Nile Therapeutics, Inc.
Form S-1
July 22, 2011

As filed with the Securities and Exchange Commission on July 22, 2011 Registration No. 333-

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

FORM S-1

REGISTRATION STATEMENT UNDER THE SECURITIES ACT OF 1933

NILE THERAPEUTICS, INC.
(Exact name of registrant as specified in its charter)

Delaware	2834	88-0363465
(State or other jurisdiction of incorporation or organization)	(Primary Standard Industrial Classification Code Number)	(I.R.S. Employer Identification No.)

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4 West 4th Street, Suite 400
San Mateo, California 94402
(650) 458-2670
(Address, including zip code, and telephone number, including area code, of registrant's principal executive offices)

Daron Evans
Chief Financial Officer
Nile Therapeutics, Inc.
4 West 4th Street, Suite 400
San Mateo, California 94402
(650) 458-2670
(Name, address, including zip code, and telephone number, including area code, of agent for service)

Copies to:
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Approximate date of commencement of proposed sale to the public: From time to time after the effective date of this registration statement, as shall be determined by the selling stockholders identified herein.

If any of the securities being registered on this Form are to be offered on a delayed or continuous basis pursuant to Rule 415 under the Securities Act of 1933, as amended, check the following box. þ

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

If this Form is a post effective amendment filed pursuant to Rule 462(c) under the Securities Act, check the following

box and list the Securities Act registration statement number of the earlier effective registration statement for the same offering. ¨

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

Indicate by check mark whether the registrant is a large accelerated filer, an accelerated filer, a non-accelerated filer, or a smaller reporting company. See the definitions of "large accelerated filer," "accelerated filer" and "smaller reporting company" in Rule 12b-2 of the Exchange Act.

Large accelerated filer ¨	Accelerated filer ¨
Non-accelerated filer ¨ (Do not check if a smaller reporting company)	Smaller reporting company þ

CALCULATION OF REGISTRATION FEE (1)

Title of Each Class of Securities to be Registered	Amount to be Registered(1)	Proposed Maximum Offering Price Per Share (2)	Proposed Maximum Aggregate Offering Price	Amount of Registration Fee
Common stock, par $.001 par value per share	5,000,000	$ 0.75	$ 3,750,000	$ 435.38
Common stock, par $.001 par value per share (3)	2,750,000	$ 0.75	$ 2,062,500	$ 239.46
Total	7,750,000		$ 5,812,500	$ 674.83

(1) Pursuant to Rule 416 under the Securities Act, the shares being registered hereunder include such indeterminate number of shares as may be issuable with respect to the shares being registered hereunder as a result of stock splits, stock dividends or similar transactions.

(2) Estimated solely for purposes of calculating the amount of the registration fee pursuant to Rule 457. The offering price per share and the aggregate offering price are based upon the average of the high and low prices of the registrant's common stock as reported on the OTCQB Pink Sheets on July 18, 2011.

(3) Represents shares of common stock issuable upon exercise of outstanding warrants.

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

A registration statement relating to these securities has been filed with the Securities and Exchange Commission. These securities may not be sold nor may offers to buy be accepted prior to the time the registration statement becomes effective. This prospectus shall not constitute an offer to sell or the solicitation of an offer to buy nor shall there be any sale of these securities in any state in which such offer, solicitation or sale would be unlawful prior to registration or qualification under the securities laws of any such state.

Subject to completion, dated July 22, 2011

OFFERING PROSPECTUS

7,750,000 Shares
Common Stock

The selling stockholders identified in this prospectus are offering on a resale basis a total of 7,750,000 shares of our common stock, including 2,750,000 shares issuable upon the exercise of outstanding warrants.

Our common stock is quoted on the OTCQB under the symbol “NLTX.PK” On , 2011, the last sale price of our common stock as reported on the OTCQB was $.

The securities offered by this prospectus involve a high degree of risk.
See “Risk Factors” beginning on page 3.

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 , 2011.

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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 contained in or incorporated by reference into this prospectus or the registration statement of which this prospectus is a part before making an investment decision. References to the "Company," "Nile," "we," "us," or "our" in this prospectus refer to Nile Therapeutics, Inc., a Delaware corporation, unless the context indicates otherwise.

Company Overview

We are a development stage biopharmaceutical company in the business of commercially developing innovative products for the treatment of cardiovascular diseases. We currently have rights to develop two drug candidates:

- Cenderitide (formerly CD-NP), our lead product candidate, is a chimeric natriuretic peptide that we are developing for the treatment of heart failure. We are currently developing cenderitide for the treatment of patients for up to 90 days following admission for acutely decompensated heart failure, or ADHF. We also believe cenderitide may be useful in several other cardiovascular and renal indications.

- CU-NP, is a pre-clinical rationally designed natriuretic peptide that consists of amino acid chains identical to those produced by the human body, specifically the ring structure of C-type natriuretic peptide, or CNP, and the N- and C-termini of Urodilatin, or URO. We are currently evaluating the potential for the chronic dosing of CU-NP, which could be used to treat a number of cardiovascular and renal diseases.

We were originally incorporated under Delaware law in August 2005 under the name Nile Pharmaceuticals, Inc. and we changed our name to Nile Therapeutics, Inc. in January 2007. On September 17, 2007, we were acquired by SMI Products, Inc., or SMI, which was then a public shell company, in a reverse merger transaction whereby a wholly-owned subsidiary of SMI merged with and into Nile Therapeutics, with Nile Therapeutics remaining as the surviving corporation and a wholly-owned subsidiary of SMI. In accordance with the terms of this transaction, the stockholders of Nile Therapeutics exchanged all of their shares of Nile Therapeutics common stock for shares of SMI common stock, which immediately following the transaction represented approximately 95 percent of the issued and outstanding common stock of SMI. Upon completion of the merger, the sole officer and director of SMI resigned and was replaced by the officers and directors of Nile Therapeutics. Additionally, following the merger, Nile Therapeutics, or Old Nile, was merged into SMI, and SMI changed its name to Nile Therapeutics, Inc., or Nile, and adopted the business plan of Old Nile. We collectively refer to these two merger transactions in this Annual Report as the "Merger." Because the Merger was accounted for as a reverse acquisition under generally accepted accounting principles, the financial statements for periods prior to September 17, 2007 reflect only the operations of Old Nile.

Our executive offices are located at 4 West 4th Ave., Suite 400, San Mateo, California 94402. Our telephone number is (650) 458-2670 and our Internet address is www.nilethera.com. Information contained in, or accessible through, our website does not constitute a part of this prospectus.

Risk Factors

As with most pharmaceutical product candidates, the development of our product candidates is subject to numerous risks, including our dependence on our cenderitide program, the risk of being unable to obtain necessary regulatory approvals to market the product candidates, unforeseen safety issues relating to our product candidates, dependence on third party collaborators to conduct research and development of our product candidates, and a lack of adequate

capital needed to develop our product candidates. Because we have only a 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 3 of this prospectus.

The Offering

The selling stockholders identified on page 23 of this prospectus are offering on a resale basis a total of 7,750,000 shares of our common stock, including 2,750,000 shares issuable upon the exercise of outstanding warrants.

Common stock offered	7,750,000 shares
Common stock outstanding before the offering(1)	39,707,764 shares
Common stock outstanding after the offering(2)	42,457,764 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 paid for the shares offered hereby that are issuable upon the exercise of certain warrants.
OTCQB Symbol	NLTX.PK

(1) Based on the number of shares outstanding as of July 18, 2011, not including 17,091,285 shares issuable upon exercise of various warrants and options to purchase our common stock.
(2) The increase in shares outstanding after the offering assumes the issuance of shares offered hereby that are issuable upon the exercise of outstanding warrants held by the selling stockholders.

RISK FACTORS

Investment in our common stock involves significant risk. You should carefully consider the information described in the following risk factors, together with the other information appearing elsewhere in this prospectus, before making an investment decision regarding our common stock. If any of these risks actually occur, our business, financial conditions, results of operations and future growth prospects would likely be materially and adversely affected. In these circumstances, the market price of our common stock could decline, and you may lose all or a part of your investment in our common stock. Moreover, the risks described below are not the only ones that we face.

Risks Related to Our Business

We need substantial additional funding before we can complete the development of our product candidates. If we are unable to raise additional 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 continue to develop cenderitide, our lead product candidate, and initiate clinical development of CU-NP, our second product candidate. In addition, our expenses could increase beyond expectations if the U.S. Food and Drug Administration, or 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, 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 drug candidates from the FDA and other regulatory authorities for our product candidates. As of March 31, 2011, we had cash and cash equivalents totaling $2.1 million. During the fiscal year ended December 31, 2010 and the three months ended March 31, 2011, we used net cash totaling $4.3 million and $1.3 million, respectively, 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, including our ongoing Phase I PK/PD study of cenderitide, we anticipate that our current resources will be sufficient to fund our operations into the fourth quarter of 2011. We will need substantial additional capital in order to complete this Phase I study and fund the next clinical study of cenderitide, which we anticipate would be a larger Phase II double-blind, placebo-controlled, dose ranging study in post-acute ADHF patients.

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 forecasts regarding the sufficiency of our financial resources to support our operations are forward-looking statements and involve significant 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, cost and results of our research and development activities, especially our ongoing Phase I clinical trial of cenderitide;
- the costs and timing of regulatory approval;
- the costs of filing, prosecuting, defending and enforcing any patent claims and other intellectual property rights;

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

We are largely dependent on the viability of cenderitide, our lead product candidate, and we cannot be certain it will receive regulatory approval to be commercialized.

We will need FDA approval to market and sell cenderitide 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 a new drug application, or 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.

We are substantially dependent on our relationship with the Mayo Foundation, from which we license the rights to both of our cenderitide and CU-NP drug candidates. If requirements under our license agreements are not met, we could suffer significant harm, including losing rights to our drug candidates.

Our rights to our cenderitide and CU-NP drug candidates are both derived from separate license agreements between us and the Mayo Foundation. Our business depends substantially on these agreements to maintain the intellectual property rights to both our product candidates. These license agreements require us to perform certain obligations that affect our rights under these licensing agreements, including making cash payments upon the achievement of certain milestones relating to the development of each product candidate. Both 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 license agreements with the Mayo Foundation, we could lose important patent and other intellectual property rights which are critical 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 product candidates and technologies. Licenses required under any such patents or proprietary rights might not be made available on terms acceptable to us, if at all.

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

Each of our two product candidates, cenderitide 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, which could take several years to complete, if ever. We cannot predict with any certainty the results of such clinical testing, including the results of our ongoing Phase I clinical trial of cenderitide in ADHF. 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.

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, cenderitide and CU-NP;
- delays in the commencement, enrollment, and timing of clinical testing;
- the success of clinical trials of our cenderitide 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 current or future products and product candidates 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 cenderitide 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 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, 2010 and 2009, respectively, we had a net loss of $6.0 million and $7.9 million. For the three months ended March 31, 2011, we had a net loss of $1.2 million, and for the period from our inception on August 1, 2005, through March 31, 2011, we have accumulated a deficit of $41.1 million and have stockholders' equity of $1.7 million. We expect to incur substantial losses and negative operating cash flows 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. 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.

The relationships between Two River Consulting, Riverbank Capital Securities and certain of our officers and directors may present potential conflicts of interest.

Arie S. Belldegrun and Joshua A. Kazam, each of whom are currently directors of our company, and David M. Tanen, a co-founder, director and secretary of our company until September 2009, are the managing members of Two River Consulting, LLC, or Two River. Since June 2009, Mr. Kazam has also served as our President and Chief Executive Officer. In July 2009, we entered into a services agreement with Two River pursuant to which it performs various

management, clinical development, operational and administrative activities and services for us. The terms of the services agreement were reviewed and approved by a special committee of our Board of Directors consisting of independent, disinterested directors. As consideration for the services provided under the services agreement, we paid Two River a monthly cash fee of $65,000 through March 2011, and since we have paid a monthly fee of approximately $31,000. In addition, upon entering into the services agreement, we issued to designees of Two River (excluding Dr. Belldegrun and Messrs. Kazam and Tanen) stock options to purchase an aggregate of 750,000 shares of our common stock at an exercise price of $0.89 per share. Twenty-five percent of the stock options vested immediately and the remaining 75% were scheduled to vest pursuant to the achievement of certain milestones relating to the clinical development of cenderitide. On January 3, 2011, the final block of stock options vested. Of the 750,000 stock options issued, 535,172 stock options vested and the remaining 214,828 stock options were forfeited. Also, in connection with an August 2010 amendment extending the term of the services agreement with Two River, we issued to designees of Two River (excluding Dr. Belldegrun and Messrs. Kazam and Tanen) fully-vested and immediately-exercisable stock options to purchase an aggregate of 250,000 shares of our common stock at an exercise price of $0.38 per share. Each of Messrs. Kazam and Tanen, as well as Peter M. Kash, a director of our Company, are also officers and directors of Riverbank Capital Securities, Inc., or Riverbank, a registered broker-dealer, which served as placement agent in connection with our June 2011 private placement. Scott L. Navins, the Financial and Operations Principal of Riverbank and Two River, serves as our Treasurer.

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. We believe that the terms of the agreements that we have entered into with Two River and Riverbank satisfy the requirements of Delaware law, but in the event one or more parties challenges the fairness of such terms we may have to expend substantial resources in resolving such challenges and can make no guarantees of the result. Further, 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 are substantially dependent on the services of Two River and other consultants.

We have only four employees, including Richard Brewer, our Executive Chairman; Daron Evans, our Chief Financial Officer; and Hsiao Lieu, our Vice President of Clinical Development. We currently rely heavily on Two River to render various other management, clinical development, regulatory, operational and administrative activities and services for us. We also rely in substantial part, and for the foreseeable future will continue to rely, on certain independent organizations and consultants to provide other important services, including substantially all aspects of regulatory approval, clinical management, and manufacturing. There can be no assurance that the services of organizations, advisors and consultants will continue to be available to us on a timely basis when needed, or that we can find qualified replacements.

Our Executive Chairman and our CEO provide their services on a part-time basis and significant other services are currently being rendered by outside consultants. If we are unable to hire additional qualified personnel in the future, our ability to grow our business may be harmed.

Although we currently engage Two River to provide personnel to perform a variety of management, clinical development and other services on our behalf on a consulting basis, we expect to directly hire employees, including at the senior management level, in the future as we further the development of our clinical programs. In addition, Joshua Kazam, our current President and Chief Executive Officer, provides his services to us on a part-time, non-employee basis, and Richard Brewer, our Executive Chairman, provides his services as a part-time employee. As we further the development of our product candidates, we intend to hire employees to perform the services currently being rendered by Two River. Accordingly, our ability to attract and retain qualified personnel will be critical to managing and growing our business in the future, especially the hiring and retention of key executive personnel and scientific staff. 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.

We may not be able to manage our growth.

Should we achieve our near-term milestones, such as completion of our ongoing Phase I clinical trial of cenderitide with positive data, of which no assurance can be given, our long-term viability 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.

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We face potential product liability exposure, and if claims are brought against us or if we are found liable, 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 are controlled by current directors, officers, and principal stockholders.

Our directors, officers, and principal stockholders beneficially own approximately 38% of our outstanding common stock. 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.

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 leading to decreased spending by businesses and consumers alike. Continued turbulence in the U.S. and international markets and economies and prolonged declines in business and 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

If clinical trials of our cenderitide 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 if they show undesirable side effects, we will be unable to commercialize these product candidates.

To receive regulatory approval for the commercial sale of cenderitide, 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 cenderitide, CU-NP or any other product candidates would prevent regulatory approval and, ultimately, the commercialization of that product candidate.

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 our ongoing Phase I clinical trial of cenderitide will be completed on schedule or at all. Thereafter, subject to the results of our ongoing Phase I trial, we do not know whether further planned clinical trials for cenderitide 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;

- 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;
- unexpected delays in approvals of protocol amendments by regulatory authorities;
- unforeseen safety issues or any determination that a trial presents unacceptable health risks;
- lack of adequate funding to continue the clinical trial, including the incurrence of unforeseen costs due to enrollment delays; or
- 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 cenderitide and CU-NP product candidates, we or our development partners, if any, 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 cenderitide 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.

As the results of earlier clinical trials are not necessarily predictive of future results, cenderitide, 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, including our ongoing Phase I clinical trial of cenderitide, we cannot be certain that their results will support the claims of our product candidates. Positive results in pre-clinical testing and early clinical trials does not ensure that results from later clinical trials will also be positive, 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 to date involve a small patient population. Because of the small sample size, the results of these clinical trials may not be indicative of future results.

