Nile Therapeutics, Inc.
Form 10-K
March 03, 2010

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

FORM 10-K

x Annual Report Pursuant to Section 13 or 15(D) of the Securities Exchange Act of 1934

for the fiscal year ended December 31, 2009

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

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. o

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, 2009: $15,685,641

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 1, 2010, there were 27,085,824 shares of the issuer's common stock, par value $0.001 per share, issued and outstanding.

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References to “the Company,” “we”, “us” or “our” in this Annual Report on Form 10-K refer to Nile Therapeutics, Inc., a 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:

- CD-NP, our lead product candidate, is a chimeric natriuretic peptide that we are developing for the treatment of heart failure. We are currently studying CD-NP in Phase II clinical studies for the treatment of heart failure. We believe CD-NP may be useful in several cardiovascular and renal indications. We are currently developing CD-NP for an initial indication of acute decompensated heart failure, or ADHF.

- 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. 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
CD-NP	Heart failure	Nile	Single-blind, placebo-controlled Phase 2 study of CD-NP is ongoing in patients with acute decompensated heart failure, or ADHF. The primary objective of the study is to assess the safety and tolerability of IV administration of

			CD-NP and the dose relationship of CD-NP on improvement of clinical symptoms and renal function in ADHF patients.
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 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. Heart failure 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. Sales of nesiritide achieved close to $400 million per year until the emergence of a meta-analysis that suggests the possibility of worsening renal function and a meta-analysis suggesting the possibility of increased mortality at 30 days in patients who had been exposed to nesiritide. Sales of nesiritide quickly dropped to below $100 million per year.

CD-NP Program

CD-NP is a novel chimeric natriuretic peptide in clinical development for an initial indication of ADHF. CD-NP was rationally designed by scientists at the Mayo Clinic's cardio-renal research labs. Current therapies for ADHF, including B-type natriuretic peptide, have been associated with favorable pharmacologic effects, but have also been associated with hypotension and decreased renal function which limit their utility in clinical practice. CD-NP was designed to preserve the favorable effects of existing natriuretic peptide therapies while reducing or attenuating the hypotensive response and enhancing or preserving renal function. In addition to an initial indication of ADHF, CD-NP has potential utility in other 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 CD-NP. The study placed particular emphasis on the effects of CD-NP on blood pressure and renal function. Data from the completed Phase Ia study in healthy volunteers was consistent with several pre-clinical findings, including that CD-NP was associated with increased levels of plasma cGMP, a secondary messenger of the target receptor, preserved renal function, increased urinary excretion of sodium, or natriuresis, and increased urination, or diuresis. The study also showed that CD-NP 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 CD-NP 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 CD-NP i.v. infusion was compared to the patient's baseline established in the 24 hours prior to CD-NP infusion. The patient's oral diuretic and vasoactive medications were withheld during the CD-NP infusion. While the study was not powered for statistical analysis, data from the Phase Ib study indicate the following:

- CD-NP was tolerated at doses of up to 20 ng/kg/min;
- CD-NP blood pressure effects were dose-dependent and well characterized;
-

CD-NP 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, CD-NP 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 CD-NP 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 CD-NP, or how CD-NP 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 CD-NP. Data from the Phase IIa study indicate the following:

- CD-NP was tolerated at all study doses, including 1, 3, 10 and 20 ng/kg/min;

- CD-NP 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 CD-NP infusions produced clinically relevant reductions in PCWP;

- In the second cohort, where patients were dosed at 1 and 20 ng/kg/min, the CD-NP infusions did not result in clinically relevant reductions in PCWP;

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

Current Clinical Studies

In July 2009, we dosed the first patient in a single-blind, placebo-controlled Phase II clinical trial designed to provide additional information on the safety and tolerability of CD-NP when infused for up to 72 hours in hospitalized patients with acute heart failure and renal function insufficiency. The purpose of the study is to determine a safe and tolerable dose range of CD-NP that can be used in ADHF patients in the acute setting in combination with the standard of care. The standard of care includes the use of diuretics, such as furosemide, and could also include agents that affect dilation or contraction of blood vessels (vasoactive) or contraction of the heart muscle (inotropic). The study also contains several exploratory efficacy endpoints to provide insight into the potential for CD-NP to preserve or enhance renal function in acute heart failure patients. The study was initially designed to enroll up to approximately 40 patients in three cohorts. In the study, the dosage of CD-NP was to be increased in successive cohorts to assess the dose relationship of CD-NP on improvement of clinical symptoms and renal function in ADHF patients.

After dosing seven subjects in the first cohort, four of whom received CD-NP at a dose level of 5 ng/kg/min and three of whom received placebo, we suspended enrollment of the study. While there were no study drug related serious adverse events reported by investigators in these first seven subjects, the average blood pressure decrease in both the placebo and CD-NP patients was larger than predicted. We believed the greater than predicted response may have originated from the timing and quantity of concomitant medications versus study drug in the acute setting, as well as from the inclusion of patients who were more susceptible to risks from blood pressure deviations. We therefore submitted to the FDA a protocol amendment to (1) modify the exclusion criteria relating to the timing and quantity of bolus IV furosemide administration acceptable in the first 24 hours upon hospital admission, (2) provide additional guidance on the concomitant use of vasoactive oral and IV medication, (3) increase the entry blood pressure range, and (4) add additional dose levels to be studied. Following the FDA's approval of our amended protocol, we have completed enrolling subjects in a second cohort beginning with a dose level of 1.25 ng/kg/min and we are currently enrolling a third cohort at a dose level of 2.5 ng/kg/min. At the end of 2009, we submitted an additional protocol amendment to enable us to add up to three additional cohorts of patients, which increases potential enrollment in the study to a total of approximately 75 patients. As of March 1, 2010, we have completed dosing 30 subjects in the study.

Interim top-line safety data from the on-going Phase II study suggests that CD-NP is well-tolerated at dose levels of 1.25 and 2.5 ng/kg/min. We expect full results from the expanded study to be available in the second half of 2010. Following analysis of the ongoing Phase II data and subject to such data, we expect to initiate a Phase IIb

dose-ranging, placebo-controlled, double-blind study in acute heart failure patients.

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 CD-NP's renal properties. Data from this study is expected in 2010.

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.

In 2009, in partnership with the Mayo Clinic, we progressed toward the development of formulations to enable the chronic administration of CU-NP. In 2010, we expect to initiate and complete multiple in vivo pharmacological studies with chronic formulations of CU-NP.

2NTX-99 Program

In January 2009, we discontinued the development of 2NTX-99 and terminated our license to certain patents and other intellectual property relating to that product candidate. We decided to end the 2NTX-99 program in order to focus our resources on the development of our natriuretic peptide programs.

Intellectual Property and License Agreements

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

CD-NP

On January 20, 2006, we entered into an exclusive, worldwide, royalty-bearing license agreement, or the CD-NP 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 CD-NP in all therapeutic uses. We were also entitled to rights to improvements to CD-NP that arise out of the laboratory of Dr. John Burnett, the co-inventor of CD-NP, until January 19, 2009.

Under the terms of the CD-NP 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 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. 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. Pursuant to the CD-NP 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 CD-NP 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, 2009,

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 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.

Pursuant to our CD-NP 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 CD-NP, 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. 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. 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 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.

2NTX-99

In August 2007, we entered into an exclusive, worldwide, royalty-bearing license agreement with Dr. Cesare Casagrande for the rights to the intellectual property and know-how relating to a molecule known as 2NTX-99, and all of its human therapeutic or veterinary uses. Under this license agreement, we made an up-front cash payment to Dr. Casagrande and reimbursed him for past patent expenses. We also issued to Dr. Casagrande 350,107 shares of our common stock. In January 2009, we determined to discontinue the 2NTX-99 program in order to focus our resources on the development of our natriuretic peptide programs, CD-NP and CU-NP. Accordingly, we terminated the 2NTX-99 license agreement, returning the rights to the molecule to Dr. Casagrande, effective April 16, 2009. As such, we 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.

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 its 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 CD-NP 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 CD-NP, many therapeutic options are available for patients with acute decompensated heart failure, 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.

With respect to CU-NP, competitors would include many of the same companies included as competitors for CD-NP. 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.

Employees

As of December 31, 2009, we had two employees. None of our employees are covered by a collective bargaining unit. 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 capital, we will be forced to delay, reduce or eliminate our product development programs and may not have the capital required to otherwise operate our business.

Developing biopharmaceutical products, including conducting pre-clinical studies and clinical trials and establishing manufacturing capabilities, is expensive. We expect our research and development expenses to increase in connection with our ongoing activities, particularly as we initiate our clinical programs and conduct other clinical trials of our product candidates. In addition, our expenses could increase beyond expectations if the FDA requires that we perform additional studies to those that we currently anticipate, and the timing of any potential product approval may be delayed. Other than our cash on hand, we currently have no commitments or arrangements for any additional financing to fund the research and development of our product candidates. We have not generated any product revenues, and do not expect to generate any revenues until, and only if, we receive approval to sell our drugs from the FDA and other regulatory authorities for our product candidates. As of December 31, 2009, we had cash and cash equivalents totaling $3.2 million. During the fiscal year ended December 31, 2009, we used net cash totaling $5.8 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, which include the potential dosing of additional cohorts in the ongoing Phase II study, we expect that our current resources will be sufficient to fund our operations through the end of the third quarter of 2010. We will need to raise additional capital to complete the study activities and analyze the results. Pending the results of our ongoing Phase II study, we would need substantial additional capital in order to initiate and fund the next clinical study of CD-NP, which we anticipate would be a Phase IIb clinical trial.

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

Our forecast of the period of time through which our financial resources will be sufficient to support our operations is a forward-looking statement and involves risks and uncertainties, and actual results could vary as a result of a number of factors, including the factors discussed elsewhere in this “Risk Factors” section. We have based this estimate on

assumptions that may prove to be wrong, and we could utilize our available capital resources sooner than we currently expect. Our future funding requirements will depend on many factors, including, but not limited to:

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

Our business is substantially dependent on the results of our ongoing Phase II study of CD-NP and our ability to fund, either alone or with a strategic partner, its further development.

A substantial portion of our current human and financial resources is focused on the development of CD-NP, our lead product candidate and our only product candidate in clinical development. In July 2009, we commenced a single-blind, placebo-controlled Phase II study designed to provide additional information on the safety and tolerability of CD-NP when infused for up to 72 hours in patients with acute heart failure and renal function insufficiency. The purpose of the study is to determine a safe and tolerable dose range of CD-NP that can be used in ADHF patients in the acute setting in combination with the standard of care, which includes the use of diuretics and could also include vasoactive and inotropic agents. The study also contains several exploratory efficacy endpoints to provide insight into the potential for CD-NP to preserve or enhance renal function in acute heart failure patients. We expect results from this Phase II study to be available in the second half of 2010. Subject to the results of the Phase II study, we plan to either collaborate with a strategic partner to continue further development of CD-NP or undertake such further development on our own. If we undertake the further development of CD-NP on our own, we will require substantial additional capital to fund such activities. If we are unable to identify and secure a partner to continue the further development of CD-NP or obtain the additional funds required to fund such development on our own, our business would be substantially and adversely affected and we would be forced to significantly curtail or even cease our operations. Further, our business and future prospects will also be substantially and adversely affected if the data from the ongoing Phase II study of CD-NP are insufficient to support any further development of that drug compound, in which case, we may be forced to cease our operations.

