Nile Therapeutics, Inc.
Form 10-K
March 14, 2011

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

FORM 10-K

xAnnual Report Pursuant to Section 13 or 15(D) of the Securities Exchange Act of 1934
for the fiscal year ended December 31, 2010

or

¨Transition Report Under Section 13 or 15(D) of the Securities Exchange Act of 1934
For the transition period from to

Commission File Number: 001-34058

NILE THERAPEUTICS, INC.
(Exact Name Of Registrant As Specified In Its Charter)

Delaware	88-0363465
(State or other jurisdiction of incorporation or organization)	(I.R.S. Employer Identification No.)

4 West 4th Ave. Suite 400, San Mateo, California
(Address of principal executive offices)

94402
(Zip Code)
(650) 458-2670
(Registrant's telephone number, including area code)
Not Applicable
(Former name, former address and former fiscal year, if changed since last report)

Securities registered pursuant to Section 12(b) of the Act:

Title of each class	Name of each exchange on which registered
Common Stock, par value $0.001 per share	The NASDAQ Stock Market LLC
Warrants (expiring April 21, 2015)	The NASDAQ Stock Market LLC

Securities registered pursuant to Section 12(g) of the Act:

None

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

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

Indicate by check mark whether the registrant (1) has filed all reports required to be filed by Section 13 or 15(d) of the Securities Exchange Act of 1934 during the preceding 12 months (or for such shorter period that the registrant was required to file such reports), and (2) has been subject to such filing requirements for the past 90 days. þ Yes¨ No

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

Indicate by check mark if disclosure of delinquent filers in response to Item 405 of Regulation S-K is not contained herein, and will not be contained, to the best of registrant's knowledge, in definitive proxy or information statements incorporated by reference in Part III of this Form 10-K or any amendment to this Form 10-K. þ

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 ¨	Accelerated filer ¨
Non-accelerated filer ¨	Smaller reporting company þ

Indicate by check mark whether the registrant is a shell company (as defined in Rule 12b-2 of the Act). ¨ Yes þ No

State the aggregate market value of the voting and non-voting common equity held by non-affiliates computed by reference to the price at which the common equity was last sold, or the average bid and asked price of such common equity, as of the last business day of the registrant's most recently completed second fiscal quarter.

As of June 30, 2010: $4,206,683

Indicate the number of shares outstanding of each of the registrant's classes of common stock, as of the last practicable date.

As of March 4, 2011, there were 34,698,764 shares of the issuer's common stock, par value $0.001 per share, issued and outstanding.

DOCUMENTS INCORPORATED BY REFERENCE

Portions of our definitive Proxy Statement for our 2011 Annual Meeting of Shareholders (the "2011 Proxy Statement") are incorporated by reference into Part III of this Form 10-K, to the extent described in Part III. The 2011 Proxy Statement will be filed within 120 days after the end of the fiscal year ended December 31, 2010.

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References to “the Company”, “Nile”, “we”, “us” or “our” in this Annual Report on Form 10-K refer to Nile Therapeutics, Inc. Delaware corporation, unless the context indicates otherwise.

FORWARD-LOOKING STATEMENTS

This Form 10-K contains “forward-looking statements” within the meaning of Section 27A of the Securities Act of 1933, or the Securities Act, and Section 21E of the Securities Exchange Act of 1934, or the Exchange Act. The forward-looking statements are only predictions and provide our current expectations or forecasts of future events and financial performance and may be identified by the use of forward-looking terminology, including the terms “believes,” “estimates,” “anticipates,” “expects,” “plans,” “potential,” “projects,” “intends,” “may,” “will” or “should” or, in each case, the or other variations or comparable terminology, though the absence of these words does not necessarily mean that a statement is not forward-looking. Forward-looking statements include all matters that are not historical facts and include, without limitation, statements concerning our business strategy, outlook, objectives, future milestones, plans, intentions, goals, future financial conditions, obtaining financing of our operations, our research and development programs and planning for and timing of any clinical trials, the possibility, timing and outcome of submitting regulatory filings for our products under development, potential investigational new drug applications, or INDs, and new drug applications, or NDAs, research and development of particular drug products, the development of financial, clinical, manufacturing and marketing plans related to the potential approval and commercialization of our drug products, and the period of time for which our existing resources will enable us to fund our operations. These statements are subject to risks and uncertainties that could cause actual results and events to differ materially from those expressed or implied by such forward-looking statements. For a detailed discussion of these risks and uncertainties, see the “Risk Factors” section in Item 1A of this Form 10-K. We caution the reader not to place undue reliance on these forward-looking statements, which reflect management's analysis only as of the date of this Form 10-K.

We intend that all forward-looking statements be subject to the safe-harbor provisions of the Private Securities Litigation Reform Act of 1995. Forward-looking statements are subject to many risks and uncertainties that could cause our actual results to differ materially from any future results expressed or implied by the forward-looking statements. Pharmaceutical and biotechnology companies have suffered significant setbacks in advanced clinical trials, even after obtaining promising earlier trial results. Data obtained from such clinical trials are susceptible to varying interpretations, which could delay, limit or prevent regulatory approval. Additional factors that could cause actual results to differ materially from projected results include, but are not limited to, those discussed in “Risk Factors” elsewhere in this Annual Report. Readers are expressly advised to review and consider those Risk Factors, which include risks associated with (1) our ability to successfully conduct clinical and pre-clinical trials for our product candidates, (2) our ability to obtain required regulatory approvals to develop and market our product candidates, (3) our ability to raise additional capital or to license our products on favorable terms, (4) our ability to execute our development plan on time and on budget, (5) our ability to identify and obtain additional product candidates, and (6) our ability to raise enough capital to fund our operations. Although we believe that the assumptions underlying the forward-looking statements contained in this Report are reasonable, any of the assumptions could be inaccurate, and therefore there can be no assurance that such statements will be accurate. In light of the significant uncertainties inherent in the forward-looking statements included herein, the inclusion of such information should not be regarded as a representation by us or any other person that the results or conditions described in such statements or our objectives and plans will be achieved. Furthermore, past performance in operations and share price is not necessarily indicative of future performance. Except to the extent required by applicable laws or rules, we do not undertake to update any forward-looking statements or to announce publicly revisions to any of our forward-looking statements, whether resulting from new information, future events or otherwise.

PART I

ITEM 1. 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 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. The information on, or accessible through, our website is not part of this Form 10-K.

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 planned to initiate in the second quarter of 2011. 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 worsens 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 $33 billion. 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 anticipate that data from this study will be presented at the American College of Cardiology conference in April 2011.

Future 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 March 2011, we plan to submit an investigational new drug application, or IND, relating to this planned Phase I clinical trial. In the second quarter of 2011, we plan to initiate 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, or the cenderitide License Agreement, with 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 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 ended 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 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 December 31, 2010, 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 3 issued U.S. patents and 3 pending U.S. patent applications, 16 issued foreign patents and 3 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 2028.

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 arise out of the Mayo Clinic laboratory of Dr. John Burnett and Dr. Candace Lee, the inventors of CU-NP, until 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 ended 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 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 with Mayo Foundation, 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 planned 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. We cannot be sure that any of our drugs will qualify for any of these programs, or that, if a drug does qualify, the review time will be reduced.

Section 505(b)(2) of the FDCA allows the FDA to approve a follow-on drug on the basis of data in the scientific literature or a prior FDA approval of an NDA for a related drug. This procedure potentially makes it easier for generic drug manufacturers to obtain rapid approval of new forms of drugs based on proprietary data of the original drug manufacturer.

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 December 31, 2010, we had one 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.

ITEM 1A. RISK FACTORS

An investment in our securities is speculative in nature, involves a high degree of risk, and should not be made by an investor who cannot bear the economic risk of its investment for an indefinite period of time and who cannot afford the loss of its entire investment. You should carefully consider the following risk factors and the other information contained elsewhere in this Annual Report before making an investment in our common stock. If any of the following events or outcomes actually occurs, our business, operating results, and financial condition could be materially and adversely affected. As a result, the trading price of our common stock could decline and you may lose all or part of the money you paid to purchase our common stock.

Risks Relating to Our Business

We 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 December 31, 2010, we had cash and cash equivalents totaling $3.4 million. During the fiscal year ended December 31, 2010, we used net cash totaling $4.3 million in operating activities. We expect our negative cash flows from operations to continue for the foreseeable future and beyond potential regulatory approval and any product launch. Based on our current development plans, including our planned Phase I PK/PD study of cenderitide, we anticipate that our current resources will be sufficient to fund our operations beyond 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 our beliefs of 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:

Ÿthe scope, rate of progress, cost and results of our research and development activities, especially our planned Phase I clinical trial of cenderitide;

Ÿthe costs and timing of regulatory approval;

Ÿthe costs of filing, prosecuting, defending and enforcing any patent claims and other intellectual property rights;

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

We 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 planned 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 our clinical trials through all phases of clinical development;
- 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. Since our inception on August 1, 2005, through December 31, 2010, we have accumulated a deficit of $39.9 million and have stockholders' equity of $2.6 million. We expect to incur substantial losses and negative operating cash flow for the foreseeable future, and we may never achieve or maintain profitability. Even if we succeed in developing and commercializing one or more of our product candidates, we expect to incur substantial losses for the foreseeable future, as we:

Ÿ continue to undertake pre-clinical development and clinical trials for our product candidates;

Ÿ seek regulatory approvals for our product candidates;

- Ÿ in-license or otherwise acquire additional products or product candidates;
- Ÿ implement additional internal systems and infrastructure; and
- Ÿ 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.

We are substantially dependent on the services of Two River and other consultants.

We have only three employees — 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 independent organizations, advisors and consultants will continue to be available to us on a timely basis when needed, or that we can find qualified replacements.

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 pay Two River a monthly cash fee of $65,000. 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, the chairman of our Board of Directors, 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 July 2009 private placement. Scott L. Navins, the Financial and Operations Principal of Riverbank, 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.

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 planned 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.