Despite the results reported in earlier clinical trials for our product candidates, we do not know whether any Phase II, 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.

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 or product candidates.

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. In addition, the early development stage of our product candidates may make it more difficult for us to identify and secure a strategic partner because of the additional risks inherent in early stage technologies. 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 substantial 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.

Our collaboration agreement with Medtronic may limit our ability to enter into a collaboration, co-development or similar agreement with other potential strategic partners relating to the development of cenderitide.

In February 2011, we entered into an agreement with Medtronic, Inc. pursuant to which we and Medtronic are collaborating on a Phase I clinical trial in which cenderitide will be administered to heart failure patients in the post-acute setting using Medtronic's diabetes pump technology. Under the terms of our agreement with Medtronic, we have agreed not to enter into an agreement with a third party to develop or commercialize cenderitide or any drug/device combination developed under our Medtronic collaboration agreement until the earlier of: (i) three months following delivery to Medtronic of a final database with respect to the ongoing Phase I clinical trial; and (ii) 15 months after the date of the agreement. Accordingly, we may be required to forego opportunities with other strategic partners in the pharmaceutical, biotechnology or medical device industries during such period.

Our product candidates 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 programs depend 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 supplies of our drug candidates. Our current and anticipated future reliance on a limited number of third-party manufacturers exposes us to the following risks:

ŸWe may be unable to identify manufacturers needed to manufacture our product candidates on acceptable terms or at all, because the number of potential manufacturers is limited, and subsequent to approval of a new drug application, or NDA, 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.

- Some of the raw materials needed to manufacture our product candidates are available from a very limited number of suppliers. Although we believe we have good relationships with these suppliers, we may have difficulty identifying alternative suppliers if our arrangements with our current suppliers are disrupted or terminated.

- 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 product candidates:

- 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.

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

In order to market and commercialize any product candidate 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.

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 and product candidates 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 product candidates. Compared to us, many of our potential competitors have substantially greater:

- Ÿ capital resources;
- Ÿ development resources, including personnel and technology;
- Ÿ clinical trial experience;
- Ÿ regulatory experience;
- Ÿ 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 product candidates 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 viability of our product candidates for which we obtain marketing approval from the FDA or other regulatory authorities will depend upon their acceptance 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 cenderitide, 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.

Our ability to generate significant 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 viability 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 patent and other intellectual property rights that covers our product candidates from the Mayo Foundation. We rely on the Mayo Foundation 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 the Mayo Foundation 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;
- 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 viability 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.

Risks Related to Our Common Stock

Our stock price has, and we expect it to continue to, fluctuate significantly, and the value of your investment may decline.

From January 1, 2009 to June 30, 2011, the market price of our common stock has ranged from a high of $2.30 per share to a low of $0.29 per share. The volatile price of our stock makes it difficult for investors to predict the value of their investment, to sell shares at a profit at any given time, or to plan purchases and sales in advance. You might not be able to sell your shares of common stock at or above the offering price due to fluctuations in the market price of the common stock arising from changes in our operating performance or prospects. In addition, the stock markets in general, and the markets for biotechnology and biopharmaceutical companies in particular, have experienced extreme volatility that has often been unrelated to the operating performance of particular companies. A variety of factors may affect our operating performance and cause the market price of our common stock to fluctuate. These include, but are not limited to:

- announcements by us or our competitors of regulatory developments, clinical trial results, clinical trial enrollment, regulatory filings, product development updates, new products and product launches, significant acquisitions, strategic partnerships or joint ventures;
- any intellectual property infringement, product liability or any other litigation involving us;
- developments or disputes concerning patents or other proprietary rights;
- regulatory developments in the United States and foreign countries;
- market conditions in the pharmaceutical and biotechnology sectors and issuance of new or changed securities analysts' reports or recommendations;
- economic or other crises and other external factors;
- actual or anticipated period-to-period fluctuations in our results of operations;

- departure of any of our key management personnel; or
- sales of our common stock.

These and other factors may cause the market price and demand of our common stock to fluctuate substantially, which may limit investors from readily selling their shares of common stock and may otherwise negatively affect the liquidity or value of our common stock.

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

Currently, we do not believe there are any securities analysts who cover us or our common stock. The lack of analyst coverage of our business and operations may decrease the public demand for our common stock, making it more difficult for you to resell your shares when you deem appropriate. To the extent we obtain an analyst following in the future, such analysts 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 elsewhere in this "Risk Factors" section. 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.

We are at risk of securities class action litigation.

In the past, securities class action litigation has often been brought against a company following a decline in the market price of its securities. This risk is especially relevant for us because biotechnology companies have experienced greater than average stock price volatility in recent years. If we faced such litigation, it could result in substantial costs and a diversion of management's attention and resources, which could harm our business.

Our common stock is considered a "penny stock."

The SEC has adopted regulations which generally define "penny stock" to be an equity security that has a market price of less than $5.00 per share, subject to specific exemptions. Because the market price of our common stock is currently less than $5.00 per share, and none of the specific exemptions are applicable, our common stock is considered a "penny stock" according to SEC rules. This designation requires any broker or dealer selling our common stock to disclose certain information concerning the transaction, obtain a written agreement from the purchaser and determine that the purchaser is reasonably suitable to purchase our common stock. These rules may restrict the ability of brokers or dealers to sell shares of our common stock.

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 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 is currently outstanding. Our board of directors will have the authority to fix and determine the relative rights and preferences of our preferred shares, as well as the authority to issue such shares, without approval of our common

stockholders. As a result, our board of directors could authorize the issuance of a series of preferred stock that is senior to our common stock and 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 holders of our common stock.

Because our common stock is primarily traded on the OTCQB market of the Pink Sheets, the volume of shares traded and the prices at which such shares trade may result in lower prices than might otherwise exist if our common stock was traded on a national securities exchange.

Trading of our common stock on the Nasdaq Capital Market was suspended in May 2011 and trading in our common stock has since been conducted on the OTCQB market of The Pink Sheets, an automated quotation system. Stocks traded on the OTCQB are often less liquid than stocks traded on national securities exchanges, not only in terms of the number of shares that can be bought and sold at a given price, but also in terms of delays in the timing of transactions and reduced coverage of us by security analysts and the media. This may result in lower prices for our common stock than might otherwise be obtained if our common stock were traded on a national securities exchange, and could also result in a larger spread between the bid and asked prices for our common stock.

Our certificate of incorporation and by-laws contain provisions that may discourage, delay or prevent a change in our management team that stockholders may consider favorable.

Our certificate of incorporation, our bylaws and Delaware law contain provisions that may have the effect of preserving our current management, such as:

- authorizing the issuance of "blank check" preferred stock without any need for action by stockholders;
- eliminating the ability of stockholders to call special meetings of stockholders; and
- establishing advance notice requirements for nominations for election to the board of directors or for proposing matters that can be acted on by stockholders at stockholder meetings.

These provisions could make it more difficult for our stockholders to effect our corporate policies, make changes in our Board of Directors and for a third party to acquire us, even if doing so would benefit our stockholders.

NOTE REGARDING FORWARD-LOOKING STATEMENTS

Any statements contained in this prospectus about our expectations, beliefs, plans, objectives, assumptions or future events or performance are not historical facts and may be forward-looking. These forward-looking statements include, but are not limited to, statements about:

- the development of our drug candidates, including when we expect to undertake, initiate and complete clinical trials of our product candidates;
- the regulatory approval of our drug candidates;
- our use of clinical research centers and other contractors;
- our ability to find collaborative partners for research, development and commercialization of potential products;
- acceptance of our products by doctors, patients or payors and the availability of reimbursement for our product candidates;
- our ability to market any of our products;

- our history of operating losses;
- our ability to secure adequate protection for our intellectual property;
- our ability to compete against other companies and research institutions;
- the effect of potential strategic transactions on our business;
- our ability to attract and retain key personnel;

- the volatility of our stock price; and
- other risks and uncertainties detailed in “Risk Factors” in this prospectus.

These statements are often, but not always, made through the use of words or phrases such as “anticipate,” “estimate,” “plan,” “project,” “continuing,” “ongoing,” “expect,” “believe” “intend” and similar words or phrases. Readers of this prospec cautioned not to place undue reliance on these forward-looking statements, which speak only as of the date of this prospectus. These forward-looking statements are based largely on our expectations and projections about future events and future trends affecting our business, and are subject to risks and uncertainties that could cause actual results to differ materially from those anticipated in the forward-looking statements. These forward-looking statements involve risks and uncertainties, including the risks discussed under “Risk Factors,” that could cause our actual results to differ materially from those in the forward-looking statements. Except as required by law, we undertake no obligation to publicly revise our forward-looking statements, whether resulting from new information, future events or otherwise. The risks discussed in this prospectus should be considered in evaluating our prospects and future financial performance.

In addition, past financial or operating performance is not necessarily a reliable indicator of future performance and you should not use our historical performance to anticipate results or future period trends. We can give no assurances that any of the events anticipated by the forward-looking statements will occur or, if any of them do, what impact they will have on our results of operations and financial condition.

USE OF PROCEEDS

We will receive none of the proceeds from the sale of the shares by the selling stockholders. Certain of the shares offered hereby are issuable upon the exercise of outstanding warrants. Upon exercise of such warrants we will receive the applicable exercise price paid by the holders of the warrants.

SELLING STOCKHOLDERS

This prospectus covers the resale by the selling stockholders identified below of 7,750,000 shares of common stock, including 2,750,000 shares issuable upon the exercise of outstanding warrants. Of the total number of shares offered hereby, 7,500,000 shares (including 2,500,000 shares issuable upon the exercise of outstanding warrants) were issued to the investors in our June 2011 private placement. The remaining 250,000 shares are issuable upon the exercise of outstanding warrants issued to the placement agents in connection with our June 2011 private placement and their designees. The following table sets forth the number of shares of our common stock beneficially owned by the selling stockholders as of July 18, 2011, 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(2)
Stonepine Capital, L.P. (3)	5,400,000	3,600,000	1,800,000	-
Gregory Kiernan	1,139,341	600,000	300,000	*
Timothy McInerney	1,125,000	400,000	350,000	*
M.S.B. Research Inc. (4)	450,000	300,000	150,000	-
Wolcot Capital Inc. (5)	90,000	60,000	30,000	-
Blue Ridge Capital Inc. (6)	60,000	40,000	20,000	-
Peter M. Kash (7)	2,757,693	-	19,500	6.4
Scott L. Navins (8)	206,912	-	21,500	*
Benjamin Bernstein	524,179	-	21,500	*
Ladenburg Thalmann & Co. Inc. (9)	37,500	-	37,500	-
TOTAL		5,000,000	2,750,000	

* denotes less than 1%

(1) Based on 39,707,764 shares of common stock outstanding as of July 18, 2011. Beneficial ownership is determined in accordance with Rule 13d-3 under the Securities Act, and includes any shares as to which the stockholder has sole or shared voting power or investment power, and also any shares which the 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 stockholder that it is a direct or indirect beneficial owner of those shares.

(2) Post-offering percentage ownership calculations assume the issuance of all shares offered hereby that are issuable upon the exercise of warrants.

(3)

Timothy P. Lynch and Jon M. Plexico, each general partners of the selling stockholder, hold voting and/or investment control over the shares held by the selling stockholder.

(4) Mark Berg holds voting and investment control over the shares held by the selling stockholder.

(5) Nicholas Ponzio holds voting and investment control over the shares held by the selling stockholder.

(6) Nancy Cooper holds voting and investment control over the shares held by the selling stockholder.

(7) Mr. Kash is a director of our Company.

(8) Mr. Navins is our Treasurer.

(9) Ladenburg Thalmann & Co. Inc. is a registered broker-dealer.

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 our 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 our 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, our common stock may be sold in these jurisdictions only through registered or licensed brokers or dealers. In addition, in some states our 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. The selling stockholders have agreed to indemnify us in certain circumstances against certain liabilities, including liabilities under the Securities Act.

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 or (2) the date on which the shares may be sold pursuant to Rule 144 of the Securities Act. We have agreed to pay all expenses in connection with this offering, but not including underwriting discounts, concessions, commissions or fees of the selling stockholders or any fees and expenses of counsel or other advisors to the selling stockholders.

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 42,457,764 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. 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.

DESCRIPTION OF CAPITAL STOCK

General

Our certificate of incorporation authorizes us to issue 110,000,000 shares of capital stock, par value $0.001 per share, comprised of 100,000,000 shares of common stock, and 10,000,000 shares of preferred stock, none of which is currently outstanding.

Our board of directors has the authority to issue the authorized but unissued shares of our common stock without action by our stockholders. The issuance of such shares would reduce the percentage ownership held by current stockholders. Our board of directors also has 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, our board of directors could authorize the issuance of a series of preferred stock that is senior to the common stock and 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 holders of our common stock. See “Risk Factors – Risks Related to Our Securities – There may be issuances of shares of blank check preferred stock in the future.”

As of July 18, 2011, we have issued and outstanding approximately:

- 39,707,764 shares of our common stock;
- options to purchase 8,428,801 shares of our common stock at exercise prices ranging from $0.30 to $5.75 per share; and
- warrants to purchase 8,662,484 shares of our common stock at exercise prices ranging from $0.60 to $2.71 per share.

Common Stock

The holders of our common stock are entitled to one vote for each share on all matters voted on by stockholders, including elections of directors, and, except as otherwise required by law or provided in any resolution adopted by our board with respect to any series of preferred stock, the holders of such shares possess all voting power. Our certificate of incorporation does not provide for cumulative voting in the election of directors. Subject to any preferential rights of any outstanding series of our preferred stock created by our board from time to time, the holders of common stock are entitled to such dividends as may be declared from time to time by our board from funds available therefore and upon liquidation are entitled to receive pro rata all assets available for distribution to such holders. Our common stock is not redeemable.

The holders of our common stock have no preemptive rights. The rights, preferences and privileges of holders of common stock are subject to, and may be adversely affected by, the rights of the holders of shares of any series of preferred stock which we may designate and issue in the future.

MARKET FOR COMMON EQUITY AND RELATED STOCKHOLDER MATTERS

Market for Common Stock

Prior to May 12, 2011, our common stock traded on the NASDAQ Capital Market under the symbol “NLTX.” Since May 12, 2011, our common stock has traded on the OTCQB market of The Pink Sheets under the symbol “NLTX.PK.”

The following table lists the high and low sale price for our common stock as quoted, in U.S. dollars, by the NASDAQ Capital Market and the OTCQB, as applicable, during each quarter within the last two completed fiscal years and the first two quarters of the current fiscal year.

	High	Low
Year ending December 31, 2011		
First quarter	$ 0.97	$ 0.50
Second quarter	$ 1.02	$ 0.53
Year ended December 31, 2010		
First quarter	$ 1.50	$ 0.90
Second quarter	$ 1.09	$ 0.30
Third quarter	$ 0.80	$ 0.29
Fourth quarter	$ 0.79	$ 0.41
Year ended December 31, 2009		
First quarter	$ 1.02	$ 0.28
Second quarter	$ 1.10	$ 0.25
Third quarter	$ 2.30	$ 0.89
Fourth quarter	$ 1.70	$ 1.18

Record Holders

According to the records of our transfer agent, American Stock Transfer & Trust Company, as of July 21, 2011, we had 166 holders of record of common stock, not including those held in “street name.”

Dividends

We have not paid or declared any dividends on our common stock and we do not anticipate paying dividends on our common stock in the foreseeable future.

Securities Authorized for Issuance Under Equity Compensation Plans

Our Amended and Restated 2005 Stock Option Plan, or the 2005 Plan, which is currently our only equity compensation plan, has been approved by our stockholders. The following table sets forth certain information as of December 31, 2010 with respect to the 2005 Plan:

Plan category	Number of Securities to be Issued Upon Exercise of Outstanding Options (A)	Weighted- Average Exercise Price of Outstanding Options (B)	Number of Securities Remaining Available for Future Issuance Under Equity Compensation Plans (Excluding Securities Reflected in Column (A))
Equity compensation plans approved by security holders:			
Amended and Restated 2005 Stock Option Plan	6,923,154	$ 1.52	2,267,851
Equity compensation plans not approved by stockholders:			
Outside any plan (1)	593,750	$ 2.71	—
Total	7,516,904	$ 1.61	2,267,851

(1) Represents shares of common stock issuable upon exercise of stock options issued outside of the 2005 Plan

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MANAGEMENT'S DISCUSSION AND ANALYSIS OF FINANCIAL CONDITION AND RESULTS OF OPERATIONS

The following discussion of our financial condition and results of operations should be read in conjunction with the financial statements and the notes to those statements included in this prospectus. This discussion includes forward-looking statements that involve risk and uncertainties. As a result of many factors, such as those set forth in this prospectus under "Risk Factors," actual results may differ materially from those anticipated in these forward-looking statements.