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

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

- the need to obtain regulatory approval of our two product candidates, CD-NP and CU-NP;
- delays in the commencement, enrollment, and timing of clinical testing;
- the success of our clinical trials through all phases of clinical development;
- the success of clinical trials of our CD-NP and CU-NP product candidates or future product candidates;
- any delays in regulatory review and approval of our product candidates in clinical development;
- our ability to receive regulatory approval or commercialize our products within and outside the United States;
- potential side effects of our future products that could delay or prevent commercialization or cause an approved treatment drug to be taken off the market;

- regulatory difficulties relating to products that have already received regulatory approval;
- market acceptance of our product candidates;
- our ability to establish an effective sales and marketing infrastructure once our products are commercialized;
- competition from existing products or new products that may emerge;
- the impact of competition in the market in which we compete on the commercialization of CD-NP and CU-NP;
- guidelines and recommendations of therapies published by various organizations;
- the ability of patients to obtain coverage of or sufficient reimbursement for our products;
- our ability to maintain adequate insurance policies;
- our dependency on third parties to formulate and manufacture our product candidates;
- our ability to establish or maintain collaborations, licensing or other arrangements;
- our ability and third parties' abilities to protect intellectual property rights;
- costs related to and outcomes of potential intellectual property litigation;
- compliance with obligations under intellectual property licenses with third parties;
- our ability to adequately support future growth;
- our ability to attract and retain key personnel to manage our business effectively; and

- the level of experience in running a public company of our senior management who are relatively new to their current roles as managers of a public company.

We 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, 2009 and 2008, respectively, we had a net loss of $7.9 million and 13.1 million. Since our inception on August 1, 2005, through December 31, 2009, we have accumulated a deficit of $33.9 million and have stockholders' equity of $3.0 million. We expect to incur substantial losses and negative operating cash flow for the foreseeable future, and we may never achieve or maintain profitability. Even if we succeed in developing and commercializing one or more of our product candidates, we expect to incur substantial losses for the foreseeable future, as we:

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

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

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

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

Arie S. Belldegrun, Joshua A. Kazam and Peter M. Kash, each of whom are currently directors of our company, and David M. Tanen, a director of our company until September 2009, are the managing members of Two River Group Holdings, LLC, or Two River, a merchant bank specializing in biotechnology companies, and are officers and directors of Riverbank Capital Securities, Inc., or Riverbank, a registered broker-dealer, which served as placement agent in connection with our July 2009 private placement. Mr. Kazam also serves as our President and Chief

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

We may not successfully manage our growth.

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

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

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

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

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

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

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

- withdrawal of clinical trial participants;
- termination of clinical trial sites or entire trial programs;
- costs of related litigation;
- substantial monetary awards to patients or other claimants;
- decreased demand for our product candidates;
- impairment of our business reputation;
- loss of revenues; and
- the inability to commercialize our product candidates.

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

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

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

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

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

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

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

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

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

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

Recent global market and economic conditions have been unprecedented and challenging with tighter credit conditions and recession in most major economies continuing into 2010. Continued concerns about the systemic impact of potential long-term and wide-spread recession, energy costs, geopolitical issues, the availability and cost of credit, and the global housing and mortgage markets have contributed to increased market volatility and diminished expectations for western and emerging economies. In the second half of 2008, added concerns fueled by the U.S. government conservatorship of the Federal Home Loan Mortgage Corporation and the Federal National Mortgage Association, the declared bankruptcy of Lehman Brothers Holdings Inc., the U.S. government financial assistance to American International Group Inc., Citibank, Bank of America and other federal government interventions in the U.S. financial system lead to increased market uncertainty and instability in both U.S. and international capital and credit markets. These conditions, combined with volatile oil prices, declining business and consumer confidence and increased unemployment, have contributed to volatility of unprecedented levels.

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

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

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

Delays in the commencement, enrollment, and completion of clinical testing could also significantly affect our product development costs. We do not know whether planned clinical trials for CD-NP will begin on time or be completed on schedule, if at all. The commencement and completion of clinical trials requires us to identify and maintain a sufficient number of trial sites, many of which may already be engaged in other clinical trial programs for the same indication as our product candidates, may be required to withdraw from a clinical trial as a result of changing standards of care, or may become ineligible to participate in clinical studies.

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

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

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

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

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

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

Any delays in obtaining regulatory approvals may:

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

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

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

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

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

- we may not be able to control the amount and timing of resources that our strategic partners devote to the development or commercialization of product candidates;

- strategic partners may delay clinical trials, provide insufficient funding, terminate a clinical trial or abandon a product candidate, repeat or conduct new clinical trials or require a new version of a product candidate for clinical testing;

- strategic partners may not pursue further development and commercialization of products resulting from the strategic partnering arrangement or may elect to discontinue research and development programs;

- strategic partners may not commit adequate resources to the marketing and distribution of any future products, limiting our potential revenues from these products;

- disputes may arise between us and our strategic partners that result in the delay or termination of the research, development or commercialization of our product candidates or that result in costly litigation or arbitration that diverts management’s attention and consumes resources;

- strategic partners may experience financial difficulties;

- strategic partners may not properly maintain or defend our intellectual property rights or may use our proprietary information in a manner that could jeopardize or invalidate our proprietary information or expose us to potential litigation;

- business combinations or significant changes in a strategic partner's business strategy may also adversely affect a strategic partner's willingness or ability to complete its obligations under any arrangement; and

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

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

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

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

Despite the results reported in earlier clinical trials for our product candidates, we do not know whether any Phase IIb, Phase III or other clinical programs we may conduct will demonstrate adequate efficacy and safety to result in regulatory approval to market our product candidates.

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

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

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

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

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

We will depend upon independent investigators and collaborators, such as universities and medical institutions, to conduct our pre-clinical and clinical trials under agreements with us. These collaborators are not our employees, and we cannot control the amount or timing of resources that they devote to our programs. These investigators may not assign as great a priority to our programs or pursue them as diligently as we would if we were undertaking such programs ourselves. If outside collaborators fail to devote sufficient time and resources to our drug-development programs, or if their performance is substandard, the approval of our FDA applications, if any, and our introduction of new drugs, if any, will be delayed. These collaborators may also have relationships with other commercial entities, some of whom may compete with us. If our collaborators assist our competitors at our expense, our competitive position would be harmed.

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

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

- We may be unable to identify manufacturers on acceptable terms or at all, because the number of potential manufacturers is limited, and subsequent to NDA approval, the FDA must approve any replacement contractor. This approval would require new testing and compliance inspections. In addition, a new manufacturer may have to be educated in, or develop substantially equivalent processes for, production of our products after receipt of FDA approval, if any.

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Our third-party manufacturers might be unable to formulate and manufacture our drugs in the volume and of the quality required to meet our clinical and commercial needs, if any.

- Our future contract manufacturers may not perform as agreed or may not remain in the contract manufacturing business for the time required to supply our clinical trials or to successfully produce, store, and distribute our products.

- Drug manufacturers are subject to ongoing periodic unannounced inspection by the FDA, the Drug Enforcement Agency, and corresponding state agencies to ensure strict compliance with good manufacturing practice and other government regulations and corresponding foreign standards. We do not have control over third-party manufacturers' compliance with these regulations and standards.

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

Successful sales of our products depend on the availability of adequate coverage and reimbursement from third-party payors. Healthcare providers that purchase medicine or medical products for treatment of their patients generally rely

on third-party payors to reimburse all or part of the costs and fees associated with the products. Adequate coverage and reimbursement from governmental, such as Medicare and Medicaid, and commercial payors is critical to new product acceptance. Patients are unlikely to use our products if they do not receive reimbursement adequate to cover the cost of our products.

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

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

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

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

Risks Related to Our Intellectual Property

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

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

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

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

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

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

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

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

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

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

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

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

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

Because some patent applications in the United States may be maintained in secrecy until the patents are issued, because patent applications in the United States and many foreign jurisdictions are typically not published until eighteen months after filing, and because publications in the scientific literature often lag behind actual discoveries, we cannot be certain that others have not filed patent applications for technology covered by our issued patents or our pending applications, or that we were the first to invent the technology. Our competitors may have filed, and may in the future file, patent applications covering technology similar to ours. Any such patent application may have priority over our patent applications or patents, which could further require us to obtain rights to issued patents covering such technologies. If another party has filed a United States patent application on inventions similar to ours, we may have to participate in an interference proceeding declared by the USPTO to determine priority of invention in the United States. The costs of these proceedings could be substantial, and it is possible that such efforts would be unsuccessful if unbeknownst to us, the other party had independently arrived at the same or similar invention prior to our own invention, resulting in a loss of our United States patent position with respect to such inventions.

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

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

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

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

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

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

These and other 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 never paid dividends.

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. The Board of Directors will have the authority to fix and determine the relative rights and preferences of preferred shares, as well as the authority to issue such shares, without further stockholder approval. As a result, the Board of Directors could authorize the issuance of a series of preferred stock that is senior to 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.

Following a holding period or registration period under SEC regulations following a financing event, a significant numbers of shares of our common stock may become eligible for sale over a short period of time, which could depress the market price of our common stock.

Following the holding period prescribed under SEC regulations, some or all of our shares may be offered from time to time in the open market pursuant to Rule 144, and these sales may have a depressive effect on the market for our common stock. In general, a person who has held restricted shares for a period of one year may, upon filing with the SEC a notification on Form 144, sell into the market common stock in an amount equal to the greater of 1% of the outstanding shares or the average weekly number of shares sold in the last four weeks prior to such sale. Such sales may be repeated once every three months, and any of the restricted shares may be sold by a non-affiliate after they have been held two years.

We cannot assure you that we will continue to meet NASDAQ listing requirements.

Our common stock is listed and traded on the NASDAQ Capital Market. To remain eligible to be listed on the NASDAQ Capital Market, we are required to satisfy a number of qualitative and quantitative continued listing standards, which include maintaining a minimum bid price of our stock at $1.00 and having total stockholders' equity of at least $2.5 million. For extended periods during 2008 and 2009, our stock price fell below $1.00. In addition, as of December 31, 2009, our total stockholders' equity was approximately $3.0 million.

Listing on NASDAQ may provide our shareholders with greater liquidity and provide us with greater access to capital. However, if we are unable to continue satisfying NASDAQ's continued listing standards, our common stock may be de-listed from the NASDAQ Capital Market. We cannot assure you that we will be able to maintain a listing of our common stock on NASDAQ Capital Market. If for any reason our common stock is de-listed from the NASDAQ Capital Market, trading in our common stock would likely occur on the OTC Bulletin Board, where our stockholders may experience increased difficulty selling their shares of our common stock at desired times and prices. In addition, we may experience increased difficulty raising additional capital by selling shares 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.

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. [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 was traded on the OTC Bulletin Board, or the OTCBB, under the trading symbol "SPDU.OB" until October 11, 2007. Following the Merger, our trading symbol was changed to "NILT.OB". As of May 13, 2008, our common stock has been 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, 2009 and December 31, 2008, respectively, as reported by Commodity Systems, Inc. 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, 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

	High	Low
Year ended December 31, 2008		
First quarter	$ 5.51	$ 3.75
Second quarter	$ 5.50	$ 4.25
Third quarter	$ 5.26	$ 3.28
Fourth quarter	$ 4.73	$ 0.27

Holders

According to the records of our transfer agent, American Stock Transfer & Trust Company, as of March 1, 2010, we had 195 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.

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 and commercialize two product candidates, described as follows:

- CD-NP – Our lead compound is CD-NP, a chimeric natriuretic peptide currently in Phase II clinical studies for the treatment of heart failure. We believe CD-NP may be useful in several cardiovascular and renal indications. We are currently developing CD-NP for an initial indication of acute decompensated heart failure, or ADHF. In July 2009, we began enrolling patients in a 40 patient open-label Phase II study of CD-NP in patients with ADHF and mild to moderate renal dysfunction. As of March 1, we have completed the dosing of 30 patients. Following the completion of the ongoing Phase II study, and subject to its results, we plan to initiate a Phase IIb study in a large number of patients, which, if successful, would serve as the basis for dose selection for a Phase III program. We would require substantial additional funding to complete the Phase IIb study.

