SCOLR Pharma, Inc.
Form S-3
April 29, 2010
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As filed with the Securities and Exchange Commission on April 29, 2010.

Registration No. 333-

SECURITIES AND EXCHANGE COMMISSION

Washington, D.C. 20549

FORM S-3

REGISTRATION STATEMENT

Under

THE SECURITIES ACT OF 1933

SCOLR PHARMA, INC.

(Exact Name of Registrant as Specified in Its Charter)

Delaware	**91-1689591**
(State or other jurisdiction of incorporation or organization)	**(I.R.S. Employer Identification No.)**

19204 North Creek Parkway, Suite 100

Bothell, WA 98011

(425) 368-1050

(Address, including zip code, and telephone number, including area code, of Registrant s principal executive offices)

Richard M. Levy

Chief Financial Officer

SCOLR Pharma, Inc.

19204 North Creek Parkway, Suite 100

Bothell, WA 98011

(425) 368-1050

(Name, address, including zip code, and telephone number, including area code, of agent for service)

Copies to:

Bruce A. Robertson

Garvey Schubert Barer

1191 Second Avenue

Suite 1800

Seattle, Washington 98101

(206) 464-0125

Approximate date of commencement of proposed sale to the public: From time to time after this Registration Statement becomes effective.

If the only securities being registered on this Form are being offered pursuant to dividend or interest reinvestment plans, please check the following box. ¨

If any of the securities being registered on this Form are to be offered on a delayed or continuous basis pursuant to Rule 415 under the Securities Act of 1933, other than securities offered only in connection with the dividend or interest reinvestment plans, check the following box. x

If this Form is filed to register additional securities for an offering pursuant to Rule 462(b) under the Securities Act, please check the following box and list the Securities Act registration statement number of the earlier effective registration statement for the same offering. ¨

If this Form is a post-effective amendment filed pursuant to Rule 462(c) under the Securities Act, check the following box and list the Securities Act registration statement number of the earlier effective registration statement for the same offering. ¨

If this Form is a registration statement pursuant to General Instruction I.D. or a post-effective amendment thereto that shall become effective upon filing with the Commission pursuant to Rule 462(e) under the Securities Act, check the following box. ¨

If this Form is a post-effective amendment to a registration statement filed pursuant to General Instruction I.D. filed to register additional securities or additional classes of securities pursuant to Rule 413(b) under the Securities Act, check the following box. ¨

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	¨ (Do not check if a Smaller Reporting Company)	Smaller reporting company	x

CALCULATION OF REGISTRATION FEE

Title of Each Class of Securities to be Registered	Amount to be Registered	Proposed Maximum Offering Price Per Unit	Proposed Maximum Aggregate Offering Price	Amount of Registration Fee
Common Stock, $0.01 par value per share	9,444,000 shares (1)	$1.21 (2)	$11,427,240 (2)	$814.76 (2)

(1) The common stock being registered consists of (i) 7,870,000 shares of common stock issued to investors in a private placement completed on March 12, 2010; and (ii) 1,574,000 shares of common stock issuable upon exercise of warrants granted in connection with the private placement. Pursuant to Rule 416 of the Securities Act of 1933, such shares shall include an indeterminate number of shares of common stock that may be issued in connection with a stock split, stock dividend or other distribution with respect to, or in exchange for or in replacement of, such shares of common stock.

(2) The registration fee is calculated pursuant to Rule 457(c) of the Securities Act of 1933 by taking the average of the high and low prices of the registrant s common stock, $0.001 par value per share, on April 28, as reported on the NYSE Amex Exchange.

The registrant hereby amends this registration statement on such date or dates as may be necessary to delay its effective date until the registrant shall file a further amendment that specifically states that this registration statement shall thereafter become effective in accordance with Section 8(a) of the Securities Act of 1933 or until this registration statement shall become effective on such date as the Securities and Exchange Commission, acting pursuant to said Section 8(a), may determine.

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The information in this prospectus is not complete and may be changed. The selling stockholders may not sell these securities until the registration filed with the Securities and Exchange Commission is effective. This prospectus is not an offer to sell these securities and it is not soliciting an offer to buy these securities in any state where the offer or sale is not permitted.

SUBJECT TO COMPLETION, DATED APRIL 29, 2010

PROSPECTUS

SCOLR Pharma, Inc.

9,444,000 Shares of common stock

The 9,444,000 shares of our common stock offered by this prospectus include (i) 7,870,000 shares of our common stock issued by us to the selling stockholders in a private placement completed on March 12, 2010; and (ii) 1,574,000 shares of common stock issuable upon exercise of warrants granted to the selling stockholders in connection with the private placement. The private placement was completed in reliance on Regulation D and/or Section 4(2) of the Securities Act of 1933, as amended.

