting to acquire, control of our company, even if stockholders may consider such a change in control to be in their best interests, which may cause the price of our common stock to suffer.

**Item 1B. Unresolved Staff Comments**

Not applicable.

**Item 2. Properties**

Our corporate headquarters, including administrative offices and research and development facilities, are located approximately 20 miles northeast of Seattle, Washington at 19204 North Creek Parkway, Suite 100, Bothell, Washington 98011.

The property, consisting of approximately 15,615 square feet, is leased until January 31, 2016.

**Item 3. Legal Proceedings**

We are not a party to any material litigation.

**Item 4. Removed and Reserved**

**Table of Contents****PART II****Item 5. Market for the Registrant's Common Equity, Related Stockholder Matters and Issuer Purchases of Equity Securities**

On January 13, 2011, our common stock began quotation on the OTC Bulletin Board and OTCQB under the symbol SCLR. Prior to that date our common stock was traded on the NYSE Amex Exchange under the symbol DDD. The last sale price of our common stock as reported on the OTC Bulletin Board on March 10, 2011, was \$0.17 per share. The following table sets forth the range of high and low close prices for our common stock as reported on the NYSE Amex Equities Exchange for each full quarterly period from January 1, 2009 through December 31, 2010.

**COMMON STOCK**

	<b>High</b>	<b>Low</b>
<b>2010</b>		
First Quarter	\$ .84	\$ .57
Second Quarter	1.33	.43
Third Quarter	.68	.36
Fourth Quarter	.57	.29
<b>2009</b>		
First Quarter	\$ .79	\$ .28
Second Quarter	.49	.28
Third Quarter	.57	.28
Fourth Quarter	.85	.43

As of March 10, 2011, we had 49,816,073 stockholders of record. We have not paid or declared any dividends upon our common stock since inception and do not contemplate or anticipate paying any dividends upon the common stock in the foreseeable future.

**EQUITY COMPENSATION PLAN INFORMATION**

Information relating to our equity compensation plans is incorporated by reference to the definitive proxy statement for our 2011 annual meeting of stockholders. Additional information regarding our equity compensation plans is provided in Note 13 to our financial statements in this annual report.

---

**Table of Contents**

**Item 7. Management's Discussion and Analysis of Financial Condition and Results of Operations**

We are a specialty pharmaceutical company. Our corporate objective is to combine our formulation experience and knowledge with our proprietary and patented CDT platforms to develop novel pharmaceutical, OTC, and nutritional products. Our CDT platforms are based on multiple issued and pending patents and other intellectual property for the programmed release or enhanced performance of active pharmaceutical ingredients and nutritional products.

We have developed multiple private label 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 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. 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. 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 or partnership support to initiate clinical activities in response to the FDA's action. If approved, we believe our formulation will offer attractive tablet size and cost saving opportunities when compared to similar tablets already on the market.

We expect our operating losses to decline and cash flows to improve as we advance direct sales of our nutritional products. We actively manage our liquidity by limiting the clinical and development expenses to our ibuprofen and pseudoephedrine lead products. We have deferred all significant expenditures on our other development projects. We have initiated the actual use study required by the FDA as a prerequisite to submission of our regulatory application for ibuprofen, but anticipate the need for additional financing or partnership support to fund certain significant cost items necessary to complete that study. Without additional revenues or funding, the Company does not expect to be able to complete development of its lead projects. In addition, the Company has substantially reduced its general and administrative expenses and has limited opportunities to further reduce operating expenses. During October 2009, the Company renegotiated the lease of its corporate facility to reduce its leased space and monthly cash payment for the remainder of the lease, which expires in 2016. Also, for one year commencing November 1, 2009, the Company paid down a portion of the monthly lease payment by



## **Table of Contents**

drawing down its letter of credit, and corresponding restricted cash account, by \$18,000 per month. The letter of credit is collateralized by the Company's restricted cash balance. In addition to renegotiating the lease, in August 2009 the Company reduced the number of its executives and reduced the annual cash compensation for two executive officers effective November 2009.

We will need to raise additional capital to fund operations, continue research and development projects, and commercialize our products. We may not be able to secure additional financing on favorable terms, or at all. If we are unable to obtain necessary additional financing, our business will be adversely affected and we may be required to reduce the scope of our development activities, or discontinue operations.

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

Our financial statements are presented in accordance with accounting principles that are generally accepted in the United States. All professional accounting standards effective as of December 31, 2010, have been taken into consideration in preparing the financial statements. The preparation of the financial statements requires estimates and assumptions that affect the reported amounts of assets, liabilities, revenues, expenses and related disclosures. Some of those estimates are subjective and complex, and, therefore, actual results could differ from those estimates. An accounting policy is deemed to be critical if it requires an accounting estimate to be made based on assumptions about matters that are highly uncertain at the time the estimate is made and if different estimates that reasonably could have been used, or changes in the accounting estimates that are reasonably likely to occur periodically, could materially impact the financial statements. We believe the following critical accounting policies reflect our more significant estimates and assumptions used in the preparation of our financial statements.

#### *Revenue Recognition*

Royalty income from licensees are based on reported sales of licensed products and revenue is calculated based on contract terms when reported sales are reliably measurable and collectability is reasonably assured.

Revenues for non-refundable, up-front payments received in connection with collaborative research and development and commercialization agreements are initially deferred and then recognized as licensing fees on a straight-line basis over the relevant periods specified in the agreement, generally the research or contract term. Non-refundable license fees are recognized as revenue once no future performance obligation exists, the price is fixed and determinable, delivery has occurred, and collectability is reasonably assured.

#### *Inventories*

Inventories consist primarily of nutritional tablets, bottles, and bottled nutritional supplements. The Company values these inventories on its balance sheets at the lower of average cost or market. The Company writes down inventory for estimated obsolescence and excess quantities based on usage requirements and other factors, which incorporate estimates.

#### *Deferred Taxes Valuation Allowance*

We make estimates and use our judgment in determining the provision for income taxes, deferred tax assets and liabilities, and any valuation allowance recorded against net deferred tax assets. We record a valuation allowance to reduce our deferred tax assets to the amount that is more likely than not to be realized. While we may consider any potential future taxable income and ongoing prudent and feasible tax planning strategies in assessing the need for the valuation allowance, in the event we were to determine that we would be able to realize our deferred tax assets in the future in excess of our net recorded amount, an adjustment to the deferred tax asset would increase income in the period in which we made such determination. At December 31, 2010, we had recorded full valuation totaling approximately \$20.4 million against our net deferred tax assets.

---

## **Table of Contents**

### *Share-Based Compensation*

We have granted equity incentive awards to our employees, consultants, officers, and directors under our 2004 Equity Incentive Plan (the "2004 Plan") and our 1995 Stock Option Plan (the "1995 Plan"). The 2004 Plan was approved by stockholders in June 2004, and replaced the 1995 Plan. Under the 2004 Plan, equity-based incentive awards may be granted in the form of stock options, stock appreciation rights, stock awards, performance awards, and outside director options.

Compensation cost recognized for the years ended December 31, 2010 and 2009, is based on the grant date fair value of share-based payments. Our share-based compensation expense includes expense related to our stock options, our restricted stock awards, and our stock awards.

Share-based compensation expense for performance-based options granted to non-employees is determined as the fair value of the consideration received or the fair value of the equity instruments issued, whichever is more reliably measured. The fair value of options granted to non-employees is measured as of the earlier of the performance commitment date or the date at which performance is complete ("measurement date"). When it is necessary under generally accepted accounting principles to recognize cost for the transaction prior to the measurement date, the fair value of unvested options granted to non-employees is remeasured at the balance sheet date.

The 2004 Plan, as amended, authorized the issuance of up to 4,000,000 shares of common stock, plus 388,441 shares which were previously reserved for issuance under the 1995 Plan not subject to outstanding options. On June 11, 2009, at the 2009 Annual Meeting of stockholders of SCOLR Pharma, Inc., our stockholders approved a 3,000,000 increase in the maximum aggregate number of shares that may be issued under our 2004 Plan. If any award under the 2004 Plan, or any award previously issued and outstanding under the 1995 Plan, expires, lapses or otherwise terminates for any reason without having been exercised or settled in full, or if shares subject to forfeiture or repurchase are forfeited or repurchased by us, the shares underlying the award will again become available for issuance under the 2004 Plan. As of December 31, 2010, there were 4,070,283 shares available for future grants under both Plans.

### **Restatement of Financial Statements**

The following information has been adjusted to reflect the correction of an error and the restatement of our financial results, which is further described in the Explanatory Note immediately preceding Part I, Item 1 and Note 2, Restatement of 2009 Financial Statements for an Immaterial Error and Note 17. Restatement of Quarterly Financial Information in the Notes to Financial Statements of this Form 10-K. We are correcting an immaterial error as of December 31, 2009 and for the period then ended and are restating our balance sheets, the related statements of operations, and cash flows for the first three quarters of 2010. In Item 8, Financial Statements and Supplementary Data, this Form 10-K reflects the correction of the immaterial error in the balance sheet as of December 31, 2009, the related consolidated statements of operations, stockholders' equity and cash flows for the years ended December 31, 2009 and additionally reflects the restatement for the first three quarters in 2010. Management's Discussion and Analysis of Financial Condition and Results of Operations reflects correction of the error as of and for the year ended December 31, 2009 and the restatement of financial statements as of and for each of the first three quarters in 2010. Previously filed quarterly reports on Form 10-Q for the periods as of March 31, 2010, June 30, 2010, and September 30, 2010 and for the periods then ended; affected by the restatements have not been amended and should not be relied on.

The restatement and correction of an error results from our review during the fourth quarter of 2010 of guidance relating to 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. EITF 07-5 provides guidance for determining whether an equity-linked financial instrument or embedded feature is considered indexed to an entity's own stock. EITF 07-5 establishes a two-step approach for this determination. The approach

**Table of Contents**

includes evaluating (1) the instrument's contingent exercise provisions, if any, and (2) the instrument's settlement provisions. If a financial instrument is shown not to be indexed solely to its issuing company's stock, it 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. EITF 07-5 was effective for financial statements issued for fiscal years beginning after December 15, 2008. During 2002, we issued a warrant to purchase shares of our common stock. The warrant entitles the holder to purchase 750,000 shares of our common stock at an exercise price of \$.50 per share. The warrant contains a provision which provides for a reduction in the exercise price per share of the warrant if, under certain circumstances, we issue shares of our common stock or certain securities exercisable for or convertible into shares of our common stock at a price that is less than \$.50 per share. The warrant would not be considered indexed to the Company's own stock and therefore, it 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. Upon exercise of the warrant for common shares or expiration of the warrant, the fair value at that time is reclassified to equity from liabilities.

The Company adopted EITF 07-5 in the first quarter 2009, however, it did not properly account for this warrant. This error resulted in an understatement of the Company's liabilities at each of its balance sheet dates in the prior seven quarters. Additionally, the change in fair market value of the liability was not included in reported net loss in each of the prior seven quarters. Based on the qualitative and quantitative analysis, the effect of the error was considered to be immaterial to reported results of operations as well as the Company's financial position as of and for the period ended December 31, 2009 and for each of the three quarters reported in 2009. This error had no impact on previously reported cash flows from operating, financing or investing activities. As permitted by SAB 108, codified as Topic 1N, the balance sheets and related statements of operations, stockholder's equity and cash flows as of December 31, 2009 and for the period then ended were corrected by recording the fair value of the warrant liability of \$172,000 as of December 31, 2009 and a charge to unrealized loss in the statement of operations for the year then ended. The effect of the correction of the error is included in the accumulated deficit as of December 31, 2009 in the accompanying balance sheet.

The effect of the correction of the error on our consolidated balance sheet as of December 31, 2009 is as follows (in thousands):

	Liabilities			Accumulated Deficit		
	Reported	Adjustment	Revised	Reported	Adjustment	Revised
<b>December 31, 2009</b>	\$ 910	\$ 172	\$ 1,082	\$ (70,672)	\$ (172)	\$ (70,844)

The effect of the correction of the error on our statement of operations for the year ended December 31, 2009 is as follows (in thousands):

	Unrealized Gain/(Loss) on Fair Value of Warrants			Net Loss			Basic and Diluted Net Loss Per Share		
	Reported	Adjustment	Revised	Reported	Adjustment	Revised	Reported	Adjustment	Revised
<b>Year ended December 31, 2009</b>	\$	\$ (172)	\$ (172)	\$ (6,697)	\$ (172)	\$ (6,869)	\$ (0.16)	\$ (0.01)	\$ (0.17)

We have not separately amended our quarterly Reports on Form 10-Q for the periods as of March 31, 2010, June 30, 2010, and September 30, 2010 and for the periods then ended; the periods affected by the restatement, and the financial statements and related financial information for these affected periods should no longer be relied upon. All financial and other information included in this Form 10-K reflects the correction of the immaterial error as of December 31, 2009 and for the period then ended, and the restatement of the first three quarters of 2010.

We have reported 2010 and 2009 balance sheets to account for the value of the warrant as a liability, and have restated prior consolidated statements of operations for the quarterly change in fair value of the warrants for each of the first three quarters of 2010. This restatement had no impact on previously reported revenues, operating expenses, total assets or cash position.

**Table of Contents****Quarterly Financial Information**

The restatement had no impact on previously reported quarterly revenues, operating expenses, total assets or cash position. See Note 2,

Restatement of 2009 Financial Statements for an Immaterial Error and Note 17. Restatement of Quarterly Financial Information, in the Notes to Financial Statements of this Form 10-K for additional information regarding the effects of the restatement on previously reported interim financial information.

