Nile Therapeutics, Inc.
Form 10-K
March 12, 2009
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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, 2008

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.)
115 Sansome Street, Suite #310, San Francisco, California	94104
(Address of principal executive offices)	(Zip Code)

(415) 875-7880

(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 if disclosure of delinquent filers pursuant to Item 405 of Regulation S-K (§ 229.405 of this chapter) 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. ¨

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 ¨ (Do not check if a smaller reporting company) 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

As of June 30, 2008, 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 on NASDAQ was $69,316,648. As of March 12, 2009, there were 24,149,405 shares of the issuer s common stock, par value $0.001 per share, issued and outstanding

DOCUMENTS INCORPORATED BY REFERENCE

Certain portions of the Definitive Proxy Statement with respect to the 2009 Annual Meeting of Stockholders of Nile Therapeutics, Inc., to be filed pursuant to Rule 14a-101 on Schedule 14A with the Securities and Exchange Commission within 120 days after the close of the fiscal year ended December 31, 2008, have been incorporated by reference in Part III of this Annual Report on Form 10-K.

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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, their negative, or other variations or comparable terminology, though the absence of these words does not necessarily mean that a statement is not forward-looking. Forward-looking statements include all matters that are not historical facts and include, without limitation, statements concerning our business strategy, outlook, objectives, future milestones, plans, intentions, goals, future financial conditions, obtaining financing of our operations, our research and development programs and planning for and timing of any clinical trials, the possibility, timing and outcome of submitting regulatory filings for our products under development, potential investigational new drug applications, or INDs, and new drug applications, or NDAs, research and development of particular drug products, the development of financial, clinical, manufacturing and marketing plans related to the potential approval and commercialization of our drug products, and the period of time for which our existing resources will enable us to fund our operations. These statements are subject to risks and uncertainties that could cause actual results and events to differ materially from those expressed or implied by such forward-looking statements. For a detailed discussion of these risks and uncertainties, see the Risk Factors section in 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 Annual 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.

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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. 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. 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.

We were incorporated in the State of Nevada on June 17, 1996 and reincorporated in the State of Delaware on February 9, 2007, at which time our name was SMI Products, Inc., or SMI. On September 17, 2007, we completed a merger transaction whereby Nile Merger Sub, Inc., a Delaware corporation and a wholly-owned subsidiary of SMI, merged with and into Nile Therapeutics, Inc., a privately held Delaware corporation, or Old Nile, with Old Nile becoming a wholly-owned subsidiary of SMI. Immediately following the merger described above, we filed a Certificate of Ownership with the Secretary of State of the State of Delaware pursuant to which we merged Old Nile with and into us, with us remaining as the surviving corporation to that merger. In connection with that short-form merger, and as set forth in the Certificate of Ownership, we changed our name to Nile Therapeutics, Inc., or Nile. We refer to these two transactions in this Annual Report as the Merger. Upon completion of the Merger, we adopted Old Nile s business plan.

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

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 115 Sansome Street, Suite 310, San Francisco, California 94104. Our telephone number is (415) 875-7880 and our internet address is *www.nilethera.com.* The information on, or accessible through, our website is not part of this Form 10-K.

We advise you to review the Glossary of Terms included at the end of Item 1 in this Annual Report for definitions of certain technical terms used in this Annual Report that are commonly used in the pharmaceutical and biotechnology industries.

Our Product Candidates

CD-NP

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 current therapies while eliminating or attenuating the hypotensive response, and enhancing or preserving renal function. In addition to an initial indication for ADHF, CD-NP has potential utility in other indications which include preservation of cardiac function subsequent to acute myocardial infarction, or AMI, and prevention of renal damage subsequent to cardiac surgery.

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

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

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

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

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

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

In 2009, we plan to initiate a Phase IIb study in acute heart failure patients to continue to assess the safety and tolerability of CD-NP, as well as to measure the effect of CD-NP on dyspnea and renal function. We expect to complete this Phase IIb study in 2010.