The selling stockholders may offer their SCOLR Pharma, Inc. common stock through public transactions executed through one or more broker-dealers at prevailing market prices, carried out through the NYSE Amex Exchange or one or more other stock exchanges (if the shares are listed on any other exchange at any time in the future), or in private transactions directly with purchasers at privately negotiated prices.

SCOLR Pharma, Inc. (SCOLR or the Company) common stock is listed on the NYSE Amex Exchange with the ticker symbol: DDD. On April 28, 2010, the closing price of one share of SCOLR Pharma, Inc. common stock on the NYSE Amex Exchange was $1.19. Our principal executive offices are located 19204 North Creek Parkway, Suite 100, Bothell, Washington, 98011, and our telephone number is (425) 368-1050.

Neither the Securities and Exchange Commission nor any state securities commission has approved or disapproved of these securities or determined if this prospectus is truthful or complete. Any representation to the contrary is a criminal offense.

An investment in these securities involves a high degree of risk. See Risk Factors beginning on page 3.

The date of this prospectus is , 2010.

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SUMMARY

This summary highlights information contained elsewhere in this prospectus. You should read the following summary together with the more detailed information appearing in or incorporated by reference into this prospectus, including our consolidated financial statements and related notes, and the risk factors beginning on page 3 before deciding whether to purchase shares of our common stock.

The Company

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

We have developed multiple private label controlled release nutritional products incorporating our CDT platforms that are sold by national retailers. In October 2005, we entered into a strategic alliance with a subsidiary of Perrigo Company for the manufacture, marketing, distribution, sale and use of certain dietary supplement products in the United States. We receive royalty payments based on a percentage of Perrigo s net profits derived from the sales of products covered by our agreement. We have developed additional nutritional products and are seeking to expand sales of nutritional products through additional channels in the United States, as well as in Canada, Europe and other markets.

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

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

Private Placement Transaction

On March 12, 2010, we entered into Unit Purchase Agreements with certain accredited investors for the private placement of the Company s units, consisting of one share of the Company s common stock and a common stock purchase warrant which entitles the holder to purchase one-fifth of one share of common stock. The warrants have an exercise price of $0.75 per full share of common stock and are exercisable, beginning six months from the

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warrant issuance date, for a period of five years from the warrant issuance date. Purchase and sale of the aggregate of 8,260,000 shares of the Company s common stock and warrants to purchase 1,652,000 shares of our common stock resulted in gross proceeds of $4,130,000. In addition, Taglich Brothers, Inc. received warrants to purchase 578,200 shares of our common stock and approximately $289,000 for acting as the placement agent for the private placement. Net proceeds to the Company were approximately $3,700,000 after the deduction of placement agent fees and other offering costs. As requested by the holders thereof, 390,000 of the 8,260,000 shares of our common stock sold in the private placement are not being registered hereunder. Similarly, 78,000 shares of common stock underlying warrants held by such holders, and 578,200 shares of common stock underlying the warrant issued to Taglich Brothers, Inc. are not being registered hereunder.

Pursuant to the Unit Purchase Agreements, we agreed to file a registration statement with the Securities and Exchange Commission registering the resale of the shares issued in the private placement (including shares of common stock issuable upon exercise of warrants) no later than 60 days after closing and to use our best efforts to have the registration statement declared effective as soon as practicable after the filing date.

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RISK FACTORS

The securities offered by this prospectus involve a high degree of risk. You should only acquire our securities if you can afford to lose your entire investment. You should carefully consider the following risk factors, as well as all of the other information set forth in this prospectus, before making a decision to purchase our securities.

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 expense reductions 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.

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.

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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 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 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,

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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.

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.

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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.

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.

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

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

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

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

If our 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.

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

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

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

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

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

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

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

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

The success of our operations will depend to a great extent on the collective experience, abilities and continued service of relatively few individuals. We are dependent upon the continued availability of the services of our employees, many of whom are individually key to our future success. For example, if we lose the services of Stephen J. Turner, our President and Chief Executive Officer, or our 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.

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

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

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

The NYSE Amex Exchange (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 Exchange (the Exchange) that it was not in compliance with Section 1003(a)(iii) of the NYSE Amex Company Guide (the Company Guide) with stockholders equity of less than $6 million and losses from continuing operations and net losses in its five most recent fiscal years. 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 the Exchange 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 April 13, 2010, the Company received notice from the Exchange that the Company had resolved the continued listing deficiency with respect to Section 1003(a)(iv) of the Company Guide referenced in the September 15, 2009 notice from the Exchange. The Exchange noted that the Company remains non-compliant with the stockholder s equity requirements of Section 1003(a)(iii) of the Company Guide and the Exchange staff will continue to monitor the Company for compliance. If the Company is not in compliance with the continued listing standards within the appropriate time periods, or if the Company does not make progress consistent with the plan during the plan periods, the Company may become subject to delisting proceedings. If we are delisted from the Exchange, 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 the Exchange 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 March 31, 2010, 49,572,555 shares of our common stock were outstanding, and there were 9,328,169 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;

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general conditions in the consumer products industry;

general conditions in the financial markets;

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

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

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

our failure to generate product revenues and corresponding profits;

problems incurred by our primary third party suppliers/vendors;

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

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

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

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.