The following table shows unaudited financial information for each of the three quarters in 2010, in each case, as originally reported and as restated (in thousands, except per share amounts).

(Unaudited)	Liabilities			Accumulated Deficit		
	Reported	Adjustment	Restated	Reported	Adjustment	Restated
March 31, 2010	\$ 701	\$ 390	\$ 1,091	\$ (71,505)	\$ (390)	\$ (71,895)
June 30, 2010	569	165	734	(72,211)	(165)	(72,376)
September 30, 2010	526	255	781	(73,080)	(255)	(73,335)

(Unaudited)	Unrealized Gain/(Loss) on Fair Value of Warrants			Net Loss			Basic and Diluted Net Loss Per Share		
	Reported	Adjustment	Restated	Reported	Adjustment	Restated	Reported	Adjustment	Restated
Three months ended March 31, 2010	\$	\$ (218)	\$ (218)	\$ (833)	\$ (218)	\$ (1,051)	\$ (0.02)		\$ (0.02)
Three months ended June 30, 2010		225	225	(706)	225	(481)	(0.01)		(0.01)
Six months ended June 30, 2010		7	7	(1,539)	7	(1,532)	(0.03)		(0.03)
Three months ended September 30, 2010		(90)	(90)	(869)	(90)	(959)	(0.02)		(0.02)
Nine months ended September 30, 2010	\$	\$ (83)	\$ (83)	\$ (2,408)	\$ (83)	\$ (2,491)	(0.05)		(0.05)

**Results of Operations****Fiscal 2010 Compared to Fiscal 2009****Revenues**

Total revenues decreased 34%, or \$317,000, to \$618,000 for the year ended December 31, 2010, compared to \$935,000 for the same period in 2009. This decrease is primarily due to a reduction in royalty revenue of \$443,000 attributable to a reduction in the royalty rate used to determine the amount of royalties due to the Company on sales by Perrigo of products licensed under the agreement. The reduction in the royalty rate was made in accordance with the amendment to the Company's agreement with Perrigo effective January 4, 2010. We have been 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. The decline in royalty revenue was off-set by an increase of \$125,000 in licensing fees attributable to our agreement with RedHill Pharmaceuticals and our terminated agreement with Chrono Nutraceuticals, LLC.

**Marketing and Selling Expenses**

Marketing and selling expenses increased 38%, or \$110,000, to \$399,000 for the year ended December 31, 2010, compared to \$289,000 for the same period in 2009. This increase is primarily due to an increase of \$177,000 in sales and marketing activities related to the direct sale of our nutritional products, partially offset by a decrease of \$52,000 in personnel related expense through personnel reductions.



---

## **Table of Contents**

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

Research and development expenses decreased 53%, or \$1.2 million, to \$1.2 million for the year ended December 31, 2010, compared to \$2.4 million for the same period in 2009. The decrease is attributable to a decrease in personnel related expenses of approximately \$981,000 due to personnel reductions. In addition, our deferral of development activities on certain projects pending additional funding resulted in an approximately \$100,000 reduction in expenses.

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

General and administrative expenses decreased 49%, or \$2.4 million, to \$2.5 million for the year ended December 31, 2010, compared to \$4.9 million for the same period in 2009. Personnel related expenses decreased approximately \$2.5 million due to the recognition in 2009 of approximately \$669,000 of severance costs associated with the resignation of our former Chief Executive Officer and former Senior Vice President of Business and Legal Affairs, and an approximately \$1.1 million decrease in non-cash, share-based compensation expense related to (i) stock option grants and stock awards, (ii) modification of previously outstanding stock options, and (iii) accelerated vesting of unvested options occurring in 2009 in connection with our former and current executive employees. In addition, payroll related expenses decreased approximately \$611,000 due to a reduction in personnel and decrease in cash compensation effective November 1, 2009 for our current Chief Executive Officer and Executive Vice President and Chief Financial Officer. The decrease in personnel related expenses was partially offset by an approximately \$105,000 increase in temporary staffing costs associated with the launch of our nutritional business.

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

Other income (expense) increased 260%, or \$421,000, to \$259,000 of other income for the year ended December 31, 2010, compared to \$162,000 other expense for the same period in 2009. This change was due to the award of approximately \$251,000 in federal funds under the Therapeutic Discovery Project conducted by the Department of the Treasury and the Department of Health and Human Services, and additionally a \$22,000 unrealized gain on the fair value of warrant. See the Explanatory Note immediately preceding Part I, Item I and Note 2, Restatement of 2009 Financial Statements for an Immaterial Error and Note 17, Restatement of Quarterly Financial Information, in Notes to Financial Statements of this Form 10-K for further discussion of unrealized gain (loss) on fair value of warrants to purchase common stock.

### ***Net Loss***

Net loss decreased 54% or \$3.7 million, to \$3.2 million for the year ended December 31, 2010, compared to \$6.9 million for the same period in 2009. This change was primarily due to lower operating expenses and an increase in other income, offset by a decrease in royalty income.

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

We had approximately \$1.9 million in cash and cash equivalents and approximately \$257,000 in restricted cash related to our facility lease as of December 31, 2010. We anticipate that our existing cash and cash equivalents will be sufficient to fund our operations under our current operating plan into the second quarter of 2011 unless the timing of inventory purchases necessary to fulfill any orders for our nutritional products places additional constraint on our liquidity prior to that time, or unforeseen events impact our liquidity.

These conditions raise substantial doubt about our ability to continue as a going concern. Consequently, the audit report prepared by our independent registered public accounting firm relating to our financial statements for the year ended December 31, 2010 includes a going concern explanatory paragraph.

---

**Table of Contents**

On March 12, 2010, we completed a private placement of units consisting of an aggregate of 8,260,000 shares of our common stock and warrants to purchase an aggregate of 1,652,000 shares of our common stock. The units were sold at a purchase price of \$0.50 per unit. The warrants have an exercise price of \$0.75 per share, which exercise price is not subject to adjustment on the basis of future issuances of securities at a price lower than the exercise price, or any other event other than split, combination or reclassification of our common stock. Taglich Brothers, Inc. acted as placement agent for the offering. Mr. Michael N. Taglich, a member of our board of directors, is the president and a principal shareholder of Taglich Brothers. Net proceeds of the offering were approximately \$3.6 million after placement agent fees of \$289,100 and other direct and incremental offering costs. Taglich Brothers was also issued a warrant to purchase 578,200 shares of our common stock. The warrants sold in the offering, and those issued to Taglich Brothers are identical, have an exercise period of five years, and are valued 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.

We are seeking to take advantage of an opportunity 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 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 require substantial working capital to source product from third-parties for later sale.

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 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 nutritional business or discontinue our nutritional 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<sup>®</sup> is expected to provide additional opportunities for our extended release ibuprofen product.

We actively manage our liquidity by limiting clinical and development expenses to our ibuprofen and pseudoephedrine lead products, and are reducing the cash expenses related to our general administrative activities. We initiated the actual use study required by the FDA as a prerequisite to submission of our regulatory application for ibuprofen, but anticipate the need for additional financing or partnership support to fund certain significant cost items necessary to complete that study. Without increased revenues or additional funding we do not expect to be able to complete development of our current projects.

We have a history of recurring losses and we expect such net losses to continue as we proceed with preclinical development for multiple product candidates and apply for regulatory approvals of product candidates. We will require substantial additional investment that we have not yet secured. Our current operating plan reflects reductions in personnel, marketing and other operating expenses we implemented in 2009, and additional reductions we implemented in 2010. We are actively managing liquidity by limiting clinical and development expenses to our lead products and supporting existing alliances and collaborations, but have limited additional opportunity for further reductions. We have deferred all significant expenditures on new projects pending additional financing or partnership support. Without additional funding we do not expect to be able to complete development of our current projects.

---

**Table of Contents**

Our capital resources are very limited and operations to date have been funded primarily with the proceeds from public equity financings, royalty payments, and collaborative research agreements. We are pursuing alternative sources of financing that could involve strategic transactions, including new collaborations, as well 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 enter any collaboration on terms acceptable to us, or at all, due to conditions in the pharmaceutical industry or in the economy in general. Competition for such arrangements is intense, with many biopharmaceutical companies attempting to secure alliances with more established pharmaceutical or consumer products companies.

Our failure to increase revenues or raise capital, including financial support from partnerships or other collaborations would materially adversely affect our business, financial condition and results of operations, and could force us to reduce or cease operations. If we are forced to reduce or cease our operations we may trigger additional obligations, including contractual severance obligations aggregating as much as \$599,000. In addition, we may be forced to liquidate assets at reduced levels due to our immediate liquidity requirements.

On December 22, 2010, we notified the NYSE Amex Exchange (the Exchange) of our intent to file a Form 25 with the Securities and Exchange Commission (the Commission) to effect the voluntary withdrawal of our common stock from listing on the Exchange, after concluding that we could not reasonably expect to regain compliance with the continued listing requirements of the Exchange within the extension period afforded to us. We filed the Form 25 with the Commission on January 3, 2011 and our common stock ceased trading on the Exchange on January 12, 2011. On January 13, 2011 our common stock began trading on the OTC Bulletin Board and OTCQB under the trading symbol SCLR.

*Cash flows from operating activities* Net cash used in operating activities for the year ended December 31, 2010 was approximately \$3.0 million compared to \$5.0 million for the year ended December 31, 2009. The approximately \$2.0 million decrease in cash used in operating activities primarily reflects the impact of the lower net loss and the timing of payment of invoices.

*Cash flows from investing activities* Cash flows of \$162,000 used by investing activities during the year ended December 31, 2010, represents approximately \$284,000 in patent and trademark related expenditures and approximately \$58,000 for equipment purchases. These amounts were offset by an approximately \$180,000 reduction in restricted cash. Restricted cash was established in 2008 as collateral for the outstanding letter of credit issued as collateral for our facility lease. Effective November 5, 2009, under the terms of our amended facility lease agreement, we are allowed to pay up to \$18,000 of our monthly rent for twelve months through draw downs on the letter of credit. Cash flows used in investing activities during the year ended December 31, 2009, of approximately \$74,000 represents approximately \$180,000 in patent and trademark related expenditures and approximately \$95,000 for equipment purchases. These amounts were offset by approximately \$85,000 in proceeds from an insurance settlement, approximately \$80,000 in proceeds from the sale of research and development equipment, and a \$36,000 reduction in restricted cash.

*Cash flows provided by (used in) financing activities* Cash flows provided by financing activities for the year ended December 31, 2010 of approximately \$3.8 million primarily represent the net proceeds from issuance of common stock of \$3.7 million. For the year end December 31, 2009, cash flows used in financing activities represent payments of approximately \$111,000 made on our term loan through April 2009, at which time the loan was paid off.

As of December 31, 2010, we had approximately \$2.1 million of working capital compared to \$961,000 as of December 31, 2009. We have accumulated net losses of approximately \$74 million from our inception through December 31, 2010. We have funded our operations primarily through the issuance of equity securities.



## **Table of Contents**

### **New Accounting Pronouncements**

In October 2009, the Financial Accounting Standards Board ( FASB ) issued ASU 2009-13, *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. 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. Adoption of this standard is not expected to have a material impact on the financial statements.

In July 2010, the Financial Accounting Standards Board (FASB) issued Accounting Standards Update (ASU) 2010-20, which amends Accounting Standards Codification (ASC) 310 by requiring more robust and disaggregated disclosures about the credit quality of an entity's financing receivables and its allowance for credit losses. The objective of enhancing these disclosures is to improve financial statement user's understanding of (1) the nature of an entity's credit risk associated with its financing receivables and (2) the entity's assessment of that risk in estimating its allowance for credit losses as well as changes in the allowance and the reasons for those changes. The guidance is effective for the first reporting period beginning after December 15, 2010. The Company does not expect the adoption will have a material impact on its results of operations, financial position and cash flow.

**Table of Contents**

**Item 8. Financial Statements and Supplementary Data**

**CONTENTS**

	<b>Page</b>
<u>Report of Independent Registered Public Accounting Firm</u>	43
Financial Statements	
<u>Balance Sheets</u>	44
<u>Statements of Operations</u>	45
<u>Statement of Stockholders' Equity</u>	46
<u>Statements of Cash Flows</u>	47
<u>Notes to Financial Statements</u>	48

**Table of Contents**

**Report of Independent Registered Public Accounting Firm**

Board of Directors and Shareholders of SCOLR Pharma, Inc.

We have audited the accompanying balance sheets of SCOLR Pharma, Inc. (a Delaware corporation) (the Company) as of December 31, 2010, and 2009, and the related statements of operations, stockholders' equity, and cash flows for each of the two years in the period ended December 31, 2010. These financial statements are the responsibility of the Company's management. Our responsibility is to express an opinion on these financial statements based on our audits.

We conducted our audits in accordance with the standards of the Public Company Accounting Oversight Board (United States). Those standards require that we plan and perform the audit to obtain reasonable assurance about whether the financial statements are free of material misstatement. The Company is not required to have, nor were we engaged to perform an audit of its internal control over financial reporting. Our audit included consideration of internal control over financial reporting as a basis for designing audit procedures that are appropriate in the circumstances, but not for the purpose of expressing an opinion on the effectiveness of the Company's internal control over financial reporting. Accordingly, we express no such opinion. An audit also includes examining, on a test basis, evidence supporting the amounts and disclosures in the financial statements, assessing the accounting principles used and significant estimates made by management, as well as evaluating the overall financial statement presentation. We believe that our audits provide a reasonable basis for our opinion.