CU-NP

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

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

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2NTX-99

The small molecule in our pipeline was 2NTX-99, an anti-platelet, anti-atherothrombotic agent with nitric oxide, or NO, donating properties that was in pre-clinical development. Mechanistically, 2NTX-99 inhibits the synthesis and action of thromboxane and enhances prostacyclin production. Prostacyclin and NO work together to inhibit platelet adhesion and aggregation, induce vasodilation, and protect the vascular wall from atherogenic stimuli.

We believe that the unique activity profile of 2NTX-99 has potential utility in a range of atherosclerotic, thrombotic, and microvascular diseases, including intermittent claudication and diabetic nephropathy. We performed pre-clinical toxicology and manufacturing activities for 2NTX-99 in 2008, with the intention of filing an IND and enter human testing in 2009.

On January 16, 2009, we provided notice to Dr. Cesare Casagrande, from whom we licensed 2NTX-99, that we were terminating the 2NTX-99 License Agreement effective 90 days from the date of the notice. We decided to end the 2NTX-99 program and to focus our resources on the development of our natriuretic peptides. Following the effectiveness of the termination, all rights to 2NTX-99 will revert to Dr. Casagrande.

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 with Mayo, or the Mayo License Agreement, for the rights to issued patents, patent applications and know-how relating to CD-NP for all therapeutic uses. The intellectual property portfolio for CD-NP includes issued and pending United States, European, and Japanese patents relating to its composition of matter and method of use in treating heart failure and symptoms associated with heart failure. Patent applications have been filed in other major markets around the world. We also had the rights to improvements to CD-NP that arose out of the laboratory of Dr. John Burnett, the co-inventor of CD-NP, until January 19, 2009. We intend to continue to expand our patent portfolio by filing to protect any additional patents covering expanded uses for this technology.

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Under the terms of the Mayo License Agreement, Old Nile made an up-front cash payment to Mayo and reimbursed it for past patent expenses. Old Nile also issued 1,379,419 shares of Old Nile common stock to Mayo. Additionally, Mayo will receive performance-based cash payments upon successful completion of clinical and regulatory milestones relating to 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. We also have agreed to pay Mayo substantial milestone payments 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. Pursuant to the Mayo License Agreement, we must also pay Mayo an annual maintenance fee and a percentage of net sales of licensed products. Under the terms of the Mayo License Agreement, Dr. Burnett has agreed to serve as chairman of our Scientific Advisory Board. In addition, we will pay Mayo $50,000 per year for the consulting services of Dr. Burnett while Dr. Burnett serves as chairperson of our Scientific Advisory Board. The Mayo License Agreement also contains other customary clauses and terms as are common in similar agreements in the industry.

In addition to the potential milestone payments discussed above, the Mayo License Agreement requires us 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, 2008, we received $482,235 in grant income for which we have issued to Mayo 63,478 shares (representing $182,236) of common stock. Please see the risk factor under Item 1A, entitled *If requirements under our license agreements are not met, we could suffer significant harm, including rights to our products* for a further discussion of the risks related to this license agreement.

CU-NP

Effective as of June 13, 2008, we entered into an exclusive, worldwide, royalty-bearing license agreement, or the CU-NP Mayo License Agreement, with Mayo 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 laboratory of Drs. John Burnett and Candace Lee, the inventors of CU-NP, until June 12, 2011.

Under the terms of the CU-NP Mayo License Agreement, Nile paid Mayo an up-front cash payment. Additionally, Mayo will receive performance-based cash payments upon successful completion of 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 a product. Additional milestone payments will be made upon the occurrence of certain other events. Pursuant to the agreement, Nile must also pay Mayo an annual maintenance fee and a percentage of net sales of licensed products.

In addition to the cash payments described above with respect to the CU-NP Mayo License Agreement, Nile has also agreed to issue certain amounts and types of equity 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. 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, Nile has agreed to grant to Mayo an equivalent dollar value in stock warrants to purchase the Nile s common stock. The number of warrants will be calculated using the Black-Scholes option-pricing model and will include a cashless exercise provision with language to be negotiated in good faith between the parties.