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:

- Ÿ withdrawal of clinical trial participants;
- Ÿ termination of clinical trial sites or entire trial programs;
- Ÿ costs of related litigation;
- Ÿ substantial monetary awards to patients or other claimants;
- Ÿ decreased demand for our product candidates;
- Ÿ impairment of our business reputation;
- Ÿ loss of revenues; and
- Ÿ 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 35% 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 planned Phase I clinical trial of cenderitide will be completed on schedule or at all. Thereafter, subject to the results of our planned 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:

- Ÿreaching 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;

- Ÿobtaining regulatory approval to commence a clinical trial;

Ÿobtaining institutional review board, or IRB, approval to conduct a clinical trial at numerous prospective sites;

Ÿrecruiting 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;

Ÿretaining 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;

Ÿmaintaining and supplying clinical trial material on a timely basis;

Ÿcomplying with design protocols of any applicable special protocol assessment we receive from the FDA; and

Ÿcollecting, 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:

Ÿfailure to conduct the clinical trial in accordance with regulatory requirements or our clinical protocols;

Ÿinspection of the clinical trial operations or trial sites by the FDA or other regulatory authorities resulting in the imposition of a clinical hold;

- Ÿunexpected delays in approvals of protocol amendments by regulatory authorities;
- Ÿunforeseen safety issues or any determination that a trial presents unacceptable health risks;
- Ÿlack of adequate funding to continue the clinical trial, including the incurrence of unforeseen costs due to enrollment delays; or
- Ÿrequirements 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:

- Ÿ delay commercialization of, and our ability to derive product revenues from, our product candidates;
- Ÿ impose costly procedures on us; or
- Ÿ 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 planned 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 planned 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:

- We 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;

- Ÿ regulatory authorities may require us to take our approved drug off the market;
- Ÿ sales of products may decrease significantly;
- Ÿ we may be subject to litigation or product liability claims; and
- Ÿ 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:

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

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

Developments by competitors may render our 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 Relating to Our Securities

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

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

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

- failure or delays in entering additional drug candidates into clinical trials;
- failure or discontinuation of any of our research programs;
- issuance of new or changed securities analysts' reports or recommendations;
- developments in establishing new strategic alliances;
- market conditions in the pharmaceutical, biotechnology and other healthcare related sectors;
- actual or anticipated fluctuations in our quarterly financial and operating results;
- developments or disputes concerning our intellectual property or other proprietary rights;
- introduction of technological innovations or new commercial products by us or our competitors;
- issues in manufacturing our drug candidates or drugs;

- Ÿ market acceptance of our drugs;
- Ÿ third-party healthcare coverage and reimbursement policies;
- Ÿ FDA or other United States or foreign regulatory actions affecting us or our industry;
- Ÿ litigation or public concern about the safety of our drug candidates or drugs;
- Ÿ additions or departures of key personnel; or
- Ÿ volatility in the stock prices of other companies in our industry.

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

We have received notice from the Nasdaq Stock Market that we are not in compliance with one of its continued listing requirements, which may result in the delisting of our common stock from the Nasdaq Capital Market.

Our common stock is currently listed for trading on the Nasdaq Capital Market, and the continued listing of our common stock on the Nasdaq Capital Market is subject to our compliance with a number of listing standards. On June 1, 2010, we received notice from Nasdaq informing us that that we were not in compliance with Nasdaq Marketplace Rule 5550(a)(2), which requires that our common stock maintain a minimum closing bid price of $1.00. In accordance with Nasdaq rules, we were afforded a period of 180 days, or until November 29, 2010, in which to regain compliance with the minimum closing bid price requirement. We did not regain compliance with this requirement by November 29, 2010 and, accordingly, on November 30, 2010, we received notice from Nasdaq informing us that our common stock would be subject to delisting unless we requested a hearing before a Nasdaq Listing Qualifications Panel. Upon our request, a hearing before the panel was held on January 6, 2011. At the hearing, we presented a plan to regain compliance with the minimum closing bid price requirement and requested that the panel grant us additional time within which to regain compliance. The panel rendered its decision on March 1, 2011, granting us until May 31, 2011 to regain compliance with the minimum closing bid price requirement. Nasdaq rules do not permit any further extension beyond May 31, 2011. Accordingly, unless we regain compliance with Rule 5550(a)(2) by such date, we expect that our common stock will be delisted from the Nasdaq Capital Market.

If our common stock is delisted from the Nasdaq Capital Market, trading in our common stock would likely be conducted on the OTC Bulletin Board, a regulated quotation service. If trading of our common stock is conducted on the OTC Bulletin Board, the liquidity of our common stock may be reduced, not only in terms of the number of shares that can be bought and sold at a given price, but also through delays in the timing of transactions and reduction in security analysts' and the media's coverage of us. This may result in lower prices for our common stock than might otherwise be obtained and could also result in a larger spread between the bid and asked prices for our common stock.

Further, if we are delisted from the Nasdaq Capital Market and do not obtain a listing on another national securities exchange, our common stock will be considered a "penny stock" under applicable SEC rules if it trades at a price of less than $5.00 per share. Broker-dealers who sell penny stocks must provide purchasers of these stocks with a standardized risk-disclosure document prepared by the SEC. This document provides information about penny stocks and the nature and level of risks involved in investing in the penny stock market. A broker must also give a purchaser,

orally or in writing, bid and offer quotations and information regarding broker and salesperson compensation, make a written determination that the penny stock is a suitable investment for the purchaser, and obtain the purchaser's written agreement to the purchase. Broker-dealers also must provide customers that hold penny stocks in their accounts with such broker-dealer a monthly statement containing price and market information relating to the penny stock. If a penny stock is sold to an investor in violation of the penny stock rules, he or she may be able to cancel the purchase and get his or her money back. Because of these rules, there is typically less trading in penny stocks and many brokers simply choose not to participate in penny stock transactions. Accordingly, if our common stock becomes subject to the penny stock rules, the trading volume of our common stock may significantly decline and you may not always be able to resell shares of our common stock publicly at times and prices that you feel are appropriate.

We have never paid dividends and we do not anticipate paying dividends in the future.

We have never paid dividends on our capital stock and do not anticipate paying any dividends for the foreseeable future. As a result, capital appreciation, if any, of our common stock will be your sole source of gain for the foreseeable future.

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

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

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

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

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

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

The operational and other projections and forecasts that we may make from time to time are subject to inherent risks.

The projections and forecasts that our management may provide from time to time (including, but not limited to, those relating to timing, progress and anticipated results of the clinical development, regulatory processes, clinical trial timelines and any anticipated benefits of our product candidates) reflect numerous assumptions made by management, including assumptions with respect to our specific as well as general business, economic, market and financial conditions and other matters, all of which are difficult to predict and many of which are beyond our control. Accordingly, there is a risk that the assumptions made in preparing the projections, or the projections themselves, will prove inaccurate. There will be differences between actual and projected results, and actual results may be materially different from than those contained in the projections. The inclusion of the projections in (or incorporated by reference in) this prospectus supplement should not be regarded as an indication that we or our management or representatives considered or consider the projections to be a reliable prediction of future events, and the projections should not be relied upon as such.

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.

ITEM 1B. UNRESOLVED STAFF COMMENTS

None.

ITEM 2. PROPERTIES

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. The San Francisco, California office was 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.

ITEM 3. LEGAL PROCEEDINGS

We are not involved in any pending legal proceedings and are not aware of any threatened legal proceedings against us.

ITEM 4. [REMOVED AND RESERVED]

PART II

ITEM 5. MARKET FOR REGISTRANT'S COMMON EQUITY, RELATED STOCKHOLDER MATTERS AND ISSUER PURCHASES OF EQUITY SECURITIES

Market Information

Our common stock is listed on the NASDAQ Capital Market, or the NASDAQ, under the trading symbol "NLTX". Set forth below are the high and low bid or sale prices for our common stock by quarter for the fiscal years ended December 31, 2010 and 2009, respectively, as reported by the NASDAQ. Although our common stock is quoted on the NASDAQ, it has traded sporadically with minimal volume. The quotations reflect inter-dealer prices, without retail markup, markdown, or commission, and may not represent actual transactions. Consequently, the information provided below may not be indicative of our common stock price under different conditions.

	High	Low
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

	High	Low
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

Holders

According to the records of our transfer agent, American Stock Transfer & Trust Company, as of March 4, 2011, we had 171 holders of record of common stock, not including those held in "street name."

Dividends

We have never declared or paid a dividend on our common stock and do not anticipate paying any cash dividends in the foreseeable future.

Recent Sales of Unregistered Securities; Use of Proceeds from Registered Securities

None.

Issuer Purchases of Equity Securities

None.

ITEM 6. SELECTED FINANCIAL DATA

Not Applicable.

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ITEM 7.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 elsewhere in this Annual Report. This discussion includes forward-looking statements that involve risks and uncertainties. As a result of many factors, such as those set forth under "Risk Factors" in Item 1A of this Annual Report, our 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.

- 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

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.

Cenderitide (formerly CD-NP). Although the development of cenderitide is still in its early stages, we believe that it has potential applications to treat heart failure. We expect to spend $2.0 to $2.5 million (net of funding from Medtronic) in fiscal 2011, of which $1.0 to $1.5 million will be external development costs relating to manufacturing and toxicology expenses. Our planned Phase I clinical trial and various manufacturing, analytical and preclinical expenses will be covered by Medtronic, Inc. pursuant to the terms of a February 2011 clinical trial funding agreement. The Phase I clinical trial is designed to evaluate the pharmacokinetics (PK) and pharmacodynamic (PD) response of continuous subcutaneous infusion of cenderitide, as compared with a short term subcutaneous bolus injection. 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 following admission for ADHF. 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. Our strategy for further development of cenderitide will depend to a large degree on the outcome of these planned studies. Our agreement with Medtronic does not cover any aspect of such Phase II study.

CU-NP. Since acquiring our rights to CU-NP in June 2008, we have incurred a total of approximately $0.6 million through December 31, 2010. 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 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 and for each of the last two fiscal years, and is intended to supplement the more detailed discussion that follows. The amounts stated are expressed in thousands.

	December 31,	
Liquidity and capital resources	2010	2009
Cash and cash equivalents	$ 3,378	$ 3,176
Working Capital	2,528	2,796
Stockholders' equity	2,597	2,982

Cash flow data	Year ended December 31, 2010	2009	Period from Aug. 1, 2005 (inception) to Dec. 31, 2010
Cash provided by (used in):			
Operating activities	$ (4,318)	$ (5,795)	$ (28,055)
Investing activities	(2)	(34)	(472)
Financing activities	4,523	3,504	31,905
Net increase (decrease) in cash and cash equivalents	$ 203	$ (2,325)	$ 3,378

Our total cash resources as of December 31, 2010 were $3.4 million compared to $3.2 million as of December 31, 2009. As of December 31, 2010, we had approximately $1.1 million in liabilities, and $2.5 million in net working capital. We incurred a net loss of $6.0 million and had negative cash flow from operating activities of $4.3 million for the year ended December 31, 2010. Since August 1, 2005 (inception) through December 31, 2010, we have incurred an aggregate net loss of approximately $39.9 million, while negative cash flow from operating activities has amounted to $28.1 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 December 31, 2010, 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 December 31, 2010, the clinical trial funding agreement with Medtronic, and the current plan of expenditure, which includes the new Phase I PK/PD study of cenderitide, we believe we have sufficient capital to fund our operations beyond the fourth quarter of 2011. We will need substantial additional capital in order to fund the next clinical study of cenderitide, which is expected to be a large Phase II double-blind, placebo-controlled, dose ranging study in post-acute patients. We expect to be able to initiate this Phase II study in 2012.

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 our 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. We will need additional capital to fund our operations beyond the first quarter of 2012.

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 estimate 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 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

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.

July 2009 Financing. On July 7, 2009, we entered into a securities purchase agreement with various accredited investors pursuant to which we agreed to sell in a private placement an aggregate of 2,691,394 shares of our common stock and five-year warrants to purchase an equal number of additional shares of common stock. The purchase price for each unit of one share of common stock and one warrant was $1.25. The sale of the shares and warrants resulted in aggregate gross proceeds of approximately $3.37 million, before deducting expenses. The issuance and sale of the units pursuant to the securities purchase agreement was completed on July 15, 2009.