In our opinion, the financial statements referred to above present fairly, in all material respects, the financial position of SCOLR Pharma, Inc. as of December 31, 2010, and 2009, and the results of its operations and its cash flows for each of the two years in the period ended December 31, 2010, in conformity with accounting principles generally accepted in the United States of America.

The accompanying financial statements have been prepared assuming that the Company will continue as a going concern. As discussed in Note 3, the Company incurred a net loss of \$3.2 million during the year ended December 31, 2010, and, as of that date, the Company had net working capital of \$1.9 million. These factors, among others, as discussed in Note 3 to the financial statements, raise substantial doubt about the Company's ability to continue as a going concern. Management's plans in regard to these matters are also described in Note 3. The financial statements do not include any adjustments that might result from the outcome of this uncertainty.

/s/ GRANT THORNTON LLP

Seattle, Washington

March 29, 2011

**Table of Contents****SCOLR Pharma, Inc.****BALANCE SHEETS****(In thousands, except par values and number of shares)**

	<b>December 31,</b>	
	<b>2010</b>	<b>2009</b>
		<b>(Restated<sup>1</sup>)</b>
<b>ASSETS</b>		
Current Assets		
Cash and cash equivalents	\$ 1,891	\$ 1,176
Accounts receivable and other receivables	103	269
Inventory	324	
Prepaid expenses and other assets	270	228
<b>Total current assets</b>	<b>2,588</b>	<b>1,673</b>
Property and equipment net	327	435
Intangible assets net	686	565
Restricted cash	257	438
<b>Total assets</b>	<b>\$ 3,858</b>	<b>\$ 3,111</b>
<b>LIABILITIES AND STOCKHOLDERS EQUITY</b>		
Current Liabilities		
Accounts payable	\$ 145	\$ 47
Accrued liabilities	307	640
Deferred revenue	56	25
Fair value of warrant	150	172
<b>Total current liabilities</b>	<b>658</b>	<b>884</b>
Deferred rent	159	198
<b>Total liabilities</b>	<b>817</b>	<b>1,082</b>
Commitments and Contingencies (Notes 7 and 11)		
Stockholders Equity		
Preferred stock, authorized 5,000,000 shares, \$0.01 par value, none issued or outstanding		
Common stock, authorized 100,000,000 shares, \$0.001 par value, 49,816,073 and 41,098,270 issued and outstanding as of December 31, 2010 and 2009, respectively	49	41
Additional contributed capital	77,041	72,832
Accumulated deficit	(74,049)	(70,844)
<b>Total stockholders equity</b>	<b>3,041</b>	<b>2,029</b>
<b>Total liabilities and stockholders equity</b>	<b>\$ 3,858</b>	<b>\$ 3,111</b>

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

<sup>1</sup> See Note 2, Restatement of 2009 Financial Statements for an Immaterial Error.

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

	<b>Year Ended December 31,</b>	
	<b>2010</b>	<b>2009</b>
		<b>(Restated<sup>1</sup>)</b>
<b>Revenues</b>		
Licensing fees	\$ 125	\$
Royalty income	493	935
<b>Total revenues</b>	<b>618</b>	<b>935</b>
<b>Operating expenses</b>		
Marketing and selling	399	289
Research and development	1,153	2,433
General and administrative	2,530	4,920
<b>Total operating expenses</b>	<b>4,082</b>	<b>7,642</b>
Loss from operations	(3,464)	(6,707)
<b>Other income (expense)</b>		
Interest expense		(3)
Interest income	2	13
Unrealized gain (loss) on fair value of warrant	22	(172)
Governmental therapeutic grant	251	
Other	(16)	
<b>Total other income (expense)</b>	<b>259</b>	<b>(162)</b>
Net loss	\$ (3,205)	\$ (6,869)
Net loss per share, basic and diluted	\$ (0.07)	\$ (0.17)
Shares used in calculation of basic and diluted net loss per share	48,137,120	41,100,549

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

<sup>1</sup> See Note 2, Restatement of 2009 Financial Statements for an Immaterial Error.

Table of Contents

## SCOLR Pharma, Inc.

## STATEMENT OF STOCKHOLDERS EQUITY

Years Ended December 31, 2010 and 2009

(In thousands, except shares)

	Common Stock		Additional Contributed Capital	Accumulated Deficit	Total
	Number of Shares	Amount			
<b>Balance at December 31, 2008</b>	41,130,270	\$ 41	\$ 71,256	\$ (63,975)	\$ 7,322
Repurchase of restricted stock	(32,000)				
Share-based compensation issued for employee services			1,576		1,576
Net loss (Restated <sup>1</sup> )				(6,869)	(6,869)
<b>Balance at December 31, 2009 (Restated<sup>1</sup>)</b>	41,098,270	\$ 41	\$ 72,832	\$ (70,844)	\$ 2,029
Issuance of common stock in private placement	8,260,000	8	3,684		3,692
Issuance of stock award	214,285		103		103
Exercise of common stock options	243,518		121		121
Share-based compensation issued for employee services			262		262
Share-based compensation issued for consulting services			7		7
Issuance of warrants for non-employee services			32		32
Net loss				(3,205)	(3,205)
<b>Balance at December 31, 2010</b>	49,816,073	\$ 49	\$ 77,041	\$ (74,049)	\$ 3,041

The accompanying notes are an integral part of this financial statement.

<sup>1</sup> See Note 2, Restatement of 2009 Financial Statements for an Immaterial Error.

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

	<b>Year Ended December 31,</b>	
	<b>2010</b>	<b>2009</b>
		<b>(Restated<sup>1</sup>)</b>
<b>Cash flows from operating activities:</b>		
Net loss	\$ (3,205)	\$ (6,869)
<b>Adjustments to reconcile net loss to net cash used in operating activities:</b>		
Depreciation and amortization	262	394
Gain on sale of equipment		(12)
Share-based compensation for employee services	262	1,679
Share-based compensation for non-employee services	7	
Issuance of warrants for non-employee services	32	
Unrealized (gain) loss on fair value of warrant	(22)	172
Write-off of long-term assets	67	87
<b>Changes in assets and liabilities:</b>		
Accounts receivable	167	(92)
Inventory	(324)	
Prepaid expenses and other assets	(63)	59
Accounts payable and accrued expenses	(171)	(445)
Deferred revenue	31	25
<b>Net cash used in operating activities</b>	<b>(2,957)</b>	<b>(5,002)</b>
<b>Cash flows from investing activities:</b>		
Purchase of equipment and furniture	(58)	(95)
Proceeds from insurance settlement		85
Proceeds from sale of fixed assets		80
Patent and technology rights payments	(284)	(180)
Restricted cash	180	36
<b>Net cash used in investing activities</b>	<b>(162)</b>	<b>(74)</b>
<b>Cash flows from financing activities:</b>		
Payments on long-term obligations		(111)
Net proceeds from issuance of common stock	3,713	
Proceeds from exercise of common stock options and warrants	121	
<b>Net cash provided by (used in) by financing activities</b>	<b>3,834</b>	<b>(111)</b>
<b>Net increase (decrease) in cash</b>	<b>715</b>	<b>(5,187)</b>
Cash at beginning of period	1,176	6,363
<b>Cash at end of period</b>	<b>\$ 1,891</b>	<b>\$ 1,176</b>
<b>Cash paid during the year for interest</b>	<b>\$</b>	<b>\$ 2</b>
<b>Supplemental disclosure of non-cash investing and financing activities:</b>		
Issuance of warrants in connection with equity offering	\$ 689	\$
Issuance of common stock to employee	\$ 107	\$



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

Return of leasehold improvements to landlord	\$	\$	75
--	----	----	----

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

<sup>1</sup> See Note 2, Restatement of 2009 Financial Statements for an Immaterial Error.

**Table of Contents**

**SCOLR Pharma, Inc.**

**NOTES TO FINANCIAL STATEMENTS**

**December 31, 2010 and 2009**

**Note 1 Description of Business and Summary of Significant Accounting Policies**

SCOLR Pharma, Inc. (the Company) is a specialty pharmaceutical company that develops and formulates pharmaceutical, over-the-counter (OTC), and nutritional products. The Company uses its patented Controlled Delivery Technologies (CDT<sup>®</sup>) to develop products and license technologies to pharmaceutical and nutritional product companies.

The Company has incurred net losses since 2000. As of December 31, 2010, the Company's accumulated deficit was \$74 million. The Company's strategy is to develop and commercialize prescription, OTC, and nutritional products utilizing its oral drug delivery technologies. The Company's technologies enable it to develop custom formulations of tablets or capsules that release their active ingredients predictably over a specified timeframe of up to 24 hours.

The Company's business is subject to the risks and uncertainties associated with development of drug delivery systems and products. These risks include, but are not limited to, a history of net losses, technological changes, dependence on collaborations and key personnel, the successful commercialization of the Company's product candidates, compliance with government regulations, patent infringement litigation and competition from current and potential competitors, (many of which have greater resources) dependence on third party manufacturers, and a requirement for additional funding.

A summary of the Company's significant accounting policies consistently applied in the preparation of the accompanying financial statements follows.

*Cash and Cash Equivalents*

The Company considers all highly liquid investments with an original maturity of three months or less when purchased to be cash equivalents. Cash and cash equivalents are carried at cost, which approximates market value. The Company holds cash and cash equivalents and marketable securities at major financial institutions, which often exceed Federal Deposit Insurance Corporation insured limits. Historically, the Company has not experienced any losses as a result of such concentration of credit risk.

*Accounts Receivable*

The majority of the Company's accounts receivable was due from companies that provide royalty income from the use of the Company's CDT technology. Payments are received on a quarterly basis, usually within 45 days after the end of each quarter, for royalty income receivables.

The Company determines the allowance for doubtful accounts by considering a number of factors, including the length of time trade accounts receivable are past due, the customer's previous loss history, the customer's current ability to pay its obligation, and the condition of the general economy and the industry as a whole. The Company's policy is to write off accounts receivable when they become uncollectible, and payments subsequently received on such accounts are credited to the provision for doubtful accounts.

*Financial Instruments*

The carrying values of financial instruments including cash and cash equivalents, accounts receivable, and accounts payable approximate fair value.

**Table of Contents***Inventories*

Inventories of \$324,000 at December 31, 2010, consist primarily of nutritional tablets, bottles, and bottled nutritional supplements. The Company values these inventories on its balance sheets at the lower of average cost or market. The Company writes down inventory for estimated obsolescence and excess quantities based on usage requirements and other factors, which incorporate estimates. During the year ended December 31, 2010 inventories of \$58,000 were expensed to be used as marketing samples.

*Property and Equipment*

Property and equipment are stated at cost, less accumulated depreciation and amortization. Depreciation and amortization are provided for in amounts sufficient to relate the cost of depreciable assets to operations over their estimated service lives. Leasehold improvements are amortized over the lives of the respective leases or the service lives of the improvements, whichever is shorter. The straight-line method of depreciation is followed for substantially all assets for financial reporting purposes. The estimated useful lives in determining depreciation and amortization are as follows:

Furniture and fixtures	3-5 years
Software	3 years
Machinery and equipment	3-10 years

*Intangible Assets*

Intangible assets include capitalized costs, technical and product rights, patents, and trademarks. Capitalized costs principally include legal fees incurred with the application for patents and trademarks. Technical and product rights, patents, and trademarks are stated at cost and amortized to operations over their estimated useful lives or statutory lives, whichever is shorter. The Company evaluates its long lived assets for impairments whenever events or changes in circumstances indicate that the carrying amount may not be recoverable using a fair value approach.

*Revenue Recognition*

Revenues recognized during 2010 and 2009, include amounts earned under royalty arrangements with third parties under which such parties are licensed to sell products that include technology developed or licensed by the Company. Such royalty revenues are recognized when earned, as reported to the Company by its licensees, and when collectability is reasonably assured.

Revenues for non-refundable, up-front payments received in connection with collaborative research and development and commercialization agreements are initially deferred and then recognized as licensing fees on a straight-line basis over the relevant periods specified in the agreement, generally the research or contract term. Non-refundable license fees are recognized as revenue once no future performance obligation exists, the price is fixed and determinable, delivery has occurred, and collectability is reasonably assured.

*Income Taxes*

Deferred tax assets and liabilities are provided for the temporary differences between the financial reporting basis and the tax basis of the Company's assets and liabilities, for net operating loss carryforwards, and tax credit carryforwards. Deferred tax assets and liabilities, net operating loss carryforwards, and tax credit carryforwards are measured using enacted tax rates and laws that will apply when the assets and liabilities are expected to reverse. The Company provides a valuation allowance when necessary to reduce deferred tax assets to amounts expected to be realized.

## **Table of Contents**

### *Research and Development Costs*

Research and development expenses consist of costs associated with products being developed internally as well as those products being developed under collaborative agreements with others. These expenses include related salaries and benefits, clinical trial and related clinical trial manufacturing costs, contract and other outside service fees, and facility related costs. Research and development costs are expensed as incurred. In instances where the Company enters into agreements with third parties for research, clinical trial, and related clinical trial manufacturing costs, such costs are expensed upon the earlier of when non-refundable amounts are due or as services are performed. Amounts due to the Company under such arrangements may be either fixed fee or fee for service, and may include upfront payments, monthly payments, and payments upon the completion of milestones or receipt of deliverables or termination costs incurred in the orderly termination of services.

### *Advertising Costs*

The policy of the Company is to expense advertising activities as incurred. Advertising expenses for the years ended December 31, 2010 and 2009 were approximately \$30,000 and \$26,000, respectively.