Overview

We are a development stage biopharmaceutical company in the business of commercially developing innovative products for the treatment of cardiovascular diseases. We currently have rights to develop two drug candidates:

- Cenderitide (formerly CD-NP), our lead product candidate, is a chimeric natriuretic peptide that we are developing for the treatment of heart failure. We plan to develop cenderitide for the treatment of patients for up to 90 days following admission for acutely decompensated heart failure, or ADHF. We also believe cenderitide may be useful in several other cardiovascular and renal indications. We are currently conducting a Phase I clinical trial in collaboration with Medtronic, Inc. Pursuant to an agreement with Medtronic, a portion of the costs to conduct this Phase I trial are being paid for by Medtronic.

- CU-NP, is a pre-clinical rationally designed natriuretic peptide that consists of amino acid chains identical to those produced by the human body, specifically the ring structure of C-type natriuretic peptide, or CNP, and the N- and C-termini of Urodilatin, or URO. We are currently evaluating the potential for the chronic dosing of CU-NP, which could be used to treat a number of cardiovascular and renal diseases.

We have no product sales to date and we will not generate any product revenue until we receive approval from the U.S. Food and Drug Administration, or the FDA, or equivalent foreign regulatory bodies to begin selling our pharmaceutical product candidates. Developing pharmaceutical products is a lengthy and very expensive process. Assuming we do not encounter any unforeseen safety issues during the course of developing our product candidates, we do not expect to complete the development of a product candidate for several years, if ever. To date, most of our development expenses have related to our lead product candidate, cenderitide. As we proceed with the clinical development of cenderitide and as we further develop CU-NP, our second product candidate, our research and development expenses will further increase. To the extent we are successful in acquiring additional product candidates for our development pipeline, our need to finance further research and development will continue increasing. Accordingly, our success depends not only on the safety and efficacy of our product candidates, but also on our ability to finance the development of the products. Our major sources of working capital have been proceeds from public and private sales of our equity and debt securities.

Research and development, or R&D, expenses consist primarily of salaries and related personnel costs, fees paid to consultants and outside service providers for pre-clinical, clinical, and manufacturing development, legal expenses resulting from intellectual property prosecution, contractual review, and other expenses relating to the design, development, testing, and enhancement of our product candidates. We expense our R&D costs as they are incurred.

General and administrative, or G&A, expenses consist primarily of salaries and related expenses for executive, finance and other administrative personnel, personnel recruiting fees, accounting, legal and other professional fees, business development expenses, rent, business insurance and other corporate expenses.

Our results include non-cash compensation expense as a result of the issuance of stock, stock options, and warrants. We expense the fair value of stock options and warrants over the vesting period. When more precise pricing data is unavailable, we determine the fair value of stock options using the Black-Scholes option-pricing model. The terms and vesting schedules for share-based awards vary by type of grant and the employment status of the grantee. Generally, the awards vest based upon time-based or performance-based conditions. Performance-based conditions generally include the attainment of goals related to our financial performance and product development. Stock-based compensation expense is included in the respective categories of expense in the statements of operations. We expect to record additional non-cash compensation expense in the future, which may be significant.

Results of Operations

Three Months Ended March 31, 2011 Compared to Three Months Ended March 31, 2010

General and Administrative Expenses. G&A expenses for the three months ended March 31, 2011 and 2010 were approximately $0.6 million and $0.6 million, respectively. There were no significant changes in G&A activities during the first three months of 2011 as compared to 2010.

Research and Development Expenses. R&D expenses for the three months ended March 31, 2011 and 2010 were approximately $0.6 million and $1.3 million, respectively. The decrease of approximately $0.7 million over 2010 is primarily due to the completion of our Phase II clinical study of cenderitide during the fourth quarter of 2010.

Cenderitide. Although the development of cenderitide is still in its early stages, we believe that it has potential applications to treat heart failure. In addition to the Phase I clinical trial costs being paid for by Medtronic, as of March 31, 2011, we expect to spend $0.7 to $0.8 million in external development costs in the remainder of fiscal 2011. We dosed the first patient in the Phase I trial in April 2011 and expect to enroll a total of approximately 50 patients in the trial. Our strategy for further development of cenderitide in 2012 will depend to a large degree on the outcome of this ongoing clinical trial. We plan to initiate a larger Phase IIb clinical trial in 2012, which will require significant additional capital to fund.

CU-NP. Since acquiring our rights to CU-NP in June 2008, we have incurred total research and development expenses of approximately $0.6 million through March 31, 2011. CU-NP has only undergone preclinical studies and has yet to be studied in humans. Based on our current development plans for CU-NP, we anticipate that we will expend a minimal amount on external development costs until we have obtained significant additional capital.

Our expenditures on current and future clinical development programs, particularly our cenderitide program, are expected to be substantial, particularly in relation to our available capital resources, and to increase. However, these planned expenditures are subject to many uncertainties, including the results of clinical trials and whether we develop any of our drug candidates with a partner or independently. As a result of such uncertainties, we cannot predict with any significant degree of certainty the duration and completion costs of our research and development projects or whether, when and to what extent we will generate revenues from the commercialization and sale of any of our product candidates. The duration and cost of clinical trials may vary significantly over the life of a project as a result of unanticipated events arising during clinical development and a variety of factors, including:

- the number of trials and studies in a clinical program;
- the number of patients who participate in the trials;
- the number of sites included in the trials;
- the rates of patient recruitment and enrollment;
- the duration of patient treatment and follow-up;
- the costs of manufacturing our drug candidates; and
- the costs, requirements, timing of, and the ability to secure regulatory approvals.

Interest Income. Interest income for the three months ended March 31, 2011 and 2010 were approximately $1,986 and $4,846, respectively. This decrease in interest income over 2010 is due to lower interest rates earned on cash in bank accounts, and lower average cash balances in 2011than 2010 levels.

Fiscal Year Ended 2010 Compared to Fiscal Year Ended 2009

General and Administrative Expenses. G&A expenses for the years ended December 31, 2010 and 2009 were approximately $2.2 million and $3.4 million, respectively. The decrease of approximately $1.2 million over 2009 is primarily due to an approximately $0.7 million decrease in stock based compensation expense as a result of the accelerated vesting of stock options of a former executive in 2009. Also, we had an approximately $0.2 million decrease in consulting costs due primarily to lower stock compensation resulting from forfeitures and lower valuations. Additionally, there was an approximately $0.2 million decrease in occupancy costs due to the one-time payment made in 2009 to terminate our San Francisco office space lease and the resulting lower monthly lease payments for our San Mateo office in 2010.

Research and Development Expenses. R&D expenses for the years ended December 31, 2010 and 2009 were approximately $4.1 million and $4.5 million, respectively. The decrease of approximately $0.4 million from 2009 is primarily due to a $0.5 million reduction in cenderitide related manufacturing expenses. Additionally, we had a decrease of approximately $0.2 million in R&D personnel expenses which was primarily attributable to our decision in the second quarter of 2009 to outsource significant R&D functions to a consultant instead of maintaining employees to perform such functions. These decreases were partially offset by an approximately $0.3 million increase in clinical costs relating primarily to our Phase II study of cenderitide in patients with ADHF and mild to moderate renal dysfunction.

Interest Income. Interest income for the years ended December 31, 2010 and 2009 was approximately $20,377 and $47,200, respectively. This decrease in interest income over 2009 is due to lower interest rates earned on cash in bank accounts, and lower average cash balances in 2010 than 2009 levels.

Other Income. On November 1, 2010, we were notified that we had been awarded a $244,479 grant under the Therapeutic Discovery Tax Credit program that was created as part of the Patient Protection and Affordable Care Act of 2010. This program was designed to provide a tax credit or grant of up to 50% of eligible costs and expenses for the tax years of 2009 and 2010 for qualifying research and development expenses incurred for innovative projects that are determined by the U.S. Department of Health and Human Services to have reasonable potential to result in a new therapy, reduce health care costs, or represent a significant advance in finding a cure for human disease. The grant awarded to us related to our R&D expenditures incurred in connection with our cenderitide program. We received the funds granted in the fourth quarter of 2010.

Liquidity and Capital Resources

The following table summarizes our liquidity and capital resources as of March 31, 2011 and December 31, 2010 and our net decrease in cash and cash equivalents for the three months ended March 31, 2011 and 2010 (the amounts stated are expressed in thousands):

Liquidity and capital resources	March 31, 2011	December 31,2010
Cash and cash equivalents	$ 2,124	$ 3,378
Working Capital	1,608	2,528
Stockholders' equity	1,674	2,597

	Three Months Ended March 31,	
Cash flow data	2011	2010
Cash used in:		
Operating activities	$ (1,260)	$ (1,162)
Investing activities	-	-
Cash provided by:		
Financing activities	6	-
Net decrease in cash and cash equivalents	$ (1,254)	$ (1,162)

Our total cash resources as of March 31, 2011 were $2.1 million compared to $3.4 million as of December 31, 2010. As of March 31, 2011, we had approximately $0.7 million in liabilities, and $1.6 million in net working capital. We incurred a net loss of $1.2 million and had negative cash flow from operating activities of $1.3 million for the three months ended March 31, 2011. Since August 1, 2005 (inception) through March 31, 2011, we have incurred an aggregate net loss of approximately $41.1 million, while negative cash flow from operating activities has amounted to $29.3 million. As we continue to develop our product candidates, we expect to continue to incur substantial and increasing losses, which will continue to generate negative net cash flows from operating activities as we expand our

technology portfolio and engage in further research and development activities, particularly the conducting of pre-clinical studies and clinical trials.

From inception through March 31, 2011, we have financed our operations through public and private sales of our equity and debt securities. As we have not generated any revenue from operations to date, and we do not expect to generate revenue for several years, if ever, we will need to raise substantial additional capital in order to continue to fund our research and development, including our long-term plans for clinical trials and new product development, as well as to fund operations generally. We may seek to raise additional funds through various potential sources, such as equity and debt financings, or through strategic collaborations and license agreements. We can give no assurances that we will be able to secure such additional sources of funds to support or operations, or if such funds are available to us, that such additional financing will be sufficient to meet our needs.

Based on our resources at March 31, 2011 and the current plan of expenditure on continuing development of current product candidates, which includes the enrollment of a Phase I clinical trial with cenderitide and Medtronic's pump technology, we believe that we have sufficient capital to fund our operations into the fourth quarter of 2011. We would need substantial additional capital in order to initiate and fund the next clinical study of cenderitide, which is expected to be a Phase IIb clinical trial. Our actual cash requirements may vary materially from those now planned, however, because of a number of factors, including the changes in the focus and direction of our research and development programs, including the acquisition and pursuit of development of new product candidates; competitive and technical advances; costs of commercializing any of the product candidates; and costs of filing, prosecuting, defending and enforcing any patent claims and any other intellectual property rights. If we are unable to raise additional funds when needed, we may not be able to market our products as planned or continue development and regulatory approval of our products, we could be required to delay, scale back or eliminate some or all our research and development programs and we may need to wind down our operations altogether. Each of these alternatives would likely have a material adverse effect on our business.

Our forecasted average monthly cash expenditures for the next nine months, net of funding from Medtronic, are approximately $0.3 million. Following the completion of our ongoing Phase I trial, we will need substantial additional capital, whether from a financing or a strategic partnership, in order to initiate and complete the next study, a Phase IIb clinical trial.

The actual amount of funds we will need to operate is subject to many factors, some of which are beyond our control. These factors include the following:

- the progress of our research activities;
- the number and scope of our research programs;
- the progress of our pre-clinical and clinical development activities;
- the progress of the development efforts of parties with whom we have entered into research and development agreements;
- our ability to maintain current research and development programs and to establish new research and development and licensing arrangements;
- the cost involved in prosecuting and enforcing patent claims and other intellectual property rights; and the cost and timing of regulatory approvals.

We have based our estimates on assumptions that may prove to be wrong. We may need to obtain additional funds sooner than planned or in greater amounts than we currently anticipate. Potential sources of financing include strategic relationships, public or private sales of equity or debt and other sources. We may seek to access the public or private equity markets when conditions are favorable due to our long-term capital requirements. We do not have any committed sources of financing at this time, and it is uncertain whether additional funding will be available when we need it on terms that will be acceptable to us, or at all. If we raise funds by selling additional shares of common stock or other securities convertible into common stock, the ownership interests of our existing stockholders will be diluted. If we are not able to obtain financing when needed, we may be unable to carry out our business plan. As a result, we may have to significantly limit our operations and our business, financial condition and results of operations would be materially harmed. In such an event, we will be required to undertake a thorough review of our programs and the opportunities presented by such programs and allocate our resources in the manner most prudent.

To the extent that we raise additional funds by issuing equity or convertible or non-convertible debt securities, our stockholders may experience additional significant dilution and such financing 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. These things may have a material adverse effect on our business.

The continuation of our business beyond the fourth quarter of 2011 is dependent upon obtaining further long-term financing, the successful development of our drug product candidates and related technologies, the successful and sufficient market acceptance of any product offerings that we may introduce, and, finally, the achievement of a profitable level of operations. The issuance of additional equity securities by us may result in a significant dilution in the equity interests of current stockholders. Obtaining commercial loans, assuming those loans would be available, on acceptable terms or even at all, will increase our liabilities and future cash commitments.

Financing Activities

June 2011 Financing

On June 20, 2011, we entered into a securities purchase agreement with various accredited investors pursuant to which we agreed to sell in a private placement units of our securities consisting of an aggregate of 5,000,000 shares of our common stock and five-year warrants to purchase 2,500,000 additional shares of common stock at an aggregate purchase price of $2,500,000, before deducting expenses. The issuance and sale of the units pursuant to the securities purchase agreement was completed on June 23, 2011.

The warrants sold pursuant to the June 2011 private placement are exercisable at a price per share of $0.60. These 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 250% of the then applicable exercise price of the warrants.

In connection with this private placement, we engaged Riverbank Capital Securities, Inc., or Riverbank, to serve as our placement agent, and Ladenburg Thalmann & Co. Inc. served as a sub-placement agent. We agreed to pay to the placement agents a cash fee equal to 7% of the gross proceeds resulting from the private placement, plus issue a five-year warrant to purchase a number of shares equal to 5% of the shares of common stock sold in the private placement. Pursuant to such terms, we paid the placement agents a cash fee of $175,000 and issued warrants to purchase 250,000 shares of common stock. The warrants issued to the placement agents are in substantially the same form as the warrants issued to the purchasers in the private placement, except that the placement agent warrants include a provisions allowing for cashless (net) exercise. Certain of our officers and directors are principals of Riverbank. See "Certain Relationships and Related Transactions, and Director Independence."

April 2010 Financing

On April 21, 2010, we sold, in an underwritten public offering, a total of 6,500,000 units of our securities at a public offering price of $0.70 per unit. Each unit contained one share of common stock and 0.30 warrants to purchase common stock, each whole warrant representing the right to purchase one share of common stock at an exercise price of $0.94 per share. We may call the warrants for redemption upon 30 days notice if the price of our common stock is at least $3.00 per share for any 20 trading days within a period of 30 consecutive trading days. The units separated immediately and the common stock and warrants were issued separately. The warrants are approved for trading on the Nasdaq Capital Market under the symbol "NLTXW" and began trading on April 22, 2010. The sale of these 6,500,000 units closed on April 27, 2010. Pursuant to the terms of the underwriting agreement, we granted the underwriters an option for a period of 45 days to purchase up to an additional 975,000 units to cover over-allotments, if any. We also issued the underwriters a five-year warrant to purchase 390,000 shares of our common stock at an exercise price of $0.94 per share. On May 6, 2010, the underwriters exercised their option to purchase the maximum amount of 975,000 over-allotment units. The sale of the over-allotment units closed on May 10, 2010. The net proceeds to us from the sale of the units, after deducting underwriting discounts and commissions, was approximately $4.5 million when including the proceeds from the sale of the 975,000 over-allotment units.