2NTX-99

On August 6, 2007, Old Nile entered into an exclusive, worldwide, royalty-bearing license agreement, or the 2NTX-99 License Agreement, with Dr. Cesare Casagrande for the rights to issued patents, patent applications, and know-how relating to 2NTX-99, and all of its human therapeutic or veterinary uses.

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Under the 2NTX-99 License Agreement, Old Nile made an up-front cash payment to Dr. Casagrande and reimbursed him for past patent expenses. Old Nile also issued 350,107 shares of Old Nile common stock to Dr. Casagrande having a fair market value as of August 6, 2007 equal to $1,000,000. Additionally, the agreement provided for cumulative performance-based milestone payments to Dr. Casagrande upon completion of clinical and regulatory milestones relating to 2NTX-99 in the United States, Europe, and Japan. We were also required to make certain milestone payments to Dr. Casagrande upon regulatory approval for each additional indication of 2NTX-99 and upon achieving certain annual sales milestones. The first milestone payment was to be due when the first patient is dosed in the first Company-sponsored Phase I clinical trial of 2NTX-99 in the United States or the European Union. The 2NTX-99 License Agreement also contained other customary clauses and terms as are common in similar agreements in the industry.

On January 16, 2009, we provided notice to Dr. Casagrande that we were terminating the 2NTX-99 License Agreement effective 90 days from the date of the notice. We decided to end the 2NTX-99 program and to focus our resources on the development of our natriuretic peptides. Following the effectiveness of the termination, all rights to 2NTX-99 will revert to Dr. Casagrande.

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

None of our drugs may be marketed in the United States until the drug has received FDA approval. The steps required before a drug may be marketed in the United States include:

- 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.

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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

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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.

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, inotopes, diuretics, as well as Natrecor . Some of our competitors include, without limitation, Scios (a Johnson & Johnson company), Bayer, Merck, Zealand Pharma, and Corthera.

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.

With respect to 2NTX-99, many therapeutic options are available for patients with atherosclerotic, thrombotic, and microvascular diseases, including, without limitation, antiplatlet agents (aspirin and clopidogrel), angiotensin converting enzyme, or ACE, inhibitors, angiotensin receptor blockers, or ARBs, beta-blockers, pentoxifylline, and cilostazol. Some of our competitors could have included, without limitation, Bristol-Myers Squibb Company, Eli Lilly and Company, and CardioVascular BioTherapeutics, Inc.

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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 us in pre-clinical and clinical development, manufacturing, regulatory, and global commercialization. We are also competing with academic institutions, governmental agencies, and private organizations that are conducting research in the field of cardiovascular disease. Competition for highly qualified employees is intense.

Research and Development Expenses

We spent approximately $9.5 million in fiscal year 2008, and $5.1 million in fiscal year 2007 on research and development activities. These expenses include cash and non-cash expenses relating to the development of our clinical and pre-clinical programs.

Employees

As of December 31, 2008, we had eight employees, all of whom were full-time. 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.

GLOSSARY OF TERMS

The following are definitions of certain technical terms used in this report and commonly used in the pharmaceutical and biotechnology industries.

agonist	A drug that can combine with a receptor on a cell to produce a physiological reaction.
AMI	Acute myocardial infarction
API	Active pharmaceutical ingredient
atherothrombotic	The formation of a clot in an artery that is characterized by a thickening and fatty degeneration of that vessel s inner coat.
atherosclerotic	A thickening and hardening of the artery walls characterized by fatty deposits in and fibrosis of the inner layer of the arteries.
cardiovascular	Of, relating to, or involving the heart and blood vessels.
chimeric	Of or related to an individual organ or part consisting of pieces of diverse genetic constitution.
claudication	Cramping pain and weakness in the legs and especially the calves on walking that disappears after rest and is usually associated with inadequate blood supply to the muscles.
natriuretic	Of or related to the excretion of sodium in the urine.
congestive heart failure	Heart failure in which the heart is unable to maintain adequate circulation of blood in the tissues of the body or to pump out the venous blood returned to it by the venous circulation resulting in an accumulation of blood in the vessels and fluid in the body tissues.

