

SCOLR Pharma, Inc.  
Form 10-K  
March 24, 2010  
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, 2009

.. **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:  
Common Stock, \$0.001 par value per share

NYSE Amex Equities Exchange

(Title of each class)

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

Series A Junior Participating Preferred Share Purchase Rights

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

Indicate by check mark whether the registrant is a large accelerated filer, an accelerated filer, 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, 2009, was approximately \$14.0 million, based upon the closing sale price on the NYSE Amex Equities Exchange reported for such date. The number of shares outstanding of the registrant's common stock was 49,572,555 as of March 15, 2010.

#### 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 2010 annual meeting of stockholders.



**Table of Contents**

**SCOLR Pharma, Inc.**

**FORM 10-K**

**TABLE OF CONTENTS**

	<b>Page</b>
<b>PART I</b>	
Item 1. <u>Business</u>	3
Item 1A. <u>Risk Factors</u>	16
Item 1B. <u>Unresolved Staff Comments</u>	25
Item 2. <u>Properties</u>	25
Item 3. <u>Legal Proceedings</u>	25
Item 4. <u>Reserved</u>	25
<b>PART II</b>	
Item 5. <u>Market for the Registrant's Common Equity, Related Stockholder Matters and Issuer Purchases of Equity Securities</u>	26
Item 7. <u>Management's Discussion and Analysis of Financial Condition and Results of Operations</u>	27
Item 8. <u>Financial Statements and Supplementary Data</u>	35
Item 9. <u>Changes in and Disagreements With Accountants on Accounting and Financial Disclosure</u>	58
Item 9A. <u>Controls and Procedures</u>	58
<b>PART III</b>	
Item 10. <u>Directors and Executive Officers of the Registrant</u>	59
Item 11. <u>Executive Compensation</u>	59
Item 12. <u>Security Ownership of Certain Beneficial Owners and Management</u>	59
Item 13. <u>Certain Relationships and Related Transactions</u>	59
Item 14. <u>Principal Accountant Fees and Services</u>	59
<b>PART IV</b>	
Item 15. <u>Exhibits and Financial Statement Schedules</u>	60

**Table of Contents**

**PART I**

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

**Item 1. Business**

This report includes forward-looking statements within the meaning of the Private Securities Litigation Reform Act of 1995. When used in this report, the words anticipate, believe, estimate, may, intend, expect, and similar expressions identify certain of such forward-looking statements. Although we believe that our plans, intentions and expectations reflected in such forward-looking statements are reasonable, we can give no assurance that such plans, intentions or expectations will be achieved. Actual results, performance or achievements could differ materially from historical results or those contemplated, expressed or implied by the forward-looking statements contained in this annual report. Important factors that could cause actual results to differ materially from our forward-looking statements are set forth in this annual report, including Item 1A, as well as those discussed elsewhere in this annual report and others detailed from time-to-time in our periodic reports filed with the SEC. Except as required by law, we undertake no obligation to update any forward-looking statements, whether as a result of new information, future events or otherwise.

**Overview**

We are a specialty pharmaceutical company 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. We currently generate revenues as a percentage of profits on select products sold by our partner Perrigo Company. We anticipate additional revenues in 2010 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 beginning in the fall of 2009. In total, we introduced more than 10 different extended release dietary supplements to numerous US retailers and pharmacy outlets. These products have the potential to generate contribution margins that are significantly greater than the margins we have historically realized with our royalty arrangements. We anticipate that future sales revenues, when coupled with the proceeds of our March 2010 financing, will provide sufficient cash for continuing operations and enable us to further expand our development efforts as we reinvest the profits back into the pipeline for additional future growth opportunities.

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

---

**Table of Contents**

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.

In January 2009, the FDA issued a Complete Response Letter detailing minor deficiencies in our first Abbreviated New Drug Application, or ANDA, on our 12 hour pseudoephedrine product. All minor deficiencies have been addressed in amendments to our ANDA which is currently under review. Pseudoephedrine is a decongestant that is widely used to relieve sinus pressure related to allergies and the common cold.

We have completed initial development activities on various pharmaceutical compounds. The molecules and status of our development activities can be found in our portfolio detail on our website at [www.scolr.com](http://www.scolr.com). 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 binding term sheet 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 1,625,000 shares of our 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 our board of directors, is the president and a principal shareholder of Taglich Brothers. Net proceeds of the offering are expected to be 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 \$1.2 million in cash and cash equivalents, and approximately \$438,000 in restricted cash as of December 31, 2009. We anticipate that our existing cash and cash equivalents, including the cash from our March financing, together with expected royalties from third parties, will be sufficient to fund our operations under our current operating plan into the second half of 2011, unless unforeseen events arise that negatively impact our liquidity.

On June 25, 2009 the Company received notice from the NYSE Amex LLC that it was not in compliance with Section 1003(a)(iii) of the NYSE Amex Company Guide with stockholders' equity of less than \$6,000,000 and losses from continuing operations and net losses in its five most recent fiscal years. As allowed by Exchange rules, the Company submitted a plan of compliance on July 29, 2009, advising the Exchange of action it has taken and will take, to regain compliance with Section 1003(a)(iii) of the Company Guide by December 27, 2010. In addition, the Exchange issued a notice of an additional deficiency relating to the Company's substantial losses and overall financial condition. In September 2009, the Exchange approved the Company's plan to regain compliance with the continued listing standards within the specified timeframes indicated by the Exchange. If the Company is not in compliance with the continued listing standards within the appropriate time period, or if the Company does not make progress consistent with the plan during the plan period, the Company may become subject to delisting proceedings.

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.

## **Table of Contents**

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. This efficient formulation process enables us to leverage the available capacity in existing contract manufacturing and research organizations, effectively keeping our development efforts in line with revenues. We spent \$2.4 million on product research and development in 2009 and \$6.3 million in 2008.

We are seeking to take advantage of an opportunity of providing 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.

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 recent acquisition of the global brand name Nuprin<sup>®</sup> (excluding Canada) will provide additional opportunities on our extended release ibuprofen program, in addition to potential sales revenue from conventional immediate release 200 mg ibuprofen tablets.

Extended release drug delivery technologies such as our CDT platforms can 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. 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.

---

**Table of Contents**

*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 has failed to deliver the additional payment of \$87,500. The Company has terminated the license agreement and is evaluating its remedies with respect to the owed amounts. The initial \$25,000 fee is not refundable and was recorded as revenue in March 2010.

*Perrigo Company.* On January 4, 2010, we amended our License and Distribution Agreement ( Agreement ) with Perrigo dated as of October 20, 2005 (the Amendment ). The Amendment is effective as of January 1, 2010 and provides for a reduction in the royalty rate used to determine the amount of royalties due to us on sales by Perrigo of products licensed under the Agreement. Additionally, the Amendment provides for a change to the methodology for calculation of net profits for purposes of determining the amount of such royalties. Pursuant to the Amendment, Perrigo will pay us a royalty equal to 20% of Perrigo's net profits on sales of licensed products, as calculated in accordance with the Amendment. The reduction in the applicable royalty rate is intended to enable Perrigo to price the licensed products on a more competitive basis. It is expected initially to provide a period of reduced revenue attributable to the Amendment, however, it is expected that consumer-favorable pricing of the licensed products will increase total sales in the longer term.

Additionally, the Amendment eliminates Perrigo's exclusivity rights with respect to use of our proprietary extended delivery technology in three out of the five product categories in which Perrigo had previously enjoyed exclusivity. The Amendment also eliminates Perrigo's right of first refusal and right to request the development of additional dietary supplement products utilizing our CDT technology.

In 2009, one customer accounted for 98% of total revenue. These revenues relate to the royalty income from the sale of products using our CDT technologies. In 2008, two customers accounted for 93% and 7% of total revenues.

*RedHill Biopharma, Ltd.* On February 16, 2010, the Company entered into a binding term sheet (the Term Sheet ) with RedHill Biopharma Ltd., an Israeli corporation ( RedHill ), which sets forth certain terms and conditions of a license agreement between the parties. Upon the successful completion of due diligence, a definitive agreement will be prepared.

The Term Sheet contemplates the negotiation of a definitive license agreement under which RedHill would obtain exclusive worldwide rights to market and sell ondansetron tablet formulations based on our proprietary extended delivery technology (CDT). The Term Sheet sets forth the basic terms of the contemplated licensing agreement, subject to definitive documentation and completion of due diligence by RedHill. The terms include an agreement by RedHill to make certain payments to us up to \$600,000 based on achievement of certain regulatory milestones, and thereafter to make payments to us up to a maximum of \$30 million based on the aggregate net sales by RedHill of the licensed product over a ten year period.

