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File No. 333-161339

OFFERING PROSPECTUS

5,601,088 Shares

Common Stock

The selling stockholders identified on pages 24-26 of this prospectus are offering on a resale basis a total of 5,601,088 shares of our common stock, including 2,909,694 shares issuable upon the exercise of outstanding warrants. We will not receive any proceeds from the sale of these shares by the selling stockholders.

Our common stock is quoted on the Nasdaq Capital Market under the symbol "NLTX." On August 25, 2009, the closing sale price of our common stock as reported on the Nasdaq Capital Market was $1.90.

The securities offered by this prospectus involve a high degree of risk.
See "Risk Factors" beginning on page 4.

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

The date of this prospectus is August 25, 2009.

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PROSPECTUS SUMMARY

This summary highlights information contained elsewhere in this prospectus. Because it is a summary, it may not contain all of the information that is important to you. Accordingly, you are urged to carefully review this prospectus in its entirety, including the risks of investing in our securities discussed under the caption "Risk Factors" and the financial statements and other information that is incorporated by reference into this prospectus before making an investment decision.

Company Overview

We are a development stage biopharmaceutical company in the business of commercially developing innovative products for the treatment of cardiovascular diseases. We are currently developing two product candidates: our lead compound, CD-NP, a chimeric natriuretic peptide; and CU-NP, a pre-clinical rationally designed natriuretic peptide.

Our Product Candidates

CD-NP

CD-NP is a novel chimeric natriuretic peptide in clinical development for an initial indication of acute decompensated heart failure, or ADHF. CD-NP was rationally designed by scientists at the Mayo Clinic's cardio-renal research labs. Current therapies for ADHF, including B-type natriuretic peptide, have been associated with favorable pharmacologic effects, but have also been associated with hypotension and decreased renal function which limit their utility in clinical practice. CD-NP was designed to preserve the favorable effects of current therapies while eliminating or attenuating the hypotensive response, and enhancing or preserving renal function. In addition to an initial indication for ADHF, CD-NP has potential utility in other indications which include preservation of cardiac function subsequent to acute myocardial infarction, or AMI, and prevention of renal damage subsequent to cardiac surgery.

In 2007, we completed a Phase Ia dose-escalation study in healthy volunteers to examine the safety and pharmacodynamic effects of various doses of CD-NP. The study placed particular emphasis on the effects of CD-NP on blood pressure and renal function. Data from the completed Phase Ia study in healthy volunteers was consistent with several pre-clinical findings, including that CD-NP was associated with increased levels of plasma cGMP, a secondary messenger of the target receptor, preserved renal function, increased natriuresis and diuresis, and a minimal effect on mean arterial pressure.

In 2008, we initiated two additional dose-escalation studies to assess the safety and pharmacodynamic profile of CD-NP in heart failure patients. The first study was a Phase Ib study in stable heart failure patients designed to understand the maximum tolerated dose of the product candidate, and the second study was a Phase IIa study in acute heart failure patients designed to better understand the hemodynamic properties of the product candidate.

In October 2008, we announced interim results of an ongoing Phase IIa study of CD-NP. Results from the first cohort of patients in the study suggested that CD-NP was associated with a statistically significant reduction in pulmonary capillary wedge pressure, a statistically significant increase in diuresis, a trend toward reduction in right atrial pressure, and a trend toward increase in cardiac output at dose levels where patients did not experience symptomatic hypotension or an observed change in serum creatinine. The study dosing was completed at the end of 2008.

In December 2008, we announced preliminary data from the Phase Ib study of CD-NP. Results of this study showed that CD-NP was well-tolerated at doses of up to 20 ng/kg/min, blood pressure effects were dose-dependent and well-characterized, CD-NP demonstrated diuretic effects comparable to furosemide, and CD-NP produced statistically significant changes on biomarkers consistent with enhanced renal function.

We believe that the cumulative results of the Phase Ib and IIa studies indicate that CD-NP was well tolerated at doses of up to 20 ng/kg/min in stable and acute heart failure patients; CD-NP blood pressure effects were dose-dependent and well characterized in chronic heart failure patients; CD-NP demonstrated diuretic effects alone, and CD-NP produced a statistically significant increase in diuresis concurrent with furosemide; and with a 24 hour infusion, CD-NP produced statistically significant decreases in serum creatinine and cystatin-c, consistent with enhanced renal function. We also believe that at the anticipated therapeutic dose range, CD-NP produced a statistically significant reduction in pulmonary capillary wedge pressure.

In addition to our own studies, the Mayo Clinic initiated a Phase Ib study, under an investigator-sponsored investigational new drug application, or IND, to better understand CD-NP's renal properties.

In March 2009, the US Food and Drug Administration, or FDA, placed a clinical hold on the CD-NP program. In a letter sent to us, and in a follow-up teleconference, the FDA requested additional data on our Phase IIa clinical trial, which was finalized in March 2009, and modifications to CD-NP's current Investigator Brochure or IB. We submitted a full response to the FDA in April.

On May 15, the FDA released the CD-NP program from clinical hold. Shortly following the release from clinical hold, we initiated a 30-40 patient single-blind, placebo-controlled Phase II study designed to provide additional information on the safety and tolerability of CD-NP when infused for up to 72 hours in patients with acute heart failure and renal function insufficiency. Additionally, the study contains several exploratory efficacy endpoints to provide insight into the potential for CD-NP to enhance renal function in acute heart failure patients. In July 2009, we dosed the first patient in this Phase II study. We expect to announce interim results of the study later this year, with results from the full study available in 2010.

CU-NP

CU-NP is a novel natriuretic peptide rationally designed by scientists at the cardio-renal research labs at the Mayo Clinic, or Mayo. CU-NP was designed to combine the favorable hemodynamic venodilating effects of CNP generated via NPR-B receptor agonism, with the beneficial renal effects of Urodilatin generated via NPR-A receptor agonism. In animal models, CU-NP was shown to increase natriuresis, diuresis, and glomerular filtration rate in a dose dependent manner, decrease cardiac filling pressure, and inhibit the renin-angiotensin system without inducing significant hypotension.

In 2008, we manufactured a supply of CU-NP. In the second half of 2009, we plan to complete additional pharmacological studies, investigate chronic formulations, and, if possible, initiate pre-clinical toxicology and manufacturing activities.

Corporate Information

We were incorporated in the State of Nevada on June 17, 1996 and reincorporated in the State of Delaware on February 9, 2007, at which time our name was SMI Products, Inc., or SMI. On September 17, 2007, we completed a merger transaction whereby Nile Merger Sub, Inc., a Delaware corporation and a wholly-owned subsidiary of SMI, merged with and into Nile Therapeutics, Inc., a privately held Delaware corporation, or Old Nile, with Old Nile becoming a wholly-owned subsidiary of SMI. Immediately following the merger described above, we filed a Certificate of Ownership with the Secretary of State of the State of Delaware pursuant to which we merged Old Nile with and into us, where we remained as the surviving corporation to that merger. In connection with that short-form merger, and as set forth in the Certificate of Ownership, we changed our name to "Nile Therapeutics, Inc.," or Nile. We refer to these two transactions in this prospectus as the "Merger." In accordance with the terms of the Merger, each share of common stock of Old Nile that was outstanding immediately prior to the Merger was exchanged for 2.758838 shares of our common stock, and, upon completion of the Merger, the Old Nile shareholders owned approximately 95% of our issued and outstanding common stock, assuming the exercise of all of the issued and outstanding common stock options and warrants. Upon completion of the Merger, we adopted Old Nile's business plan.

Our executive offices are located at 4 West 4th Avenue, Suite 400, San Mateo, California 94402. Our telephone number is (415) 875-7880 and our internet address is www.nilethera.com. The information contained in, or accessible through, our website does not constitute part of this prospectus.

Recent Developments

On July 7, 2009, we entered into a securities purchase agreement with various accredited investors pursuant to which we agreed to sell in a private placement an aggregate of 2,691,394 shares of our common stock and five-year warrants to purchase an equal number of additional shares of common stock. The purchase price for each unit of one share of common stock and one warrant was $1.25. The sale of the shares and warrants resulted in aggregate gross proceeds of approximately $3.37 million, before deducting expenses.

In accordance with the terms of the securities purchase agreement, the warrants issued to the investors are evidenced by three separate certificates, which collectively represent the right to purchase a number of shares of common stock equal to the number of shares purchased by such investor in the private placement, as follows:

- A warrant representing the right to purchase 25% of the warrant shares at an exercise price equal to $1.25, which represented 110% of the $1.14 consolidated closing bid price of our common stock on the date of the securities purchase agreement;
- A warrant representing the right to purchase 25% of the warrant shares at an exercise price equal to $1.71, which represented 150% of the closing bid price of our common stock on the date of the securities purchase agreement; and
- A warrant representing the right to purchase 50% of the warrant shares at an exercise price equal to $2.28, which represented 200% of the closing bid price of our common stock on the date of the securities purchase agreement.

The Warrants are redeemable by us, at a redemption price of $0.001 per warrant share, upon 30 days' notice, if at any time, the volume weighted average price of our common stock for any 20 consecutive business days is equal to or greater than 200% of the then applicable exercise price of the warrants.

In connection with the private placement, we engaged Riverbank Capital Securities, Inc., or Riverbank, a FINRA member broker dealer to serve as placement agent. Riverbank was not paid a cash commission for its services; however, we agreed to issue to Riverbank, or its authorized designees, warrants to purchase 218,300 shares of our common stock, which represents 10% of the shares sold to investors in the private placement, or Placement Warrants, excluding shares sold to (i) our directors and executive officers, (ii) employees of Riverbank, or (iii) investors referred to us by one of our executive officers. The Placement Warrants are in substantially the same form as the warrants issued to the investors, except that the Placement Warrants have an exercise price equal to $1.375 and provide for cashless (net) exercise and are not redeemable by us. We also agreed to pay to Riverbank a non-accountable expense allowance equal to $50,000 to cover expenses incurred by Riverbank in providing the services related to the private placement.

Peter M. Kash, our Chairman, Joshua A. Kazam, our President and Chief Executive Officer, and David Tanen, our Secretary, each of whom also serves on our Board of Directors, are each officers of and collectively control Riverbank. Messrs. Kash, Kazam and Tanen were allocated an aggregate of 188,300 of the Riverbank warrants. In light of the relationship between Messrs. Kash, Kazam and Tanen and Riverbank, its engagement and the terms of the engagement were reviewed and approved by a special committee of our Board of Directors consisting of Pedro Granadillo, Paul Mieyal and Gregory Schaefer, none of whom has any interest or other relationship in Riverbank or its affiliates.

Among the investors who are parties to the securities purchase agreement are Messrs. Kazam, Kash and Daron Evans, our Chief Financial Officer, who purchased shares and warrants for an aggregate purchase price of $250,000, $125,000 and $5,000, respectively. Notwithstanding the $1.25 per unit purchase price applicable to non-affiliated investors, the per unit purchase price paid by Messrs. Kazam, Kash and Evans was $1.265, which represents the sum of the closing bid price of our common stock on the date of the securities purchase agreement, plus $0.125 for each warrant share underlying the warrants issued to such persons.

Risk Factors

As with most pharmaceutical product candidates, the development of our product candidates is subject to numerous risks, including the risk of delays in or discontinuation of development from lack of financing, inability to obtain necessary regulatory approvals to market the products, unforeseen safety issues relating to the products and dependence on third party collaborators to conduct research and development of the products. Because we are a development stage company with a very limited history of operations, we are also subject to many risks associated with early-stage companies. For a more detailed discussion of some of the risks you should consider before purchasing shares of our common stock, you are urged to carefully review and consider the section entitled "Risk Factors" beginning on page 4 of this prospectus.

The Offering

The selling stockholders identified on pages 24-26 of this prospectus are offering on a resale basis a total of 5,601,088 shares of our common stock, including 2,909,694 shares issuable upon the exercise of outstanding warrants.