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diabetic nephropathy	Kidney disease and resultant kidney function impairment due to the long-standing effects of diabetes on the glomeruli (capillary blood vessels in the kidney which are actively involved in the filtration of the blood). Features include increased urine protein and declining kidney function. Severe diabetic nephropathy can lead to kidney failure and end-stage renal disease.
hypotension	Abnormally low pressure of the blood.
in vitro	Outside the living body and in an artificial environment.
in vivo	In the living body of a plant or animal.
IND	Investigational new drug application.
mean arterial pressure	A measurement that takes account of pumped blood flow in the arteries and is the best measure of the pressure of blood pumped to an organ.
metabolic disease	An illness resulting from the body s malfunction in the chemical changes in living cells by which energy is provided for vital processes and activities and new material is assimilated.
microvascular disease	An illness related to or constituting the part of the circulatory system made up of minute vessels.
nitric oxide	Synthesized within cells by NO synthase, NO relaxes smooth muscles and has been implicated almost universally in the functioning of a variety of cellular processes.
nitric oxide-donating properties	The ability to release nitric oxide.
pathological	Altered or caused by disease
peptide	Two or more amino acids formed by combination of the amino group of one acid with the carboxyl group of another.
pharmacodynamics	A branch of pharmacology dealing with the reactions between drugs and living systems.
pharmacokinetics	The study of the bodily absorption, distribution, metabolism, and excretion of drugs.
pharmacologic actions	The properties and reactions of drugs especially with relation to their therapeutic value.
platelet aggregation	The clumping of many small blood-based bodies that generally assists in blood clotting by adhering to each other and epithelium.
prostacyclin	A cyclic fatty acid that inhibits aggregation of platelets, and dilates blood vessels.
prothrombotic	Of or related to the promotion of blood clot formation.
renal	Relating to, involving, affecting, or located in the region of the kidneys.
synthetic	Of, relating to, or produced by chemical or biochemical synthesis; produced artificially.
thrombotic	Of or related to blood clot formation.
thromboxane	A substance that is produced by platelets, causes constriction of vascular and bronchial smooth muscle, and promotes blood clotting.
vasculature	The disposition or arrangement of blood vessels in an organ or part of the body.
vasodilator	An agent that widens the lumen of blood vessels.

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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.

We need substantial additional funding, and 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. 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. We had cash and cash equivalents totaling $5.5 million at December 31, 2008. During the fiscal year ended December 31, 2008, we used net cash totaling $10.6 million in operating activities. We expect our negative cash flows from operations to continue for the foreseeable future and beyond potential regulatory approval and any product launch. Based on our current development plans, we expect that our current resources will be sufficient to fund our operations through the middle of 2009.

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;

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- 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.

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 and CU-NP will begin on time or be completed on schedule, if at all. The commencement and completion of clinical trials requires us to identify and maintain a sufficient number of trial sites, many of which may already be engaged in other clinical trial programs for the same indication as our product candidates, may be required to withdraw from a clinical trial as a result of changing standards of care, or may become ineligible to participate in clinical studies.

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

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

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

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

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

unforeseen safety issues or any determination that a trial presents unacceptable health risks; or

lack of adequate funding to continue the clinical trial, including the incurrence of unforeseen costs due to enrollment delays, requirements to conduct additional trials and studies, and increased expenses associated with the services of our CROs and other third parties.

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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;

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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.