- CU-NP – We are 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, or CNP, and the N- and C-termini of Urodilatin, or URO. In 2009, in partnership with the Mayo Clinic, we progressed toward the development of formulations to enable the chronic administration of CU-NP. In 2010, we expect to initiate and complete multiple in vivo pharmacological studies with chronic formulations of CU-NP.

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, CD-NP. As we proceed with the clinical development of CD-NP 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 private sales of our common stock and debt financings.

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, 2009 and 2008 were approximately $3.4 million and $3.9 million, respectively. The decrease of approximately $0.5 million over 2008 is primarily due to an approximately $0.5 million decrease in stock based compensation expense as a result of a reduction in personnel.

Research and Development Expenses. R&D expenses for the years ended December 31, 2009 and 2008 were approximately $4.5 million and $9.5 million, respectively. The decrease of approximately $5.0 million from 2008 is primarily due to an approximately $1.9 million decrease in clinical expenses in our CD-NP program, an approximately $1.3 million reduction in expenses relating to the 2NTX-99 program, an approximately $0.8 million reduction in R&D personnel expenses, and an approximately $0.4 million reduction in CD-NP manufacturing expenses. The decrease in clinical expenses is primarily the result of having two ongoing clinical trials during 2008, and having only one ongoing clinical trial in 2009. The decrease in 2NTX-99 expenses is a result of terminating the program in January 2009. The decrease in R&D personnel expenses is 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.

CD-NP. Although the development of CD-NP is still in its early stages, we believe that it has potential applications to treat heart failure. We expect to spend an additional $1.2 to $1.4 million in external development costs in fiscal 2010 in order to complete the ongoing Phase II clinical trial and analyze its data. We would expect to spend an additional $0.3 to $1 million in external development costs in fiscal 2010 should we decide to add an additional one to three cohorts to the ongoing Phase II clinical trial. Our strategy for further development of CD-NP in 2010 will depend to a large degree on the outcome of this ongoing clinical trial. If the data from the ongoing Phase II trial is positive, we may then initiate a larger Phase IIb clinical trial in 2010, which will require significant additional capital to fund.

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, 2009. 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 CD-NP 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, 2009 and 2008 were approximately $47,200 and $333,000, respectively. This significant decrease in interest income over 2008 is due to lower interest rates earned on

cash in bank accounts, and substantially lower average cash balances in 2009 than 2008 levels.

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 intended to supplement the more detailed discussion that follows. The amounts stated are expressed in thousands.

	December 31,	
Liquidity and capital resources	2009	2008
Cash and cash equivalents	$ 3,176	$ 5,501
Working Capital	2,796	4,714
Stockholders' equity	2,982	5,104

	Year ended December 31,		Period from Aug. 1, 2005 (inception) to Dec. 31,
Cash flow data	2009	2008	2009
Cash provided by (used in):			
Operating activities	$ (5,795)	$ (10,640)	$ (23,737)
Investing activities	(34)	(93)	(470)
Financing activities	3,505	—	27,382
Net increase (decrease) in cash and cash equivalents	$ (2,325)	$ (10,733)	$ 3,176

Our total cash resources as of December 31, 2009 were $3.2 million compared to $5.5 million as of December 31, 2008. As of December 31, 2009, we had approximately $0.6 million in liabilities, and $2.8 million in net working capital. We incurred a net loss of $7.9 million and had negative cash flow from operating activities of $5.8 million for the year ended December 31, 2009. Since August 1, 2005 (inception) through December 31, 2009, we have incurred an aggregate net loss of approximately $33.9 million, while negative cash flow from operating activities has amounted to $23.7 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, 2009, we have financed our operations through 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 though 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, 2009, and the current plan of expenditure, which includes the potential dosing of additional cohorts in the ongoing Phase II study, we believe we have sufficient capital to fund our operations through the end of the third quarter of 2010. Pending results of our ongoing Phase II clinical trial of CD-NP, we would need substantial additional capital in order to initiate and fund the next clinical study of CD-NP, which is expected to be a Phase IIb clinical trial. Cost savings implemented in the quarter ended June 30, 2009 included a significant staff reduction and the increased use of part-time consultants. Our actual cash requirements may vary materially from those now planned, however, because of a number of factors, including the changes in the focus and direction of our research and development programs, including the acquisition and pursuit of development of new product candidates; competitive and technical advances; costs of commercializing any of the product candidates; and costs of filing, prosecuting, defending and enforcing any patent claims and any other intellectual property rights. If we are unable to raise additional funds when needed, we may not be able to market our products as planned or continue development and regulatory approval of our products, we could be required to delay, scale back or eliminate some or all our research and development programs and we may need to wind down our operations altogether. Each of these alternatives would likely have a material adverse effect on our business.

Our forecasted average monthly cash expenditures for the next three months are approximately $0.4 million, which is a decrease from our average monthly expenses from the previous six months. Because our plan includes the potential for dosing additional cohorts in the ongoing current Phase II study, we will need to raise additional capital to complete the study activities and fund operations into 2011. Following the completion of our ongoing Phase II study, we will need substantial additional capital, whether from a financing or strategic transaction, in order to initiate and complete the next clinical study of CD-NP.

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 2010 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

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.

September 2007 Financing. As a condition to the closing of our merger transaction with SMI Products, Inc., on September 11, 2007, we completed a private placement offering whereby we raised 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 this private placement were $102,000.

July 2007 Note Issuance. On July 24, 2007, we 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.

March 2006 Convertible Note Financing. During March 2006, we completed a private placement offering of $4,000,000 aggregate principal amount of 6% convertible promissory notes. The notes matured 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 our September 2007 common stock private placement 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 September 2007 private placement. 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, we issued fully vested warrants to purchase 168,337 shares of common stock to the note holders. 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 five year contractual term, a dividend rate of 0%, and 68% expected volatility. The cost of the warrants was included in interest expense and as an increase in additional paid-in capital.

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 the rights to CU-NP. Under the terms of the agreement, Mayo granted to us a worldwide, exclusive license for the rights to commercially develop CU-NP for all therapeutic indications. We also have the rights to improvements to CU-NP and know-how that 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 $24.25 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, 2009.

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 remeasured as the underlying options vest. The fair value of any options issued to non-employees is recorded as expense over the applicable service periods.

The terms and vesting schedules for share-based awards vary by type of grant and the employment status of the grantee. Generally, the awards vest based upon time-based or performance-based conditions. Performance-based conditions generally include the attainment of goals related to our financial and development performance.

Stock-based compensation expense is included in the respective categories of expense in the Statements of Operations. 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.

ITEM 7A. QUANTITATIVE AND QUALITATIVE DISCLOSURES ABOUT MARKET RISK

Not applicable.

ITEM 8. FINANCIAL STATEMENTS AND SUPPLEMENTARY DATA

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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, 2009, and the related statements of operations, stockholders' equity, and cash flows for the year then ended and for the period from August 1, 2005 (inception) through December 31, 2009. 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 audit. 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, 2009, 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, 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, 2009, in conformity with U.S. generally accepted accounting principles.

The accompanying financial statements have been prepared assuming that the Company will continue as a going concern. As discussed in Note 2 to the financial statements, the Company is in its development stage, has not generated any revenues and has incurred recurring losses from operations that raise substantial doubt about its ability to continue as a going concern. Management's plans in regard to these matters are also described in Note 2. The financial statements do not include any adjustments that might result from the outcome of this uncertainty.

/s/ Crowe Horwath LLP

New York, New York
March 2, 2010

REPORT OF INDEPENDENT REGISTERED PUBLIC ACCOUNTING FIRM

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

We have audited the accompanying balance sheet of Nile Therapeutics, Inc. (a development stage company) as of December 31, 2008 and the related statements of operations, stockholders' equity and cash flows for the year then ended. These financial statements are the responsibility of the Company's management. Our responsibility is to express an opinion on these financial statements based on our audit.

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 also includes examining, on a test basis, evidence supporting the amounts and disclosures in the financial statements, assessing the accounting principles used and significant estimates made by management, as well as evaluating the overall financial statement presentation. We believe that our audit provides 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. as of December 31, 2008, and the results of its operations and its cash flows for the year then ended, in conformity with accounting principles generally accepted in the United States of America.

The accompanying financial statements have been prepared assuming that the Company will continue as a going concern. As discussed in Note 2 to the financial statements, the Company is in its development stage, has not generated any revenues and has incurred recurring losses from operations that raise substantial doubt about its ability to continue as a going concern. Management's plans in regard to these matters are also described in Note 2. The financial statements do not include any adjustments that might result from the outcome of this uncertainty.

/s/ Hays & Company LLP

March 10, 2009
New York, New York

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

	December 31, 2009	December 31, 2008
ASSETS		
Current assets		
Cash and cash equivalents	$ 3,175,718	$ 5,500,790
Prepaid expenses and other current assets	257,732	544,834
Total current assets	3,433,450	6,045,624
Property and equipment, net	27,486	73,699
Intangible assets, net	106,830	209,549
Other noncurrent assets	51,938	106,597
Total assets	$ 3,619,704	$ 6,435,469
LIABILITIES AND STOCKHOLDERS' EQUITY		
Current liabilities		
Accounts payable	$ 150,628	$ 738,895
Accrued expenses and other current liabilities	402,772	586,256
Due to related party	84,154	6,700
Total current liabilities	637,554	1,331,851
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, 27,085,824 and 24,149,405 shares issued and outstanding	27,086	24,150
Additional paid-in capital	36,853,767	31,105,874
Deficit accumulated during the development stage	(33,898,703)	(26,026,406)
Total stockholders' equity	2,982,150	5,103,618
Total liabilities and stockholders' equity	$ 3,619,704	$ 6,435,469

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, 2009
	2009	2008	
Grant income	$ -	$ -	$ 482,235
Operating expenses:			
Research and development	4,466,536	9,477,823	21,778,056
General and administrative	3,417,174	3,922,164	11,996,762
Total operating expenses	7,883,710	13,399,987	33,774,818
Loss from operations	(7,883,710)	(13,399,987)	(33,292,583)
Other income (expense):			
Interest income	47,194	332,715	767,582
Interest expense	-	(137)	(1,273,734)
Other expense	(35,781)	(64,187)	(99,968)
Total other income (expense)	11,413	268,391	(606,120)
Net loss	$ (7,872,297)	$ (13,131,596)	$ (33,898,703)
Basic and diluted loss per share	$ (0.31)	$ (0.54)	
Weighted-average common shares outstanding	25,466,655	24,126,398	

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, 2009

	COMMON STOCK		ADDITIONAL PAID-IN CAPITAL	DEFICIT ACCUMULATED DURING THE DEVELOPMENT STAGE	TOTAL STOCKHOLDERS' EQUITY (DEFICIT)
	SHARES	AMOUNT			
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