Common stock offered	5,601,088 shares
Common stock outstanding before the offering(1)	26,906,871 shares
Common stock outstanding after the offering(2)	29,816,565 shares
Use of Proceeds	We will receive none of the proceeds from the sale of the shares by the selling stockholders, except for the warrant exercise price upon exercise of the warrants, which would be used for working capital and other general corporate purposes
Nasdaq Capital Market ticker symbol	NLTX

(1) Based on the number of shares outstanding as of August 25, 2009, not including 8,386,594 shares issuable upon exercise of various warrants and options to purchase our common stock.

(2) Assumes the issuance of all shares offered hereby that are issuable upon exercise of warrants.

RISK FACTORS

You should carefully consider the following risk factors and all other information contained in this prospectus before purchasing shares of our common stock. Investing in our common stock involves a high degree of risk. If any of the following events or outcomes actually occurs, our business, operating results and financial condition could be materially and adversely affected. As a result, the trading price of our common stock could decline and you may lose all or part of the money you paid to purchase our common stock.

Risks Relating to Our Business

We have a limited operating history upon which to base an investment decision, and we expect a number of factors to cause our operating results to fluctuate on a quarterly and annual basis, which may make it difficult to predict our future performance.

Our operations to date have been primarily limited to organizing and staffing our company, developing our technology, and undertaking pre-clinical studies and clinical trials of our product candidates. We have not yet obtained regulatory approvals for any of our product candidates. Consequently, any predictions you make about our future success or viability may not be as accurate as they could be if we had a longer operating history. Specifically, our financial condition and operating results have varied significantly in the past and will continue to fluctuate from quarter-to-quarter and year-to-year in the future due to a variety of factors, many of which are beyond our control. Factors relating to our business that may contribute to these fluctuations include the following factors, as well as other factors described elsewhere in this prospectus:

- the need to obtain regulatory approval of our two product candidates, CD-NP and CU-NP;
- delays in the commencement, enrollment, and timing of clinical testing;
- the success of our clinical trials through all phases of clinical development;
- the success of clinical trials of our CD-NP and CU-NP product candidates or future product candidates;
- any delays in regulatory review and approval of our product candidates in clinical development;
- our ability to receive regulatory approval or commercialize our products within and outside the United States;
- potential side effects of our future products that could delay or prevent commercialization or cause an approved treatment drug to be taken off the market;
- regulatory difficulties relating to products that have already received regulatory approval;
- market acceptance of our product candidates;
- our ability to establish an effective sales and marketing infrastructure once our products are commercialized;
- competition from existing products or new products that may emerge;
- the impact of competition in the market in which we compete on the commercialization of CD-NP and CU-NP;
- guidelines and recommendations of therapies published by various organizations;
- the ability of patients to obtain coverage of or sufficient reimbursement for our products;
- our ability to maintain adequate insurance policies;
- our dependency on third parties to formulate and manufacture our product candidates;

- our ability to establish or maintain collaborations, licensing or other arrangements;
- our ability and third parties' abilities to protect intellectual property rights;
- costs related to and outcomes of potential intellectual property litigation;
- compliance with obligations under intellectual property licenses with third parties;
- our ability to adequately support future growth;
- our ability to attract and retain key personnel to manage our business effectively; and
- the level of experience in running a public company of our senior management who are relatively new to their current roles as managers of a public company.

We need substantial additional funding before we can complete the development of our product candidates. If we are unable to raise capital, we will be forced to delay, reduce or eliminate our product development programs and may not have the capital required to otherwise operate our business.

Developing biopharmaceutical products, including conducting pre-clinical studies and clinical trials and establishing manufacturing capabilities, is expensive. We expect our research and development expenses to increase in connection with our ongoing activities, particularly as we initiate our clinical programs and conduct other clinical trials of our product candidates. In addition, our expenses could increase beyond expectations if the FDA, requires that we perform additional studies to those that we currently anticipate, and the timing of any potential product approval may be delayed. Other than our cash on hand, including the cash proceeds realized from the sale of shares of our common stock and warrants in July 2009, we currently have no commitments or arrangements for any additional financing to fund the research and development of our product candidates. We have not generated any product revenues, and do not expect to generate any revenues until, and only if, we receive approval to sell our drugs from the FDA and other regulatory authorities for our product candidates. As of March 31, 2009, before giving effect to our July 2009 private placement, we had cash and cash equivalents totaling approximately $3.6 million. During the fiscal year ended December 31, 2008, we used net cash totaling $10.6 million in operating activities, and during the first half of 2009, we used net cash totaling $3.7 million in operating activities. We expect our negative cash flows from operations to continue for the foreseeable future and beyond potential regulatory approval and any product launch. Based on our current development plans, we expect that our current resources will be sufficient to fund our operations through 2010. However, pending the results of the Company's ongoing Phase II clinical trial of CD-NP, the Company would need substantial additional capital in order to initiate and fund the next clinical study of CD-NP, which is expected to be a Phase IIb clinical trial.

Until we can generate a sufficient amount of product revenue, if ever, we expect to finance future cash needs through public or private equity offerings, debt financings, or corporate collaboration and licensing arrangements. Additional funds may not be available when we need them on terms that are acceptable to us, or at all. If adequate funds are not available, we may be required to delay, reduce the scope of, or eliminate one or more of our research or development programs or our commercialization efforts. In addition, we could be forced to discontinue product development and reduce or forego attractive business opportunities. To the extent that we raise additional funds by issuing equity securities, our stockholders may experience additional significant dilution, and debt financing, if available, may involve restrictive covenants. To the extent that we raise additional funds through collaboration and licensing arrangements, it may be necessary to relinquish some rights to our technologies or our product candidates, or grant licenses on terms that may not be favorable to us. We may seek to access the public or private capital markets whenever conditions are favorable, even if we do not have an immediate need for additional capital at that time.

Our forecast of the period of time through which our financial resources will be sufficient to support our operations is a forward-looking statement and involves risks and uncertainties, and actual results could vary as a result of a number of factors, including the factors discussed elsewhere in this "Risk Factors" section. We have based this estimate on assumptions that may prove to be wrong, and we could utilize our available capital resources sooner than we currently expect. Our future funding requirements will depend on many factors, including, but not limited to:

- the scope, rate of progress and cost of our clinical trials and other research and development activities;
- the costs and timing of regulatory approval;

- the costs of filing, prosecuting, defending and enforcing any patent claims and other intellectual property rights;
- the effect of competing technological and market developments;
- the terms and timing of any collaboration, licensing or other arrangements that we may establish;
- the cost and timing of completion of clinical and commercial-scale outsourced manufacturing activities; and
- the costs of establishing sales, marketing and distribution capabilities for any product candidates for which we may receive regulatory approval.

We have a history of net losses, expect to continue to incur substantial and increasing net losses for the foreseeable future, and we may never achieve or maintain profitability.

For the years ended December 31, 2008 and 2007, respectively, we had a net loss of $13.1 million and $10.3 million. For the three months ended June 30, 2009, we had a net loss of approximately $2.5 million. Since our inception on August 1, 2005, through June 30, 2009, we have accumulated a deficit of $30.3 million and have stockholders' equity of $1.8 million. We expect to incur substantial losses and negative operating cash flow for the foreseeable future, and we may never achieve or maintain profitability. Even if we succeed in developing and commercializing one or more of our product candidates, we expect to incur substantial losses for the foreseeable future, as we:

- continue to undertake pre-clinical development and clinical trials for our product candidates;
- seek regulatory approvals for our product candidates;
- in-license or otherwise acquire additional products or product candidates;
- implement additional internal systems and infrastructure; and
- hire additional personnel.

We also expect to experience negative cash flow for the foreseeable future as we fund our operating losses and capital expenditures. As a result, we expect to incur substantial and increasing net losses and negative cash flows for the foreseeable future. These losses and negative cash flows have had, and will continue to have, an adverse effect on our stockholders' equity and working capital. Our failure to achieve or maintain profitability could negatively impact the value of our common stock.

Because of the numerous risks and uncertainties associated with pharmaceutical product development, we are unable to accurately predict the timing or amount of increased expenses or when, or if, we will be able to achieve or maintain profitability. In addition, our expenses could increase beyond expectations if we are required by the FDA to perform studies in addition to those that we currently anticipate. Currently, we have no products approved for commercial sale, and to date we have not generated any product revenue. We have financed our operations primarily through the sale of equity securities and debt financings. The size of our future net losses will depend, in part, on the rate of growth of our expenses and the rate of growth, if any, of our revenues. Revenues from potential strategic partnerships are uncertain because we may not enter into any strategic partnerships. If we are unable to develop and commercialize one or more of our product candidates, or if sales revenue from any product candidate that receives marketing approval is insufficient, we will not achieve profitability. Even if we do achieve profitability, we may not be able to sustain or increase profitability.

There are certain interlocking relationships between us and certain affiliates of Two River Group Holdings, LLC that may present potential conflicts of interest.

Peter M. Kash, Joshua A. Kazam and David M. Tanen, each a director and substantial stockholder of our Company, are three of the four the managing members of Two River Group Holdings, LLC, or "Two River," a merchant bank specializing in biotechnology companies, and are officers and directors of Riverbank Capital Securities, Inc., or Riverbank, a broker-dealer registered with the Financial Industry Regulatory Authority (FINRA), which served as placement agent in connection with our July 2009 private placement. See "Prospectus Summary—Recent Developments." Mr. Kazam also serves as our President and Chief Executive Officer, Mr. Tanen

serves as our Secretary and Scott Navins, the Vice President of Finance for Two River and the Financial and Operations Principal of Riverbank, serves as our Treasurer. Additionally, certain employees of Two River, who are also our stockholders, perform limited activities for us, including without limitation various clinical development, operational and administrative activities currently being performed pursuant to a Services Agreement dated June 24, 2009, between Nile and Two River Consulting, LLC, an affiliate of Two River. Generally, Delaware corporate law requires that any transactions between us and any of our affiliates be on terms that, when taken as a whole, are substantially as favorable to us as those then reasonably obtainable from a person who is not an affiliate in an arms-length transaction. Nevertheless, none of our affiliates or Two River is obligated pursuant to any agreement or understanding with us to make any additional products or technologies available to us, nor can there be any assurance, and the investors should not expect, that any biomedical or pharmaceutical product or technology identified by such affiliates or Two River in the future will be made available to us. In addition, certain of our current officers and directors or certain of any officers or directors hereafter appointed may from time to time serve as officers or directors of other biopharmaceutical or biotechnology companies. There can be no assurance that such other companies will not have interests in conflict with our own.

We may not successfully manage our growth.

Our success will depend upon the expansion of our operations and the effective management of our growth, which will place a significant strain on our management and on our administrative, operational and financial resources. To manage this growth, we may need to expand our facilities, augment our operational, financial and management systems and hire and train additional qualified personnel. If we are unable to manage our growth effectively, our business would be harmed.

We rely on key executive officers and scientific and medical advisors, whose knowledge of our business and technical expertise would be difficult to replace.

We currently rely on certain key executive officers, the loss of any one or more of whom could delay our development program. We are and will be highly dependent on our principal scientific, regulatory and medical advisors. We do not have “key person” life insurance policies for any of our officers. The loss of the technical knowledge and management and industry expertise of any of our key personnel could result in delays in product development, loss of customers and sales and diversion of management resources, which could adversely affect our operating results.

If we are unable to hire additional qualified personnel, our ability to grow our business may be harmed.

Attracting and retaining qualified personnel will be critical to our success. Our success is highly dependent on the hiring and retention of key personnel and scientific staff. While we are actively recruiting additional experienced members for the management team, there is intense competition and demand for qualified personnel in our area of business and no assurances can be made that we will be able to retain the personnel necessary for the development of our business on commercially reasonable terms, if at all. Certain of our current officers, directors, scientific advisors and/or consultants or certain of the officers, directors, scientific advisors and/or consultants hereafter appointed may, from time to time, serve as officers, directors, scientific advisors and/or consultants of other biopharmaceutical or biotechnology companies. We rely, in substantial part, and for the foreseeable future will rely, on certain independent organizations, advisors and consultants to provide certain services, including substantially all aspects of regulatory approval, clinical management, and manufacturing. There can be no assurance that the services of independent organizations, advisors and consultants will continue to be available to us on a timely basis when needed, or that we can find qualified replacements.