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

For the years ended December 31, 2008 and 2007, respectively, we had a net loss of $13.1 million and $10.3 million. Since our inception on August 1, 2005, through the year ended December 31, 2008, we have accumulated a deficit of $26.0 million and have stockholders equity of $5.1 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

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approved for commercial sale, and to date we have not generated any product revenue. We have financed our operations primarily through the sale of equity securities and debt financings. The size of our future net losses will depend, in part, on the rate of growth of our expenses and the rate of growth, if any, of our revenues. Revenues from potential strategic partnerships are uncertain because we may not enter into any strategic partnerships. If we are unable to develop and commercialize one or more of our product candidates, or if sales revenue from any product candidate that receives marketing approval is insufficient, we will not achieve profitability. Even if we do achieve profitability, we may not be able to sustain or increase profitability.

We 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 Annual Report:

- 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;

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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.

Due to the various factors mentioned above, and others, the results of any prior quarterly or annual periods should not be relied upon as indications of our future operating performance.

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.

In 2007, we completed a Phase Ia dose-escalation study in healthy volunteers to examine the safety and pharmacodynamic effects of various doses of CD-NP. The study placed particular emphasis on the effects of CD-NP on blood pressure and renal function. Data from the completed Phase Ia study in healthy volunteers was consistent with several pre-clinical findings, including that CD-NP was associated with increased levels of plasma cGMP, a secondary messenger of the target receptor, preserved renal function, increased natriuresis and diuresis and a minimal effect on mean arterial pressure. In 2008, we initiated two additional dose-escalation studies to assess the safety and pharmacodynamic profile of CD-NP in heart failure patients. The first study was a Phase Ib study in stable heart failure patients designed to understand the maximum tolerated dose of the product candidate, and the second study was a Phase IIa study in acute heart failure patients designed to better understand the hemodynamic properties of the product candidate. In October 2008, we announced interim results of an ongoing Phase IIa study of CD-NP. Results from the first cohort of patients in the study suggested that CD-NP was associated with a statistically significant reduction in pulmonary capillary wedge pressure, a statistically significant increase in diuresis, a trend toward reduction in right atrial pressure, and a trend toward increase in cardiac output at dose levels where patients did not experience symptomatic hypotension or an observed change in serum creatinine. In December 2008, we announced preliminary data from the Phase Ib study of CD-NP. Results of this study showed that CD-NP was well tolerated at doses of up to 20 ng/kg/min, blood pressure effects were dose dependent and well characterized, CD-NP demonstrated diuretic effects comparable to furosemide, and CD-NP produced statistically significant changes on biomarkers consistent with enhanced renal function. The data collected from our clinical trials may not be adequate to support regulatory approval of CD-NP or any of our other product candidates. Despite the results reported in earlier clinical trials for our product candidates, we do not know whether any Phase IIb, Phase III or other clinical programs we may conduct will demonstrate adequate efficacy and safety to result in regulatory approval to market our product candidates.

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

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

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

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

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

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

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

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

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

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

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

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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.

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;

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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

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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.

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 qualified personnel. If we are unable to manage our growth effectively, our business would be harmed.

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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.

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 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

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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.

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

Peter M. Kash, Joshua A. Kazam and David M. Tanen, each a director and substantial stockholder of our Company, are three of the four the managing members of Two River Group Holdings, LLC, or Two River, a merchant bank specializing in biotechnology companies, and are officers and directors of Riverbank Capital Securities, Inc., or Riverbank, a broker-dealer registered with the Financial Industry Regulatory Authority (FINRA). Mr. Tanen also serves as our Secretary and Scott Navins, the Vice President of Finance for Two River and the Financial and Operations Principal of Riverbank, serves as our Treasurer. Additionally, certain employees of Two River, who are also our stockholders,

perform limited activities for us, including without limitation business development, financial, clinical and regulatory activities. 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

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

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

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

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

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

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

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

Our internal controls over financial reporting have not been audited by our independent registered public accounting firm as will be required for fiscal year 2009 by Section 404 of the Sarbanes-Oxley Act. In 2008, we

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completed financial control process mapping. We focused on identification of key financial reporting risks, an assessment of their potential impact and linkage of those risks to specific areas and activities within our organization. Additionally, we performed internal testing on our internal controls.