### *Loss Per Share*

Basic loss per share is calculated based on the weighted average number of shares outstanding during the year and income available to common shareholders. Diluted loss per share includes the effect of potential common stock, except when their effect is anti-dilutive. The weighted average shares for computing basic loss per share were 48,137,120 for the year ended December 31, 2010, and 41,100,549 for the year ended December 31, 2009. At December 31, 2010 and 2009, options, and warrants to purchase 8,082,165 and 7,445,018 shares of common stock, respectively, prior to the application of the treasury stock method, were not included in the calculation of diluted net loss per share as they were anti-dilutive.

### *Share-Based Compensation*

Compensation cost recognized for the years ended December 31, 2010 and 2009 are based on the grant date fair value of share-based payments. Our share-based compensation expense includes expense related to our stock options, our restricted stock awards, and our stock awards.

Share-based compensation expense for performance-based options granted to non-employees is determined as the fair value of the consideration received or the fair value of the equity instruments issued, whichever is more reliably measured. The fair value of options granted to non-employees is measured as of the earlier of the performance commitment date or the date at which performance is complete ( measurement date ). When it is necessary under generally accepted accounting principles to recognize cost for the transaction prior to the measurement date, the fair value of unvested options granted to non-employees is remeasured at the balance sheet date.

### *Warrant Valuation*

Warrants classified as liabilities on the balances sheet are adjusted to fair value at each financial reporting date. Fair value of warrants classified as liabilities is estimated using a binomial-pricing model with the following assumptions:

Expected term equal to the remaining term of the warrant.

Volatility equal to the volatility of our common stock for the remaining term of the warrant.

Risk-free interest rate based upon the U.S. Zero Coupon Treasury Strip Yields for the remaining term of the warrant.

Dividend yield equal to zero since we have not historically paid any dividends.



---

## **Table of Contents**

Upon exercise or expiration of the warrant, the fair value of the warrant at that time will be reclassified to equity from liabilities. Until that time, the fair value of the warrant is recorded as a liability at each financial reporting date and the associated unrealized gain (loss) is recorded in the statements of operations.

### *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, 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.

### *Reclassifications*

Certain prior year 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.

### *New Accounting Pronouncements*

In October 2009, the Financial Accounting Standards Board (FASB) issued ASU 2009-13, *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. 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. Adoption of this standard is not expected to have a material impact on the financial statements.

In July 2010, the Financial Accounting Standards Board (FASB) issued Accounting Standards Update (ASU) 2010-20, which amends Accounting Standards Codification (ASC) 310 by requiring more robust and disaggregated disclosures about the credit quality of an entity's financing receivables and its allowance for credit losses. The objective of enhancing these disclosures is to improve financial statement users' understanding of (1) the nature of an entity's credit risk associated with its financing receivables and (2) the entity's assessment of that risk in estimating its allowance for credit losses as well as changes in the allowance and the reasons for those

**Table of Contents**

changes. The guidance is effective for the first reporting period beginning after December 15, 2010. The Company does not expect the adoption will have a material impact on its results of operations, financial position and cash flow.

**Note 2 Restatement of 2009 Financial Statements for an Immaterial Error**

The Company restated its balance sheet as of December 31, 2009 and the related statements of operations, and cash flows for the year ended December 31, 2009 to correct for an immaterial error related to the implementation of ASC 815-40-15 Determining Whether an Instrument (or Embedded Feature) Is Indexed to an Entity's Own Stock. As permitted by SAB 108, codified as Topic 1N, the balance sheets and related statements of operations, stockholder's equity and cash flows as of December 31, 2009 and for the period then ended were corrected by recording the fair value of the warrant liability of \$172,000 as of December 31, 2009 and a charge to unrealized loss in the statement of operations for the year then ended. The effect of the correction of the error is included in the accumulated deficit as of December 31, 2009 in the accompanying balance sheet. See Note 17, Restatement of Quarterly Financial Information, for additional information on implementation of this accounting standard and the correction of a material error in the 2010 quarterly financial statements.

The effect of the correction of the immaterial error on our balance sheet as of December 31, 2009 is as follows (in thousands):

	Liabilities			Accumulated Deficit		
	Reported	Adjustment	Revised	Reported	Adjustment	Revised
<b>December 31, 2009</b>	\$ 910	\$ 172	\$ 1,082	\$ (70,672)	\$ (172)	\$ (70,844)

The effect of the correction of the immaterial error on our statement of operations for the year ended December 31, 2009 is as follows (in thousands):

Year ended	Unrealized Gain/(Loss) on Fair Value of Warrants			Net Loss			Basic and Diluted Net Loss Per Share		
	Reported	Adjustment	Revised	Reported	Adjustment	Revised	Reported	Adjustment	Revised
<b>December 31, 2009</b>	\$	\$ (172)	\$ (172)	\$ (6,697)	\$ (172)	\$ (6,869)	\$ (0.16)	\$ (0.01)	\$ (0.17)

This revision had no impact on previously reported revenues, operating expenses, total assets or cash position. Net cash flows from operating, investing and financing activities for periods presented were not affected by this restatement; however, certain components comprising cash flows from operating activities reflect the correction of the error.

**Note 3 Liquidity**

The Company has a history of losses and an accumulated deficit of \$74.0 million at December 31, 2010. The Company incurred a net loss of approximately \$3.2 million for the year ended December 31, 2010, and used cash from operations of approximately \$3.0 million. Cash flows of \$162,000 used by investing activities during the year ended December 31, 2010 represent approximately \$284,000 in patent and trademark related expenditures and approximately \$58,000 for equipment purchases. These amounts were offset by a \$180,000 reduction in restricted cash. Cash flows provided by financing activities for the period ended December 31, 2010, reflects \$3.7 million in proceeds from issuance of common stock.

The Company had approximately \$1.9 million in cash and cash equivalents and approximately \$257,000 in restricted cash related to its facility lease as of December 31, 2010. The Company is investing its cash and cash equivalents in government-backed securities. Based on the Company's existing cash and cash equivalents, the Company will be unable to fund its operations through December 31, 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

---

**Table of Contents**

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 nutritional business or discontinue its nutritional business operations.

The Company actively manages its liquidity by limiting clinical and development expenses to its ibuprofen and pseudoephedrine lead products, and is reducing the cash expenses related to its general administrative activities. The Company initiated the actual use study required by the FDA as a prerequisite to submission of its regulatory application for ibuprofen, but anticipates the need for additional financing or partnership support to fund certain significant cost items necessary to complete that study. Without increased revenues or additional funding the Company does not expect to be able to complete development of its current projects. 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.

The Company's capital resources are very limited and operations to date have been funded primarily with the proceeds from public equity financings, royalty payments, and collaborative research agreements. The Company is pursuing alternative sources of financing that could involve strategic transactions, including new collaborations, as well 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 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 materially adversely affect its business, financial condition and results of operations, and could 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 \$599,000. In addition, the Company may be forced to liquidate assets at reduced levels due to our immediate liquidity requirements.

On December 22, 2010, the Company notified the NYSE Amex Exchange (the "Exchange") of its intent to file a Form 25 with the Securities and Exchange Commission (the "Commission") to affect the voluntary withdrawal of the Company's common stock from listing on the Exchange. The Company filed the Form 25 with the Commission on January 3, 2011 and its common stock ceased trading on the Exchange on January 12, 2011. On January 13, 2011 the Company's common stock began trading on the OTC Bulletin Board and OTCQB under the trading symbol SCLR.

The Company voluntarily withdrew its common stock from registration and listing on the Exchange because it determined that it could not reasonably expect to regain compliance with the Exchange's continued listing standards by December 27, 2010, the date of expiration of a compliance extension period afforded by the Exchange following the Exchange's initial notice on June 25, 2009 that the Company was not in compliance with the Exchange's continued listing standards. The Company believes that voluntary withdrawal provided a more orderly transition of trading in its common stock to the OTC Bulletin Board, however, its delisting from NYSE Amex may limit its ability to access the capital markets or obtain capital on favorable terms.

**Note 4 Accounts Receivable**

Accounts receivable consists of royalty receivables at December 31, 2010 and 2009. The Company did not have any write-offs or bad debt expense in 2010 and 2009. In addition, the Company did not have an allowance for doubtful accounts in 2010 or 2009, as all accounts receivable were considered collectible.



**Table of Contents****Note 5 Property and Equipment**

Property and equipment consist of the following at December 31 (in thousands):

	<b>2010</b>	<b>2009</b>
Furniture and fixtures	\$	\$ 71
Software	22	41
Machinery and equipment	224	1,248
Leasehold improvements	298	347
	544	1,707
Less accumulated depreciation	(217)	(1,272)
	\$ 327	\$ 435

For the years ended December 31, 2010 and 2009, depreciation expense totaled approximately \$141,000 and \$308,000, respectively.

**Note 6 Intangible Assets**

Intangible assets consist of the following at December 31 (in thousands):

	<b>2010</b>	<b>2009</b>
Patents and trademarks	\$ 1,040	\$ 1,079
Less accumulated amortization	(354)	(514)
	\$ 686	\$ 565

For the years ended December 31, 2010 and 2009, amortization expense totaled approximately \$121,000 and \$86,000, respectively.

The following is a schedule by years of future amortization expense for each of the next five years based on existing intangible assets as of December 31, 2010 (in thousands):

<b>Year Ending December 31,</b>	
2011	\$ 105
2012	105
2013	105
2014	96
2015	87
2016 and thereafter	188
<b>Total</b>	<b>\$ 686</b>

The Company reviews its strategy related to patent initiatives on a quarterly basis, or when circumstances change as it relates to the programs, and may decide not to pursue further research and development in certain areas. As a result, capitalized costs associated with certain patent filings with net book values of approximately \$21,000 and \$87,000, were written-off in 2010 and 2009, respectively. The write-offs were recorded to research and development expense.

**Note 7 Lease Obligations and Sublease Operating Leases**

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

The Company leases office and laboratory space, and certain equipment under non-cancellable operating leases with terms expiring on various dates through 2016.

**Table of Contents**

The Company leases its office and laboratory facilities at 19204 North Creek Parkway, Bothell, Washington, under a lease which commenced on September 19, 2008, with a term of 88 months ending on January 31, 2016. The average rent under the lease is subject to annual increases of approximately 3%. Under the terms of the lease the Company received four months of free rent and leasehold improvement incentives totaling approximately \$374,000. Effective rent expense, including the amortization of deferred rent arising from the leasehold incentives, is being recognized on a straight-line basis over the term of the lease. The Company has the option to extend the lease term for one five-year period at the fair market rate at the time of extension. In connection with the lease agreement, the Company provided a \$564,000 irrevocable, unconditional standby letter of credit which is secured by a money market account and is classified as a non-current asset, restricted cash, in the balance sheet.

On November 5, 2009, the Company entered into an agreement amending its office and laboratory space lease to reduce the amount of leased space and rental payments under the lease. The Company reduced the amount of leased space from 20,468 square feet to 15,615 square feet. Also under the terms of the amended lease, the Company was allowed to pay \$18,000 of its monthly rent for twelve months through draw downs on the standby letter of credit which secures the lease through November 1, 2010. The standby letter of credit balance as of November 1, and December 31, 2010 of \$257,000 shall remain in place through the lease termination date of January 31, 2016.

The Company subleases approximately 2,000 square feet of lab and office space under two separate sublease agreements. The terms of the sublease agreements are for one year and expiring on January 16, 2012 and February 28, 2012. Under the terms of the Sublease Agreements, the Company has the right to terminate either lease with 60 days notice for any reason. The sublease income under both leases, are included as an offset to operating expenses.

In addition to the Company's facility lease, it leases certain office equipment under operating leases.

Operating lease expense was as follows (in thousands):

	Year Ended December 31,	
	2010	2009
Operating lease expense	\$ 432	\$ 500
Less: Sublease income	(15)	
<b>Total net operating lease expense</b>	<b>\$ 417</b>	<b>\$ 500</b>

The following is a schedule by year of future minimum lease payment requirements by the Company and amounts due the Company under the sublease agreements (in thousands):

	Operating Leases	Sublease Income	Operating Leases, net
2011	\$ 335	\$ (50)	\$ 285
2012	345	(3)	342
2013	355		355
2014	358		358
2015	361		361
2016 and thereafter	30		30
<b>Total future minimum lease payments</b>	<b>\$ 1,784</b>	<b>\$ (53)</b>	<b>\$ 1,731</b>

Rent expense for leased facilities and equipment was approximately \$417,000 and \$500,000, for the years ended December 31, 2010 and 2009, respectively.

**Table of Contents****Note 8 Income Taxes**

In December 2010, the Company received an award of approximately \$251,000 in federal funds under the Therapeutic Discovery Project conducted by the Department of the Treasury and the Department of Health and Human Services. The funds were awarded in connection with qualifying development expenses incurred during 2009 and 2010. Included as part of the Patient Protection and Affordable Care Act of 2010, the Therapeutic Discovery Project program provided a tax credit to encourage investments in new therapies to prevent, diagnose, and treat acute and chronic diseases. Companies, such as SCOLR, that cannot currently use a tax credit were allowed to apply for a cash grant in lieu of a tax credit. The Company was awarded the grant funds primarily in connection with expenditures on its program for development of an extended release formulation of ibuprofen, as well as its programs for development of new ondansetron and peramivir formulations. The award is recorded in other income in the results of operations for the year ended December 31, 2010.

The Company has incurred net operating losses. The Company continues to maintain a valuation allowance for the full amount of the net deferred tax asset balance, including 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 associated valuation allowance to increase in future periods as the Company incurs future net operating losses.