We face potential product liability exposure, and if successful claims are brought against us, we may incur substantial liability for a product candidate and may have to limit its commercialization.

The use of our product candidates in clinical trials and the sale of any products for which we obtain marketing approval, if at all, expose us to the risk of product liability claims. Product liability claims might be brought against us by consumers, health care providers or others using, administering or selling our products. If we cannot successfully defend ourselves against these claims, we will incur substantial liabilities. Regardless of merit or eventual outcome, liability claims may result in:

- withdrawal of clinical trial participants;
- termination of clinical trial sites or entire trial programs;
- costs of related litigation;
- substantial monetary awards to patients or other claimants;

- decreased demand for our product candidates;
- impairment of our business reputation;
- loss of revenues; and
- the inability to commercialize our product candidates.

We have obtained product liability insurance coverage for our clinical trials, both foreign and domestically. However, our insurance coverage may not reimburse us or may not be sufficient to reimburse us for any expenses or losses we may suffer. Moreover, insurance coverage is becoming increasingly expensive, and, in the future, we may not be able to maintain insurance coverage at a reasonable cost or in sufficient amounts to protect us against losses due to liability. We intend to expand our insurance coverage to include the sale of commercial products if we obtain marketing approval for our product candidates in development, but we may be unable to obtain commercially reasonable product liability insurance for any products approved for marketing. On occasion, large judgments have been awarded in class action lawsuits based on drugs that had unanticipated side effects. A successful product liability claim or series of claims brought against us could cause our stock price to fall and, if judgments exceed our insurance coverage, could decrease our cash and adversely affect our business.

We may be exposed to liability claims associated with the use of hazardous materials and chemicals.

Our research and development activities may involve the controlled use of hazardous materials and chemicals. Although we believe that our safety procedures for using, storing, handling and disposing of these materials comply with federal, state and local laws and regulations, we cannot completely eliminate the risk of accidental injury or contamination from these materials. In the event of such an accident, we could be held liable for any resulting damages and any liability could materially adversely affect our business, financial condition and results of operations. In addition, the federal, state and local laws and regulations governing the use, manufacture, storage, handling and disposal of hazardous or radioactive materials and waste products may require us to incur substantial compliance costs that could materially adversely affect our business, financial condition and results of operations.

We are controlled by current directors, officers, and principal stockholders.

Our directors, officers, and principal stockholders beneficially own approximately 36% of our outstanding voting securities. Accordingly, our executive officers, directors, and principal stockholders will have the ability to exert substantial influence over the election of our Board of Directors and the outcome of issues submitted to our stockholders.

We are required to implement additional finance and accounting systems, procedures and controls in order to satisfy requirements under the securities laws, including the Sarbanes-Oxley Act of 2002, which increase our costs and divert management's time and attention.

We have established processes, controls and procedures that will allow our management to report on, and our independent registered public accounting firm to attest to, our internal control over financial reporting when required to do so under Section 404 of the Sarbanes-Oxley Act of 2002. Additionally, we periodically review the effectiveness of our internal controls and procedures with a continuous improvement philosophy.

As a company with limited capital and human resources, we anticipate that more of management's time and attention will be diverted from our business to ensure compliance with these regulatory requirements than would be the case with a company that has well established controls and procedures. This diversion of management's time and attention may have a material adverse effect on our business, financial condition and results of operations.

In the event we identify significant deficiencies or material weaknesses in our internal control over financial reporting that we cannot remediate in a timely manner, or if we are unable to receive a positive attestation from our independent registered public accounting firm with respect to our internal control over financial reporting when we are required to do so, investors and others may lose confidence in the reliability of our financial statements. If this occurs, the trading price of our common stock, if any, and ability to obtain any necessary equity or debt financing could suffer. In addition, in the event that our independent registered public accounting firm is unable to rely on our internal control over financial reporting in connection with its audit of our financial statements, and in the further event that it is unable to devise alternative procedures in order to satisfy itself as to the material accuracy of our financial statements and related disclosures, we may be unable to file our periodic reports with the SEC. This would likely have an adverse affect on the trading price of our common stock, if any, and our ability to secure any necessary additional financing, and could result in the delisting of our common stock. In such event, the liquidity of our common stock would be severely limited and the market price of our common stock would likely decline significantly.

Our internal controls over financial reporting have not been audited by our external auditors, as will be required for the fiscal year 2009 to meet the standards contemplated by Section 404 of the Sarbanes-Oxley Act of 2002; failure to achieve and maintain effective internal controls over financial reporting in accordance with Section 404 of the Sarbanes-Oxley Act of 2002 could have a material adverse effect on our business and common stock price.

Our internal controls over financial reporting have not been audited by our independent registered public accounting firm as will be required for fiscal year 2009 by Section 404 of the Sarbanes-Oxley Act. In 2008, we completed financial control process mapping. We focused on identification of key financial reporting risks, an assessment of their potential impact and linkage of those risks to specific areas and activities within our organization. Additionally, we performed internal testing on our internal controls.

Because our financial controls have not been audited to assess if we are in accordance with Section 404, our independent registered public accounting firm will not be able to certify as to the adequacy of our internal controls over financial reporting. We do not have external certification that we do not have a material weakness in our internal controls or a combination of significant deficiencies that could result in the conclusion that we have a material weakness in our internal controls. If we are not able to implement the requirements of Section 404 in a timely manner or with adequate compliance, our independent registered public accounting firm may not be able to certify as to the adequacy of our internal controls over financial reporting. Matters impacting our internal controls may cause us to be unable to report our financial information on a timely basis and thereby subject us to adverse regulatory consequences, including sanctions by the SEC or violations of applicable stock exchange listing rules. There could also be a negative reaction in the financial markets due to a loss of investor confidence in us and the reliability of our financial statements. Confidence in the reliability of our financial statements could also suffer if our independent registered public accounting firm were to report a material weakness in our internal controls over financial reporting. This could materially adversely affect us and lead to a decline in the market price of our common stock.

Recent turmoil in the financial markets and the global recession has adversely affected and may continue to adversely affect our industry, business and ability to obtain financing.

Recent global market and economic conditions have been unprecedented and challenging with tighter credit conditions and recession in most major economies continuing into 2009. Continued concerns about the systemic impact of potential long-term and wide-spread recession, energy costs, geopolitical issues, the availability and cost of credit, and the global housing and mortgage markets have contributed to increased market volatility and diminished expectations for western and emerging economies. In the second half of 2008, added concerns fueled by the U.S. government conservatorship of the Federal Home Loan Mortgage Corporation and the Federal National Mortgage Association, the declared bankruptcy of Lehman Brothers Holdings Inc., the U.S. government financial assistance to American International Group Inc., Citibank, Bank of America and other federal government interventions in the U.S. financial system lead to increased market uncertainty and instability in both U.S. and international capital and credit markets. These conditions, combined with volatile oil prices, declining business and consumer confidence and increased unemployment, have contributed to volatility of unprecedented levels.

As a result of these market conditions, the cost and availability of credit has been and may continue to be adversely affected by illiquid credit markets and wider credit spreads. Concern about the stability of the markets generally and the strength of counterparties specifically has led many lenders and institutional investors to reduce, and in some cases, cease to provide credit to businesses and consumers. These factors have lead to a decrease in spending by businesses and consumers alike, and a corresponding decrease in global infrastructure spending. Continued turbulence in the U.S. and international markets and economies and prolonged declines in business consumer spending may adversely affect our liquidity and financial condition, including our ability to refinance any maturing liabilities and access the capital markets to meet liquidity needs. If the conditions in the U.S. and world economic markets remain uncertain or continue to be volatile, or if they deteriorate further, our industry and business may be adversely affected.

Risks Relating to the Clinical Testing, Regulatory Approval, Manufacturing and Commercialization of Our Product Candidates:

Delays in the commencement, enrollment, and completion of clinical testing could result in increased costs to us and delay or limit our ability to obtain regulatory approval for our product candidates.

Delays in the commencement, enrollment, and completion of clinical testing could also significantly affect our product development costs. We do not know whether planned clinical trials for CD-NP will begin on time or be completed on schedule, if at all. The commencement and completion of clinical trials requires us to identify and maintain a sufficient number of trial sites, many of which

may already be engaged in other clinical trial programs for the same indication as our product candidates, may be required to withdraw from a clinical trial as a result of changing standards of care, or may become ineligible to participate in clinical studies.

The commencement, enrollment, and completion of clinical trials can be delayed for a variety of other reasons, including delays related to:

- reaching agreements on acceptable terms with prospective clinical research organizations, or CROs, and trial sites, the terms of which can be subject to extensive negotiation and may vary significantly among different CROs and trial sites;
- obtaining regulatory approval to commence a clinical trial;
- obtaining institutional review board, or IRB, approval to conduct a clinical trial at numerous prospective sites;
- recruiting and enrolling patients to participate in clinical trials for a variety of reasons, including meeting the enrollment criteria for our study and competition from other clinical trial programs for the same indication as our product candidates; and
- retaining patients who have initiated a clinical trial but may be prone to withdraw due to the treatment protocol, lack of efficacy, personal issues, or side effects from the therapy, or who are lost to further follow-up;
- maintaining and supplying clinical trial material on a timely basis;
- complying with design protocols of any applicable special protocol assessment we receive from the FDA; and
- collecting, analyzing and reporting final data from the clinical trials.

In addition, a clinical trial may be suspended or terminated by us, the FDA, or other regulatory authorities due to a number of factors, including:

- failure to conduct the clinical trial in accordance with regulatory requirements or our clinical protocols;
- inspection of the clinical trial operations or trial sites by the FDA or other regulatory authorities resulting in the imposition of a clinical hold;
- unforeseen safety issues or any determination that a trial presents unacceptable health risks; or
- lack of adequate funding to continue the clinical trial, including the incurrence of unforeseen costs due to enrollment delays, requirements to conduct additional trials and studies, and increased expenses associated with the services of our CROs and other third parties.

If we are required to conduct additional clinical trials or other testing of our product candidates beyond those that we currently contemplate, particularly for our CD-NP and CU-NP product candidates, we may be delayed in obtaining, or may not be able to obtain, marketing approval for these product candidates. Based upon our discussions with the FDA, we intend to conduct clinical programs for each of our CD-NP and CU-NP product candidates. We may not be able to obtain approval for indications that are as broad as intended, or we may be able to obtain approval only for indications that are entirely different than those indications for which we sought approval.

Additionally, changes in regulatory requirements and guidance may occur, and we may need to amend clinical trial protocols to reflect these changes with appropriate regulatory authorities. Amendments may require us to resubmit our clinical trial protocols to IRBs for re-examination, which may impact the costs, timing, or successful completion of a clinical trial. If we experience delays in the completion of, or if we terminate, our clinical trials, the commercial prospects for our product candidates will be harmed, and our ability to generate product revenues will be delayed. In addition, many of the factors that cause, or lead to, a delay in the commencement or completion of clinical trials may also ultimately lead to the denial of regulatory approval of a product candidate. Even if we are able to ultimately commercialize our product candidates, other therapies for the same or similar indications may have been introduced to the market and established a competitive advantage.

Any delays in obtaining regulatory approvals may:

- delay commercialization of, and our ability to derive product revenues from, our product candidates;
- impose costly procedures on us; or
- diminish any competitive advantages that we may otherwise enjoy.

If we do not establish strategic partnerships, we will have to undertake development and commercialization efforts on our own, which would be costly and delay our ability to commercialize any future products.