See accompanying notes to financial statements

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

	Year ended December 31,		Period from August 1, 2005 (inception) through December 31, 2009
	2009	2008	
Cash flows from operating activities			
Net loss	$ (7,872,297)	$ (13,131,596)	$ (33,898,703)
Adjustment to reconcile net loss to net cash used in operating activities			
Depreciation and amortization	159,589	113,289	300,215
Stock-based compensation	2,246,181	3,035,282	8,375,830
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	11,654	35,223
Noncash interest expense	-	-	351,165
Changes in operating assets and liabilities			
Prepaid expenses and other current assets	287,102	(18,531)	(257,732)
Other non-current assets	54,659	(92,597)	(51,938)
Accounts payable	(588,267)	80,122	150,628
Accrued expenses and other current liabilities	(183,484)	(329,163)	402,772
Due to related party	77,454	(308,504)	84,154
Net cash used in operating activities	(5,795,494)	(10,640,044)	(23,736,923)
Cash flows from investing activities			
Purchase of property and equipment	(4,422)	(45,314)	(126,663)
Proceeds from sale of assets	2,500	-	2,500
Cash paid for intangible assets	(32,304)	(47,316)	(345,591)
Net cash used in investing activities	(34,226)	(92,630)	(469,754)
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	217,473	-	217,473
Proceeds from sale of common stock to founders	-	-	5,000
Proceeds from sale of common stock in private placement	3,287,175	-	23,159,922
Net cash provided by financing activities	3,504,648	-	27,382,395
	(2,325,072)	(10,732,674)	3,175,718

Net (decrease) increase in cash and cash equivalents			
Cash and cash equivalents at beginning of period	5,500,790	16,233,464	-
Cash and cash equivalents at end of period	$ 3,175,718	$ 5,500,790	$ 3,175,718
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	$ 334,992
Warrants issued to placement agent and investors, in connection with private placement	$ 2,872,200	$ -	$ 2,872,200
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 CD-NP, a chimeric natriuretic peptide currently in Phase II 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 AND GOING CONCERN

In June 2009, the Financial Accounting Standards Board ("FASB") issued the FASB Accounting Standards Codification (the "ASC"). The ASC has become the single source of non-governmental accounting principles generally accepted in the United States ("GAAP") recognized by the FASB in the preparation of financial statements. The ASC does not supersede the rules or regulations of the Securities and Exchange Commission ("SEC"), therefore, the rules and interpretive releases of the SEC continue to be additional sources of GAAP for the Company. The Company adopted the ASC as of July 1, 2009. The ASC does not change GAAP and did not have an effect on the Company's financial position, results of operations or cash flows.

The Company is a development stage enterprise since it has not yet generated any revenue from the sale of products and, through December 31, 2009, 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 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 $33.9 million at December 31, 2009. 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, 2009 were approximately $3.2 million, compared to $5.5 million as of December 31, 2008. Based on its resources at December 31, 2009, and the current plan of expenditure on continuing development of current products which includes the potential dosing of additional cohorts in the ongoing Phase II study, the Company believes that it has sufficient capital to fund its operations through the end of the third quarter of 2010. The Company will need to raise additional capital to complete the study and analyze the results. 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 can not 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 sufficient funds. The uncertainty of this situation raises substantial doubt about the Company's ability to continue as a going concern. The accompanying financial statements do not include any adjustments that might result from the outcome of this uncertainty.

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 the guidance in Appendix B of SEC Accounting Disclosure Rules and Practices Official Text, 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 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.

NILE THERAPEUTICS, INC
(A DEVELOPMENT STAGE COMPANY)
NOTES TO FINANCIAL STATEMENTS

(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.

(c) Restricted Cash

In October 2009, the Company terminated the lease agreement for the office in San Francisco, California. In connection with the lease, the Company held an irrevocable stand-by and unconditional letter of credit in the amount of approximately $55,000 as a security deposit, with the landlord as the beneficiary in case of default or failure to comply with the lease requirements. In order to fund the letter of credit, the Company deposited a compensating balance of approximately $55,000 into a certificate of deposit with a financial institution, which was classified as restricted cash and included in prepaid expenses and other current assets on the accompanying balance sheet as of December 31, 2008. Subsequent to the termination of the lease, the Company terminated the letter of credit and the compensating balance was released from restriction and made available for operations.

(d) 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

(e) 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 affect 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.

(f) 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 CD-NP 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.

(g) 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.

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(h) 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.

(i) 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.

(j) Grant income

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

(k) 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 and is periodically remeasured as the underlying options vest. The fair value of any options issued to non-employees is recorded as expense over the applicable service periods.

(l) 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, 2009	December 31, 2008
Warrants to purchase common stock	886,149	-
Options to purchase common stock	1,658,063	317,940
Total potentially dilutive securities	2,544,212	317,940

For the years ending December 31 2009, and 2008, 5,916,463 and 4,628,828 warrants and options have been excluded from the computation of the dilutive earnings per share, respectively, as their exercise prices are greater than the 200 day moving average market price per common share as of March 1, 2009, and their effects are potentially anti-dilutive.

(m) 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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(n) 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 thank not” test, no tax benefit is recorded.

(o) Recently Issued Accounting Pronouncements

In June 2009, the Financial Accounting Standards Board (“FASB”) issued the FASB Accounting Standards Codification (the “ASC”). The ASC has become the single source of non-governmental accounting principles generally accepted in the United States (“GAAP”) recognized by the FASB in the preparation of financial statements. The ASC does not supersede the rules or regulations of the Securities and Exchange Commission (“SEC”), therefore, the rules and interpretive releases of the SEC continue to be additional sources of GAAP for the Company. The Company adopted the ASC as of June 30, 2009.

Effective June 30, 2009, the Company adopted a new accounting standard issued by the FASB related to the disclosure requirements of the fair value of financial instruments. This standard expands the disclosure requirements of fair value (including the methods and significant assumptions used to estimate fair value) of certain financial instruments to interim period financial statements that were previously only required to be disclosed in financial statements for annual periods. In accordance with this standard, the disclosure requirements have been applied on a prospective basis and did not have a material impact on the Company’s financial statements.

In August 2009, the FASB issued an amendment to the accounting standards related to the measurement of liabilities that are recognized or disclosed at fair value on a recurring basis. This standard clarifies how a company should measure the fair value of liabilities and that restrictions preventing the transfer of a liability should not be considered as a factor in the measurement of liabilities within the scope of this standard. The adoption of this standard did not have a material impact on the Company’s financial statements

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, 2009 and 2008 consist of the following:

	2009	2008
Computer equipment	$ 28,135	$ 33,930

Office furniture and equipment		38,521		64,469
Leasehold improvements		—		9,528
Total property and equipment		66,656		107,927
Accumulated depreciation		(39,170)		(34,228)
Total property and equipment, net	$	27,486	$	73,699

Depreciation expense related to property and equipment for the years ended December 31, 2009 and 2008 totaled $24,566 and $22,798, respectively, and $61,454 for the period from August 1, 2005 (inception) to December 31, 2009.

6. INTANGIBLE ASSETS AND INTELLECTUAL PROPERTY

Patents

At December 31, 2009, intangible assets consisted of patents and patent applications acquired from a third party for the CD-NP and CU-NP products. Amortization expense was $135,023 and $90,491 for the years ended December 31, 2009 and 2008, respectively, and $ 238,762 for the period from August 1, 2005 (inception) to December 31, 2009. Estimated aggregate amortization expense of the Company’s current intellectual property is approximately $100,000, for each of the next two fiscal years. 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

CD-NP

On January 20, 2006, the Company entered into an exclusive, worldwide, royalty-bearing license agreement, or the CD-NP 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 CD-NP in all therapeutic indications. The Company was also entitled to rights to improvements to CD-NP that arise out of the laboratory of Dr. John Burnett, the co-inventor of CD-NP, until January 19, 2009.

Under the terms of the CD-NP 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 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. 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. Pursuant to the CD-NP 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 CD-NP 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, 2009, the Company received $482,235 in grant income for which it has issued to Mayo 63,478 shares (representing $182,236) of common stock.

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 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 challenge 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. 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 challenge 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, 2009 and 2008 consist of the following:

	2009	2008
Accrued compensation and related benefits	$ 52,232	$ 205,919
Accrued research and development expense	341,207	364,143
Accrued other expense	9,333	16,194
Total accrued liabilities	$ 402,772	$ 586,256

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.

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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.

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.

The Company agreed to file a registration statement with the SEC in order to register the resale of the shares of common stock, including shares of common stock issuable pursuant to the exercise of warrants and Placement Warrants, issued in the private placement. In the event the Company did not file the registration statement within 60 days following the closing of the financing, the Company agreed to pay liquidated damages to the investors in the amount of 1% of such investor's aggregate investment amount each month until the registration statement is filed. The Company filed such registration statement with the SEC on August 13, 2009.

(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.

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.

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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.

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. 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 three to five years.

A summary of the status of the options issued under the Plan at December 31, 2009, and information with respect to the changes in options outstanding is as follows:

		Options Outstanding		
	Shares Available for Grant	Outstanding Stock Options	Weighted-Average Exercise Price	Aggregate 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	$ -
Exercisable at December 31, 2009		3,034,941	$	2.38	$ -

During the three months ended March 31, 2009, the Company granted options in exchange for 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, 2009, 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, 2009 and 2008:

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	December 31, 2009	December 31, 2008
Expected volatility	117% to 123%	75% to 137%
Expected term	3 years	5.50 to 6.25 years
Dividend yield	0%	0%
Risk-free interest rates	1.4% to 1.7%	1.6% to 3.4%

Due to the Company's short period of publicly traded stock history, management's estimate of expected volatility is based on the average expected volatilities of a sampling of five companies with similar attributes to the Company, including: industry, stage of life cycle, size and financial leverage.

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.

Employee stock-based compensation costs for the year ended December 31, 2009 and 2008 and for the cumulative period from August 1, 2005 (inception) through December 31, 2009, are as follows:

	Year ended December 31,		Period from August 1, 2005 (inception) through December 31, 2009
	2009	2008	
General and administrative	$ 1,507,938	$ 1,990,438	$ 5,360,988
Research and development	146,907	563,917	757,335
Total	$ 1,654,845	$ 2,554,355	$ 6,118,323

The following table summarizes information about stock options outstanding at December 31, 2009:

	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	1,248,063	8.57	$ 0.81	455,563	$ 0.69
$1.14 to $2.71	2,544,490	8.46	$ 2.33	1,614,281	$ 2.15
$4.45 to $5.75	648,849	8.23	$ 4.54	333,289	$ 4.56
Total	4,441,402	8.67	$ 2.72	2,403,133	$ 2.59

The fair value of shares vested under the Plan for the year ended December 31, 2009 and 2008 and for the period from August 1, 2005 (inception) through December 31, 2009 were $2,394,048, $1,622,317, and $4,487,114 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, 2009, employees forfeited 302,214 shares related to performance-based options, which had a fair value of $560,798. 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 140,630 shares of common stock will be forfeited in the future. This estimated compensation cost of these forfeited shares is $221,617.

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During the year ended December 31, 2009, in accordance with the terms of the separation agreements of certain former employees, the Company agreed to extend to December 31, 2009 the exercise period relating to vested stock options held by those employees. In total, stock options relating to 177,049 shares of common stock with a weighted average exercise price of $2.93 were affected by such extension. No additional stock-option compensation expense was required to be recorded as a result of the extended exercise period based on the Company's analysis of modifications made to the stock option grants.

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 six months ended June 30, 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.

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, 2009, total unrecognized estimated employee (including directors) compensation cost related to stock options granted prior to that date was $1,339,029, which is expected to be recognized over a weighted-average vesting period of 1.0 year. This unrecognized estimated employee compensation cost does not include $221,617 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 remeasured as the underlying options vest. The fair value of any options issued to non-employees is recorded as expense over the applicable service periods.

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 and will record additional expense in the future as the remaining options are expected to vest.