SPECIAL NOTE REGARDING FORWARD-LOOKING STATEMENTS

This prospectus and the registration statement of which it forms a part, any prospectus supplement and the documents incorporated by reference into these documents contain forward-looking statements within the meaning of Section 27A of the Securities Act, and Section 21E of the Securities Exchange Act of 1934, as amended, or the Exchange Act. We use words such as anticipates, believes, plans, expects, future, inte will, foresee and similar expressions to identify these forward-looking statements. In addition, from time to time we or our representatives have

made or may make forward-looking statements orally or in writing. Furthermore, such forward-looking statements may be included in various filings that we make with the SEC, or press releases or oral statements made by or with the approval of one of our authorized executive officers. These forward-looking statements are subject to certain known and unknown risks and uncertainties, as well as assumptions that could cause actual results to differ materially from those reflected in these forward-looking statements. Factors that might cause actual results to differ include, but are not limited to, those discussed in the section entitled Risk Factors beginning on page of this prospectus. Readers are cautioned not to place undue reliance on any forward-looking statements contained herein, which reflect management s opinions only as of the date hereof. Except as required by law, the Company undertakes no obligation to revise or publicly release the results of any revision to any forward-looking statements. You are advised, however, to consult any additional disclosures we have made or will make in

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our reports to the SEC on Forms 10-K, 10-Q and 8-K. All subsequent written and oral forward-looking statements attributable to us or persons acting on our behalf are expressly qualified in their entirety by the cautionary statements contained in this prospectus.

USE OF PROCEEDS

All net proceeds from the sale of the shares of our common stock being offered under this prospectus will go to the selling stockholders. Accordingly, we will not receive any proceeds from sales of these shares. We are paying the expenses of registration of the shares being offered under this prospectus.

The warrants entitle the selling stockholders to purchase over a period of five years up to an aggregate of 1,574,000 shares of our common stock at an exercise price equal to $0.75 per share. We will receive the proceeds of any exercise of the warrants. All such proceeds will be used for research and development, expansion of our nutritional business, working capital and other general corporate purposes.

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SELLING STOCKHOLDERS

The following table sets forth the number of shares owned by each of the selling stockholders who acquired their shares as a result of the private placement completed on March 12, 2010. The number of shares owned also includes shares of our common stock issuable upon exercise of warrants that were issued to the selling stockholders in connection with the private placement. None of the selling stockholders has had a material relationship with us during the past three years. No estimate can be given as to the amount of our common stock that will be held by the selling stockholders after the completion of this offering because the selling stockholders may offer all or some of the common stock beneficially owned by them. There are currently no agreements, arrangements or understandings with respect to the sale of any of our common stock. The shares offered by this prospectus may be offered from time to time by the selling stockholders named below. This prospectus also covers any additional shares of common stock which may become issuable in connection with shares sold by reason of a stock dividend, stock split, recapitalization or other similar transaction effected without us receiving any cash or other value, which results in an increase in the number of our outstanding shares of common stock.

Name of Security Holder	Number of Shares Beneficially Owned Prior to Offering	Number of Shares Registered for Sale Hereby (1)	Number of Shares Beneficially Owned After the Offering	
			Number(2)	Percentage(3)
ALLISON BIBICOFF	127,000	72,000	55,000	*
ANDREW K LIGHT	184,323	142,800	41,523	*
ANDREW M SCHATZ & BARBARA F WOLF JTWROS	77,000	48,000	29,000	*
ANGUS BRUCE LAURALEE BRUCE	100,000	96,000	4,000	*
ANN B OLDFATHER	44,000	36,000	8,000	*
APPLEBAUM FAMIILY LTD PARTNERS IRVING APPLEBAUM GENERAL PTNR	62,785	36,000	26,785	*
ARTHUR D STERLING & MARIE E STERLING JT/WROS	227,619	180,000	47,619	*
ARTHUR H FINNEL	145,000	48,000	97,000	*
AUSTIN BROWN	41,000	24,000	17,000	*
DR BALDEV S BRAR & DR GURMUKH K BRAR JT TEN WROS	43,523	24,000	19,523	*
BRUCE NEWELL	68,000	48,000	20,000	*
WILLIAM C STEELE TTEE WILLIAM C STEELE LIVING TRUST UAD 5-11-98				