An element of our business strategy includes potentially partnering with pharmaceutical, biotechnology and other companies to obtain assistance for the development and potential commercialization of our product candidates, including the cash and other resources we need for such development and potentially commercialization. We intend to enter into potential strategic partnerships with third parties to develop and commercialize our product candidates that are intended for larger markets, and we may enter into strategic partnerships for product candidates that are targeted toward specialty markets. We face significant competition in seeking appropriate strategic partners, and these potential strategic partnerships can be intricate and time consuming to negotiate and document. We may not be able to negotiate strategic partnerships on acceptable terms, or at all. We are unable to predict when, if ever, we will enter into any potential strategic partnerships because of the numerous risks and uncertainties associated with establishing strategic partnerships. If we are unable to negotiate strategic partnerships for our product candidates we may be forced to curtail the development of a particular candidate, reduce or delay its development program, delay its potential commercialization, reduce the scope of our sales or marketing activities or undertake development or commercialization activities at our own expense. In addition, we will bear all the risk related to the development of that product candidate. If we elect to increase our expenditures to fund development or commercialization activities on our own, we will need to obtain additional capital, which may not be available to us on acceptable terms, or at all. If we do not have sufficient funds, we will not be able to bring our product candidates to market and generate product revenue.

If we enter into strategic partnerships, we may be required to relinquish important rights to and control over the development of our product candidates or otherwise be subject to terms unfavorable to us.

If we enter into any strategic partnerships with pharmaceutical or biotechnology companies we will be subject to a number of risks, including:

- we may not be able to control the amount and timing of resources that our strategic partners devote to the development or commercialization of product candidates;
- strategic partners may delay clinical trials, provide insufficient funding, terminate a clinical trial or abandon a product candidate, repeat or conduct new clinical trials or require a new version of a product candidate for clinical testing;
- strategic partners may not pursue further development and commercialization of products resulting from the strategic partnering arrangement or may elect to discontinue research and development programs;
- strategic partners may not commit adequate resources to the marketing and distribution of any future products, limiting our potential revenues from these products;
- disputes may arise between us and our strategic partners that result in the delay or termination of the research, development or commercialization of our product candidates or that result in costly litigation or arbitration that diverts management’s attention and consumes resources;
- strategic partners may experience financial difficulties;
- strategic partners may not properly maintain or defend our intellectual property rights or may use our proprietary information in a manner that could jeopardize or invalidate our proprietary information or expose us to potential litigation;
- business combinations or significant changes in a strategic partner’s business strategy may also adversely affect a strategic partner’s willingness or ability to complete its obligations under any arrangement; and

- strategic partners could independently move forward with a competing product candidate developed either independently or in collaboration with others, including our competitors.

As the results of earlier clinical trials are not necessarily predictive of future results, CD-NP, CU-NP or any other product candidate we advance into clinical trials may not have favorable results in later clinical trials or receive regulatory approval.

Even if our clinical trials are completed as planned, we cannot be certain that their results will support the claims of our product candidates. Success in pre-clinical testing and early clinical trials does not ensure that later clinical trials will be successful, and we cannot be sure that the results of later clinical trials will replicate the results of prior clinical trials and pre-clinical testing. A number of companies in the pharmaceutical industry, including those with greater resources and experience, have suffered significant setbacks in Phase III clinical trials, even after seeing promising results in earlier clinical trials.

Our clinical trial process may fail to demonstrate that our product candidates are safe for humans and effective for indicated uses. This failure would cause us to abandon a product candidate and may delay development of other product candidates. Any delay in, or termination of, our clinical trials will delay the filing of our NDAs with the FDA and, ultimately, our ability to commercialize our product candidates and generate product revenues. In addition, our clinical trials involve a small patient population. Because of the small sample size, the results of these clinical trials may not be indicative of future results.

The data collected from our clinical trials may not be adequate to support regulatory approval of CD-NP or any of our other product candidates. Despite the results reported in earlier clinical trials for our product candidates, we do not know whether any Phase IIb, Phase III or other clinical programs we may conduct will demonstrate adequate efficacy and safety to result in regulatory approval to market our product candidates.

Each of our product candidates is in an early stage of development.

Each of our product candidates, CD-NP and CU-NP, is in an early stage of development and requires extensive clinical testing before it will be approved by the FDA or another regulatory authority in a jurisdiction outside the United States. We cannot predict with any certainty the results of such clinical testing. We cannot predict with any certainty if, or when, we might commence any such clinical trials or whether such trials will yield sufficient data to permit us to proceed with additional clinical development and ultimately submit an application for regulatory approval of our product candidates in the United States or abroad, or whether such applications will be accepted by the appropriate regulatory agency.

Our products use novel alternative technologies and therapeutic approaches, which have not been widely studied.

Our product development efforts focus on novel alternative technologies and therapeutic approaches that have not been widely studied. These approaches and technologies may not be successful. We are applying these approaches and technologies in our attempt to discover new treatments for conditions that are also the subject of research and development efforts of many other companies.

Our drug-development program depends upon third-party researchers who are outside our control.

We will depend upon independent investigators and collaborators, such as universities and medical institutions, to conduct our pre-clinical and clinical trials under agreements with us. These collaborators are not our employees, and we cannot control the amount or timing of resources that they devote to our programs. These investigators may not assign as great a priority to our programs or pursue them as diligently as we would if we were undertaking such programs ourselves. If outside collaborators fail to devote sufficient time and

resources to our drug-development programs, or if their performance is substandard, the approval of our FDA applications, if any, and our introduction of new drugs, if any, will be delayed. These collaborators may also have relationships with other commercial entities, some of whom may compete with us. If our collaborators assist our competitors at our expense, our competitive position would be harmed.

We rely exclusively on third parties to formulate and manufacture our product candidates.

We have no experience in drug formulation or manufacturing and do not intend to establish our own manufacturing facilities. We lack the resources and expertise to formulate or manufacture our own product candidates. We currently, and intend in the future to, contract with one or more manufacturers to manufacture, supply, store, and distribute drug supplies for our clinical trials. If any of our product candidates receive FDA approval, we will rely on one or more third-party contractors to manufacture our drugs. Our anticipated future reliance on a limited number of third-party manufacturers exposes us to the following risks:

- We may be unable to identify manufacturers on acceptable terms or at all, because the number of potential manufacturers is limited, and subsequent to NDA approval, the FDA must approve any replacement contractor. This approval would require new testing and compliance inspections. In addition, a new manufacturer may have to be educated in, or develop substantially equivalent processes for, production of our products after receipt of FDA approval, if any.
- Our third-party manufacturers might be unable to formulate and manufacture our drugs in the volume and of the quality required to meet our clinical and commercial needs, if any.
- Our future contract manufacturers may not perform as agreed or may not remain in the contract manufacturing business for the time required to supply our clinical trials or to successfully produce, store, and distribute our products.
- Drug manufacturers are subject to ongoing periodic unannounced inspection by the FDA, the Drug Enforcement Agency, and corresponding state agencies to ensure strict compliance with good manufacturing practice and other government regulations and corresponding foreign standards. We do not have control over third-party manufacturers' compliance with these regulations and standards.

Each of these risks could delay our clinical trials, the approval, if any, of our product candidates by the FDA, or the commercialization of our product candidates, or result in higher costs or deprive us of potential product revenues.

Our product candidates may have undesirable side effects and cause our approved drugs to be taken off the market.

If any of our product candidates receive marketing approval and we or others later identify undesirable side effects caused by such products:

- regulatory authorities may require the addition of labeling statements, specific warnings, a contraindication, or field alerts to physicians and pharmacies;
- regulatory authorities may withdraw their approval of the product;
- we may be required to change the way the product is administered, conduct additional clinical trials or change the labeling of the product;
- we may have limitations on how we promote our drugs;
- regulatory authorities may require us to take our approved drug off the market;
- sales of products may decrease significantly;
- we may be subject to litigation or product liability claims; and
- our reputation may suffer.

Any of these events could prevent us from achieving or maintaining market acceptance of the affected product or could substantially increase our commercialization costs and expenses, which in turn could delay or prevent us from generating significant revenues from its sale.

We are largely dependent on the success of our two product candidates, CD-NP and CU-NP, and we cannot be certain that either of these product candidates will receive regulatory approval to be commercialized.

We will need FDA approval to commercialize our product candidates in the United States and approvals from the FDA-equivalent regulatory authorities in foreign jurisdictions to commercialize our product candidates in those jurisdictions. In order to obtain FDA approval of any of our product candidates, we must submit to the FDA an NDA demonstrating that the product candidate is safe for humans and effective for its intended use. This demonstration requires significant research and animal tests, which are referred to as pre-clinical studies, as well as human tests, which are referred to as clinical trials. Satisfaction of the FDA's regulatory requirements typically takes many years, depends upon the type, complexity, and novelty of the product candidate, and requires substantial resources for research, development, and testing. We cannot predict whether our research and clinical approaches will result in drugs that the FDA considers safe for humans and effective for indicated uses. The FDA has substantial discretion in the drug approval process and may require us to conduct additional pre-clinical and clinical testing or to perform post-marketing studies. The approval process may also be delayed by changes in government regulation, future legislation, or administrative action or changes in FDA policy that occur prior to or during our regulatory review.

Even if we comply with all FDA requests, the FDA may ultimately reject one or more of our NDAs. We cannot be sure that we will ever obtain regulatory clearance for our product candidates. Failure to obtain FDA approval of any of our product candidates will severely undermine our business by reducing our number of salable products and, therefore, corresponding product revenues, and will have a material and adverse impact on our business.

Even if our product candidates receive regulatory approval in the United States, we may never receive approval or commercialize our products outside of the United States.

In order to market and commercialize any products outside of the United States, we must establish and comply with numerous and varying regulatory requirements of other countries regarding safety and efficacy. Approval procedures vary among countries and can involve additional product testing and additional administrative review periods. For example, European regulatory authorities generally require a trial comparing the efficacy of the new drug to an existing drug prior to granting approval. The time required to obtain approval in other countries might differ from that required to obtain FDA approval. The regulatory approval process in other countries may include all of the risks detailed above regarding FDA approval in the United States as well as other risks. Regulatory approval in one country does not ensure regulatory approval in another, but a failure or delay in obtaining regulatory approval in one country may have a negative effect on the regulatory approval process in others. Failure to obtain regulatory approval in other countries or any delay or setback in obtaining such approval could have the same adverse effects detailed above regarding FDA approval in the United States. Such effects include the risks that our product candidates may not be approved for all indications requested, which could limit the uses of our product candidates and have an adverse effect on product sales and potential royalties, and that such approval may be subject to limitations on the indicated uses for which the product may be marketed or require costly, post-marketing follow-up studies.

If clinical trials of our CD-NP and CU-NP product candidates or future product candidates do not produce results necessary to support regulatory approval in the United States or elsewhere or show undesirable side effects, we will be unable to commercialize these products.

To receive regulatory approval for the commercial sale of CD-NP, CU-NP or any other product candidates, we must conduct adequate and well-controlled clinical trials to demonstrate efficacy and safety in humans. Clinical testing is expensive, takes many years and has an uncertain outcome. Clinical failure can occur at any stage of the testing. Our clinical trials may produce negative or inconclusive results, and we may decide, or regulators may require us, to conduct additional clinical and/or non-clinical testing. In addition, the results of our clinical trials may show that our product candidates may cause undesirable side effects, which could interrupt, delay or halt clinical trials, resulting in the denial of regulatory approval by the FDA and other regulatory authorities.

In light of widely publicized events concerning the safety risk of certain drug products, regulatory authorities, members of Congress, the Government Accounting Office, medical professionals and the general public have raised concerns about potential drug safety issues. These events have resulted in the withdrawal of drug products, revisions to drug labeling that further limit use of the drug products and establishment of risk management programs that may, for instance, restrict distribution of drug products. The increased attention to drug safety issues may result in a more cautious approach by the FDA to clinical trials. Data from clinical trials may receive greater scrutiny with respect to safety, which may make the FDA or other regulatory authorities more likely to terminate clinical trials before completion, or require longer or additional clinical trials that may result in substantial additional expense and a delay or failure in obtaining approval or approval for a more limited indication than originally sought.

Our failure to adequately demonstrate the efficacy and safety of CD-NP, CU-NP or any other product candidates would prevent regulatory approval and, ultimately, the commercialization of that product candidate.

We have no experience selling, marketing, or distributing products and no internal capability to do so. If we are unable to establish an effective and focused sales force and marketing infrastructure, we will not be able to commercialize our product candidates successfully.