Stock-based compensation costs incurred for services by non-employees for the year ended December 31, 2009 and 2008, and for the cumulative period from August 1, 2005 (inception) through December 31, 2009 totaled $473,584, $13,687, and $496,604, 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 $5,291, $9,011 and $21,947 for the years ended December 31, 2009 and 2008 and for the cumulative period from August 1, 2005 (inception) through December 31, 2009, respectively. For the year ended December 31, 2009, 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 four years ended December 31, 2009.

NILE THERAPEUTICS, INC
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NOTES TO FINANCIAL STATEMENTS

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 2009, 2008 and the period from August 1, 2005 (inception) through December 31, 2009 and as of December 31, 2009 and 2008, had no amounts accrued for interest and penalties.

At December 31, 2009, the Company had no federal income tax expense or benefit but did have federal tax net operating loss carry-forwards of approximately $8,484,156, and a R&D credit carry-forward of $934,172. The federal net operating loss carry-forwards will begin to expire in 2026, unless previously utilized.

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, 2009 are shown below. A valuation allowance of $11,966,004 has been established to offset the net deferred tax assets at December 31, 2009, as realization of such assets is uncertain.

	For Years Ended December 31,	
	2009	2008
Current deferred tax asset		
Non-cash stock issue	$ -	$ -
Others	-	-
	-	-
Non-current deferred tax assets		
Research tax credit	935,172	661,882
Net operating loss carry forwards	8,484,156	5,902,875
Others	2,546,676	1,923,460
Total deferred tax asset	11,966,004	8,488,217
Non-current deferred tax liability	-	-
Total net deferred tax asset	11,966,004	8,488,217
Loss valuation allowance	(11,966,004)	(8,488,217)
Net deferred tax asset	$ -	$ -

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. The total estimated fair-value of the stock options is $479,338.Twenty-five percent of the shares subject to the stock option vested immediately and the remaining 75% vest pursuant to the achievement of certain milestones relating to the clinical development of CD-NP. 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, 2009 and 2008 and for the period from August 1, 2005 (inception) through December 31, 2009, total cash services and reimbursed expenses totaled $482,840 $0 and $482,840, respectively. As of December 31, 2009 the Company has a payable to TRC of $84,154.

NILE THERAPEUTICS, INC
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NOTES TO FINANCIAL STATEMENTS

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, 2009 and 2008 and for the period from August 1, 2005 (inception) through December 31, 2009, reimbursable expenses totaled $26,374, $22,364 and $153,238, respectively. In addition, during 2007 the Company paid $70,245 to Two River for consulting and due diligence efforts performed by Two River employees related to the licensing of 2NTX-99 and were included in research and development expense in the statement of operations. As of December 31, 2009 the Company has no balance payable to Two River.

As consideration for the performance of consulting and due diligence efforts related to the licensing of 2NTX-99, the Company issued fully vested warrants to purchase 206,912 shares of its common stock at an exercise price of $2.71. Of the total issued, warrants to purchase 137,567 shares were issued to employees of Two River. 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.

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.

Peter M. Kash, the Chairman of the Company's Board of Directors, Joshua A. Kazam, the Company's President and Chief Executive Officer and director, 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 March 3, 2008 the Company signed a non-cancelable operating lease agreement to lease office space in San Francisco, California. In October 2009, the Company entered into a lease termination agreement for the office space in San Francisco. The Company paid $130,000 to satisfy the remaining lease liability. The standby letter of credit that served as a security deposit was cancelled and the corresponding restricted cash, approximately $55,000, held by the Company will no longer be subject to restriction.

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.

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

Not applicable.

ITEM 9A(T). CONTROLS AND PROCEDURES

Management's Annual Report on Internal Control Over Financial Reporting

Our management is responsible for establishing and maintaining adequate internal control over financial reporting and for the assessment of the effectiveness of internal controls over financial reporting. Our internal control system over financial reporting is a process designed under the supervision of our Chief Executive Officer and our Chief Financial Officer to provide reasonable assurance regarding the reliability of financial reporting and the preparation of the financial statements in accordance with U.S. generally accepted accounting principles. Our disclosure controls and procedures are designed based on criteria established in Internal Control – Integrated framework issued by the Committee of Sponsoring Organizations of the Treadway Commission, or COSO Framework of information that is required to be disclosed in the reports that we file under the Securities Exchange Act of 1934 and to make sure the information we are required to disclose is recorded, processed, summarized and reported within the time periods specified in the Securities and Exchange Commission’s rules and forms, and that such information is accumulated and communicated to our management to allow timely decisions regarding required disclosures. All internal control systems, however, no matter how well designed, have inherent limitations. Therefore, even those systems determined to be effective can provide only reasonable assurance with respect to financial statement preparation and presentation. 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.

As of December 31, 2009, we carried out an evaluation, under the supervision and with the participation of our Chief Executive Officer and Chief Financial Officer, of the effectiveness of the design and operation of our disclosure controls and procedures (as defined in Rules 13a-15(e) and 15d-15(e) of the Securities Exchange Act of 1934, as amended). Based upon that evaluation, our Chief Executive Officer and Chief Financial Officer concluded that the disclosure controls and procedures as of that date were effective to ensure that information required to be disclosed in the reports filed under the Securities and Exchange Act was recorded, processed, summarized and reported on an accurate and timely basis. There were no changes in our internal controls over financial reporting during the quarter ended December 31, 2009 that have materially affected, or are likely to materially affect, our internal controls over financial reporting.

This Annual Report does not include an attestation report of our registered public accounting firm regarding internal control over our financial reporting. Our management’s report was not subject to attestation by our registered public accounting firm pursuant to temporary rules of the Securities and Exchange Commission that permit the company to provide only management’s report in this annual report.

As a non-accelerated filer with a fiscal year end of December 31, we must first begin to comply with certain requirements of Section 404 of the Sarbanes-Oxley Act of 2002 for the fiscal year ending December 31, 2010. We believe that our present internal control program has been effective at a reasonable assurance level to ensure that our financial reporting has not been materially misstated. Nonetheless, during the remaining periods through December 31, 2010, we will review, and where necessary, enhance our internal control design and documentation, management review, and ongoing risk assessment as part of our internal control program, including implementing the requirements of Section 404 of the Sarbanes-Oxley Act of 2002.

Changes in Internal Control Over Financial Reporting

There were no changes in our internal control over financial reporting during the three months ended December 31, 2009 that have materially affected, or are reasonably likely to materially affect, our internal control over financial reporting.

ITEM 9B. OTHER INFORMATION

At the Annual Meeting of Stockholders held on December 10, 2009, we submitted to a vote of our stockholders the following matters, which received the indicated votes:

1. To elect seven directors to hold office until our 2010 Annual Meeting of Stockholders, or until their respective successors have been elected and have qualified, or until their earlier resignation or removal:

	For	Withhold
Arie S. Belldegrun	13,953,196	14,525
Pedro Granadillo	13,953,196	14,525
Peter M. Kash	13,780,802	186,919
Joshua A. Kazam	13,819,402	148,319
Frank Litvack	13,953,196	14,525
Paul A. Mieyal	13,953,196	14,525
Gregory W. Schafer	13,953,196	14,525

2. To ratify the appointment of Crowe Horwath LLP as our independent registered public accounting firm for our fiscal year ending December 31, 2009:

For	Against	Abstain
13,947,011	20,610	100

Part III

ITEM 10. DIRECTORS, EXECUTIVE OFFICERS AND CORPORATE GOVERNANCE

Directors and Executive Officers

The following table lists our executive officers and directors and their respective ages and positions as of the date of this report:

Name	Age	Position
Joshua A. Kazam	33	President and Chief Executive Officer, Director
Daron Evans	36	Chief Financial Officer
Hsiao Lieu, M.D.	38	Vice President, Clinical Research
Arie S. Belldegrun, M.D.	59	Director
Pedro Granadillo	63	Director
Peter M. Kash	48	Chairman of the Board
Frank Litvack, M.D.	54	Director
Paul A. Mieyal, Ph.D.	40	Director
Gregory W. Schafer	45	Director

Joshua A. Kazam has served as our non-employee President and Chief Executive Officer since June 2009, and has served as a director of the Company since inception in August 2005. In September 2004, Mr. Kazam co-founded Two River Group Holdings, LLC, and currently serves as Vice President and Director of Two River's managing member, Two River Group Management, LLC. Mr. Kazam also serves as an Officer and Director of Riverbank Capital Securities, Inc. From 1999 to 2004, Mr. Kazam was a Managing Director of Paramount BioCapital, Inc. where he was responsible for ongoing operations of venture investments, and as the Director of Investment for the Orion Biomedical Fund, LP. Mr. Kazam currently serves as a director of several privately-held biotechnology and biopharmaceutical companies, including Arno Therapeutics, Inc. (since its August 2005 inception), and Velcera, Inc. (since its inception in May 2004). Mr. Kazam is a graduate of the Wharton School of the University of Pennsylvania.

Daron Evans has been our Chief Financial Officer since September 2007 and was our Chief Operating Officer from February 2007 to September 2007. Mr. Evans has over fifteen years of professional experience in drug development financial analysis and fiscal control. From 2006 to 2007, Mr. Evans served as Director of Business Assessment at Vistakon, a Johnson & Johnson company, where he led efforts to improve R&D efficiency and speed to market. From 2004 to 2006, he was a Director of Portfolio & Business Analytics for Scios R&D, a Johnson & Johnson company, where he was responsible for financial controls and reporting for portfolio of six clinical stage programs and five preclinical stage programs. While at Scios, Mr. Evans also served as Project Manager for the European Registration Trial of Nesiritide. Mr. Evans also has experience as co-founder of a biotechnology diagnostic company, and has worked as a Management Consultant in the pharmaceutical industry with Booz Allen Hamilton. Mr. Evans received his M.B.A. from The Fuqua School of Business at Duke University, his M.S. in Biomedical Engineering from Southwestern Medical School and University of Texas at Arlington and his B.S. in Chemical Engineering from Rice University.

Hsiao D. Lieu, M.D., F.A.C.C. has been the Company's Vice President of Clinical Research since March 2008. Dr. Lieu has over 13 years of experience in the biopharmaceutical/biotech industry including academic medicine (cardiology), molecular cardiology research, translational and clinical drug development including execution of large multinational Phase III clinical trials and responsibility for interactions with regulatory authorities and key opinion leaders in the U.S., Canada, and Europe. From 2006 to 2008, Dr. Lieu was Director of Clinical Development for

Portola Pharmaceuticals, Inc. From 2003 to 2006 Dr. Lieu worked at CV Therapeutics, Inc., where he served as Director, Clinical Research and Development. Dr. Lieu also worked as a researcher at the J. David Gladstone Institute of Cardiovascular Disease at the University of California at San Francisco ("UCSF") from 2001 to 2003 where he conducted molecular cardiology research. Dr. Lieu currently serves as an Adjunct Assistant Clinical Professor of Medicine, Cardiology Division at UCSF. Dr. Lieu completed his clinical cardiology fellowship at UCSF and his residency in internal medicine at Columbia University. He received his M.D. from the Albert Einstein College of Medicine with distinction in molecular biology research, and his B.A. from New York University. Dr. Lieu is a Fellow of the American College of Cardiology.