The Company's recorded provision for income taxes (zero in all years presented) differs from the amount computed by applying the statutory federal income tax rate of 34% to its net loss. The sources of the differences are as follows at December 31 (in thousands):

	2010	2009 (Restated <sup>1</sup> )
Tax benefit at statutory rate	\$ (1,090)	\$ (2,335)
Stock based compensation	5	217
Expiring net operating loss	161	97
Other permanent differences	313	304
Increase in valuation allowance	611	1,717
Total provision	\$	\$

<sup>1</sup> See Note 2, Restatement of 2009 Financial Statements for an Immaterial Error

Deferred income tax assets and liabilities reflect the net effect of temporary differences between the carrying amounts of assets and liabilities for financial reporting purposes and the amounts used for income tax purposes. Deferred tax assets are also recorded for the future tax benefit of net operating losses and tax credit carryforwards. The Company had no deferred tax liabilities in 2010 and 2009. Significant components of the Company's deferred tax assets are as follows at December 31 (in thousands):

	2010	2009 (Restated <sup>1</sup> )
Deferred Tax Assets:		
Net operating loss carry forwards	\$ 19,008	\$ 18,058
Depreciation and amortization	194	193
Stock options	968	1,227
Other assets	183	259
Deferred tax assets	\$ 20,353	\$ 19,737
Valuation allowance	(20,353)	(19,737)
Net deferred tax asset	\$	\$

<sup>1</sup> See Note 2, Restatement of 2009 Financial Statements for an Immaterial Error

---

## **Table of Contents**

The Company has established a valuation allowance for the full amount of the net deferred tax asset balance as sufficient uncertainty exists regarding its ability to realize such tax assets in the future. The net increase in the valuation allowance for the years ending December 31, 2010 and 2009, was approximately \$0.6 million and \$1.7 million, respectively.

At December 31, 2010, the Company had available net operating loss carryforwards of approximately \$55.9 million of which approximately \$4.1 million related to stock option deductions. Net operating loss carryforwards of approximately \$473,000, and \$285,000, expired during 2010 and 2009, respectively. The remaining net operating loss carryforwards may be used to offset future federal taxable income through the year ending December 31, 2030 and begin to expire in 2011. The use of net operating losses may be limited in any given year under Internal Revenue Code Section 382 upon the occurrence of certain events, including significant changes in ownership interests which may have occurred, or which may occur in future years.

Historically, the Company has not incurred any interest or penalties associated with tax matters and no interest or penalties were recognized during the year ended December 31, 2010. However, the Company has adopted a policy whereby amounts related to interest and penalties associated with tax matters are classified as a general and administrative expense when incurred.

Tax years that remain open for examination include 2007, 2008, 2009, and 2010. In addition, tax years from 1996 to 2006, may be subject to examination in the event that the Company utilizes the net operating losses from those years in its current or future tax returns. The Company does not have any uncertain tax positions.

### **Note 9 Technical Rights, Patent License and Royalty Agreements**

#### **Emerson Sales/Services Agreement**

On August 27, 2010, the Company entered into a Sales Agency Agreement (the Sales Agreement) with S. Emerson Group, Inc. (Emerson Group), effective August 1, 2010. Also on August 27, 2010, the Company and Emerson Healthcare LLC (Emerson Health), an affiliate of Emerson Group, entered into an Account Services Agreement (the Services Agreement).

Pursuant to the Sales Agreement, Emerson Group acts as the Company's non-exclusive agent to provide strategy consulting, sales, marketing and account management services in support of the Company's new line of extended-release nutritional products. The initial term of the Sales Agreement is 36 months, followed by successive 12-month renewal terms. The Sales Agreement may be terminated by either party upon 12 months' written notice to the other party, or upon 10 days' written notice to the other party for good cause as defined in the Sales Agreement. In consideration of the services to be provided by Emerson Group under the Sales Agreement, Emerson Group will receive a monthly retainer of \$4,000 and commissions based on the net sales of the Company's products. As further consideration for the services performed under the Sales Agreement, the Company issued to Emerson Group a warrant to purchase 100,000 shares of the Company's common stock at an exercise price of \$0.50 per share. The fair value of the warrants was estimated at \$0.33 per share using the Black-Scholes option-pricing model. The Black-Scholes valuation was based on the following assumptions: volatility of 88.35%; contractual term of ten years; risk-free interest rate of 2.66%; and 0% dividend yield. Total value of issued warrants, which approximated \$32,000 was expensed as a part of the Company's selling expenses.

Under the Services Agreement, Emerson Health will act as the Company's non-exclusive agent to perform warehousing, distribution, logistics, fulfillment, accounts receivable management, invoicing, collections, cash management and other operational services in support of sales of the Company's extended-release nutritional products. The initial term of the Services Agreement is 12 months, followed by successive 12-month renewal terms. The Services Agreement may be terminated by either party for any reason upon 12 months' written notice to the other party, or upon 10 days' written notice to the other party for good cause, as defined in the Services Agreement. As consideration for the services to be provided by Emerson Health under the Services Agreement,

---

**Table of Contents**

Emerson Health shall receive a monthly fee equal to a specified percentage of the gross sales of the Company's nutritional products covered under the Sales Agreement. In addition, scheduled fees will be payable to Emerson Health for warehouse, freight, and certain other itemized services rendered at Emerson Health's distribution center and warehouse facility.

**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. 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. In addition, the Company may at times be engaged by RedHill to assist with research and development activities for a fee.

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 will pay the remaining \$50,000 when services performed by SCOLR are complete. The estimated term of the study and agreement is four to five months. As of December 31, 2010, the initial up-front fee of \$50,000 was recorded as deferred revenue.

**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 its economic useful life of ten years. The purchase of the right, title and interest provide us the opportunity and option to utilize the NUPRIN® brand in conjunction with commercialization of ibuprofen.

**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

**Table of Contents**

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 years ended December 31, 2010 and 2009, the Company recorded royalty revenues earned under the Perrigo agreement of approximately \$493,000 and \$919,000, respectively. 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 decrease substantially as a result of such discontinuance as remaining product is sold through during the first half of 2011.

**Chrono Nutraceuticals, LLC.**

On November 20, 2009, the Company entered into a license agreement with Chrono Nutraceuticals LLC, a newly formed Arizona limited liability company ( Chrono ), providing Chrono with exclusive rights in Canada to manufacture and sell four extended release dietary supplements using our proprietary CDT drug delivery platform. In addition, the Company granted Chrono the rights to manufacture and sell two of such products in the United States on a nonexclusive basis.

Under the terms of the license agreement, Chrono paid an initial fee of \$25,000 and agreed to pay an additional \$87,500 that became due on January 31, 2010. Chrono has failed to deliver the additional payment of \$87,500. The Company has terminated the license agreement. The initial \$25,000 fee is not refundable and was recorded as revenue in March 2010.

**Temple University**

The Company has agreements with Temple University ( Temple ) providing the Company with exclusive worldwide rights for certain patents related to its CDT technology, with the right to sublicense. Under the terms of the agreements with Temple, the Company is required to make a minimum annual royalty payment of approximately \$49,000, which is recorded in general and administrative expense. The total amount expensed was \$81,000 and \$95,000 for 2010 and 2009, respectively.

**Note 10 Warrants**

During the year ended December 31, 2010, there were no warrants exercised. The Company had the following warrants to purchase common stock outstanding at December 31, 2010:

<b>Issue Date</b>	<b>Issued Warrants</b>	<b>Exercise Price</b>	<b>Term</b>	<b>Outstanding Warrants</b>	<b>Expiration Date</b>
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
<b>Grand Total</b>	<b>4,481,750</b>			<b>4,481,750</b>	

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

On March 12, 2010, the Company completed a private placement of units consisting of an aggregate of 8,260,000 shares of its common stock and warrants to purchase an aggregate of 1,652,000 shares of its common stock. The units 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, a member of the Company's board of directors, is the president and a



## **Table of Contents**

principal shareholder of Taglich Brothers. Net proceeds of the offering were approximately \$3.6 million after placement agent fees of \$289,100 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 period of five years, and are valued 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.

As described in Note 2, Restatement of 2009 Financial Statements for an Immaterial Error and Note 17, Restatement of Quarterly Financial Information, the Company has restated its financial information to reflect a reclassification of a warrant from equity to a liability in accordance with EITF 07-5. The 2002 warrant had a fair value of \$172,000 as of December 31, 2009. The cumulative unrealized gain of \$22,000 for 2010 for the change in fair value of the 2002 warrant has been recognized in the statement of operations. The fair value of the 2002 warrant as of December 31, 2010 was \$150,000.

The Company valued the warrant using a binomial model with the following assumptions:

Expected term equal to the remaining term of the warrant.

Volatility equal to the volatility of our common stock for the remaining term of the warrant.

Risk-free interest rate based upon the U.S. Zero Coupon Treasury Strip Yields for the remaining term of the warrant.

Dividend yield equal to zero since we have not historically paid any dividends.

### **Note 11 Future Commitments**

The Company has certain material agreements with its manufacturing and testing vendors related to its ongoing clinical trial work associated with its drug delivery technology. Contract amounts are paid based on materials used and on a work performed basis. Generally, the Company has the right to terminate these agreements upon 30 days notice and would be responsible for services and materials and related costs incurred prior to termination. Certain leases as discussed in Note 6 related to leased office facilities have terms expiring through 2016. In addition, as of December 31, 2010, the Company had outstanding commitments to purchase inventory, consisting of finished nutritional tablets, bottles, and bottled nutritional supplements of \$88,000.

### **Note 12 Retirement Plan**

The Company has a defined contribution 401(k) retirement plan which covers all employees. The Company matches 25% of employee contributions, up to 8% of eligible compensation. The Company contributed approximately \$9,000 and \$25,000, to the Plan for the years ended December 31, 2010 and 2009, respectively.

### **Note 13 Share-Based Compensation**

The Company has granted equity incentive awards to its employees, consultants, officers, and directors under its 2004 Equity Incentive Plan (the 2004 Plan) and its 1995 Stock Option Plan (the 1995 Plan). The 2004 Plan was approved by stockholders in June 2004, and replaced the 1995 Plan. Under the 2004 Plan, equity-based incentive awards may be granted in the form of stock options, stock appreciation rights, stock awards, performance awards, and outside director options.

The equity incentive awards granted to employees are generally granted at exercise prices equal to the market value of the Company's common stock on the date of grant, vest over three years, and expire ten years from the date of grant.

---

**Table of Contents**

Under the terms of the 2004 Plan, non-employee directors receive automatic annual grants of stock options at exercise prices equal to the market value of the Company's common stock on the date of grant, which generally vest in equal monthly installments over one year and expire ten years from the date of grant.

The 2004 Plan, as amended, authorized the issuance of up to 4,000,000 shares of common stock, plus 388,441 shares which were previously reserved for issuance under the 1995 Plan not subject to outstanding options. On June 11, 2009, the Company's stockholders approved an additional 3,000,000 share increase in the maximum aggregate number of shares that may be issued under the 2004 Equity Incentive Plan. If any award under the 2004 Plan, or any award previously issued and outstanding under the 1995 Plan, expires, lapses or otherwise terminates for any reason without having been exercised or settled in full, or if shares subject to forfeiture or repurchase are forfeited or repurchased by the Company, the shares underlying the award will again become available for issuance under the 2004 Plan. As of December 31, 2010, the Company had an aggregate 4,070,283 shares available for future grants under both Plans.

On January 30, 2009, the date of his appointment as the Company's President and Chief Executive Officer, Dr. Bruce Morra was awarded stock options exercisable for 500,000 shares of the Company's common stock with a fair value of approximately \$218,000. One half of the option award vested immediately, 25% of the option award vested on June 18, 2009, and the remaining 25% of the option award was scheduled to vest on June 18, 2010, provided Dr. Morra continued to serve as President and Chief Executive Officer of the Company at that date. On August 28, 2009, Dr. Morra resigned as President and Chief Executive Officer of the Company. In connection with Dr. Morra's resignation, the Company entered into a Separation and Release Agreement with Dr. Morra which provided for the acceleration of vesting of the remaining 25% of the January 30, 2009 option award previously scheduled to vest on January 18, 2010. Consequently, the total fair value of the January 30, 2009 award of approximately \$218,000 is included in general and administrative expense for the year ended December 31, 2009.

Additionally, in connection with the Separation and Release Agreement, the Company agreed to issue to Dr. Morra 214,285 shares of common stock on January 4, 2010, which shares were issued as scheduled. A liability of approximately \$103,000 was recognized 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 2004 Plan, at the date the shares were to be issued. The related share-based compensation expense was recorded in general and administrative expense for the year ended December 31, 2009.

On November 2, 2009, the Company entered into an agreement with its current Chief Executive Officer and Chief Financial Officer to accept a reduction in cash compensation to a rate of \$175,000 per year effective November 1, 2009. In connection with this agreement, on October 28, 2009, the Company's Board of Directors granted each such officer fully vested options to purchase 500,000 shares of the Company's common stock at \$0.48 per share. The options are exercisable for up to two years after termination of employment for any reason. The aggregate fair value of the awards of \$404,000 is recorded in general and administrative expense for the year ended December 31, 2009.