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

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

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

- A warrant representing the right to purchase 50% of the warrant shares at an exercise price equal to $2.28, which represented 200% of the closing bid price of our common stock on the date of the securities purchase agreement.

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 200% of the then applicable exercise price of the warrants.

Issuance costs related to the financing were $282,773, including the issuance of warrants to purchase 218,300 shares of common stock to designees of Riverbank Capital Securities, Inc., or Riverbank, which served as our placement agent in connection with the private placement. Certain of our officers and directors are principals of Riverbank. See "Item 13 – Certain Relationships and Related Transactions, and Director Independence" of this Form 10-K.

License Agreement Commitments

CD-NP License Agreement

Pursuant to our license agreement with Mayo for CD-NP, 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 CD-NP. This aggregate amount is subject to increase upon the receipt of regulatory approval for each additional indication of CD-NP as well as for additional compounds or analogues contained in the intellectual property.

The CD-NP 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 our 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 arise out of the laboratory of Dr. John Burnett and Dr. Candace Lee, the inventors of CU-NP and employees of the Mayo Clinic, until 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.

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 Mayo. In June 2008, we issued 49,689 shares of common stock to Mayo having a fair market value as of June 13, 2008 equal to $250,000. This amount has been recorded in research and development expenses in the accompanying Statements of Operations. 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 Mayo 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. 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.

Off -Balance Sheet Arrangements

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

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. Except for capitalized patent expenses, 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 CRO's 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.

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 the Company's Scientific Advisory Board) issued as consideration for goods or services received by the Company 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 re-measured 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. We expect to record additional non-cash compensation expense in the future, which may be significant.

In the quarter ending March 31, 2009, with two years of employee performance and forfeiture history, we began to estimate forfeitures of performance-based stock options. Prior to December 31, 2008, we did not include an estimate for forfeitures in our compensation expenses on a quarterly basis. Instead, adjustments to the performance-based stock compensation expense for the full year were made in the fourth quarter at the time of performance assessment. Forfeiture rates for performance stock options vested in 2008, 2009 and 2010 were between 0% and 55%.

ITEM 7A. QUANTITATIVE AND QUALITATIVE DISCLOSURES ABOUT MARKET RISK

Not applicable.

ITEM 8. FINANCIAL STATEMENTS AND SUPPLEMENTARY DATA

Financial Statements Index

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
Non-employee stock-based compensation	-	-	13,687	-	13,687
Issuance of common shares pursuant to licensing agreement	49,689	50	249,950	-	250,000
Net loss				(13,131,596)	(13,131,596)
Balance at December 31, 2008	24,149,405	24,150	31,105,874	(26,026,406)	5,103,618
Employee stock-based compensation	-	-	1,772,597	-	1,772,597
Non-employee stock-based compensation	-	-	473,584	-	473,584
Units sold in private placement, net of issuance costs of $282,773	2,691,394	2,691	3,083,284	-	3,085,975
Warrants issued to placement agent in connection with private placement	-	-	201,200	-	201,200
Stock option and warrant exercises	245,025	245	217,228	-	217,473
Net loss				(7,872,297)	(7,872,297)

Balance at December 31, 2009	27,085,824	27,086	36,853,767	(33,898,703)	2,982,150
Employee stock-based compensation			1,142,552	-	1,142,552
Non-employee stock-based compensation	-	-	(19,249)	-	(19,249)
Units sold in private placement, net of issuance costs of $715,801	7,475,000	7,475	4,509,224	-	4,516,699
Stock option and warrant exercises	68,970	69	6,138	-	6,207
Net loss				(6,031,491)	(6,031,491)
Balance at December 31, 2010	34,629,794	$34,630	$ 42,492,432	$ (39,930,194)	$ 2,596,868

See accompanying notes to financial statements

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

	Year ended December 31,		Period from August 1, 2005 (inception) through December 31, 2010
	2010	2009	
Cash flows from operating activities			
Net loss	$(6,031,491)	$(7,872,297)	$ (39,930,194)
Adjustment to reconcile net loss to net cash used in operating activities			
Depreciation and amortization	12,926	159,589	313,141
Stock-based compensation	1,123,303	2,246,181	9,499,133
Write-off of intangible assets	106,830	-	106,830
Warrants issued in connection with note conversion	-	-	288,000
Note discount arising from beneficial conversion feature	-	-	483,463
Loss on disposal of assets	-	23,569	35,223
Noncash interest expense	-	-	351,165
Changes in operating assets and liabilities			
Prepaid expenses and other current assets	38,637	287,102	(219,095)
Other non-current assets	-	54,659	(51,938)
Accounts payable	181,752	(588,267)	332,380
Accrued expenses and other current liabilities	249,503	(183,484)	652,275
Due to related party	276	77,454	84,430
Net cash used in operating activities	(4,318,264)	(5,795,494)	(28,055,187)
Cash flows from investing activities			
Purchase of property and equipment	(2,205)	(4,422)	(128,868)
Proceeds from sale of assets	-	2,500	2,500
Cash paid for intangible assets	-	(32,304)	(345,591)
Net cash used in investing activities	(2,205)	(34,226)	(471,959)
Cash flows from financing activities			
Proceeds from issuance of notes payable	-	-	5,500,000
Repayment of notes payable	-	-	(1,500,000)
Proceeds from exercise of stock options and warrants	6,207	217,473	223,680
Proceeds from sale of common stock to founders	-	-	5,000
Proceeds from sale of common stock in private placement	4,516,699	3,287,175	27,676,621
Net cash provided by financing activities	4,522,906	3,504,648	31,905,301
Net increase (decrease) in cash and cash equivalents	202,437	(2,325,072)	3,378,155
Cash and cash equivalents at beginning of period	3,175,718	5,500,790	-
Cash and cash equivalents at end of period	$3,378,155	$3,175,718	$ 3,378,155
Supplemental schedule of cash flows information:			

Cash paid for interest	$-	$-	$	150,000
Supplemental schedule of non-cash investing and financing activities:				
Warrants issued in sastisfaction of accrued liability	$-	$-	$	334,992
Warrants issued to placement agent and investors, in connection with private placement	$1,765,300	$2,872,000	$	4,637,300
Conversion of notes payable and interest to common stock	$-	$-	$	4,351,165
Common shares of SMI issued in reverse merger transaction	$-	$-	$	1,250

See accompanying notes to financial statements

Nile Therapeutics, Inc

(A Development Stage Company)
Notes to Financial Statements

1. DESCRIPTION OF BUSINESS

Nile Therapeutics, Inc. ("Nile" or the "Company") develops innovative products for the treatment of cardiovascular diseases. Nile's lead compound is cenderitide (formerly CD-NP), a chimeric natriuretic peptide currently in clinical studies for the treatment of heart failure. The Company is also developing CU-NP, 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 ("CNP") and the N- and C-termini of Urodilatin ("URO").

The Company was incorporated in the State of Nevada on June 17, 1996 and reincorporated in Delaware on February 9, 2007, at which time its name was SMI Products, Inc. ("SMI"). On September 17, 2007, the Company completed a merger transaction whereby Nile Merger Sub, Inc., a Delaware corporation and a wholly-owned subsidiary of SMI, merged with and into Nile Therapeutics, Inc., a privately held Delaware corporation ("Old Nile"), with Old Nile becoming a wholly-owned subsidiary of SMI. Immediately following the merger described above, Old Nile was merged with and into the Company, with the Company remaining as the surviving corporation to that merger. In connection with that short-form merger, the Company changed its name to "Nile Therapeutics, Inc." These two merger transactions are hereinafter collectively referred to as the "Merger." All costs incurred in connection with the Merger have been expensed. Upon completion of the Merger, the Company adopted Old Nile's business plan.

2. BASIS OF PRESENTATION

The Company is a development stage enterprise since it has not yet generated any revenue from the sale of products and, through December 31, 2010, its efforts have been principally devoted to developing its licensed technologies, recruiting personnel, establishing office facilities, and raising capital. Accordingly, the accompanying financial statements have been prepared in accordance with the provisions of Accounting Standards Codification ("ASC") 915, "Development Stage Entities." The Company's financial statements have been prepared on a going concern basis, which contemplates the realization of assets and the settlement of liabilities and commitments in the normal course of business. The Company has experienced net losses since its inception and has an accumulated deficit of approximately $39.9 million at December 31, 2010. The Company expects to incur substantial and increasing losses and have negative net cash flows from operating activities as it expands its technology portfolio and engages in further research and development activities, particularly the conducting of pre-clinical and clinical trials.

Cash resources as of December 31, 2010 were approximately $3.4 million, compared to $3.2 million as of December 31, 2009. Based on its resources at December 31, 2010, the clinical trial funding agreement with Medtronic (see Note 15) and the current plan of expenditure of $2.0 to $2.5 million (net of funding from Medtronic) on the continuing development of current products which includes a new Phase I study of cenderitide, the Company believes that it has sufficient capital to fund its operations beyond the fourth quarter of 2011. The Company will need to raise additional capital to continue operations beyond the first quarter of 2012. Additionally, the Company will need substantial additional financing in the future until it can achieve profitability, if ever. The Company's continued operations will depend on its ability to raise additional funds through various potential sources, such as equity and debt financing, or to license its compounds to another pharmaceutical company. The Company will continue to fund operations from cash on hand and through sources of capital similar to those previously described. The Company cannot assure that it will be able to secure such additional financing, or if available, that it will be sufficient to meet its needs.

The success of the Company depends on its ability to discover and develop new products to the point of FDA approval and subsequent revenue generation and, accordingly, to raise enough capital to finance these developmental efforts. Management plans to raise additional equity capital or license one or more of its products to finance the continued operating and capital requirements of the Company. Amounts raised will be used to further develop the Company's products, acquire additional product licenses and for other working capital purposes. While the Company will extend its best efforts to raise additional capital to fund all operations for the next 12 to 24 months, management can provide no assurances that the Company will be able to raise such sufficient funds.

Nile Therapeutics, Inc
(A Development Stage Company)
Notes to Financial Statements

3. THE MERGER

(a) Description of the Merger and Private Placement Offering

On September 17, 2007, the Company completed the Merger. In accordance with the terms of the Merger, each share of common stock of Old Nile that was outstanding immediately prior to the Merger was exchanged for 2.758838 shares of the Company's common stock, and one share of Old Nile common stock was issued to SMI. In addition, all securities convertible into or exercisable for shares of Old Nile common stock outstanding immediately prior to the Merger were cancelled, and the holders thereof received similar securities convertible into or exercisable for the purchase of an aggregate of 3,572,350 shares of the Company's common stock. In consideration for their shares of the Company's pre-merger common stock, the Company's shareholders received an aggregate of 22,849,716 shares of SMI common stock. Immediately prior to the effective time of the Merger, 755,100 shares of SMI's common stock were issued and outstanding. In addition, prior to the effective time of the Merger, 56,364 shares of SMI's common stock were issued to Fountainhead Capital Partners Limited and 438,536 shares of SMI's common stock were issued to Ko Zen Asset Management, Inc. pursuant to the conversion of convertible promissory notes and accrued interest. Upon completion of the Merger, the Old Nile shareholders owned approximately 95% of the Company's issued and outstanding common stock, assuming the exercise of all of the issued and outstanding common stock options and warrants.