License Agreement Commitments

Cenderitide License Agreement

Pursuant to our license agreement with the Mayo Foundation for Medical Education and Research, or Mayo, for cenderitide, in July 2008 we made a milestone payment of $400,000 to Mayo upon the dosing of the first patient in a Phase II trial. Subsequent milestones achieved will require us to make additional milestone payments to Mayo. We

agreed to make contingent cash payments up to an aggregate of $31.9 million upon successful completion of specified clinical and regulatory milestones relating to cenderitide. This aggregate amount is subject to increase upon the receipt of regulatory approval for each additional indication of cenderitide as well as for additional compounds or analogues contained in the intellectual property.

The cenderitide license agreement, unless earlier terminated, will continue in full force and effect until January 20, 2026. However, to the extent any patent covered by the license is issued with an expiration date beyond January 20, 2026, the term of the agreement will continue until such expiration date. Mayo may terminate the agreement earlier (i) for our material breach of the agreement that remains uncured after 90 days' written notice to us, (ii) our insolvency or bankruptcy, or (iii) if we challenge the validity or enforceability of any of the patents in any manner. We may terminate the agreement without cause upon 90 days' written notice.

CU-NP License Agreement

On June 13, 2008, we entered into a second license agreement with Mayo pursuant to which we acquired the rights to CU-NP. Under the terms of the agreement, Mayo granted to us a worldwide, exclusive license for the rights to commercially develop CU-NP for all therapeutic indications. We also have the rights to improvements to CU-NP and know-how that arose out of the laboratory of Dr. John Burnett and Dr. Candace Lee, the inventors of CU-NP and employees of the Mayo Clinic, prior to June 12, 2011.

Under the terms of the CU-NP license agreement, we made an up-front cash payment to Mayo and agreed to make future contingent cash payments up to an aggregate of $24.3 million upon achievement of specific clinical and regulatory milestones relating to CU-NP, including a milestone payment due in connection with the initiation of the first Phase II clinical trial of the licensed product. This aggregate amount of $24.3 million is subject to increase upon the receipt of regulatory approval for each additional indication of CU-NP, as well as for additional compounds or analogues contained in the intellectual property. Pursuant to the agreement, we must also pay Mayo an annual maintenance fee and a percentage of net sales of licensed products.

The CU-NP License Agreement, unless earlier terminated, will continue in full force and effect until June 13, 2028. However, to the extent any patent covered by the license is issued with an expiration date beyond June 13, 2028, the term of the agreement will continue until such expiration date. Mayo may terminate the agreement earlier (i) for our material breach of the agreement that remains uncured after 90 days' written notice to us, (ii) our insolvency or bankruptcy, (iii) if we challenge the validity or enforceability of any of the patents in any manner, or (iv) or upon receipt of notice from the Company that we have terminated all development efforts under the agreement. We may terminate the agreement without cause upon 90 days' written notice.

Collaboration Agreement

In February 2011, we entered into a Clinical Trial Funding Agreement with Medtronic, Inc. Pursuant to the agreement, Medtronic will provide the funding and equipment necessary for us to conduct our ongoing Phase I clinical trial to assess the pharmacokinetics and pharmacodynamics of cenderitide when delivered to heart failure patients through continuous subcutaneous infusion using Medtronic's diabetes pump technology. In accordance with the agreement, Medtronic will provide the funding necessary to conduct the Phase I clinical trial and will supply the pumps and related equipment for use therein.

Under the agreement, we have agreed not to enter into an agreement with a third party to develop or commercialize cenderitide or any drug/device combination developed under the agreement until the earlier of: (i) three months following delivery to Medtronic of a final database with respect to the Phase I trial; and (ii) 15 months after the date of the agreement.

The agreement provides that intellectual property conceived in or otherwise resulting from the performance of the Phase I clinical trial shall be jointly owned by us and Medtronic (the "Joint Intellectual Property"), and that we shall pay royalties to Medtronic based on the net sales of any Nile product, the manufacture, use or sale of which is covered or claimed in one or more issued patents constituting Joint Intellectual Property. The agreement further provides that, if

the parties fail to enter into a definitive commercial license agreement with respect to cenderitide, then each party shall have a right of first negotiation to license exclusive rights to any Joint Intellectual Property.

The agreement will remain in effect until the completion of the Phase I clinical trial unless terminated earlier by either party (i) if the other has materially breached its obligations thereunder, (ii) if the other party becomes subject to a bankruptcy or similar proceeding, (iii) for reasons related to the safety, efficacy, toxicity or formulation of cenderitide, or (iv) for a failure of the study to meet its endpoints. Also, Medtronic may terminate the agreement without cause at any time upon 90 days written notice to us, in which event Medtronic shall be obligated to pay for any non-cancelable costs incurred by us prior to such termination.

Off -Balance Sheet Arrangements

There were no off-balance sheet arrangements as of December 31, 2010 or March 31, 2011.

Critical Accounting Policies and Estimates

Our financial statements are prepared in accordance with generally accepted accounting principles. The preparation of these financial statements requires us to make estimates and assumptions that affect the reported amounts of assets, liabilities, revenues, expenses and related disclosures. We evaluate our estimates and assumptions on an ongoing basis, including research and development and clinical trial accruals, and stock-based compensation estimates. Our estimates are based on historical experience and various other assumptions that we believe to be reasonable under the circumstances. Our actual results could differ from these estimates. We believe the following critical accounting policies reflect the more significant judgments and estimates used in the preparation of our financial statements and accompanying notes.

Research and Development Expenses and Accruals

R&D expenses consist primarily of salaries and related personnel costs, fees paid to consultants and outside service providers for pre-clinical, clinical, and manufacturing development, legal expenses resulting from intellectual property prosecution, contractual review, and other expenses relating to the design, development, testing, and enhancement of our product candidates. R&D costs are expensed as incurred. Amounts due under such arrangements may be either fixed fee or fee for service, and may include upfront payments, monthly payments, and payments upon the completion of milestones or receipt of deliverables.

Our cost accruals for clinical trials and other R&D activities are based on estimates of the services received and efforts expended pursuant to contracts with numerous clinical trial centers and CROs, clinical study sites, laboratories, consultants, or other clinical trial vendors that perform the activities. Related contracts vary significantly in length, and may be for a fixed amount, a variable amount based on actual costs incurred, capped at a certain limit, or for a combination of these elements. Activity levels are monitored through close communication with the CROs and other clinical trial vendors, including detailed invoice and task completion review, analysis of expenses against budgeted amounts, analysis of work performed against approved contract budgets and payment schedules, and recognition of any changes in scope of the services to be performed. Certain CRO and significant clinical trial vendors provide an estimate of costs incurred but not invoiced at the end of each quarter for each individual trial. The estimates are reviewed and discussed with the CRO or vendor as necessary, and are included in R&D expenses for the related period. For clinical study sites, which are paid periodically on a per-subject basis to the institutions performing the clinical study, we accrue an estimated amount based on subject screening and enrollment in each quarter. All estimates may differ significantly from the actual amount subsequently invoiced, which may occur several months after the related services were performed.

In the normal course of business we contract with third parties to perform various R&D activities in the on-going development of our product candidates. The financial terms of these agreements are subject to negotiation and vary from contract to contract and may result in uneven payment flows. Payments under the contracts depend on factors such as the achievement of certain events, the successful enrollment of patients, and the completion of portions of the clinical trial or similar conditions. The objective of our accrual policy is to match the recording of expenses in our financial statements to the actual services received and efforts expended. As such, expense accruals related to clinical trials and other R&D activities are recognized based on our estimate of the degree of completion of the event or events specified in the specific contract.

We have entered into a collaboration agreement with Medtronic, Inc. relating to our ongoing Phase I clinical trial of cenderitide. Under this agreement, we are reimbursed for certain costs of the Phase I trial. We record all of these expenses as research and development expense and the reimbursements from the collaborator as revenue.

No adjustments for material changes in estimates have been recognized in any period presented.

Stock-Based Compensation

Our results include non-cash compensation expense as a result of the issuance of stock, stock options and warrants. We have issued stock options to employees, directors, consultants and Scientific Advisory Board members under our Amended and Restated 2005 Stock Option Plan.

We expense the fair value of stock-based compensation over the vesting period. When more precise pricing data is unavailable, we determine the fair value of stock options using the Black-Scholes option-pricing model. This valuation model requires us to make assumptions and judgments about the variables used in the calculation. These variables and assumptions include the weighted-average period of time that the options granted are expected to be outstanding, the volatility of our common stock, the risk-free interest rate and the estimated rate of forfeitures of unvested stock options.

Stock options or other equity instruments to non-employees (including consultants and all members of our Scientific Advisory Board) issued as consideration for goods or services received by us are accounted for based on the fair value of the equity instruments issued (unless the fair value of the consideration received can be more reliably measured). The fair value of stock options is determined using the Black-Scholes option-pricing model and is periodically remeasured as the underlying options vest. The fair value of any options issued to non-employees is recorded as expense over the applicable service periods.

The terms and vesting schedules for share-based awards vary by type of grant and the employment status of the grantee. Generally, the awards vest based upon time-based or performance-based conditions. Performance-based conditions generally include the attainment of goals related to our financial and development performance. Stock-based compensation expense is included in the respective categories of expense in the Statements of Operations appearing elsewhere in this prospectus. We expect to record additional non-cash compensation expense in the future, which may be significant.

OUR BUSINESS

Company Overview

We are a development stage biopharmaceutical company in the business of commercially developing innovative products for the treatment of cardiovascular diseases. We currently have rights to develop two drug candidates:

- Cenderitide (formerly CD-NP), our lead product candidate, is a chimeric natriuretic peptide that we are developing for the treatment of heart failure. We plan to develop cenderitide for the treatment of patients for up to 90 days following admission for acutely decompensated heart failure, or ADHF. We also believe cenderitide may be useful in several other cardiovascular and renal indications.

- CU-NP, is a pre-clinical rationally designed natriuretic peptide that consists of amino acid chains identical to those produced by the human body, specifically the ring structure of C-type natriuretic peptide, or CNP, and the N- and C-termini of Urodilatin, or URO. We are currently evaluating the potential for the chronic dosing of CU-NP, which could be used to treat a number of cardiovascular and renal diseases.

We were originally incorporated under Delaware law in August 2005 under the name Nile Pharmaceuticals, Inc. and we changed our name to Nile Therapeutics, Inc. in January 2007. On September 17, 2007, we were acquired by SMI Products, Inc., or SMI, which was then a public shell company, in a reverse merger transaction whereby a wholly-owned subsidiary of SMI merged with and into Nile Therapeutics, with Nile Therapeutics remaining as the surviving corporation and a wholly-owned subsidiary of SMI. In accordance with the terms of this transaction, the stockholders of Nile Therapeutics exchanged all of their shares of Nile Therapeutics common stock for shares of SMI common stock, which immediately following the transaction represented approximately 95 percent of the issued and outstanding common stock of SMI. Upon completion of the merger, the sole officer and director of SMI resigned and was replaced by the officers and directors of Nile Therapeutics. Additionally, following the merger, Nile Therapeutics, or Old Nile, was merged into SMI, and SMI changed its name to Nile Therapeutics, Inc., or Nile, and adopted the business plan of Old Nile. We collectively refer to these two merger transactions in this prospectus as the "Merger." Because the Merger was accounted for as a reverse acquisition under generally accepted accounting principles, the financial statements for periods prior to September 17, 2007 reflect only the operations of Old Nile.

Our executive offices are located at 4 West 4th Ave., Suite 400, San Mateo, California 94402. Our telephone number is (650) 458-2670 and our Internet address is www.nilethera.com. The information on, or accessible through, our website is not part of this prospectus.

Our Product Candidates

The following table summarizes our product development programs:

Product	Indications	Commercial Rights	Ongoing Studies / Status
Cenderitide	Heart failure	Nile	Single-blind, placebo-controlled Phase I study of cenderitide in chronic heart failure patients is ongoing. The primary objective of the study is to assess the pharmacokinetics of cenderitide delivered through a subcutaneous micro-needle pump.

CU-NP	Cardiovascular / Renal	Nile	Preclinical.

Background on Heart Failure

Heart failure, or HF, is a condition that exists when the heart cannot pump blood to the body as quickly as needed. Blood returning to the heart faster than the heart can eject it, congests the system behind it. Decreased blood flow to organs, such as the kidneys, causes the body to retain more fluid, which further complicates the problem. As a result, HF can often cause damage to the kidneys and other organs, which in turn can worsen the condition of the heart.

HF is the fastest-growing clinical cardiac disease in the United States according to the American Heart Association, affecting over 5 million Americans. Over 1.2 million patients in the U.S. each year are hospitalized with ADHF, an acute exacerbation of their condition. This hospitalization rate is almost double the rate seen 15 years ago. HF is the most frequent cause of hospital admission in the U.S. for patients older than 65 years, generating annual inpatient costs of more than $35 billion, according to the American Heart Association. We believe that approval of a novel agent with safety and efficacy improvements over existing therapies could significantly expand the HF market.

Patients with heart failure are treated with a combination of drugs in an attempt to improve cardiac output and reverse fluid overload. Diuretics, such as furosemide, are used as a first-line treatment to relieve the symptoms of ADHF patients by helping to remove excess fluid from the body, which then helps to increase cardiac output. However, some studies have correlated high doses of intravenous (i.v.) furosemide, a diuretic, with a decreased kidney function and some patients can become resistant to the effects of furosemide. Second-line treatments are often palliative, and can come at the cost of an increased mortality rate. Despite aggressive therapy, 1 in 3 patients die of the disease within a year of diagnosis, reflecting a substantial need for novel treatments.

Only one new treatment for ADHF patients has been approved by the FDA in over 20 years: nesiritide, which is also known as Natrecor®, or B-type natriuretic peptide, or BNP. Nesiritide, a drug marketed by Johnson & Johnson, is a natriuretic peptide that targets the A-type natriuretic peptide receptor and was approved in 2001 by the FDA.

Within 90 days following hospital admission for ADHF, which we refer to as the “post-acute” period, approximately 40% of patients with ADHF return to the hospital. To prevent a return to the hospital, post-acute patients need sustained cardiac and renal function support to prevent a recurrence of their acute symptoms. While this post-acute indication is a novel indication in the HF space, we believe that post-acute patients represent one of the greatest areas of unmet need in the HF market.

Cenderitide Program

Cenderitide is a novel chimeric natriuretic peptide in clinical development for the treatment of HF patients. Cenderitide was rationally designed by scientists at the Mayo Clinic’s cardio-renal research labs. Current therapies for ADHF, including nesiritide, 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. Cenderitide was designed to preserve the favorable effects of existing natriuretic peptide therapies while reducing or attenuating the hypotensive response and enhancing or preserving renal function. We believe that cenderitide has potential utility in multiple cardio-renal indications, including preservation of cardiac function following acute myocardial infarction and prevention of renal damage following cardiac surgery.

Prior Clinical Studies

In 2007, we completed a Phase Ia dose-escalation study in healthy volunteers to examine the safety and pharmacodynamic effects of various doses of cenderitide. The study placed particular emphasis on the effects of cenderitide 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 cenderitide was associated with increased levels of plasma cGMP, a secondary messenger of the target receptor, preserved renal function, increased urinary excretion of sodium, or natriuresis, and increased urination, or diuresis. The study also showed that cenderitide had a minimal effect on mean arterial pressure, a measurement of pumped blood flow in the arteries.

In 2008, we initiated two additional dose-escalation studies to assess the safety and pharmacodynamic profile of cenderitide in heart failure patients. The first study was a Phase Ib study in chronic heart failure patients with signs of fluid overload designed to understand the maximum tolerated dose of the product candidate. Patients with chronic

heart failure with signs of fluid overload were enrolled into the study. The effects of 24 hours of cenderitide delivered though i.v. infusion was compared to the patient's baseline established in the 24 hours prior to cenderitide infusion. The patient's oral diuretic and vasoactive medications were withheld during the cenderitide infusion. While the study was not powered for statistical analysis, data from the Phase Ib study indicate the following:

- Cenderitide was tolerated at doses of up to 20 ng/kg/min;
- Cenderitide blood pressure effects were dose-dependent and well characterized;
- Cenderitide infusion resulted in increases in diuresis at doses of 3, 10 and 20 ng/kg/min as compared to each patient's base-line, which included oral diuretic medication;

- With a 24-hour infusion, cenderitide produced decreases in serum creatinine and cystatin-c in stable heart failure patients, consistent with enhanced renal function; and
- As expected, the limiting toxicity of cenderitide was shown to be symptomatic hypotension, which was experienced by one of six patients at the maximum tolerated dose of 20 ng/kg/min, and by two of two patients at a dose of 30 ng/kg/min.