We currently have no sales, marketing, or distribution capabilities. We do not anticipate having resources in the foreseeable future to allocate to the sales and marketing of our proposed products. Our future success depends, in part, on our ability to enter into and maintain sales and marketing collaborative relationships, or on our ability to build sales and marketing capabilities internally. If we enter into a sales and marketing collaborative relationship, then we will be dependent upon the collaborator's strategic interest in the products under development, and such collaborator's ability to successfully market and sell any such products. We intend to pursue collaborative arrangements regarding the sales and marketing of our products, however, there can be no assurance that we will be able to establish or maintain such collaborative arrangements, or if able to do so, that they will have effective sales forces. To the extent that we decide not to, or are unable to, enter into collaborative arrangements with respect to the sales and marketing of our proposed products, significant capital expenditures, management resources, and time will be required to establish and develop an in-house marketing and sales force with technical expertise. There can also be no assurance that we will be able to establish or maintain relationships with third-party collaborators or develop in-house sales and distribution capabilities. To the extent that we depend on third parties for marketing and distribution, any revenues we receive will depend upon the efforts of such third parties, and there can be no assurance that such efforts will be successful. In addition, there can also be no assurance that we will be able to market and sell our product in the United States or overseas.

We will experience intense competition with respect to our existing and future product candidates.

The pharmaceutical industry is highly competitive, with a number of established, large pharmaceutical companies, as well as many smaller companies. Many of these companies have greater financial resources, marketing capabilities, and experience in obtaining regulatory approvals for product candidates. There are many pharmaceutical companies, biotechnology companies, public and private universities, government agencies, and research organizations actively engaged in research and development of products which may target the same indications as our product candidates. We expect any future products we develop to compete on the basis of, among other things, product efficacy and safety, time to market, price, extent of adverse side effects, and convenience of treatment procedures. One or more of our competitors may develop products based upon the principles underlying our proprietary technologies earlier than us, obtain approvals for such products from the FDA more rapidly than us, or develop alternative products or therapies that are safer, more effective and/or more cost effective than any products developed by us.

Competitors may seek to develop alternative formulations of our product candidates that address our targeted indications. The commercial opportunity for our product candidates could be significantly harmed if competitors are able to develop alternative formulations outside the scope of our products. Compared to us, many of our potential competitors have substantially greater:

- capital resources;
- development resources, including personnel and technology;
- clinical trial experience;
- regulatory experience;
- expertise in prosecution of intellectual property rights;
- manufacturing and distribution experience; and
- sales and marketing experience.

As a result of these factors, our competitors may obtain regulatory approval of their products more rapidly than we are able to or may obtain patent protection or other intellectual property rights that limit our ability to develop or commercialize our product candidates. Our competitors may also develop drugs that are more effective, useful, and less costly than ours, and may also be more successful than us in manufacturing and marketing their products.

Developments by competitors may render our products or technologies obsolete or non-competitive.

The biotechnology and pharmaceutical industries are intensely competitive and subject to rapid and significant technological change. The drugs that we are attempting to develop will have to compete with existing therapies. In addition, a large number of companies are pursuing the development of pharmaceuticals that target the same diseases and conditions that we are targeting. We face competition from pharmaceutical and biotechnology companies in the United States and abroad. In addition, companies pursuing different but related fields represent substantial competition. Many of these organizations competing with us have substantially greater capital resources, larger research and development staffs and facilities, longer drug development history in obtaining regulatory approvals, and greater manufacturing and marketing capabilities than we do. These organizations also compete with us to attract qualified personnel and parties for acquisitions, joint ventures, or other collaborations.

If any of our product candidates for which we receive regulatory approval do not achieve broad market acceptance, the revenues that we generate from their sales will be limited.

The commercial success of our product candidates for which we obtain marketing approval from the FDA or other regulatory authorities will depend upon the acceptance of these products among physicians, the medical community, and patients, and coverage and reimbursement of them by third-party payors, including government payors. The degree of market acceptance of any of our approved products will depend on a number of factors, including:

- limitations or warnings contained in a product's FDA-approved labeling;
- changes in the standard of care for the targeted indications for any of our product candidates, which could reduce the marketing impact of any claims that we could make following FDA approval;
- limitations inherent in the approved indication for any of our product candidates compared to more commonly understood or addressed conditions;
- lower demonstrated clinical safety and efficacy compared to other products;
- prevalence and severity of adverse effects;
- ineffective marketing and distribution efforts;
- lack of availability of reimbursement from managed care plans and other third-party payors;
- lack of cost-effectiveness;
- timing of market introduction and perceived effectiveness of competitive products;
- availability of alternative therapies at similar costs; and
- potential product liability claims.

Our ability to effectively promote and sell our product candidates in the marketplace will also depend on pricing and cost effectiveness, including our ability to manufacture a product at a competitive price. We will also need to demonstrate acceptable evidence of safety and efficacy and may need to demonstrate relative convenience and ease of administration. Market acceptance could be further limited depending on the prevalence and severity of any expected or unexpected adverse side effects associated with our product candidates. If our product candidates are approved but do not achieve an adequate level of acceptance by physicians, health care payors, and patients, we may not generate sufficient revenue from these products, and we may not become or remain profitable. In addition, our efforts to educate the medical community and third-party payors on the benefits of our product candidates may require significant resources and may never be successful. If our approved drugs fail to achieve market acceptance, we will not be able to generate significant revenue, if any.

Even if our product candidates receive regulatory approval, we may still face future development and regulatory difficulties.

Even if United States regulatory approval is obtained, the FDA may still impose significant restrictions on a product's indicated uses or marketing, or impose ongoing requirements for potentially costly post-approval studies. Given the number of recent high-profile adverse safety events with certain drug products, the FDA may require, as a condition of approval, costly risk management programs which may include safety surveillance, restricted distribution and use, patient education, enhanced labeling, special packaging or labeling, expedited reporting of certain adverse events, pre-approval of promotional materials, and restrictions on direct-to-consumer advertising. Furthermore, heightened Congressional scrutiny on the adequacy of the FDA's drug approval process and the agency's efforts to assure the safety of marketed drugs has resulted in the proposal of new legislation addressing drug safety issues. If enacted, any new legislation could result in delays or increased costs during the period of product development, clinical trials, and regulatory review and approval, as well as increased costs to assure compliance with any new post-approval regulatory requirements. Any of these restrictions or requirements could force us to conduct costly studies or increase the time for us to become profitable. For example, any labeling approved for CD-NP, CU-NP, or any other product candidates may include a restriction on the term of its use, or it may not include one or more of our intended indications.

Our product candidates will also be subject to ongoing FDA requirements for the labeling, packaging, storage, advertising, promotion, record-keeping, and submission of safety and other post-market information on the drug. In addition, approved products, manufacturers, and manufacturers' facilities are subject to continual review and periodic inspections. If a regulatory agency discovers previously unknown problems with a product, such as adverse events of unanticipated severity or frequency, or problems with the facility where the product is manufactured, a regulatory agency may impose restrictions on that product or us, including requiring withdrawal of the product from the market. If our product candidates fail to comply with applicable regulatory requirements, such as current cGMPs, a regulatory agency may:

- issue warning letters;
- require us to enter into a consent decree, which can include imposition of various fines, reimbursements for inspection costs, required due dates for specific actions, and penalties for noncompliance;
- impose other civil or criminal penalties;
- suspend regulatory approval;
- suspend any ongoing clinical trials;
- refuse to approve pending applications or supplements to approved applications filed by us;
- impose restrictions on operations, including costly new manufacturing requirements; or
- seize or detain products or require a product recall.

Our ability to generate product revenues will be diminished if our drugs sell for inadequate prices or patients are unable to obtain adequate levels of reimbursement.

Successful sales of our products depend on the availability of adequate coverage and reimbursement from third-party payors. Healthcare providers that purchase medicine or medical products for treatment of their patients generally rely on third-party payors to reimburse all or part of the costs and fees associated with the products. Adequate coverage and reimbursement from governmental, such as Medicare and Medicaid, and commercial payors is critical to new product acceptance. Patients are unlikely to use our products if they do not receive reimbursement adequate to cover the cost of our products.

In addition, the market for our future products will depend significantly on access to third-party payors' drug formularies, or lists of medications for which third-party payors provide coverage and reimbursement. Industry competition to be included in such formularies results in downward pricing pressures on pharmaceutical companies. Third-party payors may refuse to include a particular branded drug in their formularies when a generic equivalent is available.

All third-party payors, whether governmental or commercial, whether inside the United States or outside, are developing increasingly sophisticated methods of controlling healthcare costs. In addition, in the United States, no uniform policy of coverage and reimbursement for medical technology exists among all these payors. Therefore, coverage of and reimbursement for medical products can differ significantly from payor to payor.

Further, we believe that future coverage and reimbursement may be subject to increased restrictions both in the United States and in international markets. Third-party coverage and reimbursement for our products may not be available or adequate in either the United States or international markets, limiting our ability to sell our products on a profitable basis.

Significant uncertainty exists as to the reimbursement status of newly approved healthcare products. Healthcare payors, including Medicare, are challenging the prices charged for medical products and services. Government and other healthcare payors increasingly attempt to contain healthcare costs by limiting both coverage and the level of reimbursement for drugs. Even if our product candidates are approved by the FDA, insurance coverage may not be available, and reimbursement levels may be inadequate, to cover our drugs. If government and other healthcare payors do not provide adequate coverage and reimbursement levels for any of our products, once approved, market acceptance of our products could be reduced.

Risks Related to Our Intellectual Property:

It is difficult and costly to protect our proprietary rights, and we may not be able to ensure their protection. If we fail to protect or enforce our intellectual property rights adequately or secure rights to patents of others, the value of our intellectual property rights would diminish.

Our commercial success will depend in part on obtaining and maintaining patent protection and trade secret protection of our product candidates, and the methods used to manufacture them, as well as successfully defending these patents against third-party challenges. Our ability to stop third parties from making, using, selling, offering to sell, or importing our products is dependent upon the extent to which we have rights under valid and enforceable patents or trade secrets that cover these activities.

We license certain intellectual property from third parties that covers our product candidates. We rely on certain of these third parties to file, prosecute, and maintain patent applications, and otherwise protect the intellectual property to which we have a license, and we have not had and do not have primary control over these activities for certain of these patents or patent applications and other intellectual property rights. We cannot be certain that such activities by third parties have been or will be conducted in compliance with applicable laws and regulations, or will result in valid and enforceable patents and other intellectual property rights. Our enforcement of certain of these licensed patents or defense of any claims asserting the invalidity of these patents would also be subject to the cooperation of the third parties.

The patent positions of pharmaceutical and biopharmaceutical companies can be highly uncertain and involve complex legal and factual questions for which important legal principles remain unresolved. No consistent policy regarding the breadth of claims allowed in biopharmaceutical patents has emerged to date in the United States. The biopharmaceutical patent situation outside the United States is even more uncertain. Changes in either the patent laws or in interpretations of patent laws in the United States and other countries may diminish the value of our intellectual property. Accordingly, we cannot predict the breadth of claims that may be allowed or enforced in the patents we own or to which we have a license or third-party patents. Further, if any of our patents are deemed invalid and unenforceable, it could impact our ability to commercialize or license our technology.

The degree of future protection for our proprietary rights is uncertain because legal means afford only limited protection and may not adequately protect our rights or permit us to gain or keep our competitive advantage. For example:

- others may be able to make compounds that are similar to our product candidates but that are not covered by the claims of any of our patents;
- we might not have been the first to make the inventions covered by any issued patents or patent applications we may have (or third parties from whom we license intellectual property may have);
- we might not have been the first to file patent applications for these inventions;
- others may independently develop similar or alternative technologies or duplicate any of our technologies;
- it is possible that any pending patent applications we may have will not result in issued patents;
- any issued patents may not provide us with any competitive advantages, or may be held invalid or unenforceable as a result of legal challenges by third parties;

- we may not develop additional proprietary technologies that are patentable; or
- the patents of others may have an adverse effect on our business.