Following the Merger, the business conducted by the Company is the business conducted by Old Nile prior to the Merger. In addition, the director and officer of SMI was replaced by the directors and officers of Old Nile.

As a condition to the closing of the Merger, on September 11, 2007, Old Nile completed a financing whereby it received gross proceeds of $19,974,747 through the sale of 6,957,914 shares of common stock in a private placement to certain qualified investors (the "Financing"). Contemporaneously with the Financing, the Company converted $4,351,165 of convertible debt and interest into 1,684,085 shares of common stock, and issued five-year warrants to purchase an aggregate of 168,337 shares of common stock at an exercise price of $2.71per share.

All references to share and per share amounts in these financial statements have been restated to retroactively reflect the number of common shares of Nile common stock issued pursuant to the Merger.

(b) Accounting Treatment of the Merger; Financial Statement Presentation

The Merger was accounted for as a reverse acquisition pursuant to ASC 805-40-25.1, which provides that the "merger of a private operating company into a non-operating public shell corporation with nominal net assets typically results in the owners and management of the private company having actual or effective operating control of the combined company after the transaction, with the shareholders of the former public shell continuing only as passive investors. These transactions are considered by the Securities and Exchange Commission to be capital transactions in substance, rather than business combinations. That is, the transaction is equivalent to the issuance of stock by the private company for the net monetary assets of the shell corporation, accompanied by a recapitalization." Accordingly, the Merger has been accounted for as a recapitalization, and, for accounting purposes, Old Nile is considered the acquirer in a reverse acquisition.

SMI's historical accumulated deficit for periods prior to September 17, 2007, in the amount of $234,218, was eliminated against additional-paid-in-capital, and the accompanying financial statements present the previously issued

shares of SMI common stock as having been issued pursuant to the Merger on September 17, 2007. The shares of common stock of the Company issued to the Old Nile stockholders in the Merger are presented as having been outstanding since August 2005 (the month when Old Nile first sold its equity securities).

Because the Merger was accounted for as a reverse acquisition under Generally Accepted Accounting Principals (“ GAAP”), the financial statements for periods prior to September 17, 2007 reflect only the operations of Old Nile.

4. SUMMARY OF SIGNIFICANT ACCOUNTING POLICIES

(a) Use of Estimates

The preparation of financial statements in conformity with GAAP requires that management make estimates and assumptions that affect the reported amounts of assets and liabilities and disclosure of contingent assets and liabilities at the date of the financial statements and the reported amounts of revenues and expenses during the reporting period. Estimates and assumptions principally relate to services performed by third parties but not yet invoiced, estimates of the fair value of stock options issued to employees, directors and consultants, and estimates of the probability and potential magnitude of contingent liabilities. Actual results could differ from those estimates.

(b) Cash and Cash Equivalents

The Company considers all highly liquid investments with a remaining maturity of three months or less at the time of acquisition to be cash equivalents.

Nile Therapeutics, Inc
(A Development Stage Company)
Notes to Financial Statements

(c) Property and Equipment

Property and equipment are stated at cost. Repairs and maintenance costs are expensed in the period incurred. Depreciation is computed using the straight-line method over the related estimated useful lives, except for leasehold improvements, which are depreciated over the shorter of the useful life of the asset or the lease term.

Description	Estimated Useful Life
Office equipment & furniture	5 – 7 years
Leasehold improvements	3 years
Computer equipment	3 years

(d) Intangible Assets and Intellectual Property

Intangible assets consist of costs related to acquiring patents and to prosecuting and maintaining intellectual property rights, and are amortized using the straight-line method over the estimated useful lives. Beginning in 2008, the Company changed its estimate of the expected useful life of its recorded intangibles from twenty years to three years. The Company believes that a three year useful life better reflects the uncertainty of the future benefit of the patent assets. The change in the useful life of the Company's patent assets did not have a material effect on the Company's financial position or results of operations. Certain costs of acquiring intellectual property rights to be used in the research and development process, including licensing fees and milestone payments, are charged to research and development expense as incurred.

During the first quarter of 2010, the Company revised its estimate for the useful lives of its patent and patent applications to zero. As a result of this change in estimates, the Company recorded an impairment of $106,830 to research and development expense, which was the net book value of its intangible assets as of December 31, 2009. Management believes this revised estimate better reflects the uncertainty surrounding drug product development. Management does not believe that the change in this estimate will have a material impact on its financial statements.

(e) Impairment or Disposal of Long-lived Assets

The Company evaluates its long-lived assets, primarily its intellectual property, for impairment whenever events or changes in circumstances indicate that the carrying amount of such assets or intangibles may not be recoverable. Recoverability of assets to be held and used is measured by a comparison of the carrying amount of an asset to future undiscounted net cash flows expected to be generated by the asset. If such assets are considered to be impaired, the impairment to be recognized is measured by the amount by which the carrying amount of the assets exceeds the fair value of the assets. Assets to be disposed of are reported at the lower of the carrying amount or fair value less cost to sell. On January 16, 2009, the Company announced that it will focus resources on the development of its natriuretic peptide franchise, including cenderitide which is in Phase II development for acute heart failure, and CU-NP which is a pre-clinical compound. The Company terminated the 2NTX-99 program and returned the rights to the molecule to Dr. Cesare Casagrande. As such, the Company recorded an impairment of the intangibles related to 2NTX-99 of approximately $48,000 in the first quarter of 2009, which is included in research and development expense in the accompanying Statement of Operations for the year ended December 31, 2009.

(f) Fair Value of Financial Instruments

The Company measures fair value in accordance with generally accepted accounting principles. Fair value measurements are applied under other accounting pronouncements that require or permit fair value measurements. The provisions are to be applied prospectively as of the beginning of the fiscal year in which it is initially adopted, with any transition adjustment recognized as a cumulative-effect adjustment to the opening balance of retained earnings. The adoption of this standard had no significant impact on the Company’s financial statements.

Nile Therapeutics, Inc
(A Development Stage Company)
Notes to Financial Statements

(g) Concentration of Credit Risk

Financial instruments which potentially subject the Company to concentrations of credit risk consist principally of cash and cash equivalents. The Company deposits cash and cash equivalents with high credit quality financial institutions and is insured to the maximum limitations. Balances in these accounts may exceed federally insured limits at times, which expose the Company to institutional risk.

(h) Research and Development

Research and development costs are charged to expense as incurred. Research and development includes employee costs, fees associated with operational consultants, contract clinical research organizations, contract manufacturing organizations, clinical site fees, contract laboratory research organizations, contract central testing laboratories, licensing activities, and allocated office, insurance, depreciation, and facilities expenses. The Company accrues for costs incurred as the services are being provided by monitoring the status of the trial and the invoices received from its external service providers. As actual costs become known, the Company adjusts its accruals in the period when actual costs become known. Costs related to the acquisition of technology rights for which development work is still in process are charged to operations as incurred and considered a component of research and development costs.

(i) Grant income

Grant income is recorded when funding is received and qualifying expenses are incurred.

(j) Stock-Based Compensation

Stock-based compensation cost is measured at the grant date based on the value of the award and is recognized as expense over the required service period, which is generally equal to the vesting period. Share-based compensation is recognized only for those awards that are ultimately expected to vest; therefore, the Company has applied an estimated forfeiture rate to unvested awards for the purpose of calculating compensation cost. These estimates will be revised, if necessary, in future periods if actual forfeitures differ from estimates. Changes in forfeiture estimates impact compensation cost in the period in which the change in estimate occurs.

Common stock, stock options or other equity instruments issued to non-employees (including consultants and all members of the Company’s Scientific Advisory Board) as consideration for goods or services received by the Company 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. The fair value of any options issued to non-employees is recorded as expense over the applicable service periods.

(k) Loss per Common Share

Basic loss per share is computed by dividing the loss available to common shareholders by the weighted-average number of common shares outstanding. Diluted loss per share is computed similarly to basic loss per share except that the denominator is increased to include the number of additional common shares that would have been outstanding if the potential common shares had been issued and if the additional common shares were dilutive.

For all periods presented, potentially dilutive securities are excluded from the computation of fully diluted loss per share as their effect is anti-dilutive.

Potentially dilutive securities include:

	December 31, 2010	December 31, 2009
Warrants to purchase common stock	-	886,149
Options to purchase common stock	2,818,970	1,658,063
Total potentially dilutive securities	2,818,970	2,544,212

For the years ending December 31 2010, and 2009, 10,610,418 and 5,916,463 warrants and options have been excluded from the computation of the dilutive earnings per share, respectively, as their exercise prices are greater than the 100 day moving average market price per common share as of February 1, 2010, and February 18, 2009, respectively.

(l) Comprehensive Loss

The Company has no components of other comprehensive loss other than its net loss, and accordingly, comprehensive loss is equal to net loss for all periods presented.

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(m) Income Taxes

The Company recognizes deferred tax assets and liabilities for the expected future tax consequences of events that have been included in the financial statements or tax returns. Under this method, deferred income taxes are recognized for the tax consequences in future years of differences between the tax bases of assets and liabilities and their financial reporting amounts at each year-end based on enacted tax laws and statutory tax rates applicable to the period in which the differences are expected to affect taxable income. The Company provides a valuation allowance when it appears more likely than not that some or all of the net deferred tax assets will not be realized.

A tax position is recognized as a benefit only if it is “more likely than not” that the tax position would be sustained in a tax examination, with a tax examination being presumed to occur. The amount recognized is the largest amount of tax benefit that is greater than 50% likely of being realized on examination. For tax positions not meeting the “more likely than not” test, no tax benefit is recorded.

(n) Recently Issued Accounting Pronouncements

In April 2010, the Financial Accounting Standards Board (“FASB”) issued a new accounting standard, which provides guidance in applying the milestone method of revenue recognition to research or development arrangements. Under this guidance, management may recognize revenue contingent upon the achievement of a milestone in the period in which the milestone is achieved only if the milestone meets all the criteria within the guidance to be considered substantive. This standard is effective on a prospective basis for research and development milestones achieved in fiscal years beginning on or after June 15, 2010. The Company is currently evaluating the potential impact of this accounting standard on its financial statements, however the Company does not believe it will have a significant impact.

Management does not believe that any other recently issued, but not yet effective, accounting pronouncements, if currently adopted, would have a material effect on the Company’s financial statements.

5. PROPERTY AND EQUIPMENT

Property and equipment as of December 31, 2010 and 2009 consist of the following:

	2010	2009
Computer equipment	$ 30,340	$ 28,135
Office furniture and equipment	38,521	38,521
Total property and equipment	68,861	66,656
Accumulated depreciation	(52,096)	(39,170)
Total property and equipment, net	$ 16,765	$ 27,486

Depreciation expense related to property and equipment for the years ended December 31, 2010 and 2009 totaled $12,926 and $24,566, respectively, and $61,454 for the period from August 1, 2005 (inception) to December 31, 2010.