The second study was a Phase IIa study in acute heart failure patients designed to better understand the hemodynamic properties of cenderitide, or how cenderitide affected blood circulation. The subjects were enrolled 24-48 hours after admission to the hospital for acute heart failure. In the first 24-48 hours after admission, subjects were treated with the standard of care. The subjects were enrolled into the study only after an investigator had determined that the patient needed a Swan-Ganz catheter to better monitor pulmonary capillary wedge pressure, or PCWP, and after the patient's acute condition had stabilized. All patients received a continuous i.v. infusion of furosemide throughout the administration of cenderitide. Data from the Phase IIa study indicate the following:

- Cenderitide was tolerated at all study doses, including 1, 3, 10 and 20 ng/kg/min;
- Cenderitide had minimal blood pressure effects at all doses;
- In the first cohort, where patients were dosed at 3 and then 10 ng/kg/min, the cenderitide infusions produced clinically relevant reductions in PCWP;
- In the second cohort, where patients were dosed at 1 and 20 ng/kg/min, the cenderitide infusions did not result in clinically relevant reductions in PCWP;
- Cenderitide produced a clinically relevant increase in diuresis at doses of 3, 10 and 20 ng/kg/min when administered concurrently with i.v. furosemide; and
- There was no clinically relevant change in serum creatinine and there were no cases of symptomatic hypotension in any subject.

In March 2009, the FDA placed a clinical hold on the cenderitide program. The FDA requested additional data on our Phase IIa clinical trial, which was finalized in March 2009, and modifications to cenderitide's current investigator brochure. We submitted a full response to the FDA in April 2009 and the cenderitide program was released from clinical hold on May 15, 2009.

In June 2010, we completed dosing of a 77 patient, open-label Phase II study of cenderitide in patients with ADHF and mild to moderate renal dysfunction. Cenderitide infusion at 1.25, 2.5 and 3.75 ng/kg/min appeared to be well tolerated. A dose-related effect on blood pressure was observed, with minimal or mild blood pressure reduction at 1.25 and 2.5 ng/kg/min, and moderate blood pressure reduction at 3.75 ng/kg/min. Dose escalation was limited by significant blood pressure reduction at 5 ng/kg/min. Secondary and exploratory analyses demonstrated favorable effects of cenderitide on renal function, particularly at the 1.25 and 2.5 ng/kg/min doses. At these doses, cenderitide appeared to preserve or enhance renal function compared to placebo, as evidenced by favorable trends in several biomarkers correlated with kidney function, including creatinine and cystatin-c.

In addition to our own studies, in July 2008, the Mayo Clinic initiated a Phase Ib study, under an investigator-sponsored investigational new drug application, or IND, to better understand cenderitide's renal properties. We presented data from this study at the American College of Cardiology conference in April 2011.

Ongoing Clinical Studies

In January 2011, we met with the FDA to discuss the future path of our cenderitide program and to propose a new paradigm of treatment for ADHF patients. We proposed to treat ADHF patients with cenderitide for 90 days following admission for ADHF, the post-acute period. To treat post-acute patients with a natriuretic peptide outside of the hospital setting, we plan to utilize subcutaneous micro-needle pump technology, which is currently used for

continuous insulin delivery to Type I diabetic patients. We entered into a clinical trial funding agreement with Medtronic, Inc. pursuant to which we will collaborate a) to develop a new formulation of cenderitide for subcutaneous delivery and b) to perform a Phase I clinical study to understand the pharmacokinetics (PK) and pharmacodynamics (PD) of cenderitide when delivered through continuous subcutaneous infusion. Under the terms of our agreement with Medtronic, Medtronic will fund costs of the Phase I trial, as well as various manufacturing, analytical, and preclinical activities.

In May 2011, we commenced the placebo-controlled Phase I clinical trial designed to evaluate the PK and PD response of continuous subcutaneous infusion of cenderitide, as compared with a short term subcutaneous bolus injection, in chronic heart failure patients. Patients will receive either a subcutaneous bolus injection of cenderitide, or a 24 hour continuous infusion of cenderitide delivered through a Medtronic subcutaneous micro-needle pump. The primary purpose of the trial is to understand the subcutaneous dose required to achieve optimal steady-state plasma levels of cenderitide, as determined by previous i.v. studies.

Following completion of the subcutaneous Phase I PK/PD study, we plan to initiate a large Phase II double-blind, placebo-controlled, dose ranging study in post-acute patients. The Phase II study will evaluate the endpoints of cardiac remodeling, renal function, re-hospitalization and mortality in patients following 90 days of therapy. We expect to be able to initiate this Phase II study in 2012.

CU-NP Program

CU-NP is our novel natriuretic peptide rationally designed by scientists at the Mayo Clinic's cardio-renal research labs. 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.

Intellectual Property, License and Collaboration Agreement

Our goal is to obtain, maintain and enforce patent protection for our products, formulations, processes, methods and other proprietary technologies, preserve our trade secrets, and operate without infringing on the proprietary rights of other parties, both in the United States and abroad. Our policy is to actively seek to obtain, where appropriate, the broadest intellectual property protection possible for our current product candidates and any future product candidates, proprietary information and proprietary technology through a combination of contractual arrangements and patents, both in the United States and abroad. Even patent protection, however, may not always afford us with complete protection against competitors who seek to circumvent our patents. If we fail to adequately protect or enforce our intellectual property rights or secure rights to patents of others, the value of our intellectual property rights would diminish.

We will continue to depend upon the skills, knowledge and experience of our scientific and technical personnel, as well as that of our advisors, consultants and other contractors, none of which is patentable. To help protect our proprietary know-how, which is not patentable, and for inventions for which patents may be difficult to enforce, we currently rely and will in the future rely on trade secret protection and confidentiality agreements to protect our interests. To this end, we require all of our employees, consultants, advisors and other contractors to enter into confidentiality agreements that 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.

License Agreements

Cenderitide

On January 20, 2006, we entered into an exclusive, worldwide, royalty-bearing license agreement with the Mayo Foundation for Medical Education and Research, or the Mayo Foundation, for the rights to issued patents, patent applications and know-how relating to the use of cenderitide in all therapeutic uses. We were also entitled to rights to improvements to cenderitide that arise out of the laboratory of Dr. John Burnett, the co-inventor of cenderitide, until January 19, 2009.

Under the terms of the cenderitide license agreement, we paid the Mayo Foundation an up-front cash payment and reimbursed it for past patent expenses. We issued to the Mayo Foundation 1,379,419 shares of our common stock. Additionally, we agreed to make contingent cash payments up to an aggregate of $31.9 million upon successful completion of specified clinical and regulatory milestones relating to cenderitide. This aggregate amount is subject to increase upon the receipt of regulatory approval for each additional indication of cenderitide as well as for additional compounds or analogues contained in the intellectual property. In July 2008, we made a milestone payment of $400,000 to the Mayo Foundation upon the dosing of the first patient in a Phase II trial. Based on the current stage of research we do not expect to make any milestone payments for the year ending December 31, 2011. Pursuant to the cenderitide license agreement, we will pay the Mayo Foundation an annual maintenance fee and a percentage of net sales of licensed products, as well as $50,000 per year for the consulting services of Dr. Burnett while serving as chairman of the Company's Scientific Advisory Board.

In addition to the potential milestone payments discussed above, the cenderitide license agreement requires us to issue shares of our common stock to the Mayo Foundation for an equivalent dollar amount of grants received in excess of $300,000, but not to exceed $575,000. For the period from August 1, 2005 (inception) through March 31, 2011, the Company received $482,235 in grant income for which it has issued to the Mayo Foundation 63,478 shares (representing $182,236) of common stock.

The cenderitide license agreement, unless earlier terminated, will continue in full force and effect until January 20, 2026. However, to the extent any patent covered by the license is issued with an expiration date beyond January 20, 2026, the term of the agreement will continue until such expiration date. Mayo may terminate the agreement earlier (i) for our material breach of the agreement that remains uncured after 90 days' written notice to us, (ii) our insolvency or bankruptcy, or (iii) if we challenge the validity or enforceability of any of the patents in any manner. We may terminate the agreement without cause upon 90 days' written notice.

Pursuant to our cenderitide license agreement with Mayo Foundation, we have exclusive rights to 4 issued U.S. patents and 2 pending U.S. patent applications, 16 issued foreign patents and 2 pending foreign applications, covering composition of matter and methods of use. These patents and patent applications cover cenderitide, and other similar natriuretic peptides, as well as methods of use of the peptides in the treatment of multiple cardiovascular and renal indications. The issued composition of matter patent expires in 2019 and, if allowed, the last of the pending U.S. patents would expire in 2029.

CU-NP

On June 13, 2008, we entered into an exclusive, worldwide, royalty-bearing license agreement, or the CU-NP License Agreement, with the Mayo Foundation for the rights to intellectual property and to develop commercially CU-NP for all therapeutic indications. We also hold the rights to improvements to CU-NP that arose out of the Mayo Clinic laboratory of Dr. John Burnett and Dr. Candace Lee, the inventors of CU-NP, prior to June 12, 2011.

Under the terms of the CU-NP License Agreement, we made an up-front cash payment to the Mayo Foundation and agreed to make future contingent cash payments up to an aggregate of $24.3 million upon achievement of specific clinical and regulatory milestones relating to CU-NP, including a milestone payment due in connection with the initiation of the first Phase II clinical trial of the licensed product. This aggregate amount of $24.3 million is subject to increase upon the receipt of regulatory approval for each additional indication of CU-NP, as well as for additional compounds or analogues contained in the intellectual property. Based on the current stage of research the Company does not expect to make any milestone payments for the year ending December 31, 2011. Pursuant to the agreement, we must also pay the Mayo Foundation an annual maintenance fee and a percentage of net sales of licensed products.

In addition to these cash payments payable with respect to the CU-NP License Agreement, we also agreed to issue shares of our common stock and warrants to the Mayo Foundation. In June 2008, we issued 49,689 shares of our common stock to the Mayo Foundation having a fair market value as of June 13, 2008 equal to $250,000. Additionally, Dr. Burnett has applied for funding through Mayo's Discovery-Translation Program. In the event Dr. Burnett is awarded funding through this program, and the funding is used for the development of the licensed product based on the patent applications, we agreed to grant to the Mayo Foundation an equivalent dollar value in warrants to purchase shares of our common stock. The number of shares purchasable under these warrants will be calculated using the Black-Scholes option-pricing model and the warrants will include a cashless exercise provision with language to be negotiated in good faith between the parties.

The CU-NP License Agreement, unless earlier terminated, will continue in full force and effect until June 13, 2028. However, to the extent any patent covered by the license is issued with an expiration date beyond June 13, 2028, the term of the agreement will continue until such expiration date. The Mayo Foundation may terminate the agreement

earlier (i) for our material breach of the agreement that remains uncured after 90 days' written notice to us, (ii) our insolvency or bankruptcy, (iii) if we challenge the validity or enforceability of any of the patents in any manner, or (iv) or upon receipt of notice from us that we have terminated all development efforts under the agreement. We may terminate the agreement without cause upon 90 days' written notice.

Pursuant to our CU-NP License Agreement, we have exclusive rights to 1 pending U.S. patent application and 3 pending foreign applications, covering composition of matter and methods of use. These patents and patent applications cover CU-NP, and other similar natriuretic peptides, as well as methods of use of the peptides in the treatment of multiple cardiovascular and renal indications. If allowed, the pending U.S. patent would expire in 2028.

Collaboration Agreement

In February 2011, we entered into a Clinical Trial Funding Agreement with Medtronic, Inc. Pursuant to the agreement, Medtronic will provide the funding and equipment necessary for us to conduct our ongoing Phase I clinical trial to assess the pharmacokinetics and pharmacodynamics of cenderitide when delivered to heart failure patients through continuous subcutaneous infusion using Medtronic's diabetes pump technology.

Under the agreement, we have agreed not to enter into an agreement with a third party to develop or commercialize cenderitide or any drug/device combination developed under the agreement until the earlier of: (i) three months following delivery to Medtronic of a final database with respect to the Phase I trial; and (ii) 15 months after the date of the agreement.

The agreement provides that intellectual property conceived in or otherwise resulting from the performance of the Phase I clinical trial shall be jointly owned by us and Medtronic (the "Joint Intellectual Property"), and that we shall pay royalties to Medtronic based on the net sales of any Nile product, the manufacture, use or sale of which is covered or claimed in one or more issued patents constituting Joint Intellectual Property. The agreement further provides that, if the parties fail to enter into a definitive commercial license agreement with respect to cenderitide, then each party shall have a right of first negotiation to license exclusive rights to any Joint Intellectual Property.

The agreement will remain in effect until the completion of the Phase I clinical trial unless terminated earlier by either party (i) if the other has materially breached its obligations thereunder, (ii) if the other party becomes subject to a bankruptcy or similar proceeding, (iii) for reasons related to the safety, efficacy, toxicity or formulation of cenderitide, or (iv) for a failure of the study to meet its endpoints. Also, Medtronic may terminate the agreement without cause at any time upon 90 days written notice to us, in which event Medtronic shall be obligated to pay for any non-cancelable costs incurred by us prior to such termination.

Government Regulation

The research, development, testing, manufacture, labeling, promotion, advertising, distribution, and marketing, among other things, of our product candidates are extensively regulated by governmental authorities in the United States and other countries. In the United States, the Food and Drug Administration, or FDA, regulates drugs under the Federal Food, Drug, and Cosmetic Act, or the FDCA, and it's implementing regulations. Failure to comply with the applicable United States requirements may subject us to administrative or judicial sanctions, such as FDA refusal to approve a pending NDA, warning letters, product recalls, product seizures, total or partial suspension of production or distribution, injunctions, and/or criminal prosecution.

Drug Approval Process

A drug or drug candidate may not be marketed or sold in the United States until it has received FDA approval. The process to receiving such approval is long, expensive and risky, and includes the following steps:

- pre-clinical laboratory tests, animal studies, and formulation studies;
- submission to the FDA of an IND for human clinical testing, which must become effective before human clinical trials may begin;
- adequate and well-controlled human clinical trials to establish the safety and efficacy of the drug for each indication;
- submission to the FDA of an NDA;
- satisfactory completion of an FDA inspection of the manufacturing facility or facilities at which the drug is produced to assess compliance with current good manufacturing practices, or cGMPs; and

- FDA review and approval of the NDA.

Pre-clinical tests include laboratory evaluation of product chemistry, toxicity, and formulation, as well as animal studies. The conduct of the pre-clinical tests and formulation of the compounds for testing must comply with federal regulations and requirements. The results of the pre-clinical tests, together with manufacturing information and analytical data, are submitted to the FDA as part of an IND, which must become effective before human clinical trials may begin. An IND will automatically become effective 30 days after receipt by the FDA, unless before that time the FDA raises concerns or questions about issues such as the conduct of the trials as outlined in the IND. In such a case, the IND sponsor and the FDA must resolve any outstanding FDA concerns or questions before clinical trials can proceed. We cannot be sure that submission of an IND will result in the FDA allowing clinical trials to begin.

Clinical trials involve the administration of the investigational drug to human subjects under the supervision of qualified investigators. Clinical trials are conducted under protocols detailing the objectives of the study, the parameters to be used in monitoring safety, and the effectiveness criteria to be evaluated. Each protocol must be submitted to the FDA as part of the IND.

Clinical trials are typically conducted in three sequential "Phases," although the Phases may overlap. The study protocol and informed consent information for study subjects in clinical trials must also be approved by an Institutional Review Board for each institution where the trials will be conducted. Study subjects must sign an informed consent form before participating in a clinical trial. Phase I usually involves the initial introduction of the investigational drug into human patients to evaluate its short-term safety, dosage tolerance, metabolism, pharmacokinetics and pharmacologic actions, and, if possible, to gain an early indication of its effectiveness. Phase II usually involves trials in a limited patient population to (i) evaluate dosage tolerance and appropriate dosage; (ii) identify possible adverse effects and safety risks; and (iii) evaluate preliminarily the efficacy of the drug for specific indications. Phase III trials usually further evaluate clinical efficacy and test further for safety by using the drug in its final form in an expanded patient population. There can be no assurance that Phase I, Phase II, or Phase III testing will be completed successfully within any specified period of time, if at all. Furthermore, we or the FDA may suspend clinical trials at any time on various grounds, including a finding that the subjects or patients are being exposed to an unacceptable health risk.