Additionally, the Term Sheet provides for a ninety day exclusivity period during which we are prohibited from engaging in negotiations related to the product contemplated to be licensed to RedHill with any other party. Further, the Agreement provides that either party shall pay to the other a termination fee in the amount of one hundred thousand dollars (\$100,000) in the event that either party is unable to execute the licensing agreement under certain circumstances after the satisfactory completion of due diligence. As of March 24, 2010 a final agreement has not been entered into with RedHill.



## **Table of Contents**

*Dr. Reddy's Laboratories.* On July 6, 2009, the Company's collaboration and license agreement with Dr. Reddy's Laboratories ( Dr. Reddy's ) was terminated. Dr. Reddy's informed the Company that it had decided not to pursue the commercialization of the undisclosed oral prescription drug for the cardiovascular market based on its assessment of the financial opportunity, including competition for the particular product candidate.

*BioCryst Pharmaceuticals INC.* On September 5, 2006, we entered into research collaboration with BioCryst Pharmaceuticals INC. ( BioCryst ) to develop an oral formulation of peramivir, using our CDT platforms. Peramivir is a novel therapeutic being developed by BioCryst for treatment of seasonal and life threatening influenza with a focus on intravenous and intramuscular delivery. The goal of the collaboration was to develop a tablet or capsule formulation for the oral administration of peramivir. While we made initial progress towards the goal BioCryst has not proceeded to the next stage in this alliance and we believe future activities are unlikely.

### **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. 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.

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 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

## **Table of Contents**

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.

## **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 are being generated through our alliances with Perrigo, and we expect sales to begin in 2010 via our direct efforts in the United States. Our CDT extended release dietary supplement products are currently available throughout 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 and pseudoephedrine 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 dietary supplements. 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  Currently under review  Anticipate approval and commercialization in 2010

**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, Hypertriglyceridemia	Immediate release tablet 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

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

\*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 continue to work with the FDA on the AUS required prior to submission of our NDA including protocol and study documentation currently under review. We expect to fund the remaining activities via a strategic partnership or additional financing. 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. Our submission was accepted by the FDA in September 2008 and is currently under review. We anticipate approval in late 2010 and we will then seek to commercialize the product. Our strategy is to manufacture and distribute the product with the help of contract manufacture companies as we seek to sell the product under the SCOLR name and private label to US retail outlets, with eventual expansion to foreign markets. We believe our formulation offers attractive tablet size and cost savings when compared to similar tablets currently on the market. Our ability to commercialize products containing pseudoephedrine may be adversely impacted by legislative and market changes relating to drug diversion.

### ***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 currently generate revenues as a percentage of profits on select products sold by our partner Perrigo Company. We anticipate additional revenues in 2010 through our own direct sales efforts.

### **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 five 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 the Temple University School of Pharmacy. Dr. Fassihi currently serves as a consultant. We are obligated to pay annual license maintenance fees, share in some up-front payments from customers, and pay royalties based on product sales with respect to the CDT patents licensed from Temple University or assigned to us by Dr. Fassihi. In the future, we plan to file further U.S. and foreign patent applications directed to new or improved products or processes.

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 was filed on October 27, 1997 and will expire on the same date in 2017. The majority of the IP was filed on, or after, November 30, 2001 and will have full patent life to 2021 and beyond.

## **Table of Contents**

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, Biovail, Inc., Penwest, 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 capabilities. Generally, either our collaborators manufacture the pharmaceutical products or we use a contract manufacturer. Accordingly, we have to rely on third party manufacturers to produce the pharmaceutical products we are evaluating in clinical trials and the nutritional products we plan to sell directly. We currently have agreements with several outside manufacturers to support our efforts. Our dependence on third parties for the manufacture of our potential products and clinical supplies 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 active chemical raw materials essential to our business are generally readily available from multiple sources in the United States and throughout the world. Certain raw materials used in the manufacture of our products are, however, available from limited sources and, in some cases a single source. Any curtailment in the availability of such raw materials could result in production or other delays and, in the case of products for which only one raw material supplier exists or has been approved by the FDA, could result in material loss of sales with consequent adverse effects on our business and results of operations. Raw material sources for pharmaceutical products must generally be identified and approved by regulatory authorities. Changes in raw material suppliers may result in production delays, higher raw material costs, and loss of sales and customers. We obtain a portion of our raw materials from foreign suppliers, and our arrangements with such suppliers are subject to, among other risks, FDA approval, governmental clearances, export duties, political instability, and restrictions on the transfers of funds.



## **Table of Contents**

### **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; 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

**Table of Contents**

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 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, 2009 we employed 9 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, 2010:

Name	Age	Office	Position Since
Stephen J. Turner	39	President and CEO	2009
Richard M. Levy	51	Vice President of Finance 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 on August 28, 2009 and has worked for us since the fall of 1999 where 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 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.

---

## **Table of Contents**

*Richard M. Levy* has been our Chief Financial Officer and Vice President of Finance since 2005. 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 is licensed as a C.P.A.

### **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 development of our drug delivery operations.***

We anticipate that, based on our current operating plan, our existing cash and cash equivalents, together with expected royalties from third parties and revenues anticipated from direct sales of nutritional products will be sufficient to fund our operations into the second half of 2011. Our current operating plan reflects reductions in personnel, and other operating expenses implemented during 2009, however, our marketing, personnel and working capital requirements are expected to increase through 2010 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:

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

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

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 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 \$690,000. 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 and we may continue to incur substantial losses in the future, which would negatively impact our ability to run our business.***

We have a history of operating losses and we may to 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 or relationships to pursue our programs through 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. If our efforts to increase revenues through direct sales of nutritional products are not successful we will need to seek additional funds through the issuance of equity securities or other sources of financing. If we are unable to obtain necessary additional 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.

***Our efforts to increase direct sales of nutritional products 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 manufacturers to produce and in some cases distribute our nutritional products. Our direct sales efforts in the nutritional market will not be successful if, among other factors, 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.

***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

---

## **Table of Contents**

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 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 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:

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 scheduled 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 Biovail, Inc., Penwest, 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 are waiting on approval from the FDA and intend to commercialize an 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 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.



## **Table of Contents**

*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.*

Some of our products are being developed and commercialized in collaboration with corporate partners. Under these collaborations, we may be dependent on our collaborators to fund some 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;

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

---

**Table of Contents**

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 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 and stock price.

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.

---

**Table of Contents**

***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 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 also rely on members of our scientific staff for product research and development. 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.

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;

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.

---

**Table of Contents**

***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.

***The NYSE Amex Equities (formerly the American Stock Exchange or AMEX) may consider delisting our common stock.***

On June 25, 2009 the Company received notice from the NYSE Amex LLC that it was not in compliance with Section 1003(a)(iii) of the NYSE Amex Company Guide with stockholders' equity of less than \$6,000,000 and losses from continuing operations and net losses in its five most recent fiscal years. As allowed by Exchange rules, the Company submitted a plan of compliance on July 29, 2009, advising the Exchange of action it has taken and will take, to regain compliance with Section 1003(a)(iii) of the Company Guide by December 27, 2010. In addition, the Exchange issued a notice of an additional deficiency relating to the Company's substantial losses and overall financial condition. In September 2009, the Exchange approved the Company's plan to regain compliance with the continued listing standards within the specified timeframes indicated by the Exchange. If the Company is not in compliance with the continued listing standards within the appropriate time period, or if the Company does not make progress consistent with the plan during the plan period, the Company may become subject to delisting proceedings. If we are delisted from the AMEX then our common stock will trade, if at all, only on the over-the-counter markets, such as the OTC Bulletin Board securities market, and then only if one or more registered broker-dealer market makers comply with quotation requirements. In addition, delisting of our common stock could further depress our stock price, substantially limit the liquidity of our common stock and materially adversely affect our ability to raise capital on terms acceptable to us, or at all. Delisting from AMEX could also have other negative results, including the potential loss of confidence by suppliers and employees, the loss of institutional investor interest and fewer business development opportunities.

***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, 2009, 41,098,270 shares of our common stock were outstanding, and there were 7,445,018 shares of our common stock issuable upon the exercise of outstanding options and warrants. Our stockholders may experience substantial dilution if we raise additional funds through the sale of equity securities, 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 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;

## **Table of Contents**

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,

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 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**

None.

### **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.

1. 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. Reserved**

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

Our common stock is traded on the NYSE Amex Equities Exchange under the symbol DDD. The last sale price of our common stock as reported on the NYSE Amex Equities Exchange on March 15, 2010, was \$0.78 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, 2008, through December 31, 2009.