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

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

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

Frank Litvack, M.D. has been a director of the Company since September 2009. Dr. Litvack served as Chairman (from 2002) and CEO (from 2003) of Conor MedSystems, Inc., a publicly-held company focused on the development of vascular drug delivery systems, until its acquisition by Johnson & Johnson in February 2007. From 2000 to 2005, Dr. Litvack was Chairman of Savacor, Inc., a medical device company that was acquired by St. Jude Medical, Inc. in late 2005. Since 2000, Dr. Litvack has been a Professor of Medicine at University of California, Los Angeles. From 1989 until 1997, Dr. Litvack was a founder and director of Progressive Angioplasty Systems Inc., which was acquired by United States Surgical Corporation. Since 1996, Dr. Litvack has been a member of Calmedica, LLC. Since 1985, Dr. Litvack has been an attending cardiologist at Cedars-Sinai Medical Center. Dr. Litvack co-directed the Cardiovascular Intervention Center at Cedars-Sinai Medical Center from 1986 to 2000. Dr. Litvack currently serves as a director of several privately-held corporations. Dr. Litvack holds an M.D. from McGill University.

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

Gregory W. Schafer has served as a director of the Company since January 2008, and also serves as Chairman of the Audit Committee. Since April 2009, Mr. Schafer has served as an independent consultant to private and public biotechnology companies. From April 2006 to January 2009, Mr. Schafer served as the Vice President and Chief Financial Officer of Onyx Pharmaceuticals, Inc. Prior to Onyx, from 2004 to 2006, Mr. Schafer served as a consultant to several private and public biotechnology companies. From 1997 to 2004, Mr. Schafer held various executive positions at Cerus Corporation, a public biotechnology company, including Vice President and Chief Financial Officer. Prior to joining Cerus, Mr. Schafer worked as a management consultant for Deloitte & Touche LLP. Mr. Schafer holds an M.B.A from the Anderson Graduate School of Management at UCLA and a BSE in Mechanical Engineering from the University of Pennsylvania.

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

Section 16(a) Beneficial Ownership Reporting Compliance

Section 16(a) of the Securities Exchange Act of 1934, as amended, requires the Company's directors and officers and persons who own more than ten percent of a registered class of the Company's equity securities to file reports of ownership and reports of changes in the ownership with the SEC. Such persons are required by SEC regulations to furnish the Company with copies of all Section 16(a) forms they file. Based solely on its review of the copies of the forms submitted to it during the last fiscal year, the Company believes that, during the last fiscal year, all such reports were timely filed. With respect to the prior fiscal year, however, Dr. Mieyal filed a Form 4 on January 22, 2009 to report an option grant made on December 23, 2008.

Code of Business Conduct and Ethics

The Board of Directors has adopted a Code of Business Conduct and Ethics, or the Code, that applies to all directors, officers, employees, consultants, contractors and agents, wherever they are located and whether they work for us on a full- or part-time basis. The Code was designed to help such directors, employees and other agents to resolve ethical issues encountered in the business environment. The Code covers topics such as conflicts of interest, compliance with laws, confidentiality of Company information, encouraging the reporting of any illegal or unethical behavior, fair dealing and use of Company assets. You can access the Code at the Corporate Governance page of our website at www.nilethera.com. Please note that information contained on our website is not incorporated by reference in, or considered to be a part of, this Annual Report. We may post amendments to or waivers of the provisions of the Code, if any, made with respect to any directors and employees on that website.

Audit Committee

The current members of our Audit Committee are Mr. Schafer (Chair), Mr. Granadillo and Dr. Mieyal. Our Board of Directors has reviewed the definition of independence for Audit Committee members and has determined that each member of our Audit Committee is independent (as independence is currently defined in the applicable Nasdaq listing standards). The Board has further determined that Mr. Schafer qualifies as an "audit committee financial expert," as defined by applicable rules of the Securities and Exchange Commission.

ITEM 11. EXECUTIVE COMPENSATION

Summary Compensation Table

The following summary compensation table reflects cash and non-cash compensation for the 2008 and 2009 fiscal years awarded to or earned by (i) each individual serving as our principal executive officer during the fiscal year ended December 31, 2009; and (ii) each individual that served as an executive officer at the end of the fiscal year ended December 31, 2009 and who received in excess of $100,000 in total compensation during such fiscal year. We refer to these individuals as our “named executive officers.”

Name and Principal Position	Year	Salary ($)	Bonus ($)	Option Awards ($)(1)	All Other Compensation ($)	Total ($)
Joshua Kazam (2)	2009	-	-	80,963		80,963
Chief Executive Officer, Director						
Peter M. Strumph (3)	2009	143,559	-	54,774	250,404 (4)	448,737
Former CEO, Director	2008	316,329	-	—	1,210 (5)	317,539
Daron Evans	2009	200,000	20,000 (6)	80,034	530 (5)	300,564
Chief Financial Officer	2008	175,000	-	—	530 (5)	175,530
Hsiao Lieu (7)	2009	187,504	30,750 (9)	130,394	-	348,648
VP, Clinical Development (8)	2008	202,724	55,685 (10)	1,011,300	-	1,269,709

(1) Amounts reflect the grant date fair value of awards granted under the Company's Amended and Restated Stock Option Plan, computed pursuant to Financial Accounting Standards Board's Accounting Standards Codification 718 "Compensation – Stock Compensation". Assumptions used in the calculation of these amounts are included in Note 10 of the Notes to Audited Financial Statements included in this Annual Report. For awards that are subject to performance conditions, amounts reflect the assumption that the highest level of performance conditions will be achieved. See the "Outstanding Equity Awards at Fiscal Year-End" table in this report for information regarding all option awards outstanding as of December 31, 2009.

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

(3) Mr. Strumph's employment with Nile terminated on June 10, 2009, on which date Mr. Strumph also resigned as a director.

(4) Consists of (i) $230,000 in severance benefits, (ii) $19,194 in vacation accrual payout, and (ii) a life insurance premium of $1,210.

(5) Represents premiums paid for life insurance.

(6) Represents a performance bonus for the period from January 1, 2009 to December 31, 2009, pursuant to the terms of Mr. Evans' employment agreement, which was paid in January 2010.

(7) Effective July 7, 2009, Dr. Lieu transitioned to part-time (50%) employment, which reduced his base salary to $125,000.

(8) Dr. Lieu joined the Company in March 2008.

(9) Consists of (i) a retention bonus of $12,000 in connection with Dr. Lieu's transition to part-time employment, and (ii) a performance bonus in the amount of $17,500 for the period from January 1, 2009 to December 31, 2009, which was paid in January 2010.

(10) Consists of (i) a performance bonus in the amount of $13,685 for the period from March 10, 2008 to December 31, 2008 and (ii) a signing bonus of $42,000.

Employment Agreements and Post-Termination Benefits

Peter M. Strumph – Former Chief Executive Officer

Mr. Strumph's employment with us was governed by an employment agreement dated May 11, 2007, as amended on March 4, 2008 and March 10, 2009, respectively. The employment agreement provided for Mr. Strumph's employment as Chief Executive Officer for a three-year term commencing on June 4, 2007, unless terminated earlier. The agreement provided for an initial annual base salary of $310,000, which amount was to be reviewed by the Board on an annual basis and never decreased. Effective as of January 1, 2009, Mr. Strumph's annual base salary was increased to $320,000. Under the agreement, Mr. Strumph was entitled to an annual performance bonus of up to $150,000 upon the successful completion of annual corporate and individual milestones. Mr. Strumph was also entitled to a bonus upon a "change of control," the amount of which varied from $50,000 to $200,000 depending on the valuation ascribed to the Company at the time of the change of control. The agreement also provided for the awarding of certain stock options to Mr. Strumph, referred to as Employment Options, Performance Options, and Technology

Options.

Mr. Strumph's employment with us terminated on June 10, 2009, pursuant to the terms of a separation agreement and release executed on such date. The separation agreement provides for a lump sum payment to Mr. Strumph in the amount of $230,000, and for us to continue providing for Mr. Strumph's participation in our health and dental plans for a period of six months. The separation agreement also provides that Mr. Strumph is entitled to a payment of $100,000 if, within 24 months following the separation date, we complete a transaction resulting in a change of control. We further agreed to accelerate the vesting of the remaining unvested installment of Mr. Strumph's Employment Options relating to 329,857 shares of our common stock. The separation agreement also provides that all vested stock options held by Mr. Strumph as of the separation date will remain exercisable for a period of five years following the separation date. As of the separation date, after taking into account the acceleration of vesting discussed above, Mr. Strumph held vested Employment Options representing the right to purchase 989,572 shares of our common stock and vested Performance Options representing the right to purchase 242,482 shares of our common stock, in both cases at an exercise price of $2.71 per share. In addition, Mr. Strumph held a vested stock option to purchase 149,148 shares of our common stock at an exercise price of $0.88 per share, which was granted in January 2009 and subsequently exercised.

The term "change of control" under both the employment and separation agreements means any of the following: (A) a private transaction (or series of related private transactions) leading to a merger, acquisition, consolidation, or sale of substantially all of the assets of the Company; (B) any transaction resulting in a single party (or group of affiliated parties) acquiring or holding capital stock of the Company representing a majority of the Company's outstanding voting power; or (C) the disposition by us of all or substantially all of our business and/or assets in one transaction or series of related transactions (other than a merger effected exclusively for the purpose of changing our state of domicile). Notwithstanding the forgoing, neither of the following shall be considered a change of control: (i) if the stockholders prior to such transaction(s) continue to hold more than 50% of the securities or assets of the surviving or resulting company; or (ii) a private placement of our equity securities in connection with the financing of our on-going operations.

Daron Evans – Chief Financial Officer

Mr. Evans' employment with us was initially governed by an employment agreement dated January 19, 2007, as amended on August 19, 2007 and March 4, 2008, respectively. The employment agreement, which initially provided for Mr. Evans's employment as Chief Operating Officer of our predecessor entity, a privately-held Delaware corporation, or Old Nile, provides for a term that expired on February 13, 2010. Despite the expiration of the employment agreement, Mr. Evans employment with us continues on an indefinite basis on substantially the same compensation terms. Under his former employment agreement, Mr. Evans was initially entitled to an annual base salary of $175,000. As of January 1, 2009, his annual base salary was increased to $200,000. In addition, Mr. Evans is eligible to receive an annual performance bonus of up to $60,000 upon the successful completion of annual corporate and individual milestones.

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

Hsiao Lieu, M.D., F.A.C.C. – Vice President, Clinical Research

Dr. Lieu's employment with us is governed by an offer letter dated February 22, 2008, as amended on March 10, 2009. The offer letter provides for Dr. Lieu's employment as our Vice President, Clinical Research as of March 10, 2008, on an at-will basis. Under the offer letter, Dr. Lieu is entitled to an annual base salary of $250,000, which was reduced by 50% to $125,000 effective July 7, 2009 in connection with Dr. Lieu's transition to part-time (50%) employment. In addition, Dr. Lieu is eligible to receive an annual performance bonus of up to 30% of his base salary upon the successful completion of annual corporate and individual milestones. Pursuant to the offer letter, Dr. Lieu also received a signing bonus of $42,000.

The offer letter also provides for the awarding of certain stock options to Dr. Lieu, referred to as Employment Options, Performance Options, and Technology Options. On March 10, 2008, Dr. Lieu was granted Employment Options to purchase 200,000 shares of our common stock at an exercise price of $4.45, with one-fourth vesting after one year and the remainder vesting in 36 equal monthly installments thereafter. Dr. Lieu was also granted Performance Options to purchase 100,000 shares of our common stock at an exercise price of $4.45, vesting up to one-fourth in each calendar year, or a pro-rata portion thereof for a period less than a full year, based on the successful completion of annual corporate and individual milestones as determined by our Board of Directors or its Compensation Committee. To the extent our Board or Compensation Committee declines to vest the maximum amount of Performance Options in any given calendar year, or a pro-rata portion thereof for a period less than a full year, such unvested amount are deemed forfeited by Dr. Lieu. On January 16, 2009, the Board determined that, for the pro-rated period ending December 31, 2008, Dr. Lieu's Performance Options would vest in the amount of 9,123 shares out of a possible 20,274 shares, resulting in the forfeiture of Performance Options to purchase 11,151 shares. On January 19, 2010, the Board determined that, for the calendar year ending December 31, 2009, Dr. Lieu's Performance Options would vest in the amount of 12,500 shares out of a possible 25,000 shares, resulting in the forfeiture of Performance Options to purchase 12,500 shares. In the event that we acquire by license, acquisition or otherwise, an additional product for development that is first identified by Dr. Lieu, he will receive Technology Options to purchase 50,000 shares of our common stock if the product is in pre-clinical development or 75,000 shares if the product is in human clinical trials.