The FDCA permits the FDA and the IND sponsor to agree in writing on the design and size of clinical studies intended to form the primary basis of an effectiveness claim in an NDA. This process is known as Special Protocol Assessment. These agreements may not be changed after the clinical studies begin, except in limited circumstances.

Assuming successful completion of the required clinical testing, the results of the pre-clinical studies and of the clinical studies, together with other detailed information, including information on the manufacture and composition of the drug, are submitted to the FDA in the form of an NDA requesting approval to market the product for one or more indications. The testing and approval process requires substantial time, effort, and financial resources. The FDA reviews the application and may deem it to be inadequate to support the registration, and companies cannot be sure that any approval will be granted on a timely basis, if at all. The FDA may also refer the application to the appropriate advisory committee, typically a panel of clinicians, for review, evaluation, and a recommendation as to whether the application should be approved. The FDA is not bound by the recommendations of the advisory committee.

The FDA has various programs, including fast track, priority review, and accelerated approval, that are intended to expedite or simplify the process for reviewing drugs, and/or provide for approval on the basis of surrogate endpoints. Generally, drugs that may be eligible for one or more of these programs are those for serious or life-threatening conditions, those with the potential to address unmet medical needs, and those that provide meaningful benefit over existing treatments. In March 2011, we were granted fast-track status for the development of cenderitide in the post-acute ADHF setting, however, we cannot be sure that this program will maintain its fast-track status or that the review time will be reduced.

Before approving an NDA, the FDA usually will inspect the facility or the facilities at which the drug is manufactured and will not approve the product unless cGMP compliance is satisfactory. If the FDA evaluates the NDA and the manufacturing facilities as acceptable, the FDA may issue an approval letter, or in some cases, an approvable letter followed by an approval letter. Both letters usually contain a number of conditions that must be met in order to secure final approval of the NDA. When and if those conditions have been met to the FDA's satisfaction, the FDA will issue an approval letter. The approval letter authorizes commercial marketing of the drug for specific indications. As a condition of NDA approval, the FDA may require post-marketing testing and surveillance to monitor the drug's safety or efficacy, or impose other conditions.

After approval, certain changes to the approved product, such as adding new indications, making certain manufacturing changes, or making certain additional labeling claims, are subject to further FDA review and approval. Before we can market our product candidates for additional indications, we must obtain additional approvals from the FDA. Obtaining approval for a new indication generally requires that additional clinical studies be conducted. We cannot be sure that any additional approvals for new indications for any product candidate will be approved on a timely basis, or at all.

Post-Approval Requirements

Often times, even after a drug has been approved by the FDA for sale, the FDA may require that certain post-approval requirements be satisfied, including the conduct of additional clinical studies. If such post-approval requirements are not satisfied, the FDA may withdraw its approval of the drug. In addition, holders of an approved NDA are required to report certain adverse reactions to the FDA, comply with certain requirements concerning advertising and promotional labeling for their products, and continue to have quality control and manufacturing procedures conform to cGMP after approval. The FDA periodically inspects the sponsor's records related to safety reporting and/or manufacturing facilities; this latter effort includes assessment of compliance with cGMP. Accordingly, manufacturers must continue to expend time, money, and effort in the area of production and quality control to maintain cGMP compliance. We intend to use third-party manufacturers to produce our products in clinical and commercial quantities, and future FDA inspections may identify compliance issues at the facilities of our contract manufacturers that may disrupt production or distribution, or require substantial resources to correct. In addition, discovery of problems with a product after approval may result in restrictions on a product, manufacturer, or holder of an approved NDA, including withdrawal of the product from the market.

Manufacturing

We do not currently have our own manufacturing facilities. We intend to continue to use our financial resources to accelerate development of our product candidates rather than diverting resources to establish our own manufacturing facilities. We meet our pre-clinical and clinical trial manufacturing requirements by establishing relationships with third-party manufacturers and other service providers to perform these services for us. We rely on individual proposals and purchase orders to meet our needs and typically rely on terms and conditions proposed by the third party or us to govern our rights and obligations under each order (including provisions with respect to intellectual property, if any). We do not have any long-term agreements or commitments for these services. Likewise, we do not have any long-term agreements or commitments with vendors to supply the underlying component materials of our product candidates, some of which are available from only a single supplier.

Should any of our product candidates obtain marketing approval, we anticipate establishing relationships with third-party manufacturers and other service providers in connection with the commercial production of our products. We have some flexibility in securing other manufacturers to produce our product candidates; however, our alternatives may be limited due to proprietary technologies or methods used in the manufacture of some of our product candidates.

Competition

We face significant competition from companies with substantial financial, technical, and marketing resources, which could limit our future revenues from sales of cenderitide and CU-NP. Our success will depend, in part, upon our ability to achieve market share at the expense of existing and future products in the relevant target markets. Existing and future products, therapies, technologies, technological innovations, and delivery systems will likely compete directly with our products.

The development and commercialization of new products to treat cardiovascular diseases is highly competitive, and there will be considerable competition from major pharmaceutical, biotechnology, and other companies. With respect to cenderitide, many therapeutic options are available for patients with ADHF, including, without limitation, nitroglycerine, inotropic agents, diuretics, as well as Natrecor®. Some of our competitors include, without limitation, Scios (a Johnson & Johnson company), Bayer, Merck, Zealand Pharma, and Novartis. We are not currently aware of other compounds being developed to treat ADHF patients in the post-acute period.

With respect to CU-NP, competitors would include many of the same companies included as competitors for cenderitide. Because of our intent to investigate the compound's potential for chronic administration, additional competitors could include, without limitation, Teva Pharmaceuticals and Palatin Technologies.

Our competitors generally have substantially more resources than we do, including both financial and technical resources. In addition, many of these companies have more experience than Nile in pre-clinical and clinical development, manufacturing, regulatory, and global commercialization. We are also competing with academic institutions, governmental agencies, and private organizations that are conducting research in the field of cardiovascular disease. Competition for highly qualified employees is intense.

Research and Development Expenses

Research and development, or R&D, expenses consist primarily of salaries and related personnel costs, fees paid to consultants and outside service providers for pre-clinical, clinical, and manufacturing development, legal expenses resulting from intellectual property prosecution, contractual review, and other expenses relating to the design, development, testing, and enhancement of our product candidates. R&D expenses for the years ended December 31, 2010 and 2009 were approximately $4.1 million and $4.5 million, respectively.

Employees

As of June 30, 2011, we had two full-time and two part-time employees. None of our employees are covered by a collective bargaining agreement. We believe our relations with our employees are satisfactory.

We retain several consultants who serve in various operational and administrative capacities, and we utilize clinical research organizations and third parties to perform our pre-clinical studies, clinical studies, and manufacturing. We may hire additional research and development staff, as required, to support our product development.

Legal Proceedings

We are not a party to any material legal proceedings.

Description of Property

We do not own any real property. Our principal offices are located at 4 West 4th, Ave. Suite 400, San Mateo, CA, 94402. Under the terms of an open-ended lease, cancellable upon 60 days notice, the base rent is $2,000 per month. The office space is approximately 1,200 square feet. In connection with this lease, we have made a $2,000 cash security deposit.

We relocated our principal offices effective August 15, 2009 from San Francisco, California to San Mateo, California. We occupied our former San Francisco office under a non-cancelable operating lease that was to expire in March 2012. In October 2009, we entered into a lease termination and surrender of premises agreement with the landlord.

As our operations expand, we expect our space requirements and related expenses to increase.

MANAGEMENT AND BOARD OF DIRECTORS

Directors and Executive Officers

The following table lists our executive officers and directors and their respective ages and positions:

Name of Nominee	Age	Position Held	Director Since
Arie S. Belldegrun, M.D.	61	Director	September 2009
Richard B. Brewer	60	Chairman of the Board	July 2010
Pedro Granadillo	64	Director	October 2007
Peter M. Kash	49	Director	September 2007
Joshua A. Kazam	34	Director & Chief Executive Officer	September 2007
Frank Litvack, M.D.	55	Director	September 2009
Paul A. Mieyal, Ph.D.	41	Director	September 2007
Gregory W. Schafer	47	Director	January 2008

Set forth below are descriptions of the backgrounds of each member of the Board of Directors, his principal occupations for at least the past five years and his current public-company directorships.

Arie S. Belldegrun, M.D., FACS has been a director of Nile since September 2009. Dr. Belldegrun is Director of the Institute of Urologic Oncology at UCLA, Professor of Urology and Chief of the Division of Urologic Oncology. He holds the Roy and Carol Doumani Chair in Urologic Oncology at the David Geffen School of Medicine at the University of California, Los Angeles (UCLA). In 1997, Dr. Belldegrun founded Agensys, Inc., an early-stage privately-held biotechnology company based in Los Angeles, California, that is focused on the development of fully human monoclonal antibodies to treat solid tumor cancers in a variety of cancer targets. Dr. Belldegrun served as founding Chairman of Agensys from 1997 to 2002 and then as a director until December 2007, when the company was acquired by Astellas Pharma. Dr. Belldegrun served as Vice Chairman of the Board and Chairman of the Scientific Advisory Board of Cougar Biotechnology, Inc., a Los Angeles-based biopharmaceutical company, from December 2003 until its acquisition by Johnson & Johnson in July 2009. Since March 2008, Dr. Belldegrun has served as a director of Arno Therapeutics, Inc., a publicly-held, New Jersey-based biopharmaceutical company focused on the treatment of cancer patients. Dr. Belldegrun has also served as Executive Chairman of the Board of Directors of Kite Pharma, Inc., a privately-held, California-based biotechnology company dedicated to the development of pioneering immune-based cancer therapies, since its inception in 2009. From February 2004 to December 2009, Dr. Belldegrun also served on the Board of Directors of Hana Biosciences, Inc., a publicly-held biopharmaceutical company. He is also Chairman and Partner of Two River Group Holdings LLC, a New York based venture capital firm. Dr. Belldegrun also serves as an officer of the managing member of Two River Consulting, LLC, an organization that provides management, consulting and operational services for development stage biotechnology companies, including Nile. Dr. Belldegrun's prior experience also includes serving as principal investigator of more than 50 clinical trials of anti-cancer drug candidates and therapies. Dr. Belldegrun completed his M.D. at the Hebrew University Hadassah Medical School in Jerusalem, his post graduate fellowship at the Weizmann Institute of Science and his residency in Urological Oncology at Harvard Medical School. Prior to UCLA, Dr. Belldegrun was at the National Cancer Institute/NIH as a research fellow in surgical oncology under Steven A. Rosenberg, M.D., Ph.D. He is certified by the American Board of Urology and is a Fellow of the American College of Surgeons and the American Association of Genitourinary Surgeons.

Richard B. Brewer was appointed to serve as our Executive Chairman in July 2010. Mr. Brewer also currently serves as Chairman of the Boards of Dendreon Corporation, a publicly-held biotechnology company based in Seattle, and Arca Biopharma, Inc., a publicly-held biotechnology company developing genetically targeted therapies for patients with heart failure and other cardiovascular diseases. Mr. Brewer was President and Chief Executive Officer of Arca

Biopharma from November 2006 to December 2009. Prior to joining Arca Biopharma, from January 2003, Mr. Brewer was Managing Partner of Crest Asset Management, where he provided guidance to and invested in biotechnology opportunities. Before that, Mr. Brewer was President and Chief Executive Officer of Scios, Inc., a biopharmaceutical company that was acquired by Johnson & Johnson in 2004. Additionally, Mr. Brewer is a member of the Board of Directors of SRI (Stanford Research Institute), as well as a Member of the Board of Advisors for Northwestern University, Kellogg School of Business, Biotechnology Section. Mr. Brewer possesses deep knowledge of the natriuretic peptide space having served as CEO and President of Scios Inc., where he led the company in achieving FDA approval for Natrecor® (nesiritide). Previous to Scios, Mr. Brewer served as Chief Operating Officer of Heartport, a cardiovascular device company developing minimally invasive approaches to major heart surgery. Before Heartport, he spent over a decade at Genentech, ultimately serving as Senior Vice President of U.S. Marketing and Senior Vice President of Genentech Europe and Canada. Mr. Brewer holds an M.B.A. from Northwestern University and a B.S. from Virginia Polytechnic Institute & State University.

Pedro Granadillo has served as a director of the Company since October 2007, and also serves as Chairman of the Compensation Committee and as a member of the Nominating & Corporate Governance Committee and Audit Committee. Mr. Granadillo served as Senior Vice President for Eli Lilly and Company, or Lilly, until 2004 when he retired after 34 years of service. He was a member of Lilly's Executive Committee. As Lilly's top human resources, manufacturing and quality executive, he was responsible for policies affecting a global workforce of more than 45,000 employees, as well as a broad network of manufacturing facilities for its extensive line of products. He also oversaw more than 20 sites and 13,000 employees involved in the manufacturing of Lilly's conventional "small-molecule" pharmaceuticals and "large-molecule" biotech therapies. Mr. Granadillo currently serves as a director of Dendreon Corp., Noven Pharmaceuticals, Inc., and Haemonetics Corporation, all of which are publicly-held biopharmaceutical companies, and First Indiana Bank. Mr. Granadillo received his B.S. in Industrial Engineering from Purdue University.

Peter M. Kash has served as a director of the Company since its inception in August 2005, and also currently serves as the Chairman of the Nominating & Corporate Governance Committee and as a member of the Compensation Committee. Mr. Kash has also served as a director of Arno Therapeutics, Inc., a publicly-held, New Jersey-based biopharmaceutical company focused on the treatment of cancer patients, since its inception in August 2005. From December 2004 to December 2006, Mr. Kash served as a director of Javelin Pharmaceuticals, Inc., a publicly-held biopharmaceutical company focused on pain management. In September 2004, Mr. Kash co-founded Two River Group Holdings, LLC, a venture capital firm that specializes in the creation of new companies to acquire rights to commercially develop early stage biotechnology products. He serves as President of Two River Group Management, LLC, the managing member of Two River Group Holdings, LLC. Mr. Kash is also the President and Chairman of Riverbank Capital Securities, Inc., a broker-dealer registered with the Financial Industry Regulatory Authority, or FINRA (formerly NASD). From 1992 until 2004, Mr. Kash was a Senior Managing Director of Paramount BioCapital, Inc., a FINRA member broker-dealer, specializing in conducting private financings for public and private development stage biotechnology companies as well as Paramount BioCapital Investments, LLC, a venture capital company. Mr. Kash also served as Director of Paramount Capital Asset Management, Inc., the general partner of several biotechnology-related hedge funds and as member of the General Partner of the Orion Biomedical Fund, LP, a private equity fund. Mr. Kash received his B.S. in Management Science from SUNY Binghamton and his M.B.A. in Banking and International Finance from Pace University. Mr. Kash is currently completing his doctorate in education at Yeshiva University.

Joshua A. Kazam has served as our non-employee President and Chief Executive Officer since June 2009, and has served as a director of the Company since inception in August 2005. In September 2004, Mr. Kazam co-founded Two River Group Holdings, LLC, and currently serves as Vice President and Director of Two River's managing member, Two River Group Management, LLC. Mr. Kazam also serves as an officer of the managing member of Two River Consulting, LLC, an organization that provides management, consulting and operational services for development stage biotechnology companies, including Nile. Mr. Kazam also serves as an Officer and Director of Riverbank Capital Securities, Inc. From 1999 to 2004, Mr. Kazam was a Managing Director of Paramount BioCapital, Inc. where he was responsible for ongoing operations of venture investments, and as the Director of Investment for the Orion Biomedical Fund, LP. Mr. Kash has also served as a director of Arno Therapeutics, Inc., a publicly-held, New Jersey-based biopharmaceutical company focused on the treatment of cancer patients, since its inception in August 2005 until April 2011. Mr. Kazam currently serves as a director of Tigris Pharmaceuticals, Inc., a privately-held biotechnology company, and an officer or director of several privately held companies. Mr. Kazam is a graduate of the Wharton School of the University of Pennsylvania.