Also on October 28, 2009, in connection with the agreement with the Company's Chief Executive Officer and Chief Financial Officer to reduce their cash compensation, the Company's Board of Directors authorized a modification of previously issued and outstanding stock options granted to each such officer under the 2004 Plan and 1995 Plan. Under the terms of the modification, the post-termination exercise period for outstanding stock options previously issued to each such officer was extended from ninety-days after termination of employment, to two years after termination of employment, for any reason, provided however that no such stock option is exercisable beyond its scheduled contractual expiration date. The modification of the previously issued and outstanding stock options resulted in the cancellation and replacement of an aggregate total of 859,498 stock options. The resultant incremental expense of approximately \$108,000 was measured as the excess of the fair value of the replacement stock options over the fair value of the cancelled stock options at the modification date. Incremental expense associated with the fully vested modified stock options totaled approximately \$94,000 and is recorded in general and administrative expense for the year ended December 31, 2009.

**Table of Contents**

On November 2, 2009, the Company's Board of Directors granted its former Senior Vice President Business and Legal Affairs, Mr. Alan Mitchel, options to purchase 200,000 shares of its common stock at \$0.48 per share. The option vesting schedule provided for one-third of such options to vest on October 28, 2009, with monthly vesting thereafter for 24 months until all options are fully vested. The fair value of the award is approximately \$81,000. The options are exercisable for one year after termination of employment. On December 18, 2009, Mr. Mitchel was terminated without cause. In accordance with provisions of his Employment Agreement with the Company, Mr. Mitchel received full accelerated vesting of all unvested stock options. As a result, vesting for 216,001 unvested options was accelerated and share-based compensation costs of approximately \$110,000 was recognized in general and administrative expense for the year ended December 31, 2009.

The following tables set forth the aggregate share-based compensation expense, net of estimated forfeitures, 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 each of the years ended December 31, 2010 and 2009. When estimating forfeitures, the Company considers the potential for voluntary and involuntary terminations (in thousands):

	2010	2009
Share-based compensation:		
Marketing and selling	\$	\$ 13
Research and development	36	290
General and administrative	226	1,376
<b>Total share-based compensation expense for employees</b>	<b>\$ 262</b>	<b>\$ 1,679</b>
Marketing, non-employee services	38	
General and administrative, non-employee services	1	
<b>Total share-based compensation expense</b>	<b>\$ 301</b>	<b>\$ 1,679</b>

The fair value of share-based awards is estimated using the Black-Scholes option pricing model with the following assumptions for the years ended December 31, 2010, and 2009.

	<b>Black-Scholes Model Assumptions</b>			
	<b>December 31,</b>			
	<b>2010</b>		<b>2009</b>	
Expected volatility	88%	93%	74%	84%
Expected dividend yield	0%		0%	
Risk-free interest rate	.73%	3.33%	2.27%	3.88%
Expected life	3 10 years		6 10 years	

The Company's computation of expected volatility is based on historical realized volatility. The options granted to non-executive employees meet the definition of "plain vanilla" options. Therefore, management utilizes the shortcut method described in determining the expected life of non-executive employee options. The shortcut method estimates the expected term based on the midpoint between the vesting date and the end of the contractual term. The Company's computation of expected life for executive employees, non-employee director's awards, and for outside consultant awards is based on the contractual term of the award. The risk-free interest rate is based on the U.S. Treasury yield curve in effect at the time of the grant for issues with a term that approximates the expected life used as the assumption in the model.

**Table of Contents**

A summary of the Company's stock option activity for the year ended December 31, 2010 is as follows:

<b>Stock Options</b>	<b>Shares</b>	<b>Weighted-Average Exercise Price</b>	<b>Weighted-Average Remaining Contractual Term (years)</b>	<b>Aggregate Intrinsic Value</b>
Outstanding at December 31, 2009	5,218,468	\$ 1.89		
Granted	577,500	\$ .53		
Exercised	(243,518)	\$ .50		
Forfeited	(199,239)	\$ .69		
Expired	(1,752,796)	\$ 2.23		
Outstanding at December 31, 2010	3,600,415	\$ 1.67	6.78	\$ 420
Outstanding vested or expected to vest options at December 31, 2010	3,570,569	\$ 1.68	6.76	\$ 305
Options exercisable at December 31, 2010	3,131,947	\$ 1.83	6.39	\$

Cash received from options exercised was approximately \$121,000 and \$0, for the years ended December 31, 2010 and 2009, respectively. No actual tax benefit was realized for tax deductions from option exercise of the share-based payment arrangements because the Company has recorded a full valuation allowance against all deferred tax assets due to the uncertainty of realization of such assets. The Company has a policy of issuing new shares to satisfy share option exercises.

The weighted-average grant date fair value of stock options granted during the years ended December 31, 2010 and 2009, was \$0.44 and \$0.33, respectively. The total intrinsic value of options exercised for the years ended December 31, 2010 and 2009, was approximately \$120,000 and \$0, respectively. The total fair value of stock options vested during the years ended December 31, 2010 and 2009, was approximately \$174,000, and \$1.5 million, respectively.

As of December 31, 2010, there was approximately \$178,000 total unrecognized non-cash compensation cost related to non-vested options granted under the 2004 Plan and 1995 Plan. That cost is expected to be recognized over a weighted-average period of 1.26 years.

**Restricted Stock**

On January 27, 2009, in accordance with its repurchase rights under the Company's Restricted Stock Purchase Agreement, the Company repurchased and cancelled 32,000 unvested restricted stock shares forfeited by a former employee upon their termination. The purchase price per share paid by the Company to repurchase the shares was equal to the former employee's original cost of \$0.001 per share.

A summary of the Company's restricted stock activity for the year ended December 31, 2010, is as follows:

<b>Restricted stock</b>	<b>Shares</b>	<b>Weighted-Average Grant date fair value</b>
Non-vested at December 31, 2009	26,500	\$ 1.29
Granted		
Vested		
Non-vested at December 31, 2010	26,500	\$ 1.29



**Table of Contents**

Common shares outstanding as of December 31, 2010 and 2009, include 54,500 participating restricted stock shares outstanding, respectively. The shares will generally become vested on the third anniversary of the date of grant. As of December 31, 2010, there was approximately \$4,000 total unrecognized non-cash compensation cost related to non-vested restricted stock granted under the 2004 Plan. That cost is expected to be recognized over a weighted-average period of .12 years.

**Note 14 Fair Value Measurement**

Fair value is defined as the price that would be received upon sale of an asset or paid upon transfer of a liability in an orderly transaction between market participants. As such, fair value is a market-based measurement that should be determined based on assumptions that market participants would use in pricing an asset or liability. As a basis for considering such assumptions, the authoritative guidance establishes a three-tier value hierarchy, which prioritizes the inputs used in measuring fair value as follows:

Level 1 observable inputs such as quoted prices in active markets;

Level 2 observable inputs other than the quoted prices in active markets, such as quoted prices for similar assets and liabilities in active markets, quoted prices for identical or similar assets and liabilities in markets that are not active, or other inputs that are observable or can be corroborated by observable market data;

Level 3 unobservable inputs reflecting management's own assumptions, consistent with reasonably available assumptions made by other market participants. Level 3 valuations require significant judgment.

This hierarchy requires companies to use observable market data, when available, and to minimize the use of unobservable inputs when determining fair value.

During 2010, the Company corrected an immaterial error by recording a warrant liability related to a warrant with a repricing provision at its fair market value of \$172,000, as of December 31, 2009. The fair market value of the warrant was determined utilizing unobservable inputs (Level 3). The change in fair market value of the warrant liability is included in Other income (expense) in the Statements of Operations. The Company valued the warrant using a binomial valuation model with the following assumptions:

Expected term equal to the remaining term of the warrant.

Volatility equal to the volatility of our common stock for the remaining term of the warrant.

Risk-free interest rate based upon the U.S. Zero Coupon Treasury Strip Yields for the remaining term of the warrant.

Dividend yield equal to zero since we have not historically paid any dividends.

Additionally, the binomial valuation model considers the probability that the exercise price of the warrant will be reset.

The following table provides a reconciliation of the beginning and ending balances of the warrant liability (Level 3) as of December 31, 2010 (in thousands):

Beginning balance as of December 31, 2009 (Restated <sup>1</sup> )	\$ 172
Change in fair market value of warrant liability	(22)
Ending balance as of December 31, 2010	\$ 150

<sup>1</sup> See Note 2, Restatement of 2009 Financial Statements for an Immaterial Error

## **Table of Contents**

Certain financial instruments are carried at cost on the balance sheets, which approximates fair value due to their short-term, highly liquid nature. These instruments include cash and cash equivalents, accounts receivable, accounts payable and accrued expenses.

### **Note 15 Major Customers and Concentration of Credit Risk**

In 2010, two customers, Perrigo and RedHill, accounted for 95% of total revenue. These revenues relate to the royalty income from the sale of products using our CDT technologies. In 2009, one customer, Perrigo, accounted for 98% of total revenues.

The Company maintains its cash balances in two financial institutions, which at times, may exceed federally insured limits. The Company is investing its cash and cash equivalents in government-backed securities. These securities are considered Level 1 securities as the securities have quoted prices in active markets. The Company has not experienced any losses in such accounts and believes it is not exposed to any significant credit risk on cash.

### **Note 16 Related Party Transactions**

On March 12, 2010, the Company completed a private placement of units consisting of an aggregate of 8,260,000 shares of its common stock and warrants to purchase an aggregate of 1,652,000 shares of its common stock. The Units 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, a member of the Company's board of directors, is the president and a principal shareholder of Taglich Brothers. 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 period of five years, and are valued at \$0.31 using the Black-Scholes option-pricing model.

### **Note 17 Restatement of Quarterly Financial Information (Unaudited)**

The Company is restating its balance sheets, the related statements of operations, and cash flows for the first three quarters of 2010. Previously filed quarterly reports on Form 10-Q for the periods as of March 31, 2010, June 30, 2010 and September 30, 2010 and for the periods then ended; the period affected by the restatements, have not been amended and should not be relied on.

The restatement results from the review during fourth quarter of 2010 of guidance relating to 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. EITF 07-5 provides guidance for determining whether an equity-linked financial instrument or embedded feature is considered indexed to an entity's own stock. EITF 07-5 establishes a two-step approach for this determination. The approach includes evaluating (1) the instrument's contingent exercise provisions, if any, and (2) the instrument's settlement provisions. If a financial instrument is shown not to be indexed solely to its issuing company's stock, it 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. EITF 07-5 was effective for financial statements issued for fiscal years beginning after December 15, 2008. During 2002, the Company issued a warrant to purchase shares of its common stock. The warrant entitles the holder to purchase 750,000 shares of the Company's common stock at an exercise price of \$.50 per share. The warrant contains a provision which provides for a reduction in the exercise price per share of the warrant if, under certain circumstances, the Company issues shares of our common stock or certain securities exercisable for or convertible into shares of its common stock at a price that is less than \$.50 per share. The warrant would not be considered indexed to the Company's own stock and therefore, it 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.

The Company adopted EITF 07-5 in the first quarter 2009, however, it did not properly account for this warrant. This error resulted in an understatement of the Company's liabilities at each of its balance sheet dates in



**Table of Contents**

the prior seven quarters. Additionally, the change in fair market value of the liability was not included in reported net loss in each of the prior seven quarters. Based on the qualitative and quantitative analysis, the effect of the error was considered to be immaterial to reported results of operations as well as the Company's financial position as of and for the period ended December 31, 2009 and for each of the three quarters reported in 2009. This error had no impact on previously reported cash flows from operating, financing or investing activities. See Note 2,

Restatement of 2009 Financial Statements for an Immaterial Error. We determined that the error was material as of and for the three month period ended March 31, 2010. We restated the financial statements for the first three quarters of 2010 to correct the accounting for the warrant.

This restatement had no impact on previously reported revenues, operating expenses, total assets or cash position. Net cash flows from operating, investing and financing activities for periods presented were not affected by this restatement; however, certain components comprising cash flows from operating activities in 2010 and 2009 reflect the correction of the error.

The table below shows the effects of this restatement on previously reported quarterly information for 2010. Basic and diluted net losses per share are computed independently for each of the quarters presented.

Unaudited (In thousands, except per share data)	Three months ended March 31, 2010			Three months ended June 30, 2010			Three months ended September 30, 2010		
	2010	Adjustment	Restated	2010	Adjustment	Restated	2010	Adjustment	Restated
<b>Revenues</b>									
Licensing fees	\$ 25	\$	\$ 25	\$ 100	\$	\$ 100	\$	\$	\$
Royalty income	141		141	123		123	124		124
Total revenues	166		166	223		223	124		124
<b>Operating expenses</b>									
Marketing and selling	36		36	63		63	86		86
Research and development	340		340	256		256	257		257
General and administrative	624		624	595		595	650		650
Total operating expenses	1,000		1,000	914		914	993		993
Loss from operations	(834)		(834)	(691)		(691)	(869)		(869)
<b>Other income (expense)</b>									
Interest income	1		1						
Unrealized gain (loss) on fair value of warrant		(218)	(218)		225	225		(90)	(90)
Total other income (expense)	1	(218)	(217)	(15)	225	210		(90)	(90)
Net loss	\$ (833)	\$ (218)	\$ (1,051)	\$ (706)	\$ 225	\$ (481)	\$ (869)	\$ (90)	\$ (959)
Net loss per share, basic and diluted	\$ (0.02)		\$ (0.02)	\$ (0.01)		\$ (0.01)	\$ (0.02)		\$ (0.02)
Shares used in computing basic and diluted	43,141		43,141	49,684		49,684	49,816		49,816

**Table of Contents**

The tables below show the effects of the restatement on previously reported quarterly balance sheet information for the first three quarters of 2010 (in thousands, except par values and number of shares).