The offer letter further provides that, immediately following a "change in control," all Employment Options and any subsequently granted options that vest over a period of time, and not based on performance, shall immediately vest and shall become exercisable immediately and shall remain exercisable for a period equal to the lesser of five years from the date of the change of control or ten years from the date of grant of such options. If within the twelve-month period following a change in control, Dr. Lieu experiences a "covered termination" or a "constructive termination," and if, within 60 days of such covered termination or constructive termination, Dr. Lieu executes and does not revoke during any applicable revocation period a general release of all claims against the Company and our affiliates in a form acceptable to us, then, as a severance benefit, he shall be entitled to (i) six months of his base salary then in effect, payable in full within 30 days of his last day of employment; (ii) immediate vesting of all Performance Options (including the initial Performance Options and any subsequently granted performance-based stock options), to the extent that the shares subject to such options have not been terminated or forfeited pursuant to the option agreements, which shall become exercisable immediately and shall remain exercisable for a period equal to the lesser of five years from the date of Dr. Lieu's covered termination or constructive termination or ten years from the date of grant of such Performance Options; and (iii) a prorated portion of his maximum annual performance bonus.

The term "change of control" under the offer letter means a transaction or series of transactions (other than an offering of the Company's stock to the general public through a registration statement filed with the Securities and Exchange Commission) resulting in a single party (or group of affiliated parties) acquiring or holding capital stock of the Company representing a majority of the Company's outstanding voting power. Notwithstanding the forgoing, neither of the following shall be considered a change of control: (i) if the stockholders prior to such transaction(s) continue to

hold more than 50% of the securities or assets of the surviving or resulting company; or (ii) a private placement of our equity securities in connection with the financing of our on-going operations.

The term “covered termination” means the termination of Dr. Lieu’s employment by the Company other than for “cause,” which constitutes a “separation from service” within the meaning of Section 409A of the Internal Revenue Code of 1986, as amended (the “Code”), and the Department of Treasury regulations and other guidance promulgated thereunder. The term “cause” means the following conduct or actions taken by Dr. Lieu: (i) gross negligence or willful misconduct in the performance of his duties to the Company; (ii) repeated unexplained or unjustified absence from the Company; (iii) a material and willful violation of any federal or state law; (iv) commission of any act of fraud with respect to the Company; (v) conviction of a felony or a crime involving moral turpitude causing material harm to the standing and reputation of the Company; or (vi) a material failure to perform his duties or to follow the instructions of our Chief Executive Officer, in each case as determined in good faith by our Chief Executive Officer.

The term “constructive termination” means Dr. Lieu’s resignation which constitutes a “separation from service” within the meaning of Section 409A of the Code and the Department of Treasury regulations and other guidance promulgated thereunder within 90 days of the first to occur of one or more of the following events which remains uncured 30 days after Dr. Lieu’s delivery to the Company of written notice thereof: (i) any change in Dr. Lieu’s position with the Company that diminishes in any material respect the duties and responsibilities of his position as in effect immediately preceding such action; provided, however, that a reduction in duties, level of responsibilities or the requirements of his position solely by virtue of the Company being acquired and made part of a larger entity shall not by itself constitute grounds for a constructive termination; (ii) any material reduction by the Company in Dr. Lieu’s base salary or in the percentage of his annual bonus opportunity as a percentage of his base salary; or (iii) the Company’s relocation of our principal office to a place more than a material distance from our present headquarters (except that required travel on the Company’s business to an extent substantially consistent with Dr. Lieu’s present business travel obligations shall not be considered a relocation).

Outstanding Equity Awards at Fiscal Year-End

The following table sets forth information concerning stock options held by the named executive officers at December 31, 2009:

Name	Number of Securities Underlying Unexercised Options Exercisable	Number of Securities Underlying Unexercised Options Unexercisable	Equity Incentive Plan Awards: Number of Securities Underlying Unexercised Unearned Options	Option Exercise Price ($)	Option Expiration Date	
Joshua Kazam	—	25,000	—	0.93	12/23/2018	(1)
	—	65,000	—	1.77	7/21/2019	(1)
	33,333	16,667	—	4.50	1/25/2018	(1)
Peter M. Strumph	989,572	—	—	2.71	6/10/2015	(2)
	242,482	—	—	2.71	6/10/2015	(3)
Daron Evans	49,020	—	—	0.88	1/16/2019	(4)
	25,000	—	75,000	0.89	6/24/2019	(5)
	159,933	79,966	—	2.71	9/14/2017	(6)
	119,797	—	107,743	2.71	9/14/2017	(7)
Hsiao Lieu	31,103	—	—	0.88	1/16/2019	(8)
	37,500	—	112,500	1.14	6/24/2019	(9)
	87,503	112,497	—	4.45	3/10/2018	(10)
	9,123	—	79,726	4.45	3/10/2018	(11)

(1) Mr. Kazam's options were granted as compensation for his service as a director.

(2) Options were scheduled to vest in equal amounts annually over three years, commencing on May 15, 2008. The first two annual installments vested on May 15, 2008 and May 15, 2009, respectively, and the final installment vested on June 10, 2009, pursuant to the terms of Mr. Strumph's separation agreement.

(3) Options with respect to 886,919 shares were scheduled to vest, subject to milestone achievements determined by the Board, up to a maximum of one third in each calendar year, or a pro rata portion thereof for a period less than a full year. On March 4, 2008, the Board determined that options for the prorated period ending December 31, 2007 would vest in the amount of 139,008 shares, with options in the amount of 29,466 shares consequently being forfeited. On January 16, 2009, the Board determined that options for the 2008 calendar year would vest in the amount of 103,474 shares, with options in the amount of 192,166 shares consequently being forfeited. The remainder of the options were forfeited on June 10, 2009, as a result of the termination of Mr. Strumph's employment.

(4) Options were granted in exchange for 2008 accrued performance cash bonuses.

(5) Options with respect to 25,000 shares vested immediately upon grant. Options with respect to 75,000 shares are subject to milestone achievements determined by the Board.

(6) Options vest in equal amounts annually over three years, commencing on January 18, 2008.

(7)

Options with respect to 288,458 shares vest, subject to milestone achievements determined by the Board, up to a maximum of one third in each calendar year, or a pro rata portion thereof for a period less than a full year. On March 4, 2008, the Board determined that options for the prorated period ending December 31, 2007 would vest in the amount of 76,528 shares out of a possible 84,562 shares, with options in the amount of 8,034 shares consequently being forfeited. On January 16, 2009, the Board determined that options for the 2008 calendar year would vest in the amount of 43,269 shares out of a possible 96,153 shares, with options in the amount of 52,884 shares consequently being forfeited. On January 19, 2010, the Board determined that options for the 2009 calendar year would vest in the amount of 50,000 shares out of a possible 96,153 shares, with options in the amount of 46,153 shares consequently being forfeited.

(8) Options were granted in exchange for 2008 accrued performance cash bonuses.

(9) Options with respect to 37,500 shares vested immediately upon grant. Options with respect to 112,500 shares are subject to milestone achievements determined by the Board.

(10) Options vested in the amount of 50,000 shares on March 10, 2009; the remainder vest in 36 monthly installments of 4,167 shares, commencing on April 10, 2009.

(11) Options with respect to 100,000 shares vest, subject to milestone achievements determined by the Board, up to a maximum of one fourth in each calendar year, or a pro rata portion thereof for a period less than a full year. On January 16, 2009, the Board determined that options for the prorated period ending December 31, 2008 would vest in the amount of 9,123 shares out of a possible 20,274 shares, with options in the amount of 11,151 shares consequently being forfeited. On January 19, 2010, the Board determined that options for the 2009 calendar year would vest in the amount of 12,500 shares out of a possible 25,000 shares, with options in the amount of 12,500 shares consequently being forfeited.

Director Compensation

On July 21, 2009, the Compensation Committee of our Board of Directors approved a compensation plan for our non-employee directors. Under the newly adopted plan, the Company will not pay cash compensation to its directors, who are instead entitled to receive annual stock option grants relating to 65,000 shares of the Company's common stock. The chairmen of our Board of Directors and of its Audit and Compensation Committees are entitled to annual stock options to purchase an additional 15,000 shares. Newly appointed directors are entitled to an initial stock option to purchase 130,000 shares.

Prior to the adoption of this plan, our non-employee directors did not receive any cash fees for their service, but were periodically awarded stock options. The following table sets forth the compensation received by our directors for their service in 2009.

Name (1)	Fees Earned or Paid in Cash	Option Awards (2)	Total
Arie Belldegrun, M.D.	$	$ 136,514	$ 136,514
Pedro Granadillo	-	99,646	99,646
Peter M. Kash	-	99,646	99,646
Joshua A. Kazam	-	80,963	80,963
Frank Litvack, M.D.	-	136,514	136,514
Paul A. Mieyal, Ph.D.	-	80,963	80,963
Gregory W. Schafer	-	99,646	99,646
David M. Tanen (3)	-	80,963	80,963

(1) Peter M. Strumph, our former Chief Executive Officer, has been omitted from this table since he received no additional compensation for serving on our Board; his compensation is described above.

(2) Amounts reflect the grant date fair value of awards granted under the Company's Amended and Restated Stock Option Plan, computed pursuant to Financial Accounting Standards Board's Accounting Standards Codification 718 "Compensation – Stock Compensation". Assumptions used in the calculation of these amounts are included in Note 10 of the Notes to Audited Financial Statements included in this Annual Report.

(3) Mr. Tanen resigned as a director effective as of the appointment of Drs. Belldegrun and Litvack as directors in September 2009.

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

Security Ownership of Certain Beneficial Owners and Management

The following table sets forth certain information known to us regarding the beneficial ownership of our common stock as of March 1, 2010 by:

- each of our directors,

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

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

Name of Beneficial Owner	Shares of Common Stock Beneficially Owned (#)	Percentage of Common Stock Beneficially Owned (%)(1)
Directors and Named Executive Officers		
Arie Belldegrun (2)	1,315,630	4.75%
Daron Evans (3)	553,920	2.01%
Pedro Granadillo (4)	102,588	*
Peter M. Kash (5) 689 Fifth Avenue, 12th Floor New York, NY 10022	2,558,193	9.34%
Joshua A. Kazam (6) 689 Fifth Avenue, 12th Floor New York, NY 10022	2,510,740	9.17%
Hsiao Lieu (7)	258,147	*
Frank Litvack (8)	400,000	1.47%
Paul Mieyal c/o Wexford Capital LP 411 West Putnam Avenue Greenwich, CT 06830	-	-
Gregory W. Schafer (9)	75,100	*
Peter M. Strumph (10)	1,240,034	4.38%
Directors and executive officers as a group, 10 individuals	9,014,352	29.41%

5% Stockholders		
David M. Tanen (11) 689 Fifth Avenue, 12th Floor New York, NY 10022	1,830,296	6.71%
Wexford Capital LP (12) 411 West Putnam Avenue Greenwich, CT 06830	2,681,952	9.87%

* Represents less than 1%.