We also may rely on trade secrets to protect our technology, especially where we do not believe patent protection is appropriate or obtainable. However, trade secrets are difficult to protect. Although we use reasonable efforts to protect our trade secrets, our employees, consultants, contractors, outside scientific collaborators, and other advisors may unintentionally or willfully disclose our information to competitors. Enforcing a claim that a third party illegally obtained and is using any of our trade secrets is expensive and time consuming, and the outcome is unpredictable. In addition, courts outside the United States are sometimes less willing to protect trade secrets. Moreover, our competitors may independently develop equivalent knowledge, methods, and know-how.

If any of our trade secrets, know-how or other proprietary information is disclosed, the value of our trade secrets, know-how and other proprietary rights would be significantly impaired and our business and competitive position would suffer.

Our success also depends upon the skills, knowledge and experience of our scientific and technical personnel, our consultants and advisors as well as our licensors and contractors. To help protect our proprietary know-how and our inventions for which patents may be unobtainable or difficult to obtain, we rely on trade secret protection and confidentiality agreements. To this end, we require all of our employees, consultants, advisors and contractors to enter into agreements which prohibit the disclosure of confidential information and, where applicable, require disclosure and assignment to us of the ideas, developments, discoveries and inventions important to our business. These agreements may not provide adequate protection for our trade secrets, know-how or other proprietary information in the event of any unauthorized use or disclosure or the lawful development by others of such information. If any of our trade secrets, know-how or other proprietary information is disclosed, the value of our trade secrets, know-how and other proprietary rights would be significantly impaired and our business and competitive position would suffer.

We may incur substantial costs as a result of litigation or other proceedings relating to patent and other intellectual property rights and we may be unable to protect our rights to, or use of, our technology.

If we choose to go to court to stop someone else from using the inventions claimed in our patents, that individual or company has the right to ask the court to rule that these patents are invalid and/or should not be enforced against that third party. These lawsuits are expensive and would consume time and other resources even if we were successful in stopping the infringement of these patents. In addition, there is a risk that the court will decide that these patents are not valid and that we do not have the right to stop the other party from using the inventions. There is also the risk that, even if the validity of these patents is upheld, the court will refuse to stop the other party on the ground that such other party's activities do not infringe our rights to these patents. In addition, the United States Supreme Court has recently invalidated some tests used by the United States Patent and Trademark Office, or USPTO, in granting patents over the past 20 years. As a consequence, several issued patents may be found to contain invalid claims according to the newly revised standards. Some of our own or in-licensed patents may be subject to challenge and subsequent invalidation in a re-examination proceeding before the USPTO or during litigation under the revised criteria which make it more difficult to obtain patents.

Furthermore, a third party may claim that we or our manufacturing or commercialization partners are using inventions covered by the third party's patent rights and may go to court to stop us from engaging in our normal operations and activities, including making or selling our product candidates. These lawsuits are costly and could affect our results of operations and divert the attention of managerial and technical personnel. There is a risk that a court would decide that we or our commercialization partners are infringing the third party's patents and would order us or our partners to stop the activities covered by the patents. In addition, there is a risk that a court will order us or our partners to pay the other party damages for having violated the other party's patents. We have agreed to indemnify certain of our commercial partners against certain patent infringement claims brought by third parties. The biotechnology industry has produced a proliferation of patents, and it is not always clear to industry participants, including us, which patents cover various types of products or methods of use. The coverage of patents is subject to interpretation by the courts, and the interpretation is not always uniform. If we are sued for patent infringement, we would need to demonstrate that our products or methods of use either do not infringe the patent claims of the relevant patent and/or that the patent claims are invalid, and we may not be able to do this. Proving invalidity, in particular, is difficult since it requires a showing of clear and convincing evidence to overcome the presumption of validity enjoyed by issued patents.

Because some patent applications in the United States may be maintained in secrecy until the patents are issued, because patent applications in the United States and many foreign jurisdictions are typically not published until eighteen months after filing, and because publications in the scientific literature often lag behind actual discoveries, we cannot be certain that others have not filed patent applications for technology covered by our issued patents or our pending applications, or that we were the first to invent the technology.

Our competitors may have filed, and may in the future file, patent applications covering technology similar to ours. Any such patent application may have priority over our patent applications or patents, which could further require us to obtain rights to issued patents covering such technologies. If another party has filed a United States patent application on inventions similar to ours, we may have to participate in an interference proceeding declared by the USPTO to determine priority of invention in the United States. The costs of these proceedings could be substantial, and it is possible that such efforts would be unsuccessful if unbeknownst to us, the other party had independently arrived at the same or similar invention prior to our own invention, resulting in a loss of our United States patent position with respect to such inventions.

Some of our competitors may be able to sustain the costs of complex patent litigation more effectively than we can because they have substantially greater resources. In addition, any uncertainties resulting from the initiation and continuation of any litigation could have a material adverse effect on our ability to raise the funds necessary to continue our operations.

If requirements under our license agreements are not met, we could suffer significant harm, including losing rights to our products.

We depend on licensing agreements with third parties to maintain the intellectual property rights to our products under development. Presently, we have licensed rights from Mayo for both of our products. These agreements require us and our licensors to perform certain obligations that affect our rights under these licensing agreements. All of these agreements last either throughout the life of the patents, or with respect to other licensed technology, for a number of years after the first commercial sale of the relevant product. If we fail to comply with our obligations in our intellectual property licenses with third parties, we could lose license rights that are important to our business.

In addition, we are responsible for the cost of filing and prosecuting certain patent applications and maintaining certain issued patents licensed to us. If we do not meet our obligations under our license agreements in a timely manner, we could lose the rights to our proprietary technology.

Finally, we may be required to obtain licenses to patents or other proprietary rights of third parties in connection with the development and use of our products and technologies. Licenses required under any such patents or proprietary rights might not be made available on terms acceptable to us, if at all.

Risks Related to this Offering:

Because we became public by means of a reverse merger, we may not be able to attract the attention of major brokerage firms.

Additional risks may exist since we became public through a “reverse merger.” Security analysts of major brokerage firms may not provide coverage of us since there is no incentive to brokerage firms to recommend the purchase of our common stock. No assurance can be given that brokerage firms will want to conduct any secondary offerings on behalf of our company in the future. The lack of such analyst coverage may decrease the public demand for our common stock, making it more difficult for you to resell your shares when you deem appropriate.

We expect that our stock price will fluctuate significantly, and you may not be able to resell your shares at or above your investment price.

The stock market, particularly in recent years, has experienced significant volatility, particularly with respect to pharmaceutical, biotechnology and other life sciences company stocks. The volatility of pharmaceutical, biotechnology and other life sciences company stocks often does not relate to the operating performance of the companies represented by the stock. Factors that could cause volatility in the market price of our common stock include, but are not limited to:

- results from, delays in, or discontinuation of, any of the clinical trials for our drug candidates, and including delays resulting from slower than expected or suspended patient enrollment or discontinuations resulting from a failure to meet pre-defined clinical end-points;
- announcements concerning clinical trials;
- failure or delays in entering additional drug candidates into clinical trials;
- failure or discontinuation of any of our research programs;

- issuance of new or changed securities analysts' reports or recommendations;
- developments in establishing new strategic alliances;
- market conditions in the pharmaceutical, biotechnology and other healthcare related sectors;
- actual or anticipated fluctuations in our quarterly financial and operating results;
- developments or disputes concerning our intellectual property or other proprietary rights;
- introduction of technological innovations or new commercial products by us or our competitors;
- issues in manufacturing our drug candidates or drugs;
- market acceptance of our drugs;
- third-party healthcare coverage and reimbursement policies;
- FDA or other United States or foreign regulatory actions affecting us or our industry;
- litigation or public concern about the safety of our drug candidates or drugs;
- additions or departures of key personnel; or
- volatility in the stock prices of other companies in our industry.

These and other factors may cause the market price and demand for our common stock to fluctuate substantially, which may limit or prevent investors from readily selling their shares of common stock and may otherwise negatively affect the liquidity of our common stock. In addition, when the market price of a stock has been volatile, holders of that stock have instituted securities class action litigation against the company that issued the stock. This risk is especially relevant for us because biotechnology companies have experienced greater than average stock price volatility in recent years. If any of our stockholders brought a lawsuit against us, we could incur substantial costs defending the lawsuit. Such a lawsuit could also divert our management's time and attention.

Because we do not expect to pay dividends, you will not realize any income from an investment in our common stock unless and until you sell your shares at profit.

We have never paid dividends on our common stock and do not anticipate paying any dividends for the foreseeable future. You should not rely on an investment in our common stock if you require dividend income. Further, you will only realize income on an investment in our shares in the event you sell or otherwise dispose of your shares at a price higher than the price you paid for your shares. Such a gain would result only from an increase in the market price of our common stock, which is uncertain and unpredictable.

There may be issuances of shares of blank check preferred stock in the future.

Our certificate of incorporation authorizes the issuance of up to 10,000,000 shares of preferred stock, none of which are issued or currently outstanding. The Board of Directors will have the authority to fix and determine the relative rights and preferences of preferred shares, as well as the authority to issue such shares, without further stockholder approval. As a result, the Board of Directors could authorize the issuance of a series of preferred stock that is senior to our common stock that would grant to holders preferred rights to our assets upon liquidation, the right to receive dividends, additional registration rights, anti-dilution protection, the right to the redemption to such shares, together with other rights, none of which will be afforded to holders of our common stock.

Substantial sales of shares may impact the market price of our common stock.

The number of shares of our common stock covered by this prospectus represents a significant portion of our total outstanding common stock. As of the date of this prospectus, we have outstanding a total of 26,906,871 shares of our common stock. If the selling stockholders sell substantial amounts of our common stock covered by this prospectus, including shares issued upon the exercise of outstanding warrants, the market price of our common stock may decline. We are unable to predict the effect that sales may have on the prevailing market price of our common stock.

In addition to the shares of our common stock covered by this prospectus, a substantial portion of our shares will become eligible for resale pursuant to the provisions of Rule 144 promulgated under the Securities Act. These sales may also have a depressive effect on the market price of our common stock. In general, a person who has held restricted shares for a period of one year may, upon filing with the SEC a notification on Form 144, sell into the market common stock in an amount equal to the greater of 1% of the outstanding shares or the average weekly number of shares sold in the last four weeks prior to such sale. Such sales may be repeated once every three months, and any of the restricted shares may be sold by a non-affiliate after they have been held two years.

If our results do not meet analysts' forecasts and expectations, our stock price could decline.

In the future, analysts who cover our business and operations may provide valuations regarding our stock price and make recommendations whether to buy, hold or sell our stock. Our stock price may be dependent upon such valuations and recommendations. Analysts' valuations and recommendations are based primarily on our reported results and their forecasts and expectations concerning our future results regarding, for example, expenses, revenues, clinical trials, regulatory marketing approvals and competition. Our future results are subject to substantial uncertainty, and we may fail to meet or exceed analysts' forecasts and expectations as a result of a number of factors, including those discussed above under the sections "Risks Related to Our Business" and "Risks Related to the Clinical Testing, Regulatory Approval, Manufacturing and Commercialization of Our Product Candidates." If our results do not meet analysts' forecasts and expectations, our stock price could decline as a result of analysts lowering their valuations and recommendations or otherwise.