**COMMON STOCK**

	<b>High</b>	<b>Low</b>
<b>2009</b>		
First Quarter	\$ .79	\$ .28
Second Quarter	.49	.28
Third Quarter	.57	.28
Fourth Quarter	.85	.43
<b>2008</b>		
First Quarter	\$ 1.41	\$ 1.03
Second Quarter	1.30	.93
Third Quarter	1.19	.79
Fourth Quarter	1.04	.49

As of March 15, 2010, we had 1,991 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 2010 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. In October 2005, we entered into a strategic alliance with a subsidiary of Perrigo Company for the manufacture, marketing, distribution, sale and use of certain dietary supplement products in the United States. We receive royalty payments based on a percentage of Perrigo's net profits derived from the sales of products covered by our agreement. We have developed additional nutritional products and are seeking to expand sales of nutritional products through additional channels in the United States, as well as in Canada, Europe and other markets.

We are seeking to take advantage of an opportunity of providing 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.

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. The application is currently under review and we anticipate approval later in 2010. 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 the direct sales of the nutritional products and Nuprin immediate release ibuprofen. 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 development projects, including the actual use study required by the FDA as a prerequisite to submission of our regulatory application for ibuprofen, pending additional financing, revenues or partnership support. Without additional revenues or funding, the Company does not expect to be able to complete development of its lead projects. In addition, the Company has reduced its cash marketing and general and administrative expenses and continues to evaluate opportunities to reduce operating expenses. During October 2009, the Company renegotiated the lease of its corporate facility to reduce its monthly cash payment for the remainder of the lease with the reduction in leased space. Also, for one year commencing November 1, 2009, the Company will pay down a portion of the monthly lease payment by 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 may 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.



---

**Table of Contents**

**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, 2009, 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.

*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, 2009, we had recorded full valuation totaling approximately \$20.0 million against our net deferred tax assets.

*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 year ended December 31, 2009, is based on the grant date fair value of share-based payments. Effective January 1, 2006, we adopted the fair value recognition provisions using the modified-prospective-transition method. Under that transition method, compensation cost recognized for the period ended December 31, 2008, includes: (a) compensation cost for all share-based payments granted prior to, but not yet vested as of January 1, 2006, based on the previous grant date fair value, and (b) compensation cost for all share-based payments granted or modified subsequent to January 1, 2006, based on the estimated grant date fair value at the date of grant. 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 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.

## **Table of Contents**

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, 2009, there were 2,910,033 shares available for future grants under both Plans.

On January 30, 2009, the date of his appointment as our President and Chief Executive Officer, Dr. Bruce Morra was awarded stock options exercisable for 500,000 shares of our 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 January 18, 2010, provided Dr. Morra continued to serve as our Chief Executive Officer 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, we 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, we agreed to issue to Dr. Morra 214,285 shares of common stock on January 4, 2010, and shares were issued as scheduled. We recognized a liability of approximately \$103,000 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, we entered into an agreement with our 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, our Board of Directors granted each such officer fully vested options to purchase 500,000 shares of our 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 approximately \$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 our Chief Executive and Chief Financial Officers to reduce their cash compensation, our 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 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.

On November 2, 2009, our Board of Directors granted our former Senior Vice President Business and Legal Affairs, Mr. Alan Mitchel, options to purchase 200,000 shares of our 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 grant date fair value of the award was approximately \$81,000. The options are exercisable for one year after termination of employment.

---

**Table of Contents**

On December 18, 2009, Mr. Mitchel was terminated without cause. In accordance with provisions of his Employment Agreement with us, 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.

**Results of Operations**

*Fiscal 2009 Compared to Fiscal 2008*

*Revenues*

Total revenues decreased 2%, or \$23,000, to \$935,000 for the year ended December 31, 2009, compared to \$958,000 for the same period in 2008. This decrease is primarily due to an approximately \$64,000 decrease in royalty income from our relationship with Nutraceutix, as the agreement was terminated effective December 31, 2007 subject to the rights of Nutraceutix to continue sales of certain inventories through December 31, 2008. No royalty income attributable to Nutraceutix was recognized in 2009. The decline in royalty income attributable to our Nutraceutix agreement was offset by an approximately \$36,000 increase in royalty income from our agreement with Perrigo.

*Marketing and Selling Expenses*

Marketing and selling expenses decreased 71%, or \$479,000, to \$194,000 for the year ended December 31, 2009, compared to \$673,000 for the same period in 2008, primarily due to a decrease of approximately \$298,000 in personnel related expenses through personnel reductions, and a decrease of approximately \$166,000 in advertising and tradeshow expense.

*Research and Development Expenses*

Research and development expenses decreased 61%, or \$3.8 million, to \$2.4 million for the year ended December 31, 2009, compared to \$6.3 million for the same period in 2008. Our deferral of development activities on certain projects pending additional funding resulted in an approximately \$2.9 million reduction in expenses. In addition, personnel related expenses decreased approximately \$441,000 due to personnel reductions and the classification in 2009 of \$73,000 expense for our Chief Technical Officer in general and administrative expenses, effective with his promotion on August 28, 2009 to President and Chief Executive Officer.

*General and Administrative Expenses*

General and administrative expenses increased 15%, or \$659,000, to \$5.0 million for the year ended December 31, 2009, compared to \$4.4 million for the same period in 2008. Personnel related expenses increased approximately \$1.5 million due to the recognition 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 \$797,000 increase in non-cash, share-based compensation expense for executive employee s stock options related to 2009 stock option grants and stock awards, modification of previously issued and outstanding stock option grants, and accelerated vesting of unvested options. These increases were offset by a net reduction in payroll related expenses of approximately \$240,000 due to a reduction in personnel and decrease in cash compensation effective November 1, 2009 for the our current Chief Executive Officer and Chief Financial Officer. In addition, non-cash share-based compensation expense for non-executive employee s and outside director s stock option grants decreased approximately \$231,000 due to a decrease in the combined number of 2009 grants, a decline in the fair value of the awards, and the completion of the vesting period for outstanding awards. A reduction in insurance premium expense of approximately \$113,000, a decrease in director and shareholder relations expense of approximately \$104,000 due to a reduced number of directors, and decreases in other individually insignificant expenses also offset the increase in expenses attributable to personnel related matters.

---

## **Table of Contents**

### ***Lease Termination***

In May 2008, we entered into a lease termination and surrender agreement, under which we agreed to terminate the lease for our corporate facility for \$4.1 million. Under the terms of the agreement, we received \$1.0 million upon execution of the agreement and the remaining \$3.1 million in September 2008, when we vacated the premises. We incurred costs of approximately \$117,000 related to relocation to our new facility and the lease buyout which were recognized in operating expense in September 2008.

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

Other income decreased 95%, or \$206,000, to \$10,000 for the year ended December 31, 2009, compared to \$216,000 for the same period in 2008. This change was due to a decrease in interest income from lower cash balances.

### ***Net Loss***

Net loss increased 9%, or \$557,000, to \$6.7 million for the year ended December 31, 2009, compared to \$6.1 million for the same period in 2008. This change was primarily due to slightly lower royalty income, and approximately \$328,000 increase in operating expenses and approximately \$206,000 decrease in other income. With respect to operating expenses, the year-over-year increase in costs resulting from the \$4.0 million net cash payment we received in 2008 on our lease termination, which was recognized as a reduction in operating expense, was substantially offset in 2009 by reduced research and development and marketing expenses.

### **Liquidity and Capital Resources**

We had approximately \$1.2 million in cash and cash equivalents, and approximately \$438,000 in restricted cash as of December 31, 2009. 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. 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 are expected to be 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.

Based on our current operating plan, our existing cash and cash equivalents, together with expected royalties from third parties and revenues anticipated from direct sales of nutritional products will be sufficient to fund our operations into the second half of 2011, unless unforeseen events arise that negatively impact our liquidity. In the event we are unsuccessful generating additional revenues or raising additional funds, it will be necessary to substantially reduce our operations to preserve capital or seek bankruptcy protection or otherwise wind up our business. If we are forced to reduce or cease our operations we may trigger additional obligations, including contractual severance obligations aggregating as much as \$690,000. In addition, the Company may be forced to liquidate assets at reduced levels due to our immediate liquidity requirements. There can be no assurance that additional financing will be available on favorable terms or at all.

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

## **Table of Contents**

source product from third-parties for later sale. Our revenues may not be sufficient to support these levels of working capital.

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 recent acquisition of the global (excluding Canada) brand Nuprin<sup>®</sup> is expected to provide additional opportunities on our extended release ibuprofen program, in addition to potential sales revenue from conventional immediate release 200 mg ibuprofen tablets.

Extended release drug delivery technologies such as our CDT platforms can 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 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 have deferred all significant expenditures on our development projects, including the actual use study required by the FDA as a prerequisite to submission of our regulatory application for ibuprofen, pending additional financing, revenues or partnership support. Without increased revenues or additional funding we do not expect to be able to complete development of our current projects.