Unaudited	March 31, 2010	Adjustment	March 31, 2010 Restated
<b>ASSETS</b>			
Current Assets			
Cash and cash equivalents	\$ 3,965	\$	\$ 3,965
Accounts receivable	145		145
Prepaid expenses and other assets	297		297
Total current assets	4,407		4,407
Property and Equipment net of accumulated depreciation of \$1,309	400		400
Intangible assets net of accumulated amortization of \$531	755		755
Restricted cash	383		383
	\$ 5,945	\$	\$ 5,945
<b>LIABILITIES AND STOCKHOLDERS EQUITY</b>			
Current Liabilities			
Accounts payable	\$ 117	\$	\$ 117
Accrued liabilities	396		396
Deferred revenue			
Fair value of warrant		390	390
Total current liabilities	513	390	903
Deferred rent	188		188
Total liabilities	701	390	1,091
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 49,572,555 issued and outstanding as of March 31, 2010	51		51
Additional paid-in capital	76,698		76,698
Accumulated deficit	(71,505)	(390)	(71,895)
Total stockholders equity	5,244	(390)	4,854
	\$ 5,945	\$	\$ 5,945

**Table of Contents**

Unaudited	June 30, 2010	Adjustment	June 30, 2010 Restated
<b>ASSETS</b>			
Current Assets			
Cash and cash equivalents	\$ 3,270	\$	\$ 3,270
Accounts receivable	124		124
Prepaid expenses and other assets	412		412
Total current assets	3,806		3,806
Property and Equipment net of accumulated depreciation of \$1,347	361		361
Intangible assets net of accumulated amortization of \$556	741		741
Restricted cash	383		383
	\$ 5,291	\$	\$ 5,291
<b>LIABILITIES AND STOCKHOLDERS EQUITY</b>			
Current Liabilities			
Accounts payable	\$ 39	\$	\$ 39
Accrued liabilities	352		352
Deferred revenue			
Fair value of warrant		165	165
Total current liabilities	391	165	556
Deferred rent	178		178
Total liabilities	569	165	734
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 June 30, 2010	50		50
Additional paid-in capital	76,883		76,883
Accumulated deficit	(72,211)	(165)	(72,376)
Total stockholders equity	4,722	(165)	4,557
	\$ 5,291	\$	\$ 5,291

**Table of Contents**

Unaudited	September 30, 2010	Adjustment	September 30, 2010 Restated
<b>ASSETS</b>			
Current Assets			
Cash and cash equivalents	\$ 2,439	\$	\$ 2,439
Accounts receivable	125		125
Prepaid expenses and other assets	543		543
Total current assets	3,107		3,107
Property and Equipment net of accumulated depreciation of \$1,386	356		356
Intangible assets net of accumulated amortization of \$584	731		731
Restricted cash	275		275
	\$ 4,469	\$	\$ 4,469
<b>LIABILITIES AND STOCKHOLDERS EQUITY</b>			
Current Liabilities			
Accounts payable	\$ 76	\$	\$ 76
Accrued liabilities	282		282
Deferred revenue			
Fair value of warrant		255	255
Total current liabilities	358	255	613
Deferred rent	168		168
Total liabilities	526	255	781
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 September 30, 2010	50		50
Additional paid-in capital	76,973		76,973
Accumulated deficit	(73,080)	(255)	(73,335)
Total stockholders equity	3,943	(255)	3,688
	\$ 4,469	\$	\$ 4,469

---

**Table of Contents**

**Item 9. Changes in and Disagreements with Accountants on Accounting and Financial Disclosures**

None.

**Item 9A. 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 Exchange Act Rule 13a-15. 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.

**Management's Report on 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. 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 as of December 31, 2010 and identified the following 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. On January 1, 2009 we adopted 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. Upon review of our outstanding warrants during the fourth quarter of 2010, we identified that we had not adequately reviewed the provisions of our outstanding warrants upon adoption of EITF 07-5 January 1, 2009. As a result, management's control procedures in effect at that time did not determine that a warrant issued should have been accounted for as a liability. Management did not maintain effective controls for reviewing and implementing new accounting pronouncements. Based on our qualitative and quantitative analysis, the effect of the error was considered to be immaterial to reported results of operations as well as the Company's financial position as of and for the period ended December 31, 2009 and for each of the three quarters reported in 2009. This error had no impact on previously reported cash flows from operating, financing or investing activities. However, we determined that the error was material as of and for the three month period ended March 31, 2010. We restated the financial statements for the first three quarters of 2010 to correct the accounting for the warrant. The adjustments affected the reported amounts of accumulated deficit, current liabilities, and unrealized gain (loss) on fair value of warrants.

Management has 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

## **Table of Contents**

financial statements will not be prevented or detected. As a result of the material weakness described above, management believes that, as of December 31, 2010, the Company's internal control over financial reporting was not effective based on the criteria in Internal Control Integrated Framework.

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

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.

In November 2010, we hired a new Controller to provide additional experienced staff in our finance and accounting group.

We 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.

We continued to work with an independent third party to assist our efforts to comply with Section 404 of the Sarbanes-Oxley Act of 2002.

Management has identified additional steps necessary to address the material weakness described above. These measures include the implementation of procedures requiring more detailed documentation of our complex, non-routine transactions and the application of generally accepted accounting principles to such transactions. We also expect to implement 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. 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 fourth quarter of our fiscal year ended December 31, 2010, that has materially affected, or is reasonably likely to materially affect, our internal control over financial reporting.

Additionally, during the first quarter of 2011, we implemented additional processes and procedures and have effected a reorganization of our accounting and finance department in an effort to assure adequate review of non-routine transactions.

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

The Company believes that a control system, no matter how well designed and operated, cannot provide absolute assurance that the objectives of the control system are met, and no evaluation of controls can provide absolute assurance that all controls issues and instances of fraud, if any, within a company have been detected. The Company's disclosure controls and procedures are designed to provide reasonable assurance of achieving their objectives.

This annual report does not include an attestation report of the Company's registered public accounting firm regarding internal control over financial reporting. Management's report was not subject to attestation by the Company's registered public accounting firm pursuant to rules of the Securities and Exchange Commission that permit the Company to provide only management's report in this annual report.

**Table of Contents**

**PART III**

**Item 10. Directors and Executive Officers of the Registrant**

The information required by this item regarding our directors, executive officers and corporate governance is incorporated by reference to the definitive proxy statement for our 2011 annual meeting of stockholders. The information required by this item regarding executive officers is set forth in Item 1 of this annual report under the caption Executive Officers.

**Item 11. Executive Compensation**

The information required by this item is incorporated by reference to the definitive proxy statement for our 2011 annual meeting of stockholders.

**Item 12. Security Ownership of Certain Beneficial Owners and Management and Related Stockholder Matters**

The information required by this item is incorporated by reference to the definitive proxy statement for our 2011 annual meeting of stockholders.

**Item 13. Certain Relationships and Related Transactions**

The information required by this item is incorporated by reference to the definitive proxy statement for our 2011 annual meeting of stockholders.

**Item 14. Principal Accountant Fees and Services**

The information required by this item is incorporated by reference to the definitive proxy statement for our 2011 annual meeting of stockholders.

**Table of Contents****PART IV****Item 15. Exhibits and Financial Statement Schedules**

The following exhibits are filed herewith:

<b>Exhibit</b>	<b>No.</b>	<b>Description</b>	<b>Filed Herewith</b>	<b>Form</b>	<b>Incorporated by Reference</b>		
					<b>Exhibit</b>	<b>File No.</b>	<b>Filing Date</b>
	4.1	Certificate of Incorporation as amended on July 31, 2004		10-QSB	3	001-31982	8/13/2004
	4.2	Certificate of designation of Series A Junior Participating Preferred Stock		10-K	4.2	001-31982	3/11/2008
	4.3	Bylaws, as amended		10-QSB	3	001-31982	5/17/2004
	4.4	Rights Agreement, dated as of November 1, 2002, by and between SCOLR, Inc. and OTR, Inc.		10-K	4.4	001-31982	3/11/2008
	4.5	Form of Common Stock Purchase Warrant dated as of February 8, 2005		8-K	4.1	001-31982	2/11/2005
	4.6	Form of Warrant dated as of December 4, 2007		8-K	4.1	001-31982	11/30/2007
	10.1	Form of Common Stock Purchase Warrant dated June 25, 2003		S-2	10.3	333-107906	8/13/2003
	10.2	Form of Common Stock Purchase Warrant dated February 24, 2004		8-K	10.3	001-31982	2/26/2004
	10.3	Warrant Agreement dated September 30, 2002		10-K	10.3	001-31982	3/11/2008
	10.4	1995 Stock Option Plan, together with amendment No. 1 thereto*		10-K	10.6	001-319822	3/13/2007
	10.5	Amendment No. 2 to Company 1995 Stock Option Plan*		S-8	4.2	333-40290	6/28/2000
	10.6	Form of Incentive Stock Agreement*		S-2	10.8	333-107906	8/13/2003
	10.7	Form of Nonqualified Stock Option Agreement*		S-2	10.9	333-107906	8/13/2003
	10.8	Research and Transfer Agreement dated September 11, 1998, among Temple University, Dr. Reza Fassihi, and the Company		S-2	10.11	333-107906	8/13/2003
	10.9	License agreement dated December 22, 1998, as amended, between Temple University and the Company		S-2	10.12	333-107906	8/13/2003
	10.10	License Agreement dated September 6, 2000, between Temple University and the Company		S-2	10.13	333-107906	8/13/2003



**Table of Contents**

Exhibit No.	Description	Filed Herewith	Incorporated by Reference Exhibit			
			Form	No.	File No.	Filing Date
10.11	Master Research and Development Agreement dated May 1, 2001, between Temple University and the Company		S-2	10.14	333-107906	8/13/2003
10.12	Consulting Agreement dated December 22, 2000, between Dr. Reza Fassihi and the Company*		S-2	10.15	333-107906	8/13/2003
10.13	Intellectual Property Assignment and Assumption Agreement dated May 24, 2001, between Dr. Reza Fassihi and the Company		S-2	10.16	333-107906	8/13/2003
10.14	License Agreement dated September 1, 2001, between Temple University and the Company		S-2	10.17	333-107906	8/13/2003
10.15	Intellectual Property Assignment and Assumption Agreement dated August 1, 2002, between Dr. Reza Fassihi and the Company		S-2	10.18	333-107906	8/13/2003
10.16	Additional Services Agreement dated August 7, 2002, between Dr. Reza Fassihi and the Company*		S-2	10.19	333-107906	8/13/2003
10.17	Form of Option Agreement under the 2004 Equity Incentive Plan*		10-QSB	10.2	001-31982	11/12/2004
10.18	Form of Outside Director Option Agreement for Annual grants to directors under the 2004 Equity Incentive Plan*		10-QSB	10.3	001-31982	11/12/2004
10.19	Form of Non Employee Director Option Agreement for stock based fee awards under the 2004 Equity Incentive Plan*		10-QSB	10.4	001-31982	11/12/2004
10.20	Amendment No. 1 to Intellectual Property Assignment and Assumption Agreement dated July 16, 2004, between Dr. Reza Fassihi and the Company.		10-QSB	10.1	001-31982	11/12/2004
10.21	Employment Agreement dated November 12, 2004, between Daniel O. Wilds and the Company*		8-K	10.1	001-31982	11/18/2004
10.22	Employment Agreement dated January 10, 2005, between Alan M. Mitchel and the Company*		8-K	10.1	001-31982	1/11/2005
10.23	Manufacture, License and Distribution Agreement dated October 20, 2005, between the Company and Perrigo Company of South Carolina		10-K	10.33	001-31982	3/23/2006

**Table of Contents**

Exhibit No.	Description	Filed Herewith	Incorporated by Reference Exhibit			
			Form	No.	File No.	Filing Date
10.24	First Amendment to Lease, effective as of October 12, 2005		10-K	10.35	001-31982	3/23/2006
10.25	Amendment to License Agreement dated as of June 1, 2006, (executed July 11, 2006) between SCOLR Pharma, Inc. and Temple University		10-Q	10.1	001-31982	11/7/2006
10.26	Amendment to License Agreement dated as of August 10, 2006, between Temple University and the Company		10-Q	10.4	001-31982	11/7/2006
10.27	Amendment to Consulting Agreement effective as of December 31, 2006, between Dr. Reza Fassihi and the Company*		10-K	10.42	001-319822	3/13/2007
10.28	Executive Employment Agreement dated April 14, 2008, between Richard M. Levy and the Company*		8-K	10.1	001-31982	4/16/2008
10.29	Executive Employment Agreement dated April 14, 2008, between Stephen J. Turner and the Company*		8-K	10.2	001-31982	4/16/2008
10.30	Standard Multi-Tenant Lease dated June 19, 2008, between Arden Realty Limited Partnership and the Company		8-K	10.1	001-31982	6/24/2008
10.31	Lease Termination and Surrender Agreement dated April 30, 2008, between Newport Corporate Center, LLC and the Company		10-Q	10.2	001-31982	8/7/2008
10.32	2004 Equity Incentive Plan, as Amended*		10-K	10.32	001-31982	3/11/2009
10.33	Form of Restricted Stock Purchase Agreement under the 2004 Equity Incentive Plan*		10-K	10.33	001-31982	3/11/2009
10.34	Executive Employment Agreement dated January 30, 2009, between Bruce S. Morra and the Company*		10-K	10.34	001-31982	3/11/2009
10.35	Form of Director Indemnification Agreement, dated May 26, 2009*		8-K	10.1	001-31982	5/29/2009
10.36	Form of Officer Indemnification Agreement, dated May 26, 2009*		8-K	10.2	001-31982	5/29/2009
10.37	Confidential Separation Agreement and Release of Claims dated August 28, 2009 between Bruce Morra and the Company*		10-Q	10.3	001-31982	11/6/2009