NOTE REGARDING FORWARD-LOOKING STATEMENTS

This prospectus contains "forward-looking statements" within the meaning of Section 27A of the Securities Act of 1933, or the Securities Act, and Section 21E of the Securities Exchange Act of 1934, or the Exchange Act. The forward-looking statements are only predictions and provide our current expectations or forecasts of future events and financial performance and may be identified by the use of forward-looking terminology, including the terms "believes," "estimates," "anticipates," "expects," "plans," "potential," "projects," "intends," "may," "will" or "should" or, in each case, their negative, or other variations or comparable terminology, though the absence of these words does not necessarily mean that a statement is not forward-looking. Forward-looking statements include all matters that are not historical facts and include, without limitation, statements concerning our business strategy, outlook, objectives, future milestones, plans, intentions, goals, future financial conditions, obtaining financing of our operations, our research and development programs and planning for and timing of any clinical trials, the possibility, timing and outcome of submitting regulatory filings for our products under development, potential investigational new drug applications, or INDs, and new drug applications, or NDAs, research and development of particular drug products, the development of financial, clinical, manufacturing and marketing plans related to the potential approval and commercialization of our drug products, and the period of time for which our existing resources will enable us to fund our operations. These statements are subject to risks and uncertainties that could cause actual results and events to differ materially from those expressed or implied by such forward-looking statements. For a detailed discussion of these risks and uncertainties, see the "Risk Factors" section in this prospectus. We caution the reader not to place undue reliance on these forward-looking statements, which reflect management's analysis only as of the date of this prospectus.

We intend that all forward-looking statements be subject to the safe-harbor provisions of the Private Securities Litigation Reform Act of 1995. Forward-looking statements are subject to many risks and uncertainties that could cause our actual results to differ materially from any future results expressed or implied by the forward-looking statements. Pharmaceutical and biotechnology companies have suffered significant setbacks in advanced clinical trials, even after obtaining promising earlier trial results. Data obtained from such clinical trials are susceptible to varying interpretations, which could delay, limit or prevent regulatory approval. Additional factors that could cause actual results to differ materially from projected results include, but are not limited to, those discussed in "Risk Factors" elsewhere in this prospectus. Readers are expressly advised to review and consider those Risk Factors, which include risks associated with:

- our ability to successfully conduct clinical and pre-clinical trials for our product candidates;
- our ability to obtain required regulatory approvals to develop and market our product candidates;
- our ability to raise additional capital or to license our products on favorable terms;
- our ability to execute our development plan on time and on budget;
- our ability to identify and obtain additional product candidates; and
- our ability to raise enough capital to fund our operations.

Although we believe that the assumptions underlying the forward-looking statements contained in this prospectus are reasonable, any of the assumptions could be inaccurate, and therefore there can be no assurance that such statements will be accurate. In light of the significant uncertainties inherent in the forward-looking statements included herein, the inclusion of such information should not be regarded as a representation by us or any other person that the results or conditions described in such statements or our objectives and plans will be achieved. Furthermore, past performance in operations and share price is not necessarily indicative of future performance. Except to the extent required by applicable laws or rules, we do not undertake to update any forward-looking statements or to announce publicly revisions to any of our forward-looking statements, whether resulting from new information, future events or otherwise.

USE OF PROCEEDS

We will receive none of the proceeds from the sale of the shares by the selling stockholders, except for the warrant exercise price upon exercise of the warrants, which would be used for working capital and other general corporate purposes.

SELLING STOCKHOLDERS

This prospectus covers the resale by the selling stockholders identified below of 5,601,088 shares of common stock, including 2,909,694 shares issuable upon the exercise of outstanding warrants. Of the total number of shares offered hereby, 5,382,788 shares (including 2,691,394 shares issuable upon the exercise of outstanding warrants) were issued to the investors in our July 2009 private placement. The remaining 218,300 shares are issuable upon the exercise of outstanding warrants issued to designees of Riverbank Capital Securities, Inc., the placement agent for the private placement. The following table sets forth the number of shares of our common stock beneficially owned by the selling stockholders as of August 12, 2009 and after giving effect to this offering, except as otherwise referenced below.

Selling Stockholder	Shares beneficially owned before offering (1)	Number of outstanding shares offered by selling stockholder	Number of shares offered by selling stockholder upon exercise of warrants	Percentage beneficial ownership after offering(1)
Securities issued to investors in July 2009 private placement				
Aaronson, Oren	40,000	20,000	20,000	—
A. Lapidot Pharmaceuticals, Ltd. (2)	66,993	24,000	24,000	*
Arie & Rebecka Belldegrun as TTEES of the Belldegrun Family Trust Dated 2-18-94	616,000	64,800	64,800	—
Arie S. Belldegrun, M.D., Inc. Profit Sharing Plan (3)	616,000	243,200	243,200	—
Beechwood Ventures (4)	120,570	40,000	40,000	*
Calmedica Capital (5)	400,000	200,000	200,000	—
Clal Insurance Company Ltd.	502,157	164,000	164,000	*
Crockett, Michael	60,035	24,000	24,000	*
Dankner, Ythzak	390,229	120,000	120,000	*
Diversified Fund (6)	125,112	40,000	40,000	*
Evans, Daron Gareth (7)	328,585	3,952	3,952	1.06%
Evans, Preston W. and Patricia Mary	61,700	24,000	24,000	*
Falk, Robert I.	255,535	100,000	100,000	*
Fink, Steven	80,000	40,000	40,000	—
High Glen Properties, Ltd. (8)	97,926	40,000	40,000	*
JJS SBT 2008 Trust (9)	257,987	100,000	100,000	*
Kash, Peter and Donna (10)	1,861,074	98,814	98,814	5.15%
Kashef, Afshin	160,000	80,000	80,000	—
Kazam, Joshua and Joia (11)	1,540,839	197,628	197,628	3.73%
Kessler, Irvin R. (12)	731,094	300,000	300,000	*
KT4 Partners, LLC (13)	160,000	80,000	80,000	—
Lakeside Partners, LLC (14)	80,000	40,000	40,000	—
Leumi Overseas Trust Corporation Limited As TTEE of Tampere Trust (15)	584,000	292,000	292,000	—
McInerney, Timothy	284,147	75,000	75,000	*
MCM Family Partners, LLC	53,794	20,000	20,000	*
Precision Dermatology (16)	40,000	20,000	20,000	—
Primafides (Suisse) SA & Earl Trust AG as TTEEs of the Sirius Trust (17)	240,000	120,000	120,000	—
Speisman Family 2000 LP (18)	60,283	20,000	20,000	*
Thacker, Troy and Allison	74,833	20,000	20,000	*
Thompson, Stephen	67,588	20,000	20,000	*

Selling Stockholder	Shares beneficially owned before offering(1)	Number of outstanding shares offered by selling stockholder	Number of shares offered by selling stockholder upon exercise of warrants	Percentage beneficial ownership after offering(1)
Tibbs, Adam	40,000	20,000	20,000	—
Trovario, LLC (19)	80,000	40,000	40,000	—
Subtotal		**2,691,394**	**2,691,394**	
Warrants issued to designees of Placement Agent in July 2009 private placement				
Blum, Steve (20)	45,000	—	20,000	*
Kash, Peter (10)	1,861,074	—	125,000	5.15%
Kazam, Joshua (11)	1,540,839	—	31,650	3.73%
McInerney, Timothy	284,147	—	10,000	*
Tanen, David (21)	1,585,355	—	31,650	5.21%
Subtotal			**218,300**	
TOTAL		**2,691,394**	**2,909,694**	

* denotes less than 1%

(1) Based on 29,816,565 shares of outstanding common stock, which assumes the issuance of all shares offered hereby that are issuable upon exercise of warrants. Beneficial ownership is determined in accordance with Rule 13d-3 under the Exchange Act, and includes any shares as to which the security or stockholder has sole or shared voting power or investment power, and also any shares which the security or stockholder has the right to acquire within 60 days of the date hereof, whether through the exercise or conversion of any stock option, convertible security, warrant or other right. The indication herein that shares are beneficially owned is not an admission on the part of the security or stockholder that he, she or it is a direct or indirect beneficial owner of those shares.

(2) Mr. Ami Lapidot, chief executive officer of the selling stockholder, holds voting and/or dispositive power over the shares held by the selling stockholder.

(3) Dr. Arie Belldegrun holds voting and/or dispositive power over the shares held by the selling stockholder. Dr. Belldegrun also has a pecuniary interest in the shares beneficially owned by Leumi Overseas Trust Corporation Limited.

(4) Mr. Ruki Renov, manager of the selling stockholder, holds voting and/or dispositive power over the shares held by the selling stockholder. Beneficial ownership includes 2,104 shares of common stock issuable upon the exercise of outstanding warrants.

(5) Mr. Robert Hess, general partner of the selling stockholder, holds voting and/or dispositive power over the shares held by the selling stockholder.

(6) Mr. Carlo L.E. Pagani holds voting and/or dispositive power over the shares held by the selling stockholder. Beneficial ownership includes 1,052 shares of common stock issuable upon the exercise of outstanding warrants.

(7) Mr. Evans currently serves as our Chief Financial Officer. Beneficial ownership includes 310,481 shares of common stock issuable upon the exercise of options that are currently exercisable or will become exercisable within the next 60 days. Beneficial ownership does not include (i) 9,200 shares of common stock held by Mr. Evans' wife or (ii) 400 shares of common stock held by Mr. Evans' wife as custodian for the benefit of their minor children under the UGMA.

(8) Lorna T. Ulmer and Zippora Orland hold voting and/or dispositive power over the shares held by the selling stockholder.

(9) Mr. Joseph J. Sitt, trustee, holds voting and/or dispositive power over the shares held by the selling stockholder. Beneficial ownership includes (i) 55,883 shares of outstanding common stock and (ii) 2,104 shares of common stock issuable upon the exercise of outstanding warrants held by Mr. Sitt in his individual capacity.

(10) Mr. Kash currently serves as the Chairman of our Board of Directors. Beneficial ownership includes (i) 40,000 shares of common stock issuable upon the exercise of options that are currently exercisable or will become exercisable within the next 60 days and (ii) 1,052 shares of common stock issuable upon the exercise of warrants expiring on September 17, 2011 at an exercise price equal to $2.71 per share. Beneficial ownership does not include (i) 496,589 shares of common stock held by Mrs. Kash as custodian for the benefit of their minor children under the UGMA or (ii) 165,530 shares of common stock held by the Kash Family Foundation.

(11) Mr. Kazam currently serves as our Chief Executive Officer, President and as a director. Beneficial ownership includes 33,000 shares of common stock issuable upon the exercise of options that are currently exercisable or will become exercisable within the next 60 days. Beneficial ownership does not include (i) 165,530 shares of common stock held by Mrs. Kazam as custodian for the

benefit of their minor children under the UGMA or (ii) 613,841 shares of common stock held by the Kazam Family Foundation. Also excluded are 165,530 shares of common stock held by the Kash Family Foundation; Mr. Kazam is the trustee and controls the right to vote and dispose of, but has no pecuniary interest in, the shares held by the Kash Family Foundation.

(12) Beneficial ownership includes 4,210 shares of common stock issuable upon the exercise of outstanding warrants.

(13) Mr. Marc Abramowitz holds voting and/or dispositive power over the shares held by the selling stockholder.

(14) Mr. Jamie J. Stahler holds voting and/or dispositive power over the shares held by the selling stockholder.

(15) Mr. John Le M. Gerdain, on behalf of Leumi Overseas Trust Corporation Limited, trustee, holds voting and/or dispositive power over the shares held by the selling stockholder.

(16) Mr. Suneel Chilukuri holds voting and/or dispositive power over the shares held by the selling stockholder.

(17) Nigel Mifsud and Phillippe De Salis are directors of Primafides (Suisse) SA, co-trustee of the Sirius Trust, and share voting and/or dispositive power over the shares held by the Sirius Trust.

(18) Mr. Aaron Speisman holds voting and/or dispositive power over the shares held by the selling stockholder. Beneficial ownership includes 1,052 shares of common stock issuable upon the exercise of outstanding warrants.

(19) Mr. Daniel Nissanoff holds voting and/or dispositive power over the shares held by the selling stockholder.

(20) Beneficial ownership includes 25,000 shares of common stock issuable upon the exercise of options that are currently exercisable or will become exercisable within the next 60 days.

(21) Mr. Tanen currently serves as our Secretary and as a director. Beneficial ownership includes 33,333 shares of common stock issuable upon the exercise of options that are currently exercisable or will become exercisable within the next 60 days. Beneficial ownership does not include 137,941 shares of common stock held by Mr. Tanen's wife as custodian for the benefit of their minor children under the UGMA.