During October 2009, we renegotiated the lease of our corporate facility to reduce our monthly cash payment for the remainder of the lease with the reduction in leased space. Also, for one year commencing November 1, 2009, the Company will pay down a portion of the monthly lease payment by drawing down our letter of credit, and corresponding restricted cash account, by \$18,000 per month. The letter of credit is collateralized by our restricted cash balance. In addition to renegotiating our lease, in August 2009 we reduced the number of our executives and reduced the annual cash compensation for two executive officers effective November 2009.

Our capital resources are very limited and operations to date have been funded primarily with the proceeds from public equity financings, royalty payments, and collaborative research agreements. We are pursuing additional sources of financing that could involve strategic transactions, including 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.

In addition to our efforts to enter into alliances and licensing agreements, we may continue to seek access to the capital markets to fund our operations. We filed a shelf registration statement in the amount of \$40 million which was declared effective by the Securities and Exchange Commission on November 25, 2008 under which we may offer from time-to-time, one or more offerings of securities up to an aggregate public offering price of \$40 million. We expect to register the common stock and common stock underlying warrants sold in our March 2010 financing using our shelf registration statement. Following such registration, we expect there will be approximately \$29.5 million of securities available for registration under our shelf.

On June 25, 2009 the Company received notice from the NYSE Amex LLC that it was not in compliance with Section 1003(a)(iii) of the NYSE Amex Company Guide with stockholders' equity of less than \$6,000,000 and losses from continuing operations and net losses in its five most recent fiscal years. As allowed by Exchange rules, the Company submitted a plan of compliance on July 29, 2009, advising the Exchange of action it has taken and will take, to regain compliance with Section 1003(a)(iii) of the Company Guide by December 27, 2010. In addition,

---

## **Table of Contents**

the Exchange issued a notice of an additional deficiency relating to the Company's substantial losses and overall financial condition. In September 2009, the Exchange approved the Company's plan which demonstrated the Company's ability to regain compliance with the continued listing standards within the specified timeframes indicated by the Exchange. If the Company is not in compliance with the continued listing standards within the appropriate time period, or if the Company does not make progress consistent with the plan during the plan period, the Company may become subject to delisting proceedings.

While we have provided the NYSE Amex with a plan to regain compliance with applicable listing standards, any inability to maintain listing of our common stock on the NYSE Amex may limit our ability to access the capital markets. Any issuance of additional securities would be extremely dilutive to our existing stockholders.

Our failure to increase revenues or raise capital, including financial support from partnerships or other collaborations 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 \$690,000. In addition, we may be forced to liquidate assets at reduced levels due to our immediate liquidity requirements.

*Cash flows from operating activities* Net cash used in operating activities for the year ended December 31, 2009 was approximately \$5.0 million compared to \$4.7 million for the year ended December 31, 2008. The approximately \$275,000 increase in cash used in operating activities primarily reflects the impact of the increase in net loss and the timing of payment of invoices. In 2008, we received a cash payment of approximately \$4.0 million related to our facility lease buyout, which was recognized as a reduction in operating expense. The increase in 2009, of cash flows used by operating activities resulting from the non-recurring cash payment received in 2008, was offset by the reduction in 2009 of our cash research and development and marketing costs of approximately \$4.2 million.

*Cash flows from investing activities* Cash flows of \$74,000 used by investing activities during the year ended December 31, 2009, 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. 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, 2008, of approximately \$695,000 represents the restricted cash of approximately \$474,000, plus payments made for patent rights.

*Cash flows from financing activities* Cash flows used by financing activities for the year ended December 31, 2009 primarily represent payments of approximately \$111,000 made on our term loan through April 2009, at which time the loan was paid off. For the year ended December 31, 2008, cash flows used by financing activities primarily represented payments made on our term loan offset by the proceeds from the exercise of options and warrants.

As of December 31, 2009, we had approximately \$961,000 of working capital compared to \$5.8 million as of December 31, 2008. We have accumulated net losses of approximately \$70.7 million from our inception through December 31, 2009. We have funded our operations primarily through the issuance of equity securities.

### **New Accounting Pronouncements**

In January 2008, the Financial Accounting Standards Board (FASB) ratified former FASB reference EITF Issue 07-5, *Determining Whether an Instrument (or Embedded Feature) Is Indexed to an Entity's Own Stock*. The consensus establishes a two-step approach as a framework for determining whether an instrument or

---

**Table of Contents**

embedded feature is indexed to an entity's own stock. The approach includes evaluating (1) the instrument's contingent exercise provisions, if any, and (2) the instrument's settlement provisions.

Entities that issue financial instruments such as warrants or options on their own shares, convertible debt, convertible preferred stock, forward contracts on their own shares, or market-based employee stock option valuation instruments will be affected by this Issue.

This Issue was adopted January 1, 2009, and there was no material impact to the Company's financial statements upon adoption. The EITF was issued prior to the FASB Codification.

In June 2008, the FASB issued FASB Staff Position EITF 03-6-1, *Determining Whether Instruments Granted in Share-Based Payment Transactions Are Participating Securities*. This position states that unvested share-based payment awards that contain nonforfeitable rights to dividends (whether paid or unpaid) are participating securities and shall be included in the computation of earnings per share (EPS) under the two-class method described in paragraphs 60 and 61 of FASB Statement No. 128, *Earnings per Share*. FSP EITF 03-6-1 is effective for financial statements issued for fiscal years beginning after December 15, 2008. The adoption of EITF 03-6-1 did not have a material effect on the Company's calculation of EPS for the years ended December 31, 2009 and 2008. The Staff Position was issued prior to the FASB Codification.

In June 2009, the FASB issued Accounting Standards Codification (ASC) 105, previously known as SFAS No. 168, *FASB Accounting Standards Codification and the Hierarchy of Generally Accepted Accounting Principles* a replacement of FASB Statement No. 162. ASC 105 will become the source of authoritative U.S. generally accepted accounting principles (GAAP) recognized by the FASB to be applied by nongovernmental entities. Rules and interpretive releases of the Securities and Exchange Commission (SEC) under authority of federal securities laws are also sources of authoritative GAAP for SEC registrants. This Statement is effective for financial statements issued for interim and annual periods ending after September 15, 2009. On the effective date, the Codification will supersede all then-existing non-SEC accounting and reporting standards. All other non-grandfathered, non-SEC accounting literature not included in the Codification will become non-authoritative. As we believe that our accounting practices are consistent with the Codification, the adoption of ASC 105 did not have a material effect on our financial position, results of operations or cash flows.

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

In February of 2010, the FASB issued ASU 2010-09, *Subsequent Events (Topic 855), Amendments to Certain Recognition and Disclosure Requirements*. This amendment to Topic 855, eliminates the requirement that an SEC filer disclose the date through which subsequent events have been evaluated in both issued and revised financial statements. The ASU does not change the requirement that SEC filers evaluate subsequent events through the date the financial statements are issued.

ASC 855, which is effective for periods ending after June 15, 2009, defines subsequent events as transactions that occur after the balance sheet date but before financial statements are issued or are available to be issued. ASC 855 defines two types of subsequent events: (i) events or transactions that provide additional evidence about conditions that existed at the date of the balance sheet, including the estimates inherent in the process of preparing financial statements (that is, recognized subsequent events); and (ii) events that provide evidence about conditions that did not exist at the date of the balance sheet but arose after that date (that is, nonrecognized subsequent events). The adoption of ASC 855, effective June 30, 2009 did not have any effect on our financial position, results of operations or cash flows.

**Table of Contents**

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

**CONTENTS**

	<b>Page</b>
<u>Report of Independent Registered Public Accounting Firm</u>	36
Financial Statements	
<u>Balance Sheets</u>	37
<u>Statements of Operations</u>	38
<u>Statement of Stockholders' Equity</u>	39
<u>Statements of Cash Flows</u>	40
<u>Notes to Financial Statements</u>	41



**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, 2009, and 2008, and the related statements of operations, stockholders' equity, and cash flows for the years then ended. 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, 2009, and 2008, and the results of its operations and its cash flows for the years then ended, in conformity with accounting principles generally accepted in the United States of America.