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

Our common stock is considered a penny stock.

The SEC has adopted regulations which generally define penny stock to be an equity security that has a market price of less than $5.00 per share, subject to specific exemptions. The market price of our common stock over the last six months has, at times, been, less than $5.00 per share and our stock could be less than $5.00 per share in the future. Therefore, our stock may be a penny stock according to SEC rules. This designation requires any broker or dealer selling these securities to disclose certain information concerning the transaction, obtain a written agreement from the purchaser and determine that the purchaser is reasonably suitable to purchase the securities. These rules may restrict the ability of brokers or dealers to sell our common stock.

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;

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introduction of technological innovations or new commercial products by us or our competitors;

issues in manufacturing our drug candidates or drugs;

market acceptance of our drugs;

third-party healthcare coverage and reimbursement policies;

FDA or other United States or foreign regulatory actions affecting us or our industry;

litigation or public concern about the safety of our drug candidates or drugs;

additions or departures of key personnel; or

volatility in the stock prices of other companies in our industry.

These and other factors may cause the market price and demand for our common stock to fluctuate substantially, which may limit or prevent investors from readily selling their shares of common stock and may otherwise negatively affect the liquidity of our common stock. In addition, when the market price of a stock has been volatile, holders of that stock have instituted securities class action litigation against the company that issued the stock. 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.

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.

In 2008, we were accepted for listing on the NASDAQ Capital Market exchange, or NASDAQ. To be eligible to list on NASDAQ, we were required to meet certain qualitative and quantitative listing criteria, which included operating results, net assets, corporate governance, minimum trading price and minimums for public float, which is the amount of stock held by non-affiliates of Nile.

To remain eligible to have our securities quoted on NASDAQ Capital Market, we must file reports with the Securities and Exchange Commission pursuant to the Securities Act of 1933, we must remain current in our periodical reporting obligations and we must continue to meet certain qualitative and quantitative listing criteria, including thresholds on stock price and stockholders equity or market value of listed securities.

In 2008, our stock price dropped below $1.00, which is the minimum stock price for continued listing on NASDAQ. NASDAQ obtained agreement from the SEC to not enforce the $1.00 minimum stock price requirement until April 19, 2009. We cannot guarantee that we will be able to meet the minimum price requirement by April 19, 2009.

Listing on NASDAQ may provide our shareholders with greater liquidity and provide us with greater access to capital, however, we cannot assure you that we will be able to maintain a listing of our common stock on NASDAQ. If for any reason our securities become ineligible for quotation on the NASDAQ, purchasers of our securities may have difficulty selling their securities should they desire to do so and we may have trouble obtaining capital, if needed.

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

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

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

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.

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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

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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.

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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.

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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.

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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.

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 our common stock that would grant to holders preferred rights to our assets upon liquidation, the right to receive dividends, additional registration rights, anti-dilution protection, the right to the redemption to such shares, together with other rights, none of which will be afforded to holders of our common stock.

ITEM 1B. UNRESOLVED STAFF COMMENTS

None.

ITEM 2. DESCRIPTION OF PROPERTY

Our principal offices are located at 115 Sansome Street, Suite 310, San Francisco, California 94104. Under the terms of a three-year non-cancelable operating lease agreement with AG/SIC-115 Sansome, LLC, the monthly base rent is $9,155 per month through April 30, 2009, $9,430 per month effective May 1, 2009, and $9,713 per month effective May 1, 2010. The office space is approximately 2,891 square feet, and the lease expires on March 31, 2011. We are also responsible for payment of our share of certain pro rata common charges such as operating costs and taxes in excess of the base year and additional rent. In connection with this lease, we have made a $55,000 cash security deposit.