6. INTANGIBLE ASSETS AND INTELLECTUAL PROPERTY

Patents

During the first quarter of 2010, the Company revised its estimate for the useful lives of its patent and patent applications to zero. As a result of this change in estimates, the Company recorded an impairment of $106,830 to research and development expense, which was the net book value of its intangible assets as of December 31, 2009. Management believes this revised estimate better reflects the uncertainty surrounding drug product development. Management does not believe that the change in this estimate will have a material impact on its financial statements.

In addition, there was an impairment charge of approximately $48,000 in 2009 for the disposal of patents and patent applications associated with 2NTX-99.

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License Agreements

Cenderitide (formerly CD-NP)

On January 20, 2006, the Company entered into an exclusive, worldwide, royalty-bearing license agreement, or the Cenderitide License Agreement, with Mayo Foundation for Medical Education and Research ("Mayo") for the rights to issued patents, patent applications and know-how relating to the use of cenderitide in all therapeutic indications. The Company was 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, the Company paid Mayo an up-front cash payment, reimbursed it for past patent expenses and issued to Mayo 1,379,419 shares of common stock. Additionally, the Company 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, the Company made a milestone payment of $400,000 to Mayo upon the dosing of the first patient in a Phase II trial. Based on the current stage of research the Company does not expect to make any milestone payments for the year ended December 31, 2011. Pursuant to the Cenderitide License Agreement, the Company will pay Mayo 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 the Company to issue shares of common stock to Mayo 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 December 31, 2010, the Company received $482,235 in grant income for which it has issued to Mayo 63,478 shares (representing $182,235) 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 the Company's material breach of the agreement that remains uncured after 90 days' written notice, (ii) the Company's insolvency or bankruptcy, or (iii) if the Company challenges the validity or enforceability of any of the patents in any manner. The Company may terminate the agreement without cause upon 90 days' written notice.

CU-NP

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

Under the terms of the CU-NP License Agreement, the Company 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. Based on the current stage of research the Company does not expect to make any milestone payments for the year ended December 31, 2011. Pursuant to the agreement, the Company must also pay Mayo 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, the Company also agreed to issue shares of its common stock and warrants to Mayo. In June 2008, the Company issued 49,689 shares of common stock to Mayo having a fair market value as of June 13, 2008 equal to $250,000. This amount has been recorded in research and development expenses in the accompanying Statements of Operations. 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, the Company agreed to grant to Mayo an equivalent dollar value in warrants to purchase shares of the Company's 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. Mayo may terminate the agreement earlier (i) for the Company's material breach of the agreement that remains uncured after 90 days written notice, (ii) the Company's insolvency or bankruptcy, (iii) if the Company challenges the validity or enforceability of any of the patents in any manner, or (iv) or upon receipt of notice from the Company that it has terminated all development efforts under the agreement. The Company may terminate the agreement without cause upon 90 days' written notice.

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2NTX-99

On August 6, 2007, the Company entered into an exclusive, worldwide, royalty-bearing license agreement, or the 2NTX-99 License Agreement, with Dr. Cesare Casagrande for the rights to the intellectual property and know-how relating to 2NTX-99, and all of its human therapeutic or veterinary uses. Under the 2NTX-99 License Agreement, the Company made an up-front cash payment to Dr. Casagrande and reimbursed him for past patent expenses. The Company also issued to Dr. Casagrande 350,107 shares of common stock. In January 2009, the Company determined to discontinue the 2NTX-99 program so that it could focus its resources on the development of its natriuretic peptide franchise, including CD-NP which is in Phase II development for acute heart failure, and CU-NP which is a pre-clinical compound. Accordingly, the Company terminated the 2NTX-99 License Agreement, returning the rights to the molecule to Dr. Casagrande, effective April 16, 2009. As such, the Company recorded an impairment charge of $48,500 for unamortized patent costs, which is included in research and development expense in the accompanying Statements of Operations.

7. ACCRUED LIABILITIES

Accrued liabilities as of December 31, 2010 and 2009 consist of the following:

	2010	2009
Accrued compensation and related benefits	$ 23,775	$ 52,232
Accrued research and development expense	623,500	341,207
Accrued other expense	5,000	9,333
Total accrued liabilities	$ 652,275	$ 402,772

8. CONVERTIBLE AND OTHER NOTES PAYABLE

During March 2006, the Company completed a private placement offering for an aggregate $4,000,000 principal amount of 6% convertible promissory notes, or the Notes, due on March 28, 2008. The aggregate principal amount and accrued but unpaid interest on the Notes, which totaled $4,351,165, automatically converted upon the closing of the September 2007 equity financing into 1,684,085 shares of common stock at a conversion price of $2.58, which was equal to 90% of the per share price of the shares sold in the Financing. Due to the beneficial conversion feature resulting from the discounted conversion price, a discount of $483,463 was recorded as interest expense with a corresponding credit to additional paid-in capital. In addition, in conjunction with the conversion of the convertible debt, the Company issued fully vested warrants to the note holders to purchase 168,337 shares of common stock to the holders of the Notes. The warrants were valued at $288,000 using the Black-Scholes option-pricing model and the following assumptions: exercise price $2.71, a 3.98% risk-free interest rate, a 5 year contractual term, a dividend rate of 0%, and 68% expected volatility. The cost of the warrants was included in interest expense in the accompanying Statements of Operations, and as an increase in additional paid-in capital.

On July 24, 2007, the Company issued an 8% promissory note to an existing shareholder in the amount of $1,500,000. The note was due and payable on November 24, 2007. An upfront fee of $30,000 was netted against the gross proceeds. The note was paid in full on September 11, 2007, along with an additional fee of $120,000. The upfront and additional fees were charged to interest expense in the period ended September 30, 2007.

9. STOCKHOLDERS' EQUITY

(a) Common Stock

In August 2005, the Company issued an aggregate of 13,794,132 shares of common stock to its founders for $5,000. The founders subsequently returned 1,379,419 of these shares to the Company for issuance to Mayo. In January 2006 the Company issued 1,379,419 shares of common stock to Mayo, pursuant to the terms of the Mayo Licensing Agreement. The fair value of these shares of $500 was recorded as stock-based compensation and is included in research and development expense in the accompanying Statements of Operations.

In August 2007, pursuant to the terms of the 2NTX-99 License Agreement, the Company issued 350,107 shares of common stock to Dr. Casagrande. The fair value of the shares was $1,000,000 and was recorded as research and development expense in the accompanying Statements of Operations.

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In September 2007, also pursuant to the terms of the CD-NP License Agreement, the Company issued 63,478 shares of common stock to Mayo. The fair value of the shares, $182,236, was recorded as research and development expense in the accompanying Statements of Operations.

As a condition to the closing of the Merger, on September 11, 2007, Old Nile completed a financing whereby it received gross proceeds of $19,974,747 through the sale of 6,957,914 shares of common stock in a private placement to certain qualified investors. Issuance costs related to the financing were $102,000. Contemporaneously with the financing, the Company converted $4,351,165 of convertible debt and interest into 1,684,085 shares of common stock.

In June 2008, pursuant to the CU-NP License Agreement, the Company issued 49,689 shares of common stock to Mayo. The fair value of the shares on June 13, 2008 was $250,000 and was recorded as research and development expense in the accompanying Statements of Operations.

1,250,000 shares of common stock that were held by the original stockholders of SMI prior to the Merger are reflected in the Company's common stock outstanding in the accompanying Balance Sheets.

On July 7, 2009, the Company entered into a Securities Purchase Agreement with certain qualified investors pursuant to which it agreed to sell 2,691,394 units of its securities in a private placement in exchange for an aggregate gross purchase price of $3,368,748. Each unit included one share of common stock and one warrant to purchase a share of common stock. See Note 9(b). Issuance costs related to the financing were $282,773, including the issuance of warrants ("Placement Warrants") to purchase 218,300 shares of common stock to designees of Riverbank Capital Securities, Inc. ("Riverbank"), a FINRA member broker dealer that acted as placement agent for the Company in connection with the private placement. See Note 13. The issuance and sale of the units pursuant to the Securities Purchase Agreement was completed on July 15, 2009.

On April 21, 2010, the Company entered into an underwriting agreement (the "Underwriting Agreement"), providing for the offer and sale in a firm commitment underwritten public offering (the "Offering") of 6,500,000 units of its securities at a public offering price of $0.70 per unit (less an underwriting discount of $0.063 per unit). The Offering closed on April 27, 2010. Pursuant to the Underwriting Agreement, the Company granted the underwriters an option for a period of 45 days to purchase up to an additional 975,000 units to cover over-allotments. 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. Each unit sold in the Offering consisted of one share of the Company's common stock and 0.30 warrants to purchase common stock (the "Unit Warrants"). Each whole Unit Warrant has a term of five years and represents the right to purchase one share of the Company's common stock at an exercise price of $0.94 per share. The units separated immediately and the common stock and Unit Warrants were issued separately. Among other terms and conditions of the Unit Warrants, the agreement provides that, in the event the closing sale price of the Company's common stock is at least $3.00 per share for any 20 trading days within a period of 30 consecutive trading days, the Company may call the Unit Warrants for redemption, at a redemption price of $0.01 per Unit Warrant, by providing at least 30 days notice to each Unit Warrant holder. The Unit Warrants were approved for trading on the Nasdaq Capital Market under the symbol "NLTXW" and began trading on April 22, 2010.

In total, the Company sold 7,475,000 units under the terms of the Underwriting Agreement, consisting of an aggregate of 7,475,000 shares of common stock and 2,242,500 Unit Warrants. In addition, the Company issued the underwriters a five-year warrant to purchase 390,000 shares of the Company's common stock at an exercise price of $0.94 per share, which had a fair value of $271,900 and was accounted for as a cost of the offering and charged to stock holder's equity.

The net proceeds to the Company from the sale of all units, after deducting underwriting discounts, commissions and professional fees of $715,801, was $4,516,699.

(b) Warrants

In conjunction with the conversion of $4,351,165 of convertible debt prior to the Merger, the Company issued fully vested warrants to purchase 168,337 shares of common stock to the holders of such debt. The warrants were issued with an exercise price of $2.71 and expire in September 2012. The fair value of the warrants was determined to be $288,000. None of these warrants have been exercised to date.

In 2007, as consideration for the performance of consulting and due diligence efforts related to the licensing of 2NTX-99, the Company granted and accrued for fully vested warrants to purchase 206,912 shares of its common stock. The warrants were valued at $334,992 using the Black-Scholes option-pricing model and the following assumptions: an exercise price of $2.71, a 4.02% risk-free interest rate, a 5 year contractual term, a dividend rate of 0%, and 68% expected volatility. Of the total warrants granted, 137,567 warrants with an aggregate value of $222,770 were granted to employees of Two River Group Holdings, LLC (“Two River”), a related party, and its affiliates. See Note 13. The remaining warrants were granted to outside consultants. The warrants were recorded as an expense and a liability during the year ended December 31, 2007. In March 2008, these warrants were issued in satisfaction of the accrued liability.