/s/ GRANT THORNTON LLP

Seattle, Washington

March 24, 2010

**Table of Contents****SCOLR Pharma, Inc.****BALANCE SHEETS****(In thousands)**

	December 31,	
	2009	2008
<b>ASSETS</b>		
Current Assets		
Cash and cash equivalents	\$ 1,176	\$ 6,363
Accounts receivable	269	177
Prepaid expenses and other assets	228	288
Total current assets	1,673	6,828
Property and equipment net	435	791
Intangible assets net	565	557
Restricted cash	438	474
Total assets	\$ 3,111	\$ 8,650
<b>LIABILITIES AND STOCKHOLDERS EQUITY</b>		
Current Liabilities		
Accounts payable	\$ 47	\$ 239
Accrued liabilities	640	668
Current portion of term loan		88
Deferred revenue	25	
Total current liabilities	712	995
Long-term portion of term loan		23
Deferred rent	198	310
Total liabilities	910	1,328
Commitments and Contingencies (Notes 6 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, 41,098,270 and 41,130,270 issued and outstanding as of December 31, 2009 and 2008, respectively	41	41
Additional contributed capital	72,832	71,256
Accumulated deficit	(70,672)	(63,975)
Total stockholders equity	2,201	7,322
Total liabilities and stockholders equity	\$ 3,111	\$ 8,650

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



**Table of Contents****SCOLR Pharma, Inc.****STATEMENTS OF OPERATIONS****(In thousands, except per share data)**

	<b>Year Ended December 31,</b>	
	<b>2009</b>	<b>2008</b>
<b>Revenues</b>		
Royalty	\$ 935	\$ 958
<b>Total revenues</b>	<b>935</b>	<b>958</b>
<b>Operating expenses</b>		
Marketing and selling	194	673
Research and development	2,433	6,268
General and administrative	5,015	4,356
<b>Facility lease termination</b>		
Gain from lease buyout		(4,100)
Expenses related to relocation and lease buyout		117
<b>Total facility lease buyout</b>		<b>(3,983)</b>
<b>Total operating expenses</b>	<b>7,642</b>	<b>7,314</b>
<b>Loss from operations</b>	<b>(6,707)</b>	<b>(6,356)</b>
<b>Other income (expense)</b>		
Interest expense	(3)	(14)
Interest income	13	230
<b>Total other income (expense)</b>	<b>10</b>	<b>216</b>
<b>Net loss</b>	<b>\$ (6,697)</b>	<b>\$ (6,140)</b>
<b>Net loss per share, basic and diluted</b>	<b>\$ (0.16)</b>	<b>\$ (0.15)</b>
<b>Shares used in calculation of basic and diluted net loss per share</b>	<b>41,100</b>	<b>41,116</b>

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

Table of Contents

## SCOLR Pharma, Inc.

## STATEMENT OF STOCKHOLDERS EQUITY

Years Ended December 31, 2009 and 2008

(In thousands except for number of shares)

	Common Stock		Additional Contributed Capital	Accumulated Deficit	Total
	Number of Shares	Amount			
<b>Balance at December 31, 2007</b>	40,991,385	\$ 41	\$ 69,946	\$ (57,835)	\$ 12,152
Exercise of common stock options	126,500		40		40
Exercise of warrants	12,385				
Share-based compensation issued for employee services			1,270		1,270
Net loss				(6,140)	(6,140)
<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				(6,697)	(6,697)
<b>Balance at December 31, 2009</b>	41,098,270	\$ 41	\$ 72,832	\$ (70,672)	\$ 2,201

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

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

	<b>Year Ended December 31,</b>	
	<b>2009</b>	<b>2008</b>
<b>Cash flows from operating activities:</b>		
Net loss	\$ (6,697)	\$ (6,140)
<b>Adjustments to reconcile net loss to net cash used in operating activities:</b>		
Depreciation and amortization	394	420
(Gain) loss on sale of equipment	(12)	1
Share-based compensation for employee services	1,679	1,270
Write-off of intangible assets	87	38
<b>Changes in assets and liabilities:</b>		
Accounts receivable	(92)	48
Prepaid expenses and other assets	59	137
Accounts payable and accrued expenses	(445)	(501)
Deferred revenue	25	
<b>Net cash used in operating activities</b>	<b>(5,002)</b>	<b>(4,727)</b>
<b>Cash flows from investing activities:</b>		
Purchase of equipment, furniture, and leasehold improvements	(95)	(4)
Proceeds from insurance settlement	85	
Proceeds from sale of fixed assets	80	
Patent and technology rights payments	(180)	(217)
Restricted cash	36	(474)
<b>Net cash used in investing activities</b>	<b>(74)</b>	<b>(695)</b>
<b>Cash flows from financing activities:</b>		
Payments on long-term obligations	(111)	(80)
Proceeds from exercise of common stock options and warrants		40
<b>Net cash used in financing activities</b>	<b>(111)</b>	<b>(40)</b>
<b>Net decrease in cash</b>	<b>(5,187)</b>	<b>(5,462)</b>
Cash at beginning of period	6,363	11,825
<b>Cash at end of period</b>	<b>\$ 1,176</b>	<b>\$ 6,363</b>
Cash paid during the year for interest	\$ 2	\$ 13
<b>Non-cash investing and financing activities:</b>		
Capital assets financed through tenant improvement allowance	\$	\$ 374
Return of leasehold improvements to landlord	\$ 75	\$

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

---

**Table of Contents**

**SCOLR Pharma, Inc.**

**NOTES TO FINANCIAL STATEMENTS**

**December 31, 2009 and 2008**

**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, 2009, the Company's accumulated deficit was \$70.7 million. The Company's strategy is to develop and commercialize prescription, OTC, and nutritional products utilizing its oral drug delivery technologies. The Company plans to commercialize products that are feasible to accomplish, given its limited resources, and partner with others in order to maximize the value of the assets in its portfolio. 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 believes that its technologies are capable of significantly improving the delivery of many prescription, OTC, and nutritional products.

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 FDIC 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, accounts payable, and debt obligations approximate fair value.

**Table of Contents***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 2009 and 2008, 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.

*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



---

## **Table of Contents**

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, 2009 and 2008 were approximately \$26,000 and \$100,000, respectively.

### *Earnings (Loss) Per Share*

Basic earnings (loss) per share is calculated based on the weighted average number of shares outstanding during the year and income available to common shareholders. Diluted earnings (loss) per share include the effect of potential common stock, except when their effect is anti-dilutive. The weighted average shares for computing basic earnings (loss) per share were 41,100,549 for the year ended December 31, 2009, and 41,115,607 for the year ended December 31, 2008. At December 31, 2009 and 2008, options, and warrants to purchase 7,445,018 and 7,724,244 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 year ended December 31, 2009, is based on the grant date fair value of share-based payments. Effective January 1, 2006, we adopted the fair value recognition provisions using the modified-prospective-transition method. Under that transition method, compensation cost recognized for the period ended December 31, 2008, includes: (a) compensation cost for all share-based payments granted prior to, but not yet vested as of January 1, 2006, based on the previous estimate of grant date fair value and (b) compensation cost for all share-based payments granted or modified subsequent to January 1, 2006, based on the estimated grant date fair value at the date of grant. 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.

### *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.

---

**Table of Contents**

*New Accounting Pronouncements*

In January 2008, the Financial Accounting Standards Board (FASB) ratified former FASB reference EITF Issue 07-5, *Determining Whether an Instrument (or Embedded Feature) Is Indexed to an Entity's Own Stock*. The consensus establishes a two-step approach as a framework for determining whether an instrument or embedded feature is indexed to an entity's own stock. The approach includes evaluating (1) the instrument's contingent exercise provisions, if any, and (2) the instrument's settlement provisions.

Entities that issue financial instruments such as warrants or options on their own shares, convertible debt, convertible preferred stock, forward contracts on their own shares, or market-based employee stock option valuation instruments will be affected by this Issue.

This Issue was adopted January 1, 2009, and there was no material impact to the Company's financial statements upon adoption. The EITF was issued prior to the FASB Codification.

In June 2008, the FASB issued FASB Staff Position EITF 03-6-1, *Determining Whether Instruments Granted in Share-Based Payment Transactions Are Participating Securities*. This position states that unvested share-based payment awards that contain nonforfeitable rights to dividends (whether paid or unpaid) are participating securities and shall be included in the computation of earnings per share (EPS) under the two-class method described in paragraphs 60 and 61 of FASB Statement No. 128, *Earnings per Share*. FSP EITF 03-6-1 is effective for financial statements issued for fiscal years beginning after December 15, 2008. The adoption of EITF 03-6-1 did not have a material effect on the Company's calculation of EPS for the years ended December 31, 2009 and 2008. The Staff Position was issued prior to the FASB Codification.

In June 2009, the FASB issued Accounting Standards Codification (ASC) 105, previously known as SFAS No. 168, *FASB Accounting Standards Codification and the Hierarchy of Generally Accepted Accounting Principles* a replacement of FASB Statement No. 162. ASC 105 became the source of authoritative U.S. generally accepted accounting principles (GAAP) recognized by the FASB to be applied by nongovernmental entities. Rules and interpretive releases of the Securities and Exchange Commission (SEC) under authority of federal securities laws are also sources of authoritative GAAP for SEC registrants. This Statement is effective for financial statements issued for interim and annual periods ending after September 15, 2009. On the effective date, the Codification superseded all then-existing non-SEC accounting and reporting standards. All other non-grandfathered, non-SEC accounting literature not included in the Codification became non-authoritative. As we believe that our accounting practices are consistent with the Codification, the adoption of ASC 105 did not have a material effect on our financial position, results of operations or cash flows.