(1) Assumes 27,085,824 shares of our common stock are outstanding. Beneficial ownership is determined in accordance with Rule 13d-3 under the Exchange Act, and includes any shares as to which the security or stockholder has sole or shared voting power or investment power, and also any shares which the security or stockholder has the right to acquire within 60 days of March 1, 2010, whether through the exercise or conversion of any stock option, convertible security, warrant or other right. The indication herein that shares are beneficially owned is not an admission on the part of the security or stockholder that he, she or it is a direct or indirect beneficial owner of those shares.

(2) Consists of (i) 76,935 shares and warrants to purchase an additional 4,210 shares held by Leumi Overseas Trust Corp. Ltd. as Trustee of the BTL Trust, (ii) 64,800 shares and warrants to purchase an additional 64,800 shares held by the Belldegrun Family Trust, (iii) 243,200 shares and warrants to purchase an additional 243,200 shares held by the Arie S. Belldegrun M.D. Inc. Profit Sharing Plan, (iv) 292,000 shares and warrants to purchase an additional 292,000 shares held by Leumi Overseas Trust Corp. Ltd. as Trustee of the Tampere Trust, and (v) 34,485 shares held by Bellco Capital, LLC. Dr. Belldegrun disclaims beneficial ownership of the shares and warrants held by Leumi Overseas Trust Corp. Ltd. as Trustee of each of the BTL Trust and the Tampere Trust, except to the extent of his beneficiary interest therein.

(3) Includes (i) 526,216 shares issuable upon the exercise of stock options, (ii) 3,952 shares issuable upon the exercise of warrants, (iii) 10,200 shares held by Mr. Evans' wife, and (iv) 400 shares held by Mr. Evans' wife as custodian for the benefit of their minor children under the UGMA.

(4) Includes 75,000 shares issuable upon the exercise of stock options.

(5) Includes (i) 75,000 shares issuable upon the exercise of stock options, (ii) 224,866 shares issuable upon the exercise of warrants, and (iii) 165,530 shares held by the Kash Family Foundation. Also includes 496,589 shares held by Mr. Kash's wife as custodian for the benefit of their minor children under the UGMA, to which Mr. Kash disclaims beneficial ownership except to the extent of his pecuniary interest therein.

(6) Includes (i) 58,333 shares issuable upon the exercise of stock options, (ii) 229,278 shares issuable upon the exercise of warrants, (iii) 613,841 shares held by the Kazam Family Trust, and (iv) 165,530 shares held by the Kash Family Foundation. Also includes 165,530 shares held by Mr. Kazam's wife as custodian for the benefit of their minor daughter under the UGMA, to which Mr. Kazam disclaims beneficial ownership except to the extent of his pecuniary interest therein. Mr. Kazam is the trustee and controls the right to vote and dispose of, but has no pecuniary interest in, the shares held by the Kash Family Foundation.

(7) Includes 258,047 shares issuable upon the exercise of stock options.

(8) Consists of 200,000 shares and warrants to purchase an additional 200,000 shares held by Calmedica Capital L.P., a limited partnership of which Dr. Litvack is a limited partner. Dr. Litvack disclaims beneficial ownership of these shares and warrants except to the extent of his pecuniary interest therein.

(9) Includes 75,000 shares issuable upon the exercise of stock options.

(10) Includes 1,232,054 shares issuable upon the exercise of stock options and 400 shares held by Mr. Strumph's wife as custodian for the benefit of their minor children under the Uniform Gift to Minors Act (UGMA).

(11) Includes 140,000 shares issuable upon the exercise of stock options and 31,650 shares issuable upon the exercise of warrants. Also includes 137,941 shares held by Mr. Tanen's wife as custodian for the benefit of their minor daughter under the UGMA, to which Mr. Tanen disclaims beneficial ownership except to the extent of his pecuniary interest therein. Mr. Tanen was a director of the Company from its inception until September 2009.

(12) Includes (i) 1,910,103 shares held by Iota Investors LLC, a Delaware limited liability company ("Iota Investors"), (ii) five year warrants to purchase 16,841 shares at an exercise price of $2.71 per share held by Iota Investors, and (iii) 696,675 shares held by Wexford Spectrum Investors LLC, a Delaware limited liability company ("Wexford Spectrum"). Wexford Capital LP, a Delaware limited partnership ("Wexford Capital"), is a registered Investment Advisor and also serves as an investment advisor or sub-advisor to the members of Iota Investors and Wexford Spectrum. Wexford GP LLC, a Delaware limited liability company ("Wexford GP"), is the general partner of Wexford Capital. Mr. Charles E. Davidson is chairman, a managing member and a controlling member of Wexford GP and Mr. Joseph M. Jacobs is president, a managing member and a controlling member of Wexford GP. Beneficial ownership also includes 58,333 shares issuable upon the exercise of stock options that have been assigned to Wexford Capital by Mr. Mieyal, a director of Nile and vice president of Wexford Capital.

Securities Authorized for Issuance Under Equity Compensation Plans

Our 2005 Stock Option 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, 2009 with respect to our 2005

Stock Option 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	4,441,402	$ 2.22	836,249
Equity compensation plans not approved by stockholders:			
None.	—	—	—
Total	4,441,402	$ 2.22	836,249

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

Certain Relationships and Related Transactions

On June 24, 2009, we entered into a services agreement with Two River Consulting, LLC, or TRC, to provide us with various clinical development, operational and administrative services for a period of one year. As compensation for such services, we will pay to TRC a monthly cash fee of $65,000 and we issued stock options to purchase up to an aggregate of 750,000 shares of our common stock at a price per share equal to $0.89, the closing sale price of our common stock on June 24, 2009. Shares relating to 25% of this option vested immediately and the remaining shares will vest pursuant to the achievement of certain milestones relating to the development of CD-NP. In February 2010, an additional 318,750 shares subject to this option vested and 56,250 shares subject to the option were forfeited. As of March 1, 2010, an additional 187,500 shares currently remain unvested and will vest pursuant to the achievement of a final clinical development milestone. Instead of issuing the stock option to TRC, at TRC's direction, the options were issued to designated employees of TRC who are engaged in performing the services under the services agreement.

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

In connection with our July 2009 private placement, we engaged Riverbank Capital Securities, Inc., or Riverbank, a FINRA member broker dealer, to serve as our placement agent. Riverbank was not paid a cash commission for its services in connection with the financing. However, we issued Riverbank (or its designees) warrants to purchase 218,300 shares of our common stock. The warrants issued to Riverbank have an exercise price of $1.375, which is equal to 110% of the closing price of the units sold to investors, and have a cashless (net) exercise provision. We also paid Riverbank an expense allowance of $50,000 to cover expenses incurred during the financing.

Each of Messrs. Kazam, Tanen and Peter M. Kash, also a member of our board of directors, are officers of and collectively control Riverbank. The selection of Riverbank as placement agent and the terms of the engagement were reviewed and approved by a special committee of our Board consisting of Pedro Granadillo, Paul Mieyal and Gregory Schaefer, none of whom has any interest or other relationship in Riverbank or its affiliates. .

Director Independence

The listing standards of the Nasdaq Stock Market require that a majority of the members of a listed company's board of directors must qualify as "independent," as determined by the board. Our Board of Directors consults with our legal counsel to ensure that the Board's determinations are consistent with all relevant securities and other laws and regulations regarding the definition of "independent," including those set forth in the applicable Nasdaq listing standards. Consistent with these considerations, and after review of all relevant transactions or relationships between each director, or any of his family members, and Nile, its senior management and its independent registered public accounting firm, the Board has determined that Messrs. Granadillo, Kash and Schafer and Drs. Litvack and Mieyal are independent directors within the meaning of the applicable Nasdaq listing standards.

ITEM 14. PRINCIPAL ACCOUNTANT FEES AND SERVICES

Fees Billed to the Company by Its Independent Registered Public Accounting Firm

The following is a summary of the fees billed to us by Hays & Company LLP and Crowe Horwath LLP, our independent registered public accounting firms for professional services rendered for fiscal years ended December 31, 2009 and 2008:

	Fiscal Year Ended December 31,	
Service Category	2009	2008
Audit Fees	$ 112,100	$ 108,351
Audit-Related Fees	0	5,528
Tax Fees	6,000	6,000
All Other Fees	0	0
Total Fees	$ 118,100	$ 119,879

In the above table, in accordance with the SEC's definitions and rules, "audit fees" are fees for professional services for the audit and review of our annual financial statements, as well as the audit and review of our financial statements included in our registration statements filed under the Securities Act and issuance of consents and for services that are normally provided by the accountant in connection with statutory and regulatory filings or engagements except those not required by statute or regulation; "audit-related fees" are fees for assurance and related services that were reasonably related to the performance of the audit or review of our financial statements, including attestation services that are not required by statute or regulation, due diligence and services related to acquisitions; "tax fees" are fees for tax compliance, tax advice and tax planning; and "all other fees" are fees for any services not included in the first three categories.

Audit Committee Pre-Approval Process

Pursuant to our Audit Committee Charter, before the independent registered public accounting firm is engaged by the Company or its subsidiaries to render audit or non-audit services, the Audit Committee pre-approves the engagement. Audit Committee pre-approval of audit and non-audit services is not required if the engagement for the services is entered into pursuant to pre-approval policies and procedures established by the Audit Committee regarding the Company's engagement of the independent registered public accounting firm, provided the policies and procedures are detailed as to the particular service, the Audit Committee is informed of each service provided and such policies and procedures do not include delegation of the Audit Committee's responsibilities under the Exchange Act to the Company's management. The Audit Committee may delegate to one or more designated members of the Audit Committee the authority to grant pre-approvals, provided such approvals are presented to the Audit Committee at a subsequent meeting. If the Audit Committee elects to establish pre-approval policies and procedures regarding non-audit services, the Audit Committee must be informed of each non-audit service provided by the independent registered public accounting firm. Audit Committee pre-approval of non-audit services (other than review and attest services) also is not be required if such services fall within available exceptions established by the SEC. None of the services provided by our independent registered public accounting firm for fiscal 2008 or 2009 were obtained in reliance on the waiver of the pre-approval requirement afforded in SEC regulations.

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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 SMI Products, 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 SMI Products, 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).
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).*
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).+

Exhibit No.	Description
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.*
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	Summary terms of compensation plan for directors of Nile Therapeutics, Inc., as adopted July 21, 2009 (incorporated by reference to Exhibit 10.1 to the Company's Current Report on Form 8-K filed July 24, 2009).*
10.17	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).
23.1	Consent of Crowe Horwath LLP.
23.2	Consent of Hays and Company LLP.
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 3, 2010.

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 3, 2010
/s/ Daron Evans Daron Evans	Chief Financial Officer (Principal Financial and Accounting Officer)	March 3, 2010
/s/ Peter Kash Peter M. Kash	Chairman of the Board of Directors	March 3, 2010
/s/ Arie Belldegrun Arie Belldegrun, M.D.	Director	March 3, 2010
/s/ Pedro Granadillo Pedro Granadillo	Director	March 3, 2010
/s/ Frank Litvack Frank Litvack, M.D.	Director	March 3, 2010
/s/ Paul Mieyal Paul A. Mieyal, Ph.D.	Director	March 3, 2010
/s/ Gregory Schafer Gregory W. Schafer	Director	March 3, 2010

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INDEX OF EXHIBITS FILED WITH THIS REPORT

Exhibit No.	Description
10.14	Form of Indemnification Agreement entered into between the Company and each of its executive officers and directors.
23.1	Consent of Crowe Horwath LLP
23.2	Consent of Hays and Company LLP
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.