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In connection with its July 2009 private placement, as discussed above, the Company issued 2,691,394 shares of common stock and five-year warrants to purchase an additional 2,691,394 shares of common stock. The warrants were issued in three separate tranches, as follows:

- Warrants to purchase 672,849 shares, representing 25% of the total warrant shares issued to investors, have an exercise price equal to $1.25, which represents 110% of the $1.14 consolidated closing bid price of the Company's common stock on July 7, 2009 (the "Closing Bid Price");
- Warrants to purchase 672,848 shares, representing 25% of the total warrant shares issued to investors, have an exercise price equal to $1.71, which represents 150% of the Closing Bid Price; and
- Warrants to purchase 1,345,697 shares, representing 50% of the total warrant shares issued to investors, have an exercise price equal to $2.28, which represents 200% of the Closing Bid Price.

The warrants issued to investors in the July 2009 private placement are redeemable by the Company upon 30 days' notice, if at any time, the volume weighted average price of the common shares for any 20 consecutive business days is equal to or greater than 200% of the applicable exercise price of each warrant.

As consideration for its services as placement agent in connection with the July 2009 private placement, the Company also issued to designees of Riverbank five-year warrants to purchase 218,300 shares of common stock at a price of $1.375 per share. These warrants have an aggregate fair-value of $201,200.

In connection with the April 2010 Offering discussed above, the Company issued a total of 2,242,500 Unit Warrants, each of which has a term of five years and represents the right to purchase one share of the Company's common stock at an exercise price of $0.94 per share. In addition, the Company issued the underwriters a five-year warrant to purchase 390,000 shares of the Company's common stock at an exercise price of $0.94 per share.

The table below summarizes all outstanding warrants to purchase shares of the Company's common stock as of December 31, 2010.

Grant Date	Warrants Issued	Exercise Price Range	Weighted Average Exercise Price	Expiration Date	Exercised	Warrants Outstanding
9/11/2007	168,377	$ 2.71	$ 2.71	9/11/2012	-	168,377
3/26/2008	206,912	$ 2.71	$ 2.71	9/11/2012	-	206,912
7/15/2009	2,909,695	$ 1.25-2.28	$ 1.64	7/14/2014	5,000	2,904,695
4/21/2010	2,632,500	$ 0.94	$ 0.94	4/20/2015	-	2,632,500
	5,917,484		$ 1.50		5,000	5,912,484

10. STOCK-BASED COMPENSATION

The Company's Amended and Restated 2005 Stock Option Plan (the "Plan") was initially adopted by the Board of Directors on August 10, 2005. The Plan authorized a total of 2,000,000 shares of common stock for issuance. On September 17, 2007, pursuant to the Merger, the Plan was amended and each share of common stock then subject to the Plan was substituted with 2.758838 shares of common stock, resulting in an aggregate of 5,517,676 shares available under the Plan. On July 26, 2010, the Company's stockholders approved an amendment to the Plan

increasing the total number of shares authorized for issuance thereunder to 9,500,000, which was an increase of 3,982,324 shares to the Plan. Under the Plan, incentives may be granted to officers, employees, directors, consultants, and advisors. Incentives under the Plan may be granted in any one or a combination of the following forms: (a) incentive stock options and non-statutory stock options, (b) stock appreciation rights, (c) stock awards, (d) restricted stock and (e) performance shares.

The Plan is administered by the Board of Directors, or a committee appointed by the Board, which determines the recipients and types of awards to be granted, as well as the number of shares subject to the awards, the exercise price and the vesting schedule. The term of stock options granted under the Plan cannot exceed ten years. Currently, stock options are granted with an exercise price equal to closing price of the Company's common stock on the date of grant, and generally vest over a period of one to four years.

A summary of the status of the options issued under the Plan at December 31, 2010, and information with respect to the changes in options outstanding is as follows:

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	Available for Grant	Stock Options	Average Exercise Price	Intrinsic Value
Balance at January 1, 2006	5,310,766	206,910	$ 0.09	
Options granted under the Plan	(2,802,329)	2,802,329	$ 2.85	
Options forfeited	96,558	(96,558)	$ 0.84	
Balance at December 31, 2007	2,604,995	2,912,681	$ 2.72	
Options granted under the Plan	(1,152,588)	1,152,588	$ 4.09	
Options forfeited	87,500	(87,500)	$ 4.45	
Balance at December 31, 2008	1,539,907	3,977,769	$ 3.08	
Options granted under the Plan	(2,015,148)	2,015,148	$ 1.17	
Options exercised		(240,025)	$ 0.88	
Options forfeited	1,311,490	(1,311,490)	$ 3.45	
Balance at December 31, 2009	836,249	4,441,402	$ 2.22	
Shares authorized for issuance	3,982,324			
Options granted under the Plan	(2,800,000)	2,800,000	$ 0.35	
Options exercised	-	(68,970)	$ 0.09	
Options forfeited	249,278	(249,278)	$ 1.62	
Balance at December 31, 2010	2,267,851	6,923,154	$ 1.52	$ 1,172,081
Exercisable at December 31, 2010		4,493,844	$ 1.97	$ 378,423

During the three months ended March 31, 2009, the Company granted options in lieu of accrued performance cash bonuses (“Cash Bonus Options”). Employees received a certain amount of options in exchange for up to 50% of their accrued performance cash bonus. The Company estimated the fair value of these options to be equal to the amount of cash bonus exchanged for the options divided by the number of options granted. The options were 100% vested on the date of the grant, January 16, 2009. In addition, employees were given the option of exchanging the remaining 50% of their performance cash bonus for 50% more options than were exchanged for the first 50% of their performance cash bonus. An additional $23,293 in compensation costs was expensed in the first quarter as a result of this incremental incentive to preserve the Company’s cash.

Excluding Cash Bonus Options, for the year ended December 31, 2010, the Company estimated the fair value of each option award granted to employees using the Black-Scholes option-pricing model and the following assumptions for the year ended December 31, 2010 and 2009:

	December 31, 2010	December 31, 2009
Expected volatility	90% to 98%	117% to 123%
Expected term	3 years	3 years
Dividend yield	0%	0%
Risk-free interest rates	1%	1.4% to 1.7%

The valuation assumptions were determined as follows:

- Expected volatility – Management determined the expected volatility by using a weighted average of selected peer companies.

- Expected term – The expected term of the awards represents the period of time that the awards are expected to be outstanding. Management considered historical data and expectations for the future to estimate employee exercise and post-vest termination behavior.

- Dividend yield – The estimate for annual dividends is zero, because the Company has not historically paid dividends and does not intend to in the foreseeable future.

- Risk-free interest rates - The yield on zero-coupon U.S. Treasury securities for a period that is commensurate with the expected term of the awards.

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Share-based compensation is recognized only for those awards that are ultimately expected to vest, therefore, the Company has applied an estimated forfeiture rate of 25% to unvested awards for the purpose of calculating compensation cost. These estimates will be revised, if necessary, in future periods if actual forfeitures differ from estimates. Changes in forfeiture estimates impact compensation cost in the period in which the change in estimate occurs.

Employee stock-based compensation costs for the year ended December 31, 2010 and 2009 and for the cumulative period from August 1, 2005 (inception) through December 31, 2010, are as follows:

	Year ended December 31,		Period from August 1, 2005 (inception)
	2010	2009	through December 31, 2010
General and administrative	$ 826,040	$ 1,507,938	$ 6,187,028
Research and development	316,512	146,907	1,073,847
Total	$ 1,142,552	$ 1,654,845	$ 7,260,875

The following table summarizes information about stock options outstanding at December 31, 2010:

	Outstanding			Exercisable	
Range of Exercise Prices	Shares	Weighted-Average Remaining Contractual Life	Weighted-Average Exercise Price	Total Shares	Weighted-Average Exercise Price
$0.09 to $0.93	3,799,718	7.97	$ 0.49	1,693,468	$ 0.59
$1.14 to $2.71	2,487,087	5.60	$ 2.33	2,276,253	$ 2.41
$4.45 to $5.75	636,349	6.33	$ 4.54	524,123	$ 4.55
Total	6,923,154	7.00	$ 1.52	4,493,844	$ 1.97

The fair value of shares vested under the Plan for the year ended December 31, 2010 and 2009 and for the period from August 1, 2005 (inception) through December 31, 2010 were $1,546,869, $2,394,048, and $5,727,031 respectively.

Certain employees have been granted performance-based stock options that are subject to forfeiture based on the failure to achieve specified goals. The Company analyzed two years of annual performance measurements, and, based on that analysis, estimated forfeiture rates on performance-based stock options for future periods. For the cumulative period from August 1, 2005 (inception) through December 31, 2010, employees forfeited 379,617 shares related to performance-based options, which had a fair value of $643,094. During the year ended December 31, 2009, employment stock options and performance-based stock options relating to 894,271 shares, which had a fair value of $2,182,485, were forfeited as a result of the corporate lay-offs. Based on the forfeiture rates of the performance-based stock options, the Company estimates that options relating to an additional 24,612 shares of common stock will be forfeited in the future. The estimated compensation cost of these forfeited shares is $37,491.

In addition, pursuant to the terms of a separation agreement of a former executive dated June 10, 2009, the Company accelerated the vesting of 329,857 shares subject to a stock option, resulting in additional stock compensation expense of approximately $676,000 during the year ended December 31, 2009. The Company also agreed to extend to June 10, 2014 the exercise period relating to the vested stock options owned by the former executive. This extended exercise period did not result in any incremental stock compensation cost required to be recorded. In total, the former executive has stock options to purchase 1,381,202 shares of common stock at a weighted average exercise price of $2.51 per share.

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During the year ended December 31, 2009, in accordance with the terms of a separation agreement with a former member of the Company's Board of Directors, the Company accelerated the vesting of 123,334 shares subject to a stock option, resulting in additional compensation expense of approximately $159,515.

At December 31, 2010, total unrecognized estimated employee (including directors) compensation cost related to stock options granted prior to that date was $561,406, which is expected to be recognized over a weighted-average vesting period of 1.7 years. This unrecognized estimated employee compensation cost does not include $37,491 in management estimated forfeitures of performance-based stock options.

Common stock, stock options or other equity instruments issued to non-employees (including consultants and all members of the Company's Scientific Advisory Board) as consideration for goods or services received by the Company 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 re-measured as the underlying options vest. The fair value of any options issued to non-employees is recorded as expense over the applicable service periods.

On June 24, 2009, in conjunction with a services agreement, the Company issued to named employees of Two River Consulting, LLC ("TRC") stock options to purchase 187,500 shares of common stock that vested on issuance and have a fair-value of $116,309; and stock options to purchase 562,500 shares that vest based on the achievement of certain milestones and have an estimated fair-value of $363,028. TRC is an entity controlled by two of the Company's officers and directors. For the year ended December 31, 2009, the Company recorded an expense of $326,563 related to these options. For the year ended December 31, 2010, the Company recorded an expense of ($9,792) related to these options. In total, options to purchase 535,172 shares vest in conjunction with the services agreement.

On August 12, 2010, in conjunction with an amended services agreement, the Company issued to named employees of TRC stock options to purchase 250,000 shares of the Company's common stock that were fully vested on issuance and had an estimated fair value of $82,200 that was expensed on the date of grant.