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

In February of 2010, the FASB issued ASU 2010-09, *Subsequent Events (Topic 855), Amendments to Certain Recognition and Disclosure Requirements*. This amendment to Topic 855, eliminates the requirement that an SEC filer disclose the date through which subsequent events have been evaluated in both issued and revised financial statements. The ASU does not change the requirement that SEC filers evaluate subsequent events through the date the financial statements are issued.

ASC 855, which is effective for periods ending after June 15, 2009, defines subsequent events as transactions that occur after the balance sheet date but before financial statements are issued or are available to be

---

**Table of Contents**

issued. ASC 855 defines two types of subsequent events: (i) events or transactions that provide additional evidence about conditions that existed at the date of the balance sheet, including the estimates inherent in the process of preparing financial statements (that is, recognized subsequent events); and (ii) events that provide evidence about conditions that did not exist at the date of the balance sheet but arose after that date (that is, nonrecognized subsequent events). The adoption of ASC 855, effective June 30, 2009 did not have any effect on our financial position, results of operations or cash flows.

**Note 2 Liquidity**

The Company has a history of losses and an accumulated deficit of \$70.7 million at December 31, 2009. The Company incurred a net loss of approximately \$6.7 million for the year ended December 31, 2009, and used cash from operations of approximately \$5.0 million. Cash flows of \$74,000 used by investing activities during the year ended December 31, 2009 represent 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 used by financing activities for the period ended December 31, 2009, reflects payments on a bank term loan of approximately \$111,000 through April 2009, at which time the loan was paid off.

The Company had approximately \$1.2 million in cash and cash equivalents and approximately \$438,000 in restricted cash related to our facility lease as of December 31, 2009. The Company is investing its cash and cash equivalents in government-backed securities. These securities have quoted prices in active markets.

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. Net proceeds of the offering are expected to be 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 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.

The Company has received notice from the NYSE Amex that it is not in compliance with continued listing requirements. Its inability to maintain listing of its common stock on the NYSE Amex may further limit its ability to access the capital markets.

Cash expected to be generated from the Company's current operating plan along with the proceeds of the financing and its existing cash and cash equivalents is expected to be sufficient to fund the Company's operations through December 31, 2010, unless unforeseen events arise that negatively impact the Company's liquidity. If unforeseen events arise and the Company is unsuccessful in generating additional revenues or raising additional funds, it will be necessary to substantially reduce the Company's operations to preserve capital or otherwise wind up 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 \$690,000. In addition, the Company may be forced to liquidate assets at reduced levels due to our immediate liquidity requirements. There can be no assurance that additional financing will be available on favorable terms or at all.

The Company has deferred all significant expenditures on our development projects, including the actual use study required by the FDA as a prerequisite to submission of our regulatory application for ibuprofen, pending additional financing, revenues or partnership support. Without additional revenues or funding from a

**Table of Contents**

partnership or collaboration agreement, the Company does not expect to be able to complete development of its lead projects.

The Company's capital resources are limited and operations to date have been funded primarily with the proceeds from public equity financings, royalty payments, and collaborative research agreements. The Company is pursuing additional sources of financing that could involve strategic transactions, including mergers and business combinations, new partnerships as well as opportunities to expand product sales and other options. However, there are significant uncertainties as to the Company's ability to access potential sources of capital. The Company may not be able to enter any strategic transaction or collaboration on terms acceptable 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 specialty pharmaceutical companies attempting to secure alliances with more established pharmaceutical or consumer products companies.

The financial statements have been prepared assuming the Company will continue as a going concern and do not include any adjustments to reflect the possible future effects on the recoverability and classification of assets and liabilities that may result from the outcome of this uncertainty.

**Note 3 Accounts Receivable**

Accounts receivable consists of royalty receivables at December 31, 2009 and 2008. The Company did not have any write-offs or bad debt expense in 2009 and 2008. In addition, the Company did not have an allowance for doubtful accounts in 2009 or 2008, as all accounts receivable were considered collectible.

**Note 4 Property and Equipment**

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

	2009	2008
Furniture and fixtures	\$ 71	\$ 71
Software	41	41
Machinery and equipment	1,248	1,547
Leasehold improvements	347	422
	1,707	2,081
Less accumulated depreciation	(1,272)	(1,290)
	\$ 435	\$ 791

For the years ended December 31, 2009 and 2008, depreciation expense totaled approximately \$308,000 and \$335,000, respectively.

**Note 5 Intangible Assets**

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

	2009	2008
Patents and trademarks	\$ 1,079	\$ 1,023
Less accumulated amortization	(514)	(466)
	\$ 565	\$ 557

For the years ended December 31, 2009 and 2008, amortization expense totaled approximately \$86,000 and \$85,000, respectively.



**Table of Contents**

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, 2009 (in thousands):

<b>Year Ending December 31,</b>	
2010	\$ 82
2011	77
2012	73
2013	71
2014	66
2015 and thereafter	196
<b>Total</b>	<b>\$ 565</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 \$87,000 and \$38,000, were written-off in 2009 and 2008, respectively. The write-offs were recorded to research and development expense.

**Note 6 Lease Obligations**

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

In May 2008, the Company entered into a Lease Termination and Surrender Agreement, under which the Company agreed to terminate the lease for its corporate facility for consideration of \$4.1 million. Under the terms of the agreement, the Company received \$1.0 million upon execution of the agreement and the remaining \$3.1 million in September 2008, at the time the Company vacated the premises. The \$4.1 million cash settlement and approximately \$117,000 in costs that were incurred relating to the lease of and relocation to the Company's new office space were recognized in results of operations in 2008.

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. The standby letter of credit was reduced by \$90,300 in December 2008.

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 will be allowed to pay up to \$18,000 of its monthly rent for twelve months through draw downs on the standby letter of credit which secures the lease. The remaining standby letter of credit (estimated to be approximately \$258,000 after such reductions) shall remain in place through the lease termination date of January 31, 2016. At December 31, 2009 and 2008, the standby letter of credit and the related security totaled approximately \$438,000 and \$474,000, respectively.

**Table of Contents**

The following is a schedule of future minimum lease payments for facilities and equipment under non-cancellable operating leases as of December 31, 2009 (in thousands):

Year Ending December 31,	Operating Leases
2010	\$ 326
2011	335
2012	345
2013	355
2014	358
2015 and thereafter	392
<b>Total</b>	<b>\$ 2,111</b>

Rent expense for leased facilities and equipment was approximately \$500,000 and \$455,000, for the years ended December 31, 2009 and 2008, respectively.

**Note 7 Bank Term Loan**

In April 2009, the Company paid off the then outstanding principal and accrued interest on its bank term loan totaling approximately \$91,000. The Company does not have any borrowing capacity on this loan at December 31, 2009.

**Note 8 Income Taxes**

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):

	2009	2008
Tax benefit at statutory rate	\$ (2,277)	\$ (2,088)
Stock based compensation	217	201
Expiring net operating loss	97	292
Other permanent differences	304	91
Increase in valuation allowance	1,659	1,504
<b>Total provision</b>	<b>\$</b>	<b>\$</b>

**Table of Contents**

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 2009 and 2008. Significant components of the Company's deferred tax assets are as follows at December 31 (in thousands):

	2009	2008
<b>Deferred Tax Assets:</b>		
Net operating loss carry forwards	\$ 18,058	\$ 16,443
Depreciation and amortization	193	148
Stock options	1,227	1,220
Other assets	200	207
Deferred tax assets	\$ 19,678	\$ 18,018
Valuation allowance	(19,678)	(18,018)
Net deferred tax asset	\$	\$

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, 2009 and 2008, was approximately \$1.7 million and \$1.5 million, respectively.

At December 31, 2009, the Company had available net operating loss carryforwards of approximately \$53.1 million of which approximately \$4.1 million related to stock option deductions. Net operating loss carryforwards of approximately \$285,000, and \$859,000, expired during 2009 and 2008, respectively. The remaining net operating loss carryforwards will begin expiring in 2010 and may be used to offset future federal taxable income through the year ending December 31, 2029. 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, 2009. 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 2006, 2007, 2008, and 2009. In addition, tax years from 1995 to 2005, 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***Perrigo Company of South Carolina, Inc*

The Company has a Manufacture, License and Distribution Agreement with Perrigo Company of South Carolina, Inc. ( Perrigo ). Under the agreement, the Company has granted Perrigo a license to its CDT technology for the manufacture, marketing, distribution, sale, and use of specific dietary supplement products in the United States. The Company receives royalties based on a percentage of Perrigo's net profits derived from the sales of licensed products under the agreement. During the years ended December 31, 2009 and 2008, the Company recorded royalty revenues earned under this agreement of approximately \$919,000 and \$883,000, respectively.