Frank Litvack, M.D. has been a director of the Company since September 2009. Dr. Litvack served as Chairman (from 2002) and CEO (from 2003) of Conor MedSystems, Inc., a publicly-held company focused on the development of vascular drug delivery systems, until its acquisition by Johnson & Johnson in February 2007. From 2000 to 2005, Dr. Litvack was Chairman of Savacor, Inc., a medical device company that was acquired by St. Jude Medical, Inc. in

late 2005. Since 2000, Dr. Litvack has been a Professor of Medicine at University of California, Los Angeles. From 1989 until 1997, Dr. Litvack was a founder and director of Progressive Angioplasty Systems Inc., which was acquired by United States Surgical Corporation. Since 1996, Dr. Litvack has been a member of Calmedica, LLC. Since 1985, Dr. Litvack has been an attending cardiologist at Cedars-Sinai Medical Center. Dr. Litvack co-directed the Cardiovascular Intervention Center at Cedars-Sinai Medical Center from 1986 to 2000. Dr. Litvack currently serves as a director of several privately-held corporations. Dr. Litvack holds an M.D. from McGill University.

Paul Mieyal, Ph.D., CFA has served as a director of the Company since September 2007, and also serves as a member of the Audit Committee and the Compensation Committee. Since 2006, Dr. Mieyal has served as a Vice President of Wexford Capital LP, or Wexford, an SEC registered investment advisor located in Greenwich, CT. Prior to that, from 2000 to 2006, he was Vice President in charge of healthcare investments for Wechsler & Co., Inc., a private investment firm and registered broker-dealer. Dr. Mieyal serves as a director of Nephros, Inc. a publicly held company. Dr. Mieyal received his Ph.D. in Pharmacology from New York Medical College, a B.A. in chemistry and psychology from Case Western Reserve University, and is a Chartered Financial Analyst.

Gregory W. Schafer has served as a director of the Company since January 2008, and also serves as Chairman of the Audit Committee. Mr. Schafer has served as Chief Financial Officer Jennerex, a biotherapeutics company focused in oncology, since June 2010. From April 2009 to June 2010, Mr. Schafer served as an independent consultant to private and public biotechnology companies. From April 2006 to January 2009, Mr. Schafer served as the Vice President and Chief Financial Officer of Onyx Pharmaceuticals, Inc., a publicly-held, California-based biopharmaceutical company dedicated to developing innovative therapies that target the molecular mechanisms that cause cancer. Prior to Onyx, from 2004 to 2006, Mr. Schafer served as a consultant to several private and public biotechnology companies. From 1997 to 2004, Mr. Schafer held various executive positions at Cerus Corporation, a public biotechnology company, including Vice President and Chief Financial Officer. Prior to joining Cerus, Mr. Schafer worked as a management consultant for Deloitte & Touche LLP. Mr. Schafer holds an M.B.A from the Anderson Graduate School of Management at UCLA and a BSE in Mechanical Engineering from the University of Pennsylvania.

Experience, Qualifications, Attributes and Skills of Directors

We look to our directors to lead us through our continued growth as an early-stage public biopharmaceutical company. Our directors bring their leadership experience from a variety of life science companies and professional backgrounds which we require to continue to grow and bring value to our stockholders. With over 35 years of biotechnology and pharmaceutical industry experience, Mr. Brewer, our Executive Chairman, brings a wealth of operational, financial, and business development expertise to us, including a deep knowledge of the heart failure space in particular. Dr. Litvack's clinical expertise in cardiology offers a unique perspective into the development and practical application of our product candidates. Mr. Brewer, Mr. Kash, Mr. Kazam and Dr. Mieyal have venture capital or investment banking backgrounds and offer expertise in financing and growing small biopharmaceutical companies. Each of Mr. Brewer, Dr. Belldegrun, Mr. Kash, Mr. Kazam, Dr. Litvack, Dr. Mieyal and Mr. Schafer have significant experience with early stage private and public companies and bring depth of knowledge in building stockholder value, growing a company from inception and navigating significant corporate transactions and the public company process. Mr. Granadillo has extensive experience in the pharmaceutical industry, allowing him to contribute his significant operational experience. Mr. Kazam's current position as our CEO also allows him to provide a unique insight into our development and growth. As a result of his experience in the role of chief financial officer of public companies, Mr. Schafer also bring extensive finance, accounting and risk management knowledge to us.

Independence of the Board of Directors

Our Board of Directors consults with our legal counsel to ensure that the Board's determinations are consistent with all relevant securities and other laws and regulations regarding the definition of "independent," including those set forth in the applicable Nasdaq listing standards to which we were subject until May 2011. Consistent with these considerations, and after review of all relevant transactions or relationships between each director, or any of his family members, and Nile, its senior management and its independent registered public accounting firm, the Board has determined that Messrs. Granadillo, Kash and Schafer and Drs. Litvack and Mieyal are independent directors within the meaning of applicable Nasdaq listing standards.

Executive Compensation

The following summary compensation table reflects cash and non-cash compensation for the 2009 and 2010 fiscal years awarded to or earned by (i) each individual serving as our principal executive officer during the fiscal year ended December 31, 2010; and (ii) each individual that served as an executive officer at the end of the fiscal year ended December 31, 2010 and who received in excess of $100,000 in total compensation during such fiscal year. We refer to these individuals as our “named executive officers.”

Summary Compensation Table

Name and Principal Position	Year	Salary ($)	Bonus ($)	Option Awards($)(1)	All Other Compensation ($)	Total ($)
Richard B. Brewer (2)	2010	$ 107,384	$ –	$ 271,899	$ –	$ 379,283
Executive Chairman	2009	–	–	–	–	–
Joshua A. Kazam (3)	2010	$ –	$ –	$ 16,876	$ –	$ 16,876
President & CEO	2009	–	–	80,963	–	80,963
Daron Evans	2010	$ 226,522	$ 75,000	$ 89,170	$ 530 (4)	$ 391,222
Chief Financial Officer	2009	200,000	20,000	80,034	530 (4)	300,564

(1) Amounts reflect the grant date fair value of awards granted under the Company's Amended and Restated Stock Option Plan, computed pursuant to Financial Accounting Standards Board's Accounting Standards Codification 718 "Compensation – Stock Compensation". Assumptions used in the calculation of these amounts are included in Note 10 of the Notes to Audited Financial Statements included in our Annual Report on Form 10-K filed with the Securities and Exchange Commission on March 14, 2011. For awards that are subject to performance conditions, amounts reflect the assumption that the highest level of performance conditions will be achieved. See the "Outstanding Equity Awards at Fiscal Year-End" table in this prospectus for information regarding all option awards outstanding as of December 31, 2010.

(2) Mr. Brewer was appointed Executive Chairman on July 21, 2010. Mr. Brewer does not receive additional compensation for his service as a director of the Company.

(3) Mr. Kazam was appointed President and CEO on June 11, 2009. Mr. Kazam, also a director of Nile, does not receive additional compensation for his service as President and CEO.

(4) Represents premiums paid for life insurance.

Employment Agreements and Post-Termination Benefits

Richard B. Brewer — Executive Chairman

Mr. Brewer's employment as our Executive Chairman is subject to the terms of a letter agreement dated July 15, 2010. In accordance with the agreement, Mr. Brewer is entitled to an annual salary of $240,000. In addition, upon Mr. Brewer's appointment, we issued to him a 10-year stock option to purchase 450,000 shares of our common stock at an exercise price of $0.32 per share and which was immediately exercisable. In addition, following the effective date of the amendment of our 2005 Stock Option Plan, we issued to Mr. Brewer a second 10-year option to purchase 900,000 shares of our common stock at an exercise price of $0.37 per share, which vests and becomes exercisable in eight equal quarterly installments commencing September 30, 2011, provided that the vesting of this option will accelerate in the event of a "change of control" (as defined under our 2005 Stock Option Plan) of the Company. Both stock options were awarded pursuant to our 2005 Stock Option Plan. Mr. Brewer is not entitled to any severance or other post-termination benefits in the event his employment with us is terminated by either him or us.

Daron Evans — Chief Financial Officer

Mr. Evans' employment with us was initially governed by an employment agreement dated January 19, 2007, as amended on August 19, 2007 and March 4, 2008, respectively. The employment agreement, which initially provided for Mr. Evans's employment as Chief Operating Officer of our predecessor entity, a privately-held Delaware corporation, or Old Nile, provides for a term that expired on February 13, 2010. Despite the expiration of the employment agreement, Mr. Evans employment with us continues on an indefinite basis on substantially the same compensation terms. Under his former employment agreement, Mr. Evans was initially entitled to an annual base salary of $175,000. Mr. Evans' annual base salary was increased to $200,000 as of January 1, 2009, and to $250,000 as of July 15, 2010. In addition, Mr. Evans is eligible to receive an annual performance bonus of up to 30% of his annual base salary upon the successful completion of annual corporate and individual milestones.

Mr. Evans' former employment agreement also provided for the awarding of certain stock options, referred to as Employment Options, Performance Options, and Technology Options. On September 17, 2007, Mr. Evans was granted Employment Options to purchase 239,896 shares of our common stock at an exercise price of $2.71, vesting in three equal installments on the day before each anniversary of his employment agreement. Mr. Evans was also granted Performance Options to purchase 288,458 shares of our common stock at an exercise price of $2.71, vesting up to one-third in each calendar year, or a pro-rata portion thereof for a period less than a full year, based on the successful completion of annual corporate and individual milestones as determined by our Board of Directors or its Compensation Committee. To the extent our Board or Compensation Committee declines to vest the maximum amount of Performance Options in any given calendar year, or a pro-rata portion thereof for a period less than a full year, such unvested amount are deemed forfeited by Mr. Evans. On March 4, 2008, the Compensation Committee determined that, for the pro-rated period ending December 31, 2007, Mr. Evans' Performance Options would vest in the amount of 76,528 shares out of a possible 84,562 shares, resulting in the forfeiture of Performance Options to purchase 8,034 shares. On January 16, 2009, the Compensation Committee determined that, for the calendar year ending December 31, 2008, Mr. Evans' Performance Options would vest in the amount of 43,269 shares out of a possible 96,153 shares, resulting in the forfeiture of Performance Options to purchase 52,884 shares. On January 19, 2010, the Compensation Committee determined that, for the calendar year ending December 31, 2009, Mr. Evans' Performance Options would vest in the amount of 50,000 shares out of a possible 96,153 shares, resulting in the forfeiture of Performance Options to purchase 46,153 shares. On July 8, 2010, Mr. Evans was granted a 10-year option to purchase 200,000 shares of our common stock at an exercise price of $0.301 per share, which vests and becomes exercisable in twelve equal quarterly installments commencing September 30, 2010. On July 26, 2010, Mr. Evans was granted a 10-year option to purchase 250,000 shares of our common stock at an exercise price of $0.37 per share, which vests and becomes exercisable in twelve equal quarterly installments commencing September 30, 2010.

Pursuant to a Severance Benefits Agreement dated July 24, 2010, if Mr. Evans' employment is terminated by us other than for "cause" (as defined below), Mr. Evans shall be entitled, upon execution of a customary release, to continued payment of his then-current base salary for a period of six months. For this purpose, "cause" means the following conduct or actions taken by Mr. Evans: (i) willful failure to perform his duties to the Company or willful misconduct in the performance of such duties; (ii) any willful, intentional or grossly negligent act causing material harm to the business or reputation of the Company; (iii) any material violation of the confidentiality, invention assignment, or non-solicitation obligations set forth in the agreement; (iv) indictment of any felony or a misdemeanor involving moral turpitude; or (v) any misappropriation or embezzlement of the Company's property.

Outstanding Equity Awards at Fiscal Year-End

The following table sets forth information concerning stock options held by the named executive officers at December 31, 2010:

Name	Number of Securities Underlying Unexercised Options Exercisable	Number of Securities Underlying Unexercised Options Unexercisable	Equity Incentive Plan Awards: Number of Securities Underlying Unexercised Unearned Options	Option Exercise Price ($)	Option Expiration Date	
Richard B. Brewer	450,000	—	—	0.32	07/21/2020	
	—	900,000	—	0.37	07/26/2020	(1)
Joshua A. Kazam (2)	50,000	—	—	4.50	01/25/2018	
	25,000	—	—	0.93	12/22/2018	

	65,000	—	—	1.77	07/21/2019	
	—	80,000	—	0.37	07/26/2010	(3)
Daron G. Evans	409,696	—	—	2.71	09/17/2017	
	49,020	—	—	0.88	01/15/2019	
	67,500	—	25,000	0.89	06/24/2019	(4)
	33,333	166,667	—	0.30	07/08/2020	(5)
	41,667	208,333	—	0.37	07/26/2020	(5)

(1) Option granted on July 26, 2010 and which vests in 8 quarterly installments of 112,500 shares commencing on September 30, 2011.

(2) All stock options held by Mr. Kazam were awarded as compensation for his services as a director.

(3) Option granted July 26, 2010 and which vests in its entirety on July 26, 2011.

(4) Option granted on June 24, 2009 to purchase up to a maximum of 100,000 shares, of which the right to purchase 25,000 vested immediately and the right to purchase remaining shares vested subject to the performance of specified clinical development milestones in two installments of up to 50,000 shares and up to 25,000 shares. On February 15, 2010, Mr. Evans' right to purchase 42,500 of such 50,000-share installment vested and the remaining 7,500 shares of such installment were forfeited. On January 3, 2011, Mr. Evans' right to purchase 18,128 shares of the final 25,000-share installment vested and the remaining 6,872 shares were forfeited. This table reflects the vesting of such option as of December 31, 2010, without giving effect to the satisfaction of the vesting criteria on January 3, 2011.

(5) Option vests in 12 equal quarterly installments commencing September 30, 2010.

Compensation of Directors

On July 8, 2010, the Compensation Committee of our Board of Directors amended the compensation plan applicable to our non-employee directors. As amended, our non-employee directors receive an annual stock option grant pursuant to our 2005 Stock Option Plan relating to 80,000 shares of common stock, and the chairs of the Board's Audit and Compensation Committees each receive an additional annual stock option grant relating to 20,000 shares. All of such stock options are awarded upon each director's re-election by our stockholders and vest in their entirety on the first anniversary of the grant date. Newly-appointed non-employee directors are entitled to receive a stock option to purchase 130,000 shares of our common stock, which option vests in three equal annual installments commencing on the first anniversary of the grant date.

Prior to the adoption of this plan, our non-employee directors did not receive any cash fees for their service, but were periodically awarded stock options. The following table sets forth the compensation received by our directors for their service in 2010. Mr. Brewer is not listed below since he is an employee of Nile Therapeutics and receives no additional compensation for serving on our Board of Directors or its committees. Mr. Kazam, who is also currently serving as our Chief Executive Officer, does not receive any compensation for his service as our Chief Executive Officer and his compensation reflected below represents compensation received solely for his services as a director in accordance with the standard compensation applicable to our other non-employee directors.

Name	Fees Earned or Paid in Cash	Option Awards (1)	Total
Arie S. Belldegrun, M.D.	$ —	$ 16,876	$ 16,876
Pedro Granadillo	—	21,095	21,095
Peter M. Kash	—	16,876	16,876
Joshua A. Kazam	—	16,876	16,876
Frank Litvack, M.D.	—	16,876	16,876
Paul A. Mieyal, Ph.D.	—	16,876	16,876
Gregory W. Schafer	—	21,095	21,095

(1) Amounts reflect the grant date fair value of awards granted under the Company's Amended and Restated Stock Option Plan, computed pursuant to Financial Accounting Standards Board's Accounting Standards Codification 718 "Compensation – Stock Compensation". Assumptions used in the calculation of these amounts are included in Note 10 of the Notes to Audited Financial Statements included in our Annual Report on Form 10-K filed with the Securities and Exchange Commission on March 14, 2011.

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SECURITY OWNERSHIP OF CERTAIN BENEFICIAL OWNERS AND MANAGEMENT

The following table sets forth certain information known to us regarding the beneficial ownership of our common stock as of July 18, 2011 by:

- each of our directors,
- each named executive officer as defined and named in the Summary Compensation Table appearing herein,
- all of our directors and executive officers as a group, and,
- each person known by us to beneficially own more than five percent of our common stock (based on information supplied in Schedules 13D and 13G filed with the Securities and Exchange Commission).