Stock-based compensation costs incurred for services by non-employees for the year ended December 31, 2010 and 2009, and for the cumulative period from August 1, 2005 (inception) through December 31, 2010 totaled ($19,249), $473,584, and $477,355, respectively. These amounts were included in research and development expense in the accompanying Statements of Operations.

In addition to the options issued under the Plan, in September 2007 the Company issued fully vested options to purchase 593,750 shares outside of the Plan to a former executive of the Company pursuant to his separation agreement. The options were issued at an exercise price of $2.71 per share.

11. 401(k) SAVINGS PLAN

On April 1, 2007, the Company adopted a 401(k) savings plan (the "401(k) Plan") for the benefit of its employees. Under the 401(k) Plan the Company is required to make contributions equal to 3% of eligible compensation for each eligible employee whether or not the employee contributes to the 401(k) Plan. The Company recorded compensation expenses of $0, $5,921 and $21,947 for the years ended December 31, 2010 and 2009 and for the cumulative period from August 1, 2005 (inception) through December 31, 2010, respectively. As of December 31, 2010, the Company has fully funded the 401(k) Plan.

12. INCOME TAXES

The Company accounts for income taxes using the liability method, which requires the determination of deferred tax assets and liabilities, based on the differences between the financial statement and tax bases of assets and liabilities, using enacted tax rates in effect for the year in which differences are expected to reverse. The net deferred tax asset is adjusted by a valuation allowance, if, based on the weight of available evidence, it is more likely than not that some portion or all of the net deferred tax asset will not be realized. The income tax returns of the Company are subject to examination by federal and state taxing authorities. Such examination could result in adjustments to net income or loss, which changes could affect the income tax liabilities of the Company. The Company's tax returns are open for inspection for the five years ended December 31, 2010.

The Company's policy is to include interest and penalties related to unrecognized tax benefits within the Company's provision for (benefit from) income taxes. The Company recognized no amounts for interest and penalties related to unrecognized tax benefits in 2010, 2009 and the period from August 1, 2005 (inception) through December 31, 2010 and as of December 31, 2010 and 2009, had no amounts accrued for interest and penalties.

At December 31, 2010, the Company had no federal income tax expense or benefit but did have federal tax net operating loss carry-forwards of approximately $11,237,988, and an R&D credit carry-forward of $1,120,864. The federal net operating loss carry-forwards will begin to expire in 2026, unless previously utilized.

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Deferred income taxes reflect the net effect of temporary difference between the carrying amounts of assets and liabilities for financial reporting purposes and the amounts used for income tax purposes. Significant components of the Company's net deferred tax assets at December 31, 2010 are shown below. A valuation allowance of $15,272,163 has been established to offset the net deferred tax assets at December 31, 2010, as realization of such assets is uncertain.

	For Years Ended December 31, 2010	2009
Deferred tax assets		
Research tax credit	$ 1,120,864	$ 935,172
Net operating loss carry forwards	11,237,988	8,484,156
Others	2,913,311	2,546,676
Total deferred tax asset	15,272,163	11,966,004
Deferred tax liability	-	-
Total net deferred tax asset	15,272,163	11,966,004
Valuation allowance	(15,272,163)	(11,966,004)
Net deferred tax asset	$ -	$ -

The Company files income tax returns in the U.S. federal and California state jurisdictions, which returns are generally subject to examination by federal authorities for all tax years from 2007 to present and by California authorities from 2006 to present.

13. RELATED PARTIES

On June 24, 2009, the Company entered into a services agreement with TRC to provide various clinical development, operational and administrative services to the Company for a period of one year. Joshua A. Kazam, the Company's President and Chief Executive Officer and director, and Arie S. Belldegrun, who was appointed to serve as a member of the Company's Board of Directors on September 24, 2009, are each partners of TRC. David M. Tanen, who served as the Company's Secretary and director until his resignation from both positions on September 24, 2009, is also a partner of TRC. The terms of the services agreement were reviewed and approved by a special committee of the Company's Board of Directors consisting of independent directors. None of the members of the special committee has any interest in TRC or the services agreement. As compensation for the services contemplated by the services agreement, the Company will pay to TRC a monthly cash fee of $65,000 and issued stock options to purchase up to an aggregate of 750,000 shares of the Company's common stock at a price per share equal to $0.89, the closing sale price of the Company's common stock on June 24, 2009.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 original stock options issued, 535,172 stock options vested with a total fair value of $353,976. On August 12, 2010, the special committee of the Company's Board of Directors consisting of independent directors approved an extension of the services agreement with TRC and the issuance of fully-vested and immediately-exercisable stock options to purchase

250,000 shares of the Company's common stock at an exercise price of $0.38 per share, which had an estimated fair value of $82,200 that was expensed on the date of grant. On occasion, some of the Company's expenses are paid by TRC. No interest is charged by TRC on any outstanding balance owed by the Company. For the years ended December 31, 2010 and 2009 and for the period from August 1, 2005 (inception) through December 31, 2010, total cash services and reimbursed expenses totaled $834,032, $482,840 and $1,316,872, respectively. As of December 31, 2010 the Company has a payable to TRC of $84,430.

Prior to June 24, 2009, some of the Company's expenses were paid by Two River Group Holdings, LLC ("Two River"), a company owned by three of the Company's directors and founders. No interest is charged by Two River on any outstanding balance owed by the Company. For the years ended December 31, 2010 and 2009, and for the period from August 1, 2005 (inception) through December 31, 2010, reimbursable expenses totaled $0, $26,374 and $153,238, respectively. As of December 31, 2010 and 2009 the Company has no balance payable to Two River.

As discussed in Notes 9(a) and 9(b), pursuant to a Securities Purchase Agreement dated July 7, 2009 between the Company and certain qualified investors identified therein, the Company sold 2,691,394 units of its securities resulting in gross proceeds of $3,368,748. The sale of the units was completed on July 15, 2009. The Company engaged Riverbank Capital Securities, Inc. ("Riverbank") to serve as its placement agent. Riverbank was not paid a cash commission for its services, however, the Company issued Riverbank (or its designees) five-year warrants to purchase 218,300 shares of the Company's common stock. The warrants are exercisable at a price of $1.375 per share, which is equal to 110% of the per unit purchase price paid by investors, and have a cashless (net) exercise provision. The Company also paid Riverbank an expense allowance of $50,000 to cover expenses incurred during the financing. These costs were incurred in connection with the private placement of units and therefore, have been deducted from the capital raised on the statement of changes in stockholders' equity.

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Joshua A. Kazam, the Company's President and Chief Executive Officer and director, Peter M. Kash, a director of the Company, and David M. Tanen, a director of the Company until September 24, 2009, are each officers of and collectively control Riverbank. In light of the relationship between Messrs. Kash, Kazam and Tanen and Riverbank, the selection and terms of the engagement were reviewed and approved by a special committee of the Company's Board consisting of independent directors, none of whom had any interest or other relationship in Riverbank or its affiliates.

14. COMMITMENTS AND CONTINGENCIES

On August 15, 2009, the Company relocated its primary office space to San Mateo, California. 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, the Company made a $2,000 cash security deposit.

15. SUBSEQUENT EVENTS

On February 25, 2011, the Company entered into a Clinical Trial Funding Agreement with Medtronic, Inc. Pursuant to the agreement, Medtronic will provide the equipment necessary for the Company to conduct its planned 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. The agreement provides that Medtronic will reimburse the Company for an external expenses related to the Phase I clinical trial at the achievement of certain milestones as defined in the agreement. Any budget overages will be reviewed by the Company and Medtronic and may result in additional reimbursement. In addition under the agreement, the Company has 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.

ITEM 9. CHANGES IN AND DISAGREEMENTS WITH ACCOUNTANTS ON ACCOUNTING AND FINANCIAL DISCLOSURE

Not applicable.

ITEM 9A. CONTROLS AND PROCEDURES

Evaluation of Disclosure Controls and Procedures

We conducted an evaluation as of December 31, 2010, under the supervision and with the participation of our management, including our Chief Executive Officer and Chief Financial Officer, of the effectiveness of the design and operation of our disclosure controls and procedures, which are defined under SEC rules as controls and other procedures of a company that are designed to ensure that information required to be disclosed by a company in the reports that it files under the Securities Exchange Act of 1934, as amended, is recorded, processed, summarized and reported within required time periods. Based upon that evaluation, our Chief Executive Officer and Chief Financial Officer concluded that, as of such date, our disclosure controls and procedures were effective.

Management's Report on Internal Control over Financial Reporting

Our management is responsible for establishing and maintaining adequate internal control over financial reporting as defined in Rule 13a-15(f) of the Exchange Act. Internal control over financial reporting includes those policies and procedures that (1) pertain to the maintenance of records that in reasonable detail accurately and fairly reflect the transactions and dispositions of our assets; (2) provide reasonable assurance that transactions are recorded as necessary to permit preparation of financial statements in accordance with generally accepted accounting principles, and that our receipts and expenditures are being made only in accordance with authorizations of our management and directors; and (3) provide reasonable assurance regarding prevention or timely detection of unauthorized acquisition, use or disposition of our assets that could have a material effect on the financial statements.

Under the supervision and with the participation of our management, including our Chief Executive Officer and Chief Financial Officer, we conducted an evaluation of the effectiveness of our internal control over financial reporting based on criteria established in the Internal Control—Integrated Framework issued by the Committee of Sponsoring Organizations of the Treadway Commission. Management's assessment included evaluation of such elements as the design and operating effectiveness of key financial reporting controls, process documentation, accounting policies, and our overall control environment. Based on this evaluation, our management concluded that our internal control over financial reporting was effective as of December 31, 2010.

Limitations on the Effectiveness of Controls

Our management, including our Chief Executive Officer and Chief Financial Officer, does not expect that our disclosure controls and procedures or our internal control over financial reporting will prevent all error and all fraud. A control system, no matter how well conceived and operated, can provide only reasonable, not absolute, assurance that the objectives of the control system are met. Further, the design of a control system must reflect the fact that there are resource constraints, and the benefit of controls must be considered relative to their costs. Because of the inherent limitations in all control systems, no evaluation of controls can provide absolute assurance that all control issues and instances of fraud, if any, within Nile have been detected. Also, projections of any evaluation of effectiveness to future periods are subject to the risk that controls may become inadequate because of changes in conditions, or that the degree of compliance with the policies or procedures may deteriorate.

Changes in Internal Controls over Financial Reporting

There was no change in our internal control over financial reporting (as defined in Rule 13a-15(f) of the Exchange Act) that occurred during the fourth quarter of the year ended December 31, 2010 that has materially affected, or is reasonably likely to materially affect, our internal control over financial reporting.

ITEM 9B. OTHER INFORMATION

None.

Part III

ITEM 10. DIRECTORS, EXECUTIVE OFFICERS AND CORPORATE GOVERNANCE

Information in response to this Item is incorporated herein by reference to our 2011 Proxy Statement to be filed pursuant to Regulation 14A within 120 days after the end of the fiscal year covered by this Form 10-K.