## **Table of Contents**

On January 4, 2010, the Company amended its agreement with Perrigo ( the Amendment ). The Amendment is effective as of January 1, 2010 and provides for 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. Additionally, the Amendment provides for a change to the methodology for calculation of net profits for purposes of determining the amount of such royalties. Pursuant to the Amendment, Perrigo will pay the Company a royalty equal to 20% of Perrigo's net profits on sales of licensed products, as calculated in accordance with the Amendment. Prior to the Amendment, the royalty rate was 50% of net profits.

Additionally, the Amendment eliminates Perrigo's exclusivity rights with respect to use of the Company's proprietary extended delivery technology in three out of the five product categories in which Perrigo had previously enjoyed exclusivity. The Amendment also eliminates Perrigo's right to request the development of additional dietary supplement products utilizing the Company's CDT technology.

### **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 has failed to deliver the additional payment of \$87,500. The Company has terminated the license agreement and is evaluating its remedies with respect to the owed amounts. 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, 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 \$95,000 and \$87,000 for 2009 and 2008, respectively.

### **BioCryst Pharmaceuticals**

On September 5, 2006, the Company entered into research collaboration with BioCryst Pharmaceuticals to develop an oral formulation of peramivir, using its CDT platforms. Peramivir is a novel therapeutic being developed by BioCryst for treatment of seasonal and life threatening influenza with a focus on intravenous and intramuscular delivery. The goal of the collaboration was to develop a tablet or capsule formulation for the oral administration of peramivir. While the Company made initial progress towards the goal, BioCryst has not proceeded to the next stage in this alliance and the Company believes future activities are unlikely to continue.

### **Nutraceutix**

On December 31, 2007, the Company terminated its license agreement with Nutraceutix subject to the rights of Nutraceutix to continue sales of certain inventories for up to one year. During the years ended December 31, 2009 and 2008, the Company recorded revenue in the amount of \$0 and approximately \$64,000, respectively under this agreement.

---

**Table of Contents**

**Dr. Reddy s Laboratories**

On July 6, 2009, the Company s collaboration and license agreement with Dr. Reddy s Laboratories ( Dr. Reddy s ) was terminated. Dr. Reddy s informed the Company that it had decided not to pursue the commercialization of the undisclosed oral prescription drug for the cardiovascular market based on its assessment of the financial opportunity, including competition for the particular product candidate.

**Note 10 NYSE Amex Equities Exchange Listing**

On June 25, 2009 the Company received notice from the NYSE Amex Equities Exchange ( the Exchange ) that it was not in compliance with Section 1003(a)(iii) of the NYSE Amex Company Guide with stockholders equity of less than \$6,000,000 and losses from continuing operations and net losses in its five most recent fiscal years. As allowed by Exchange rules, the Company submitted a plan of compliance on July 29, 2009, advising the Exchange of action it has taken and will take, to regain compliance with Section 1003(a)(iii) of the Company Guide by December 27, 2010. In September 2009, the Exchange approved the Company s plan to regain compliance with the continued listing standard set forth in Section 1003(a)(iii) of the NYSE Amex Company Guide within the specified timeframes indicated by the Exchange. However, NYSE Amex LLC simultaneously issued a notice that the Company does not meet the continued listing standard set forth in Section 1003(a)(iv) of the NYSE Amex Company Guide because, based on the Exchange s review of the Company s Form 10-Q for the period ending June 30, 2009, the Company has sustained losses which are so substantial in relation to its overall operations or its existing financial resources, or its financial condition has become so impaired that it appears questionable, in the opinion of the Exchange, as to whether the Company will be able to continue operations and/or meet its obligations as they mature.

On October 15, 2009 the Company submitted additional information to the Exchange to address how it plans to regain compliance with section 1003(a)(iv) of the Company Guide by March 15, 2010. If the Exchange does not accept the plan, or even if accepted, if the Company is not in compliance with the continued listing standards at the end of the plan period or the Company does not make progress consistent with the plan during such period, then the Exchange may initiate delisting proceedings. On November 25, 2009, the Company received notice that the Exchange had accepted the Company s plan of compliance with respect to its deficiency with the Exchange s continued listing standard set forth in Section 1003(a)(iv) of the NYSE Amex Company Guide.

In addition, on November 23, 2009, the Company received a separate notice from the Exchange stating that the Company does not meet the continued listing standard set forth in Section 1003(a)(ii) of the Company Guide because it had stockholders equity of less than \$4 million and losses from continuing operations in three of its four most recent fiscal years. By the aforementioned letter dated June 25, 2009, the Exchange had previously advised the Company that it was not in compliance with Section 1003(a)(iii) of the Company Guide because it had stockholders equity of less than \$6 million and losses from continuing operations and net losses in its five most recent fiscal years. On September 15, 2009, the Exchange notified the Company that it had accepted the Company s plan that would bring it into compliance with the continued listing requirements and granted the Company an extension until December 27, 2010 to regain compliance with Section 1003(a)(iii) of the Company Guide. Due to the higher stockholders equity requirement of Section 1003(a)(iii), the Company was not required to submit an additional plan of compliance in connection with the deficiency relating to the \$4,000,000 stockholders equity standard.

The Company may be subject to delisting proceedings if the Company is not in compliance with the continued listing standards within the appropriate time period, or if the Company does not make progress consistent with the Compliance Plan during the plan period, then the Exchange may initiate delisting proceedings.

The Company s stock trading symbol will remain DDD on NYSE Amex; but will continue to include an indicator (.BC) as an extension to signify noncompliance with the continued listing standards. The .BC indicator

## **Table of Contents**

will remain as an extension on the trading symbol until the Company has regained compliance with all applicable continued listing standards.

### **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.

### **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 \$25,000 and \$37,000, to the Plan for the years ended December 31, 2009 and 2008, 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.

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, 2009, the Company had an aggregate 2,910,033 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

**Table of Contents**

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.

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.

**Table of Contents**

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 for services rendered that is recorded in the Company's results of operations for each of the years ended December 31, 2009 and 2008. When estimating forfeitures, the Company considers the potential for voluntary and involuntary terminations:

	In thousands	
	2009	2008
Share-based compensation:		
Marketing and selling	\$ 13	\$ 62
Research and development	290	399
General and administrative	1,376	809
<b>Total share-based compensation expense</b>	<b>\$ 1,679</b>	<b>\$ 1,270</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, 2009, and 2008.

	Black-Scholes Model Assumptions			
	December 31,		December 31,	
	2009	2008	2009	2008
Expected volatility	74%	84%	59%	74%
Expected dividend yield	0%		0%	
Risk-free interest rate	2.27%	3.88%	1.87%	4.06%
Expected life	6 - 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 two years ended December 31, 2009 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, 2007	3,627,403	\$ 3.36		
Granted	1,189,895	\$ 1.09		
Exercised	(40,000)	\$ 1.00		
Forfeited	(333,216)	\$ 2.28		
Outstanding at December 31, 2008	4,444,082	\$ 2.85		
Reinstatement of options previously forfeited	108,763			
Outstanding at December 31, 2008	4,552,845	\$ 2.89		
Granted	3,051,998	\$ 1.05		
Exercised		\$		
Cancelled	(859,498)	\$ 2.35		
Forfeited	(173,606)	\$ 1.48		
Expired	(1,353,271)	\$ 3.09		
Outstanding at December 31, 2009	5,218,468	\$ 1.89	6.91	\$ 11,325
Outstanding vested or expected to vest options at December 31, 2009	5,157,276	\$ 1.91	6.89	\$ 11,319
Options exercisable at December 31, 2009	4,742,769	\$ 1.99	6.70	\$ 7,163

Cash received from options exercised was \$0 and approximately \$40,000, for the years ended December 31, 2009 and 2008, 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 equity options granted during the years ended December 31, 2009 and 2008, was \$0.33 and \$0.66, respectively. The total intrinsic value of options exercised for the years ended December 31, 2009 and 2008, was \$0 and \$4,800, respectively. The total fair value of stock options vested during the years ended December 31, 2009 and 2008, was approximately \$1.5 million, and \$1.2 million, respectively.

As of December 31, 2009, there was approximately \$218,000 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 1.46 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.

**Table of Contents**

A summary of the Company's restricted stock activity for the year ended December 31, 2009, is as follows:

Restricted stock	Shares	Weighted-Average Grant date fair value
Non-vested at December 31, 2007		\$
Granted	86,500	1.29
Vested		
Forfeited		
Non-vested at December 31, 2008	86,500	\$ 1.29
Granted		
Vested	(28,000)	1.29
Repurchased	(32,000)	1.29
Non-vested at December 31, 2009	26,500	\$ 1.29

Common shares outstanding as of December 31, 2009 and 2008, include 54,500 and 86,500 participating restricted stock shares outstanding, respectively. The shares will generally become vested on the third anniversary of the date of grant. During the year ended December 31, 2009, the vesting of 28,000 unvested restricted stock shares was accelerated in accordance with provisions of certain employee termination agreements. The total fair value of restricted stock vested during the years ended December 31, 2009, and 2008, was approximately \$36,120, and \$0, respectively. As of December 31, 2009, there was approximately \$17,000 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 1.12 years.