PLAN OF DISTRIBUTION

We are registering the shares offered by this prospectus on behalf of the selling stockholders. The selling stockholders, which as used herein includes donees, pledgees, transferees or other successors-in-interest selling shares of common stock or interests in shares of common stock received after the date of this prospectus from a selling stockholder as a gift, pledge, partnership distribution or other transfer, may, from time to time, sell, transfer or otherwise dispose of any or all of their shares of common stock or interests in shares of common stock on any stock exchange, market or trading facility on which the shares are traded or in private transactions. These dispositions may be at fixed prices, at prevailing market prices at the time of sale, at prices related to the prevailing market price, at varying prices determined at the time of sale, or at negotiated prices. To the extent any of the selling stockholders gift, pledge or otherwise transfer the shares offered hereby, such transferees may offer and sell the shares from time to time under this prospectus, provided that this prospectus has been amended under Rule 424(b)(3) or other applicable provision of the Securities Act to include the name of such transferee in the list of selling stockholders under this prospectus.

The selling stockholders may use any one or more of the following methods when disposing of shares or interests therein:

- ordinary brokerage transactions and transactions in which the broker-dealer solicits purchasers;
- block trades in which the broker-dealer will attempt to sell the shares as agent, but may position and resell a portion of the block as principal to facilitate the transaction;
- purchases by a broker-dealer as principal and resale by the broker-dealer for its account;
- an exchange distribution in accordance with the rules of the applicable exchange;
- privately negotiated transactions;
- short sales;
- through the writing or settlement of options or other hedging transactions, whether through an options exchange or otherwise;
- broker-dealers may agree with the selling stockholders to sell a specified number of such shares at a stipulated price per share;
- a combination of any such methods of sale; and
- any other method permitted pursuant to applicable law.

The selling stockholders may, from time to time, pledge or grant a security interest in some or all of the shares of common stock owned by them and, if they default in the performance of their secured obligations, the pledgees or secured parties may offer and sell the shares of common stock, from time to time, under this prospectus, or under an amendment to this prospectus under Rule 424(b)(3) or other applicable provision of the Securities Act amending the list of selling stockholders to include the pledgee, transferee or other successors in interest as selling stockholders under this prospectus.

In connection with the sale of our common stock or interests therein, the selling stockholders may enter into hedging transactions with broker-dealers or other financial institutions, which may in turn engage in short sales of the common stock in the course of hedging the positions they assume. The selling stockholders may also sell shares of our common stock short and deliver these securities to close out their short positions, or loan or pledge the common stock to broker-dealers that in turn may sell these securities. The selling stockholders may also enter into option or other transactions with broker-dealers or other financial institutions or the creation of one or more derivative securities which require the delivery to such broker-dealer or other financial institution of shares offered by this prospectus, which shares such broker-dealer or other financial institution may resell pursuant to this prospectus (as supplemented or amended to reflect such transaction).

The aggregate proceeds to the selling stockholders from the sale of the common stock offered by them will be the purchase price of the common stock less discounts or commissions, if any. Each of the selling stockholders reserves the right to accept and, together with their agents from time to time, to reject, in whole or in part, any proposed purchase of common stock to be made directly or through agents. We will not receive any of the proceeds from this offering. Upon any exercise of the warrants by payment of cash, however, we will receive the exercise price of the warrants.

The selling stockholders also may resell all or a portion of the shares in open market transactions in reliance upon Rule 144 under the Securities Act of 1933, provided that they meet the criteria and conform to the requirements of that rule.

The selling shareholders might be, and any broker-dealers that act in connection with the sale of securities will be, deemed to be “underwriters” within the meaning of Section 2(11) of the Securities Act, and any commissions received by such broker-dealers and any profit on the resale of the securities sold by them while acting as principals will be deemed to be underwriting discounts or commissions under the Securities Act.

To the extent required, the shares of our common stock to be sold, the names of the selling stockholders, the respective purchase prices and public offering prices, the names of any agents, dealer or underwriter, any applicable commissions or discounts with respect to a particular offer will be set forth in an accompanying prospectus supplement or, if appropriate, a post-effective amendment to the registration statement that includes this prospectus.

In order to comply with the securities laws of some states, if applicable, the common stock may be sold in these jurisdictions only through registered or licensed brokers or dealers. In addition, in some states the common stock may not be sold unless it has been registered or qualified for sale or an exemption from registration or qualification requirements is available and is complied with.

We have advised the selling stockholders that the anti-manipulation rules of Regulation M under the Exchange Act may apply to sales of shares in the market and to the activities of the selling stockholders and their affiliates. In addition, we will make copies of this prospectus (as it may be supplemented or amended from time to time) available to the selling stockholders for the purpose of satisfying the prospectus delivery requirements of the Securities Act. The selling stockholders may indemnify any broker-dealer that participates in transactions involving the sale of the shares against certain liabilities, including liabilities arising under the Securities Act.

We have agreed to indemnify the selling stockholders against liabilities, including liabilities under the Securities Act and state securities laws, relating to the registration of the shares offered by this prospectus.

We have agreed with the selling stockholders to keep the registration statement that includes this prospectus effective until the earlier of (1) such time as all of the shares covered by this prospectus have been disposed of pursuant to and in accordance with the registration statement that contains this prospectus or (2) the date on which the shares may be sold without registration or restriction pursuant to Rule 144 of the Securities Act.

Shares Eligible For Future Sale

Upon completion of this offering and assuming the issuance of all of the shares covered by this prospectus that are issuable upon the exercise of warrants, there will be 29,816,565 shares of our common stock issued and outstanding. The shares purchased in this offering will be freely tradable without registration or other restriction under the Securities Act, except for any shares purchased by an “affiliate” of our company (as defined in the Securities Act).

The selling stockholders also may resell all or a portion of the shares in open market transactions in reliance upon Rule 144 under the Securities Act, provided they meet the criteria and conform to the requirements of such Rule. Rule 144 governs resale of “restricted securities” for the account of any person (other than us), and restricted and unrestricted securities for the account of an “affiliate” of ours. Restricted securities generally include any securities acquired directly or indirectly from us or our affiliates, which were not issued or sold in connection with a public offering registered under the Securities Act. An affiliate of ours is any person who directly or indirectly controls us, is controlled by us, or is under common control with us. Our affiliates may include our directors, executive officers, and persons directly or indirectly owing 10% or more of our outstanding common stock. In general, under Rule 144, a person (or persons whose shares are aggregated) who is not deemed to have been an affiliate of ours at the time of, or at any time during the three months preceding, a sale, and who has beneficially owned restricted securities for at least six months would be entitled to sell those shares, subject to the requirements of Rule 144 regarding publicly available information about us. Affiliates may only sell in any three month period that number of shares that does not exceed the greater of 1 percent of the then-outstanding shares of our common stock or the average weekly trading volume of our shares of common stock in the over-the-counter market during the four calendar weeks preceding the sale.

Following the date of this prospectus, we cannot predict the effect, if any, that sales of our common stock or the availability of our common stock for sale will have on the market price prevailing from time to time. Nevertheless, sales by existing stockholders of substantial amounts of our common stock could adversely affect prevailing market prices for our stock.

DISCLOSURE OF COMMISSION POSITION ON INDEMNIFICATION FOR SECURITIES ACT LIABILITIES

Pursuant to our certificate of incorporation and bylaws, we may indemnify an officer or director who is made a party to any proceeding, because of his position as such, to the fullest extent authorized by Delaware General Corporation Law, as the same exists or may hereafter be amended. In certain cases, we may advance expenses incurred in defending any such proceeding.

To the extent that indemnification for liabilities arising under the Securities Act may be permitted to directors, officers or persons controlling our company pursuant to the foregoing provisions, we have been informed that, in the opinion of the Securities and Exchange Commission, or SEC, such indemnification is against public policy as expressed in the Securities Act and is therefore unenforceable. If a claim for indemnification against such liabilities (other than the payment by us of expenses incurred or paid by a director, officer or controlling person of our company in the successful defense of any action, suit or proceeding) is asserted by any of our directors, officers or controlling persons in connection with the securities being registered, we will, unless in the opinion of our counsel the matter has been settled by controlling precedent, submit to a court of appropriate jurisdiction the question whether such indemnification by us is against public policy as expressed in the Securities Act and will be governed by the final adjudication of that issue.

ABOUT THIS PROSPECTUS

This prospectus is not an offer or solicitation in respect to these securities in any jurisdiction in which such offer or solicitation would be unlawful. This prospectus is part of a registration statement that we filed with the SEC. The registration statement that contains this prospectus (including the exhibits to the registration statement) contains additional information about our company and the securities offered under this prospectus. That registration statement can be read at the SEC website or at the SEC's offices mentioned under the heading "Where You Can Find More Information." We have not authorized anyone else to provide you with different information or additional information. You should not assume that the information in this prospectus, or any supplement or amendment to this prospectus, is accurate at any date other than the date indicated on the cover page of such documents.

WHERE YOU CAN FIND MORE INFORMATION

Federal securities law requires us to file information with the SEC concerning our business and operations. Accordingly, we file annual, quarterly, and special reports, proxy statements and other information with the SEC. You can inspect and copy this information at the Public Reference Facility maintained by the SEC at 100 F Street, N.E., Washington, D.C. 20549. You can receive additional information about the operation of the SEC's Public Reference Facilities by calling the SEC at 1-800-SEC-0330. The SEC also maintains a web site at http://www.sec.gov that contains reports, proxy and information statements and other information regarding companies that, like us, file information electronically with the SEC.

We are allowed to incorporate by reference information contained in documents that we file with the SEC. This means that we can disclose important information to you by referring you to those documents and that the information in this prospectus is not complete and you should read the information incorporated by reference for more detail. We incorporate by reference in two ways. First, we list certain documents that we have already filed with the SEC. The information in these documents is considered part of this prospectus. Second, the information in documents that we file in the future will update and supersede the current information in, and incorporated by reference in, this prospectus.

We incorporate by reference the filed documents listed below, except as superseded, supplemented or modified by this prospectus, and any future filings we will make with the SEC under Sections 13(a), 13(c), 14 or 15(d) of the Exchange Act, together with any exhibits filed therewith:

- The description of our common stock set forth in the registration statement on Form 8-A registering our common stock under Section 12(b) of the Exchange Act, which was filed with the SEC on May 9, 2008 (File No. 001-34058);
- Our Annual Report on Form 10-K for the fiscal year ended December 31, 2008, as originally filed with the SEC on March 12, 2009, and amended on April 23, 2009 (File No. 001-34058);
- Our Quarterly Reports on Form 10-Q for the fiscal quarters ended March 31, 2009, and June 30, 2009, respectively; and
- Our Current Reports on Form 8-K filed January 22, 2009, March 9, 2009, March 19, 2009, March 27, 2009, June 12, 2009, June 25, 2009, July 13, 2009, July 24, 2009, and August 11, 2009, respectively.

You may request a copy of these filings at no cost, by writing or telephoning us at the following address or telephone number:

Nile Therapeutics, Inc.
4 West 4th Ave., Suite 400
San Mateo, California 94402
Attention: Chief Financial Officer
(415) 875-7880

You should rely only on the information incorporated by reference or provided in this prospectus or any supplement. We have not authorized anyone else to provide you with different information. The selling stockholders will not make an offer of these shares in any state where the offer is not permitted. You should not assume that the information in this prospectus or any supplement is accurate as of any date other than the date on the front of these documents.

VALIDITY OF COMMON STOCK

Legal matters in connection with the validity of the shares offered by this prospectus will be passed upon by Fredrikson & Byron, P.A., Minneapolis, Minnesota.

EXPERTS

The financial statements of Nile Therapeutics, Inc. as of December 31, 2008 and 2007, and for the years then ended, and for the period from August 1, 2005 (date of inception) through December 31, 2008, incorporated by reference into this prospectus, have been incorporated herein in reliance on the report of Hays & Company LLP, independent registered public accounting firm, given on the authority of that firm as experts in accounting and auditing.

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5,601,088 Shares

Common Stock

PROSPECTUS

August 25, 2009