ITEM 11. EXECUTIVE COMPENSATION

Information in response to this Item is incorporated herein by reference to our 2011 Proxy Statement to be filed pursuant to Regulation 14A within 120 days after the end of the fiscal year covered by this Form 10-K.

ITEM 12. SECURITY OWNERSHIP OF CERTAIN BENEFICIAL OWNERS AND MANAGEMENT AND RELATED STOCKHOLDER MATTERS

Securities Authorized for Issuance Under Equity Compensation Plans

Our Amended and Restated 2005 Stock Option Plan (the "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 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 Plan

Information in response to this Item relating to security ownership of certain beneficial owners and management is incorporated herein by reference to our 2011 Proxy Statement to be filed pursuant to Regulation 14A within 120 days after the end of the fiscal year covered by this Form 10-K.

ITEM 13. CERTAIN RELATIONSHIPS AND RELATED TRANSACTIONS, AND DIRECTOR INDEPENDENCE

Information in response to this Item is incorporated herein by reference to our 2011 Proxy Statement to be filed pursuant to Regulation 14A within 120 days after the end of the fiscal year covered by this Form 10-K.

ITEM 14. PRINCIPAL ACCOUNTANT FEES AND SERVICES

Information in response to this Item is incorporated herein by reference to our 2011 Proxy Statement to be filed pursuant to Regulation 14A within 120 days after the end of the fiscal year covered by this Form 10-K.

PART IV

ITEM 15. EXHIBITS AND FINANCIAL STATEMENT SCHEDULES

Exhibit No.	Description
2.1	Agreement and Plan of Merger, by and among SMI Products, Inc., Nile Merger Sub, Inc., and Nile Therapeutics, Inc. dated as of August 15, 2007 (incorporated by reference to Exhibit 2.1 to the Company's Current Report on Form 8-K filed August 17, 2007).
3.1	Certificate of Incorporation of Nile Therapeutics, Inc. (incorporated by reference to Exhibit 3.1 to the Company's Current Report on Form 8-K filed February 9, 2007).
3.2	Bylaws of Nile Therapeutics, Inc. (incorporated by reference to Exhibit 3.2 to the Company's Current Report on Form 8-K filed February 9, 2007).
4.1	Specimen Common Stock Certificate (incorporated by reference to Exhibit 4.1 to the Company's Current Report on Form 8-K filed September 21, 2007).
4.2	Form of Nile Therapeutics, Inc. Common Stock Purchase Warrant (incorporated by reference to Exhibit 10.1 to the Company's Current Report on Form 8-K filed September 21, 2007).
4.3	Form of Warrant issued to investors in July 2009 private placement (incorporated by reference to Exhibit 4.1 to the Company's Registration Statement on Form S-3 filed August 13, 2009).
4.4	Form of Warrant issued to placement agent in July 2009 private placement (incorporated by reference to Exhibit 4.2 to the Company's Registration Statement on Form S-3 filed August 13, 2009).
4.5	Warrant Agreement between Nile Therapeutics, Inc. and American Stock Transfer & Trust Company, LLC, as Warrant Agent, dated April 21, 2010 (incorporated by reference to Exhibit 4.1 to the Company's Current Report on Form 8-K filed April 22, 2010).
4.6	Form of Unit Warrant issued to investors in April 2010 public offering (included as part of Exhibit 4.5 hereof).
4.7	Form of Representative's Warrant issued to Maxim Group, LLC in connection with April 2010 public offering (incorporated by reference to Exhibit 4.3 to the Company's Current Report on Form 8-K filed April 22, 2010).
10.1	

	Employment Agreement between Nile Therapeutics, Inc. and Daron Evans dated January 19, 2007 (incorporated by reference to Exhibit 10.3 to the Company's Current Report on Form 8-K filed September 21, 2007).*
10.2	Amendment No. 1 to Employment Agreement between Nile Therapeutics, Inc. and Daron Evans dated August 19, 2007 (incorporated by reference to Exhibit 10.4 to the Company's Current Report on Form 8-K filed September 21, 2007).*
10.3	Amendment of Employment Agreement, by and between Nile Therapeutics, Inc. and Daron Evans, dated March 4, 2008 (incorporated by reference to Exhibit 10.3 to the Company's Current Report on Form 8-K filed March 5, 2008).*
10.4	Amendment of Incentive Stock Option Agreement, by and between Nile Therapeutics, Inc. and Daron Evans, dated March 4, 2008 (incorporated by reference to Exhibit 10.5 to the Company's Current Report on Form 8-K filed March 5, 2008).*
10.5	Letter Agreement between Nile Therapeutics, Inc. and Jennifer L. Hodge, dated August 31, 2007 (incorporated by reference to Exhibit 10.5 to the Company's Current Report on Form 8-K filed September 21, 2007).*
10.6	Offer Letter between the Company and Hsiao Dee Lieu, M.D., F.A.C.C. entered into on February 22, 2008 (incorporated by reference to Exhibit 10.1 to the Company's Current Report on Form 8-K filed February 27, 2008).*
10.7	License Agreement between the Company and Mayo Foundation for Medical Education and Research, dated January 20, 2006 (incorporated by reference to Exhibit 10.6 to the Company's Current Report on Form 8-K filed September 21, 2007).+
10.8	Amended and Restated 2005 Stock Option Plan (incorporated by reference to Exhibit 10.9 to the Company's Current Report on Form 8-K filed September 21, 2007).*
10.9	Form of Stock Option Agreement (incorporated by reference to Exhibit 10.10 to the Company's Current Report on Form 8-K filed September 21, 2007).*
10.10	Form of Incentive Stock Option Agreement (incorporated by reference to Exhibit 10.11 to the Company's Current Report on Form 8-K filed September 21, 2007).*

Exhibit No.	Description
10.11	Amendment to Offer Letter, dated as of March 10, 2009, by and between Nile Therapeutics, Inc. and Hsiao D. Lieu, M.D., F.A.C.C. (incorporated by reference to Exhibit 10.19 to the Company's Annual Report on Form 10-K filed March 12, 2009).*
10.12	Technology License Agreement between the Company and Mayo Foundation for Medical Education and Research, effective as of June 17, 2008 (incorporated by reference to Exhibit 10.1 to the Company's Quarterly Report on Form 10-Q filed August 14, 2008).+
10.13	Separation Agreement and General Release between the Company and Peter M. Strumph dated June 10, 2009 (incorporated by reference to Exhibit 10.1 to the Company's Current Report on Form 8-K filed June 12, 2009).*
10.14	Form of Indemnification Agreement entered into between the Company and each of its executive officers and directors (incorporated by reference to Exhibit 10.14 to the Company's Annual Report on Form 10-K filed March 3, 2010).*
10.15	Form of Securities Purchase Agreement entered into among the Company and various accredited investors on July 7, 2009 (incorporated by reference to Exhibit 10.1 to the Company's Current Report on Form 8-K filed July 13, 2009).
10.16	Services Agreement dated June 24, 2009 between Nile Therapeutics, Inc. and Two River Consulting, LLC (incorporated by reference to Exhibit 10.2 to the Company's Quarterly Report on Form 10-Q filed August 13, 2009).
10.17	Underwriting Agreement between the Company and Maxim Group LLC, as representative of the underwriters named on Schedule A thereto, dated April 21, 2010 (incorporated by reference to Exhibit 1.1 to the Company's Current Report on Form 8-K filed April 22, 2010).
10.18	Letter Agreement between Nile Therapeutics, Inc. and Richard Brewer, dated July 15, 2010 (incorporated by reference to Exhibit 10.1 to the Company's Current Report on Form 8-K filed July 27, 2010).*
10.19	Severance Benefits Agreement between Nile Therapeutics, Inc. and Daron Evans, dated July 24, 2010 (incorporated by reference to Exhibit 10.2 to the Company's Current Report on Form 8-K filed July 27, 2010).*
10.20	Summary terms of compensation plan for directors of Nile Therapeutics, Inc., as amended July 26, 2010 (incorporated by reference to Exhibit 10.3 to the Company's Current Report on Form 8-K filed July 27, 2010).*

10.21	Amendment No. 1 to Services Agreement between Nile Therapeutics, Inc. and Two River Consulting, LLC, dated August 12, 2010 (incorporated by reference to Exhibit 10.1 to the Company's Quarterly Report on Form 10-Q filed August 16, 2010).
23.1	Consent of Crowe Horwath LLP.
24.1	Power of Attorney (included on signature page hereof).
31.1	Certification of Chief Executive Officer.
31.2	Certification of Principal Financial Officer.
32.1	Certification pursuant to Section 906 of the Sarbanes-Oxley Act of 2002.
32.2	Certification pursuant to Section 906 of the Sarbanes-Oxley Act of 2002.

+ Confidential treatment has been granted as to certain omitted portions of this exhibit pursuant to Rule 24b-2 of the Exchange Act.

* Indicates a management contract or compensatory plan or arrangement required to be filed as an exhibit to this Form 10-K.

SIGNATURES

Pursuant to the requirements of Section 13 or 15(d) of the Securities Exchange Act of 1934, the registrant has duly caused this report to be signed on its behalf by the undersigned, thereunto duly authorized, on March 14, 2011.

NILE THERAPEUTICS, INC.

By: /s/ Joshua Kazam
Joshua Kazam
Chief Executive Officer

KNOW ALL MEN BY THESE PRESENTS, that we, the undersigned officers and directors of Nile Therapeutics, Inc., hereby severally constitute Joshua Kazam and Daron Evans, and each of them singly, our true and lawful attorneys with full power to them, and each of them singly, to sign for us and in our names in the capacities indicated below, the Form 10-K filed herewith and any and all amendments to said Form 10-K, and generally to do all such things in our names and in our capacities as officers and directors to enable Nile Therapeutics, Inc. to comply with the provisions of the Securities Exchange Act of 1934, and all requirements of the U.S. Securities and Exchange Commission, hereby ratifying and confirming our signatures as they may be signed by our said attorneys, or any of them, to said Form 10-K and any and all amendments thereto.

Pursuant to the requirements of the Securities Exchange Act of 1934, this report has been signed below by the following persons on behalf of the registrant and in the capacities and on the dates indicated.

Signature	Title	Date
/s/ Joshua Kazam Joshua Kazam	Chief Executive Officer and Director (Principal Executive Officer)	March 14, 2011
/s/ Daron Evans Daron Evans	Chief Financial Officer (Principal Financial and Accounting Officer)	March 14, 2011
/s/ Richard B. Brewer Richard B. Brewer	Executive Chairman	March 14, 2011
/s/ Arie Belldegrun Arie Belldegrun, M.D.	Director	March 14, 2011
/s/ Pedro Granadillo Pedro Granadillo	Director	March 14, 2011
/s/ Peter M. Kash Peter M. Kash	Director	March 14, 2011
/s/ Frank Litvack Frank Litvack, M.D.	Director	March 14, 2011
/s/ Paul A. Mieyal Paul A. Mieyal, Ph.D.	Director	March 14, 2011

/s/ Gregory W. Schafer Gregory W. Schafer	Director	March 14, 2011

INDEX OF EXHIBITS FILED WITH THIS REPORT

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