**Note 14 Warrants**

During the year ended December 31, 2009, no warrants were issued or exercised. The Company had the following warrants to purchase common stock outstanding at December 31, 2009:

Issue Date	Issued Warrants	Exercise Price	Term	Outstanding Warrants	Expiration Date
September 30, 2002	750,000	\$ 0.50	10 years	750,000	September 30, 2012
February 8, 2005	75,000	5.00	5 years	75,000	February 7, 2010
April 21, 2006	11,000	7.50	5 years	11,000	April 20, 2011
December 4, 2007	1,390,550	2.10	5 years	1,390,550	December 3, 2012
<b>Grand Total</b>	<b>2,226,550</b>			<b>2,226,550</b>	

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

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

In 2009, one customer accounted for 98% of total revenue. These revenues relate to the royalty income from the sale of products using our CDT technologies. In 2008, two customers accounted for 93% and 7% 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.





---

**Table of Contents**

**Note 16 Related Party Transactions**

The Company's CDT platforms are currently based on five patented drug delivery technologies and includes intellectual property from two U.S. patents licensed exclusively to the Company by Temple University and three U.S. patents assigned to the Company by Dr. Reza Fassihi, a Professor of Biopharmaceutics and Industrial Pharmacy at the Temple University School of Pharmacy and a former member of the Company's board of directors. Dr. Fassihi resigned his board position effective March 31, 2009.

The Company entered into two license agreements with Temple University pursuant to which the Company obtained exclusive worldwide rights to two patents issued to Temple University which listed Dr. Fassihi as one of the inventors. Under the terms of Temple University's development policy, the inventors receive 50% of the royalty payments received by the University. On July 11, 2006, the Company amended the license agreement with Temple University relating to the salt patent. The amendment provides for a reduction in the amount of the royalty for sales of prescription drugs covered by the license as well as a reduction in the annual license maintenance fee payable to Temple University.

Dr. Fassihi also assigned the Company all of his right, title and interest in and to the technology known as oral extended release dosage form based on the principle of controlled hydration on May 24, 2001. Dr. Fassihi assigned all of his right, title and interest in the technology known as multiple compressed asymmetric composite delivery system for release-rate modulation of bioactives to the Company on August 1, 2002. The Company is obligated to pay Dr. Fassihi a share of upfront payments from customers and royalties based on product sales with respect to the intellectual property assigned to the Company under each agreement.

In addition, the Company has a consulting agreement with Dr. Fassihi. This agreement was amended effective December 31, 2006, to provide for the continuance of Dr. Fassihi's consulting services. The agreement may be terminated by either party on 30 days' notice. In each of the years ended December 31, 2009 and 2008, Dr. Fassihi was paid approximately \$49,000 for consulting services.

**Note 17 Subsequent Events**

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. Net proceeds of the offering are expected to be 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 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.

The Company filed a shelf registration statement in the amount of \$40 million which was declared effective by the Securities and Exchange Commission on November 25, 2008 under which it may offer from time-to-time, one or more offerings of securities up to an aggregate public offering price of \$40 million. We expect to register the common stock and common stock underlying warrants sold in our March 2010 financing using the shelf registration statement. Following such registration, we expect there will be approximately \$29.5 million of securities available for registration under our shelf.

On March 11, 2010, the Company purchased from Advanced Healthcare Distributors, LLC, 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.

---

**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**

Our management, with the participation of our principal executive officer and principal financial officer, evaluated the effectiveness of our disclosure controls and procedures (as defined in Rule 13a-15(e)) under the Securities Exchange Act of 1934, as of December 31, 2009. Based on this evaluation, our principal executive officer and our principal financial officer concluded that our disclosure controls and procedures were effective as of December 31, 2009.

**Management's Report on Internal Control Over Financial Reporting**

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, 2009, that has materially affected, or is reasonably likely to materially affect, our internal control over financial reporting.

Our management is responsible for establishing and maintaining adequate internal control over financial reporting, as such term is defined in Rule 13a-15(f) under the Exchange Act. Our internal control over financial reporting is a process designed under the supervision of our principal executive and principal financial officers to provide reasonable assurance regarding the reliability of financial reporting and the preparation of our financial statements for external reporting purposes in accordance with U.S. generally accepted accounting principles.

As of December 31, 2009, management assessed the effectiveness of our internal control over financial reporting based on the framework established in Internal Control - Integrated Framework issued by the Committee of Sponsoring Organizations of the Treadway Commission ( COSO ). Based on this evaluation, management has determined that our internal control over financial reporting was effective as of December 31, 2009.

Our internal control over financial reporting is designed to provide reasonable assurance regarding the reliability of financial reporting and the preparation of consolidated financial statements for external purposes in accordance with generally accepted accounting principles. Our internal control over financial reporting includes those policies and procedures that:

- i. pertain to the maintenance of records that, in reasonable detail, accurately and fairly reflect the transactions and dispositions of our assets;
- ii. provide reasonable assurance that transactions are recorded as necessary to permit preparation of consolidated financial statements in accordance with generally accepted accounting principles, and that our receipts and expenditures are being made only in accordance with authorizations of our management and directors; and
- iii. provide reasonable assurance regarding prevention or timely detection of unauthorized acquisition, use or disposition of our assets that could have a material effect on the consolidated financial statements.

Internal control over financial reporting cannot provide absolute assurance of achieving financial reporting objectives because of its inherent limitations, including the possibility of human error and circumvention by collusion or overriding of controls. Accordingly, even an effective internal control system may not prevent or detect material misstatements on a timely basis. Also, projections of any evaluation of effectiveness to future periods are subject to the risk that controls may become inadequate because of changes in conditions or that the degree of compliance with the policies or procedures may deteriorate.

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 temporary 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 2010 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 2010 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 2010 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 2010 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 2010 annual meeting of stockholders.

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

The following exhibits are filed herewith:

Exhibit No.	Description	Filed Herewith	Form	Incorporated by Reference 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

**Table of Contents**

Exhibit No.	Description	Filed Herewith	Form	Incorporated by Reference Exhibit		
				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
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

**Table of Contents**

Exhibit No.	Description	Filed Herewith	Form	Incorporated by Reference Exhibit		
				No.	File No.	Filing Date
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	X				
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	X				
10.42	Term Sheet dated February 16, 2010, between RedHill Biopharma Ltd. and the Company	X				
10.43	Form of Unit Purchase Agreement dated March 12, 2010.	X				
10.44	Form of Common Stock Purchase Warrant dated March 12, 2010.	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. 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 18, 2009

Signature	Title	Date
<i>/s/</i> STEPHEN J. TURNER  <b>Stephen J. Turner</b>	President, Chief Executive Officer (Principal Executive Officer)	March 18, 2010
<i>/s/</i> RICHARD M. LEVY  <b>Richard M. Levy</b>	Chief Financial Officer and Vice President Finance (Principal Financial and Accounting Officer)	March 18, 2010
<i>/s/</i> RANDALL L-W. CAUDILL  <b>Randall L-W. Caudill</b>	Director	March 18, 2010
<i>/s/</i> HERBERT L. LUCAS, JR.  <b>Herbert L. Lucas, Jr.</b>	Director	March 18, 2010
<i>/s/</i> BRUCE S. MORRA  <b>Bruce S. Morra</b>	Director	March 18, 2010
<i>/s/</i> JEFFREY B. REICH  <b>Jeffrey B. Reich</b>	Director	March 18, 2010
<i>/s/</i> MICHAEL N. TAGLICH  <b>Michael N. Taglich</b>	Chairman of the Board	March 18, 2010
<i>/s/</i> WAYNE L. PINES  <b>Wayne L. Pines</b>	Director	March 18, 2010

**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	Filed Herewith	Form	Incorporated by Reference		
				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	Filed Herewith	Form	Incorporated by Reference		
				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 Fassih 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

**Table of Contents**

Exhibit No.	Description	Filed Herewith	Form	Incorporated by Reference		
				Exhibit No.	File No.	Filing Date
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	X				
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	X				
10.42	Term Sheet dated February 16, 2010, between RedHill Biopharma Ltd. and the Company	X				
10.43	Form of Unit Purchase Agreement dated March 12, 2010.	X				
10.44	Form of Common Stock Purchase Warrant dated March 12, 2010.	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. 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.