**Table of Contents**

Exhibit No.	Description	Filed Herewith	Incorporated by Reference Exhibit			
			Form	No.	File No.	Filing Date
10.38	Letter Amendment to Confidential Separation Agreement and Release of Claims dated August 28, 2009 between Bruce Morra and the Company*		10-Q	10.4	001-31982	11/6/2009
10.39	First Amendment to Lease dated November 5, 2009, between Arden Realty Limited Partnership and the Company		10-Q	10.6	001-31982	11/6/2009
10.40	License Agreement dated November 20, 2009, between Chrono Nutraceuticals LLC and the Company		10-K	10.40	001-31982	03/24/2010
10.41	Amendment Number Three to Manufacture, License and Distribution Agreement dated January 4, 2010, between Perrigo Company of South Carolina, Inc. and the Company		10-K	10.41	001-31982	03/24/2010
10.42	Term Sheet dated February 16, 2010, between RedHill Biopharma Ltd. and the Company		10-K	10.42	001-31982	03/24/2010
10.43	Form of Unit Purchase Agreement dated March 12, 2010.		10-K	10.43	001-31982	03/24/2010
10.44	Form of Common Stock Purchase Warrant dated March 12, 2010.		10-K	10.44	001-31982	03/24/2010
10.45	Exclusive License Agreement dated May 2, 2010, between RedHill Biopharma Ltd. and the Company		10-Q	10.1	001-31982	08/10/2010
10.46	Sales Agency Agreement dated August 27, 2010, between Emerson Group, Inc. and the Company		10-Q	10.1	001-31982	11/12/2010
10.47	Account Services Agreement dated August 27, 2010, between Emerson Healthcare LLC and the Company		10-Q	10.2	001-31982	11/12/2010
10.48	Non-Exclusive Finder's Fee Agreement, effective February 19, 2011, between Nicholas Hall & Company and the Company	X				
23.1	Consent of Grant Thornton LLP	X				
31.1	Certification of Chief Executive Officer pursuant to Section 302 of the Sarbanes-Oxley Act of 2002	X				
31.2	Certification of Chief Financial Officer pursuant to Section 302 of the Sarbanes-Oxley Act of 2002	X				

**Table of Contents**

Exhibit	Description	Filed Herewith	Form	Incorporated by Reference Exhibit		
				No.	File No.	Filing Date
32.1	Certification of Chief Executive Officer pursuant to 18 U.S.C. Section 1350 as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002	X				
32.2	Certification of Chief Financial Officer pursuant to 18 U.S.C. Section 1350 as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002	X				

Confidential treatment granted as to certain portions, which portions are omitted and filed separately with the SEC. Portions of such exhibit have been omitted pursuant to a request for confidential treatment filed with the SEC.

\* Management contract or compensatory plan or arrangement.

**Table of Contents**

**SIGNATURES**

Pursuant to the requirements of Section 13 or 15(d) of the Securities Exchange Act of 1934, the registrant has duly caused this report to be signed on its behalf by the undersigned, thereunto duly authorized.

SCOLR PHARMA, INC.

By: */s/* STEPHEN J. TURNER  
**Stephen J. Turner**

**Chief Executive Officer and President**

**(Principal Executive Officer)**

Date: March 29, 2011

Signature	Title	Date
<i>/s/</i> STEPHEN J. TURNER  <b>Stephen J. Turner</b>	President, Chief Executive Officer (Principal Executive Officer)	March 29, 2011
<i>/s/</i> RICHARD M. LEVY  <b>Richard M. Levy</b>	Executive Vice President and Chief Financial Officer (Principal Financial and Accounting Officer)	March 29, 2011
<i>/s/</i> MARYLOU ARNETT  <b>Marylou Arnett</b>	Director	March 29, 2011
<i>/s/</i> CARL J. JOHNSON  <b>Carl J. Johnson</b>	Chairman of the Board	March 29, 2011
<i>/s/</i> HERBERT L. LUCAS, JR.  <b>Herbert L. Lucas, Jr.</b>	Director	March 29, 2011
<i>/s/</i> JEFFREY B. REICH  <b>Jeffrey B. Reich</b>	Director	March 29, 2011
<i>/s/</i> MICHAEL N. TAGLICH  <b>Michael N. Taglich</b>	Director	March 29, 2011
<i>/s/</i> WAYNE L. PINES  <b>Wayne L. Pines</b>	Director	March 29, 2011

**Table of Contents****EXHIBIT INDEX**

Exhibit No.	Description	Filed Herewith	Incorporated by Reference			
			Form	Exhibit No.	File No.	Filing Date
4.1	Certificate of Incorporation as amended on July 31, 2004		10-QSB	3	001-31982	8/13/2004
4.2	Certificate of designation of Series A Junior Participating Preferred Stock		10-K	4.2	001-31982	3/11/2008
4.3	Bylaws, as amended		10-QSB	3	001-31982	5/17/2004
4.4	Rights Agreement, dated as of November 1, 2002, by and between SCOLR, Inc. and OTR, Inc.		10-K	4.4	001-31982	3/11/2008
4.5	Form of Common Stock Purchase Warrant dated as of February 8, 2005		8-K	4.1	001-31982	2/11/2005
4.6	Form of Warrant dated as of December 4, 2007		8-K	4.1	001-31982	11/30/2007
10.1	Form of Common Stock Purchase Warrant dated June 25, 2003		S-2	10.3	333-107906	8/13/2003
10.2	Form of Common Stock Purchase Warrant dated February 24, 2004		8-K	10.3	001-31982	2/26/2004
10.3	Warrant Agreement dated September 30, 2002		10-K	10.3	001-31982	3/11/2008
10.4	1995 Stock Option Plan, together with amendment No. 1 thereto*		10-K	10.6	001-319822	3/13/2007
10.5	Amendment No. 2 to Company 1995 Stock Option Plan*		S-8	4.2	333-40290	6/28/2000
10.6	Form of Incentive Stock Agreement*		S-2	10.8	333-107906	8/13/2003
10.7	Form of Nonqualified Stock Option Agreement*		S-2	10.9	333-107906	8/13/2003
10.8	Research and Transfer Agreement dated September 11, 1998, among Temple University, Dr. Reza Fassihi, and the Company		S-2	10.11	333-107906	8/13/2003
10.9	License agreement dated December 22, 1998, as amended, between Temple University and the Company		S-2	10.12	333-107906	8/13/2003
10.10	License Agreement dated September 6, 2000, between Temple University and the Company		S-2	10.13	333-107906	8/13/2003
10.11	Master Research and Development Agreement dated May 1, 2001, between Temple University and the Company		S-2	10.14	333-107906	8/13/2003

**Table of Contents**

Exhibit No.	Description	Incorporated by Reference				
		Filed Herewith	Form	Exhibit No.	File No.	Filing Date
10.12	Consulting Agreement dated December 22, 2000, between Dr. Reza Fassihi and the Company*		S-2	10.15	333-107906	8/13/2003
10.13	Intellectual Property Assignment and Assumption Agreement dated May 24, 2001, between Dr. Reza Fassihi and the Company		S-2	10.16	333-107906	8/13/2003
10.14	License Agreement dated September 1, 2001, between Temple University and the Company		S-2	10.17	333-107906	8/13/2003
10.15	Intellectual Property Assignment and Assumption Agreement dated August 1, 2002, between Dr. Reza Fassihi and the Company		S-2	10.18	333-107906	8/13/2003
10.16	Additional Services Agreement dated August 7, 2002, between Dr. Reza Fassihi and the Company*		S-2	10.19	333-107906	8/13/2003
10.17	Form of Option Agreement under the 2004 Equity Incentive Plan*		10-QSB	10.2	001-31982	11/12/2004
10.18	Form of Outside Director Option Agreement for Annual grants to directors under the 2004 Equity Incentive Plan*		10-QSB	10.3	001-31982	11/12/2004
10.19	Form of Non Employee Director Option Agreement for stock based fee awards under the 2004 Equity Incentive Plan*		10-QSB	10.4	001-31982	11/12/2004
10.20	Amendment No. 1 to Intellectual Property Assignment and Assumption Agreement dated July 16, 2004, between Dr. Reza Fassihi and the Company.		10-QSB	10.1	001-31982	11/12/2004
10.21	Employment Agreement dated November 12, 2004, between Daniel O. Wilds and the Company*		8-K	10.1	001-31982	11/18/2004
10.22	Employment Agreement dated January 10, 2005, between Alan M. Mitchel and the Company*		8-K	10.1	001-31982	1/11/2005
10.23	Manufacture, License and Distribution Agreement dated October 20, 2005, between the Company and Perrigo Company of South Carolina		10-K	10.33	001-31982	3/23/2006
10.24	First Amendment to Lease, effective as of October 12, 2005		10-K	10.35	001-31982	3/23/2006

**Table of Contents**

Exhibit No.	Description	Incorporated by Reference				
		Filed Herewith	Form	Exhibit No.	File No.	Filing Date
10.25	Amendment to License Agreement dated as of June 1, 2006, (executed July 11, 2006) between SCOLR Pharma, Inc. and Temple University		10-Q	10.1	001-31982	11/7/2006
10.26	Amendment to License Agreement dated as of August 10, 2006, between Temple University and the Company		10-Q	10.4	001-31982	11/7/2006
10.27	Amendment to Consulting Agreement effective as of December 31, 2006, between Dr. Reza Fassihi and the Company*		10-K	10.42	001-319822	3/13/2007
10.28	Executive Employment Agreement dated April 14, 2008, between Richard M. Levy and the Company*		8-K	10.1	001-31982	4/16/2008
10.29	Executive Employment Agreement dated April 14, 2008, between Stephen J. Turner and the Company*		8-K	10.2	001-31982	4/16/2008
10.30	Standard Multi-Tenant Lease dated June 19, 2008, between Arden Realty Limited Partnership and the Company		8-K	10.1	001-31982	6/24/2008
10.31	Lease Termination and Surrender Agreement dated April 30, 2008, between Newport Corporate Center, LLC and the Company		10-Q	10.2	001-31982	8/7/2008
10.32	2004 Equity Incentive Plan, as Amended*		10-K	10.32	001-31982	3/11/2009
10.33	Form of Restricted Stock Purchase Agreement under the 2004 Equity Incentive Plan*		10-K	10.33	001-31982	3/11/2009
10.34	Executive Employment Agreement dated January 30, 2009, between Bruce S. Morra and the Company*		10-K	10.34	001-31982	3/11/2009
10.35	Form of Director Indemnification Agreement, dated May 26, 2009*		8-K	10.1	001-31982	5/29/2009
10.36	Form of Officer Indemnification Agreement, dated May 26, 2009*		8-K	10.2	001-31982	5/29/2009
10.37	Confidential Separation Agreement and Release of Claims dated August 28, 2009 between Bruce Morra and the Company*		10-Q	10.3	001-31982	11/6/2009
10.38	Letter Amendment to Confidential Separation Agreement and Release of Claims dated August 28, 2009 between Bruce Morra and the Company*		10-Q	10.4	001-31982	11/6/2009
10.39	First Amendment to Lease dated November 5, 2009, between Arden Realty Limited Partnership and the Company		10-Q	10.6	001-31982	11/6/2009



**Table of Contents**

Exhibit No.	Description	Filed Herewith	Incorporated by Reference			
			Form	Exhibit No.	File No.	Filing Date
10.40	License Agreement, dated November 20, 2009, between Chrono Nutraceuticals LLC and the Company		10-K	10.40	001-31982	03/24/2010
10.41	Amendment Number Three to Manufacture, License and Distribution Agreement dated January 4, 2010, between Perrigo Company of South Carolina, Inc. and the Company		10-K	10.41	001-31982	03/24/2010
10.42	Term Sheet dated February 16, 2010, between RedHill Biopharma Ltd. and the Company		10-K	10.42	001-31982	03/24/2010
10.43	Form of Unit Purchase Agreement dated March 12, 2010.		10-K	10.43	001-31982	03/24/2010
10.44	Form of Common Stock Purchase Warrant dated March 12, 2010.		10-K	10.44	001-31982	03/24/2010
10.45	Exclusive License Agreement dated May 2, 2010, between RedHill Biopharma Ltd. and the Company		10-Q	10.1	001-31982	8/10/2010
10.46	Sales Agency Agreement dated August 27, 2010, between Emerson Group, Inc. and the Company		10-Q	10.1	001-31982	11/21/2010
10.47	Account Services Agreement dated August 27, 2010, between Emerson Healthcare LLC and the Company		10-Q	10.2	001-31982	11/21/2010
10.48	Non-Exclusive Finder's Fee Agreement, effective February 19, 2010, between Nicholas Hall & Company and the Company	X				
23.1	Consent of Grant Thornton LLP	X				
31.1	Certification of Chief Executive Officer pursuant to Section 302 of the Sarbanes-Oxley Act of 2002	X				
31.2	Certification of Chief Financial Officer pursuant to Section 302 of the Sarbanes-Oxley Act of 2002	X				
32.1	Certification of Chief Executive Officer pursuant to 18 U.S.C. Section 1350 as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002	X				
32.2	Certification of Chief Financial Officer pursuant to 18 U.S.C. Section 1350 as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002	X				

Confidential treatment granted as to certain portions, which portions are omitted and filed separately with the SEC.

**Table of Contents**

- Portions of such exhibit have been omitted pursuant to a request for confidential treatment filed with the SEC.
- \* Management contract or compensatory plan or arrangement.