Except as indicated by footnote, and subject to applicable community property laws, each person identified in the table possesses sole voting and investment power with respect to all capital stock shown to be held by that person. The address of each named executive officer and director, unless indicated otherwise, is c/o Nile Therapeutics, Inc., 4 West 4th Ave., Suite 400, San Mateo, California 94402.

Name of Beneficial Owner	Shares of Common Stock Beneficially Owned (1)	Percentage of Common Stock Beneficially Owned (1)
Named Executive Officers and Directors:		
Richard B. Brewer (2)	450,000	1.1
Joshua A. Kazam (3)	2,737,407	6.8
Daron Evans (4)	772,048	1.9
Arie S. Belldegrun (5)	1,395,630	3.5
Pedro Granadillo (6)	302,588	*
Peter M. Kash (7)	2,757,693	6.9
Frank Litvack (8)	480,000	1.2
Paul A. Mieyal	—	—
Gregory W. Schafer (9)	275,100	*
Directors and executive officers as a group (10 individuals)	9,507,047	21.7
5% Stockholders:		
Wexford Capital LP (10) 411 West Putnam Avenue Greenwich, CT 06830	2,826,952	7.1
Stonepine Capital, L.P. (11) 475 Gate Five Road, Suite 320 Sausalito CA 94965	5,400,000	9.9

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* Represents less than 1%.

(1)

Based on 39,707,764 shares of our common stock outstanding as of July 18, 2011. 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 July 1, 2011, 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) Represents shares issuable upon the exercise of a stock option.

(3) Includes (i) 220,000 shares issuable upon the exercise of stock options held by Mr. Kazam; (ii) 244,278 shares issuable upon the exercise of outstanding warrants held by Mr. Kazam; (iii) 613,841 shares held by the Kazam Family Trust, of which Mr. Kazam's spouse is the trustee and his children are beneficiaries, and as to which Mr. Kazam's disclaims beneficial ownership except to the extent of any pecuniary interest therein; (iv) 165,530 shares held by Mr. Kazam's spouse as custodian for the benefit of their minor children, to which Mr. Kash disclaims beneficial ownership except to the extent of his pecuniary interest therein; and (v) 165,530 shares held by the Kash Family Foundation, of which Mr. Kazam is trustee but as to which he has no pecuniary interest.

(4) Includes (i) 744,344 shares issuable upon the exercise of stock options held by Mr. Evans; (ii) 3,952 shares issuable upon the exercise of warrants held by Mr. Evans; and (iii) a total of 10,600 shares held by Mr. Evans' spouse and minor children.

(5) Includes (i) 80,000 shares issuable upon the exercise of stock options held by Dr. Belldegrun, (ii) 604,210 shares issuable upon the exercise of warrants held by Dr. Belldegrun, (iii) 81,145 shares held by Leumi Overseas Trust Corp. Ltd. as Trustee of the BTL Trust, of which 4,210 shares are issuable upon the exercise of warrants, (iv) 129,600 shares held by the Belldegrun Family Trust, of which 64,800 shares are issuable upon the exercise of warrants, (v) 486,400 shares held by the Arie S. Belldegrun M.D. Inc. Profit Sharing Plan, including 243,200 shares issuable upon the exercise of warrants, (vi) 584,000 shares held by Leumi Overseas Trust Corp. Ltd. as Trustee of the Tampere Trust, of which 292,000 shares are issuable upon the exercise of warrants, and (vii) 34,485 shares held by Bellco Capital, LLC. Dr. Belldegrun disclaims beneficial ownership of the shares and warrants held by Leumi Overseas Trust Corp. Ltd. as Trustee of each of the BTL Trust and the Tampere Trust, except to the extent of his beneficiary interest therein.

(6) Includes 275,000 shares issuable upon the exercise of stock options.

(7) Includes (i) 255,000 shares issuable upon the exercise of stock options held by Mr. Kash, (ii) 244,366 shares issuable upon the exercise of warrants held by Mr. Kash, (iii) 496,589 shares held by Mr. Kash's spouse as custodian for the benefit of their minor children under the UGMA, to which Mr. Kash disclaims beneficial ownership except to the extent of his pecuniary interest therein, and (iv) 165,530 shares held by the Kash Family Foundation.

(8) Includes: (i) 80,000 shares issuable upon the exercise of stock options held by Dr. Litvack, and (ii) 400,000 shares held by Calmedica Capital L.P. ("Calmedica"), a limited partnership of which Dr. Litvack is a limited partner, including 200,000 shares issuable upon the exercise of warrants held by Calmedica. Dr. Litvack disclaims beneficial ownership of the shares and warrants held by Calmedica except to the extent of his pecuniary interest therein.

(9) Includes 275,000 shares issuable upon the exercise of stock options.

(10) Includes (i) 1,910,103 shares held by Iota Investors LLC, a Delaware limited liability company ("Iota Investors"), (ii) five year warrants to purchase 16,841 shares at an exercise price of $2.71 per share held by Iota Investors, and (iii) 696,675 shares held by Wexford Spectrum Investors LLC, a Delaware limited liability company ("Wexford Spectrum"). Wexford Capital LP, a Delaware limited partnership ("Wexford Capital"), is a registered Investment Advisor and also serves as an investment advisor or sub-advisor to the members of Iota Investors and Wexford Spectrum. Wexford GP LLC, a Delaware limited liability company ("Wexford GP"), is the general partner of Wexford Capital. Mr. Charles E. Davidson is chairman, a managing member and a controlling member of Wexford GP and Mr. Joseph M. Jacobs is president, a managing member and a controlling member of Wexford GP. Beneficial ownership also includes 203,333 shares issuable upon the exercise of stock options that have been assigned to Wexford Capital by Dr. Mieyal, a director of Nile and vice president of Wexford Capital.

(11) Represents 3,600,000 shares of common stock held by Stonepine Capital, L.P., and warrants to purchase 1,800,000 shares of common stock at a per share price of $0.60; provided, however, that such warrants provide that Stonepine Capital, L.P. may not exercise the warrants to the extent that it would beneficially own in excess of 9.99% of our outstanding common stock immediately after giving effect to such exercise. Stonepine Capital Management is the general partner of Stonepine Capital, L.P.

TRANSACTIONS WITH RELATED PERSONS, PROMOTERS AND CERTAIN CONTROL PERSONS

Two River Consulting, LLC

On June 24, 2009, we entered into a services agreement with Two River Consulting, LLC, or TRC, to provide us with various clinical development, operational and administrative services for a period of one year. As compensation for

such services, we paid to TRC a monthly cash fee of $65,000 and we issued stock options to purchase up to an aggregate of 750,000 shares of our common stock at a price per share equal to $0.89, the closing sale price of our common stock on June 24, 2009. Shares relating to 25% of this option vested immediately and the remaining shares will vest pursuant to the achievement of certain milestones relating to the development of CD-NP. In February 2010, an additional 318,750 shares subject to this option vested and 56,250 shares subject to the option were forfeited. On January 3, 2011, an additional 135,957 shares vested and the remaining 51,543 shares lapsed and were forfeited. Instead of issuing the stock option to TRC, at TRC's direction, the options were issued to designated employees of TRC who are engaged in performing the services under the services agreement. On August 12, 2010, we and TRC entered into an amendment to the Services Agreement to extend the term of the agreement and provide that it will continue on a month-to-month basis until otherwise terminated by one of the parties upon 30 days' notice. We also agreed to issue to designees of TRC a 5-year stock option to purchase 250,000 shares of our common stock at a price per share of $0.38, the closing sale price of the common stock on August 12, 2010. The stock option was fully vested and immediately exercisable at the time of grant. Since April 1, 2011, we have paid a monthly cash fee of approximately $31,000 to TRC.

Joshua A. Kazam, our President & Chief Executive Officer and director, Arie S. Belldegrun, a current director, and David M. Tanen, a director of the Company until September 2009, are the principal owners of TRC. None of Messrs. Kazam and Tanen and Dr. Belldegrun received any of the stock options issued by us pursuant to the services agreement. The terms of the Services Agreement with TRC, including the August 12, 2010 amendment, were reviewed and approved by a special committee of our Board of Directors consisting of Pedro Granadillo, Paul Mieyal and Greg Schafer. None of the members of the special committee has any interest in TRC or the Services Agreement.

Riverbank Capital Securities, Inc.

In connection with our June 2011 private placement, we engaged Riverbank Capital Securities, Inc., or Riverbank, to serve as our placement agent, and Riverbank subsequently engaged Ladenburg Thalmann & Co. Inc. as a sub-placement agent. We agreed to pay Riverbank a cash fee equal to 7% of the gross proceeds resulting from the private placement, plus issue a five-year warrant to purchase a number of shares equal to 5% of the shares of our common stock sold in the private placement. Pursuant to such terms, we paid the placement agents a cash fee of $175,000 and issued five-year warrants to purchase 250,000 shares of common stock at an exercise price of $0.60 per share.

Peter M. Kash, a director of our Company, and Joshua A. Kazam, our President and Chief Executive Officer and a director, are each officers of Riverbank. Messrs. Kash and Kazam may be allocated a portion of the warrants issuable to Riverbank. In light of our relationships with Messrs. Kash and Kazam, the selection of the Riverbank as a placement agent and the terms of the engagement were reviewed and approved by a special committee of the our Board of Directors consisting of disinterested directors with no affiliation to Riverbank or its affiliates.

WHERE YOU CAN FIND MORE INFORMATION

Federal securities laws require 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 Judiciary Plaza, 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.

LEGAL MATTERS

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 as of December 31, 2010 and 2009, and for the years then ended, and for the period from August 1, 2005 (inception) through December 31, 2010, included in this prospectus, have been so included in reliance on the report of Crowe Horwath LLP, independent registered public accounting firm, given on the authority of that firm as experts in accounting and auditing.

TRANSFER AGENT

The transfer agent for our common stock is American Stock Transfer & Trust Company, and its address is 40 Wall Street, New York, New York, 10005.

DISCLOSURE OF COMMISSION POSITION ON INDEMNIFICATION FOR SECURITIES ACT LIABILITIES

Insofar as indemnification for liabilities arising under the Securities Act of may be permitted to directors, officers or persons controlling the registrant pursuant to the foregoing provisions, the registrant has been informed that in the opinion of the Securities and Exchange Commission such indemnification is against public policy as expressed in the Securities Act and is therefore unenforceable.

INDEX TO FINANCIAL STATEMENTS

REPORT OF INDEPENDENT REGISTERED PUBLIC ACCOUNTING FIRM

To the Board of Directors and stockholders
Nile Therapeutics, Inc.
San Mateo, California

We have audited the accompanying balance sheet of Nile Therapeutics, Inc. (a development stage company) as of December 31, 2010 and 2009, and the related statements of operations, stockholders' equity, and cash flows for the years then ended and for the period from August 1, 2005 (inception) through December 31, 2010. These financial statements are the responsibility of the Company's management. Our responsibility is to express an opinion on these financial statements based on our audits. The financial statements of Nile Therapeutics, Inc. for the period from August 1, 2005 (inception) through December 31, 2008 were audited by other auditors whose report dated March 10, 2009 expressed an unqualified opinion and included an explanatory paragraph regarding the Company's ability to continue as a going concern. Our opinion on the statements of operations, stockholders' equity, and cash flows for the period from August 1, 2005 (inception) through December 31, 2010, insofar as it relates to the amounts for prior periods through December 31, 2008, is based solely on the report of other auditors.

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

In our opinion, the financial statements referred to above present fairly, in all material respects, the financial position of Nile Therapeutics, Inc. (a development stage company) as of December 31, 2010 and 2009, and the results of its operations and its cash flows for the year then ended and the period from August 1, 2005 (inception) through December 31, 2010, in conformity with U.S. generally accepted accounting principles.

/s/ Crowe Horwath LLP

New York, New York
March 14, 2011

NILE THERAPEUTICS, INC.
(A DEVELOPMENT STAGE COMPANY)
BALANCE SHEETS

	December 31, 2010	December 31, 2009
ASSETS		
Current assets		
Cash and cash equivalents	$ 3,378,155	$ 3,175,718
Prepaid expenses and other current assets	219,095	257,732
Total current assets	3,597,250	3,433,450
Property and equipment, net	16,765	27,486
Intangible assets, net	-	106,830
Other noncurrent assets	51,938	51,938
Total assets	$ 3,665,953	$ 3,619,704
LIABILITIES AND STOCKHOLDERS' EQUITY		
Current liabilities		
Accounts payable	$ 332,380	$ 150,628
Accrued expenses and other current liabilities	652,275	402,772
Due to related party	84,430	84,154
Total current liabilities	1,069,085	637,554
Commitments and contingencies		
Stockholders' equity		
Preferred stock, $0.001 par value, 10,000,000 shares authorized, none issued and outstanding	-	-
Common stock, $0.001 par value, 100,000,000 shares authorized, 34,629,794 and 27,085,824 shares issued and outstanding	34,630	27,086
Additional paid-in capital	42,492,432	36,853,767
Deficit accumulated during the development stage	(39,930,194)	(33,898,703)
Total stockholders' equity	2,596,868	2,982,150
Total liabilities and stockholders' equity	$ 3,665,953	$ 3,619,704

See accompanying notes to financial statements

NILE THERAPEUTICS, INC.
(A DEVELOPMENT STAGE COMPANY)
STATEMENTS OF OPERATIONS

	Year ended December 31,		Period from August 1, 2005 (inception) through December 31, 2010
	2010	2009	
Grant income	$-	$-	$ 482,235
Operating expenses:			
Research and development	4,080,884	4,466,536	25,858,940
General and administrative	2,212,669	3,417,174	14,209,431
Total operating expenses	6,293,553	7,883,710	40,068,371
Loss from operations	(6,293,553)	(7,883,710)	(39,586,136)
Other income (expense):			
Interest income	20,377	47,194	787,959
Interest expense	-	-	(1,273,734)
Other income (expense)	241,685	(35,781)	141,717
Total other income (expense)	262,062	11,413	(344,058)
Net loss	$(6,031,491)	$(7,872,297)	$ (39,930,194)
Basic and diluted loss per share	$(0.19)	$(0.31)	
Weighted-average common shares outstanding	32,168,433	25,466,655	

See accompanying notes to financial statements

NILE THERAPEUTICS, INC.
(A DEVELOPMENT STAGE COMPANY)
STATEMENT OF STOCKHOLDERS' EQUITY (DEFICIT)
Period from
August 1, 2005 (inception) through December 31, 2010

	COMMON STOCK				
	SHARES	AMOUNT	ADDITIONAL PAID-IN CAPITAL	DEFICIT ACCUMULATED DURING THE DEVELOPMENT STAGE	TOTAL STOCKHOLDERS' EQUITY (DEFICIT)
Issuance of common shares to founders	13,794,132	$13,794	$ (8,794)	$ -	$ 5,000
Founders shares returned to treasury	(1,379,419)	-	-	-	-
Net loss	-	-	-	(10,043)	(10,043)
Balance at December 31, 2005	12,414,713	13,794	(8,794)	(10,043)	(5,043)
Issuance of common shares pursuant to licensing agreement	1,379,419	-	500	-	500
Issuance of stock options for services	-	-	10,000	-	10,000
Net loss	-	-	-	(2,581,972)	(2,581,972)
Balance at December 31, 2006	13,794,132	13,794	1,706	(2,592,015)	(2,576,515)
Issuance of common shares pursuant to licensing agreement	63,478	64	182,172	-	182,236
Issuance of common shares pursuant to licensing agreement	350,107	350	999,650	-	1,000,000
Common shares sold in private placement, net of issuance costs of $102,000	6,957,914	6,958	19,865,789	-	19,872,747
Warrants issued in connection with note conversion	-	-	288,000	-	288,000
Conversion of notes payable upon event of merger	1,684,085	1,684	4,349,481	-	4,351,165

Note discount arising from beneficial conversion feature	-	-	483,463	-	483,463
Reverse merger transaction					
Elimination of accumulated deficit	-	-	(234,218)	-	(234,218)
Previously issued SMI stock	1,250,000	1,250	232,968	-	234,218
Employee stock-based compensation	-	-	1,902,298	-	1,902,298
Non-employee stock-based compensaton	-	-	(667)	-	(667)
Net loss				(10,302,795)	(10,302,795)
Balance at December 31, 2007	24,099,716	24,100	28,070,642	(12,894,810)	15,199,932
Warrants issued in satisfaction of accrued liabilities	-	-	334,992	-	334,992
Employee stock-based compensation	-	-	2,436,603	-	2,436,603