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We relocated our principal offices effective April 1, 2008 from Berkeley, California to San Francisco, California. The Berkeley, California office was under a non-cancelable operating lease that was to expire in April 2010. In June 2008, 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. SUBMISSION OF MATTERS TO A VOTE OF SECURITY HOLDERS

No matter was submitted during the fourth quarter of the fiscal year ended December 31, 2008 to a vote of security holders through the solicitation of proxies or otherwise.

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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 trades on 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, 2008 and December 31, 2007, respectively, as reported by Commodity Systems, Inc. Although our common stock is quoted on the NASDAQ, it has traded sporadically with no significant 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, 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
Year ended December 31, 2007		
First quarter	$ 3.50	$ 2.40
Second quarter	$ 2.05	$ 0.77
Third quarter	$ 5.00	$ 1.15
Fourth quarter	$ 7.00	$ 3.10

Stockholders

According to the records of our transfer agent, American Stock Transfer & Trust Company, as of March 2, 2009, we had 200 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.

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Securities Authorized for Issuance under Equity Compensation Plans

Our Amended and Restated 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, 2008 with respect to our Amended and Restated 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	3,977,769	$ 3.08	1,539,907
Equity compensation plans not approved by stockholders:			
None.			
Total	**3,977,769**	**$ 3.08**	**1,539,907**

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

None.

Issuer Purchases of Equity Securities

None.

ITEM 6. SELECTED FINANCIAL DATA

The selected financial data set forth below contains only a portion of our financial statement information and should be read in conjunction with the financial statements and related notes and *Management s Discussion and Analysis of Financial Condition and Results of Operations* included in Item 7 in this Annual Report.

We derived the statement of operations data for the period from August 1, 2005 (inception) through December 31, 2005, the years ended December 31, 2006, 2007, and 2008, and balance sheet data as of December 31, 2005, 2006, 2007, and 2008 from audited financial statements. Historical results are not necessarily indicative of results that we may experience in the future.

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	Year Ended December 31,			Period from August 1, 2005 (date of inception) through December 31,
	2008	2007	2006	2005
	(in thousands, except per share data)			
Statements of operations data:				
Grant income	$	$ 101	$ 381	$
Operating expenses				
Research and development	9,478	5,124	2,700	9
General and administrative	3,922	4,478	179	1
Total operating expenses	13,400	9,602	2,879	10
Loss from operations	(13,400)	(9,501)	(2,498)	(10)
Interest income	333	288	99	
Interest expense		(1,090)	(183)	
Other expense	(64)			
Net loss	$ (13,131)	$ (10,303)	$ (2,582)	$ (10)
Basic and diluted loss per share	$ (0.54)	$ (0.61)	$ (0.19)	$ (0.00)
Weighted-average common shares outstanding	24,126	16,942	13,794	12,415

	As of December 31,			
	2008(1)	2007(2)	2006	2005
	(in thousands)			
Balance sheet data:				
Cash and cash equivalents	$ 5,501	$ 16,233	$ 2,022	$ 5
Total assets	6,435	17,089	2,091	5
Deficit accumulated during the development stage	(26,026)	(12,895)	(2,592)	(10)
Total stockholders equity (deficit)	5,104	15,200	(2,577)	(5)

(1) Selected financial data does not include any adjustments to reflect the possible future effects on the recoverability and classification of assets or the amounts and classification of liabilities that may result from the possible inability of Nile to continue as a going concern (for further explanations please see Note 2 of the accompanying audited financial statements).

(2) Year to year comparability is affected as Nile completed a reverse merger on September 17, 2007 (for further explanations please see Note 1 of the financial statements).

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. 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 initially developing CD-NP as a treatment for

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heart failure. We are also developing 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 CNP, and the N- and C-termini of URO.

We have no product sales to date and we will not generate any product revenue until we receive approval from 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.

On September 17, 2007, we completed the Merger described in Item 1. In accordance with the terms of the Merger, each share of common stock of Old Nile that was outstanding immediately prior to the Merger was exchanged for 2.758838 shares of our common stock, and 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 our common stock. In consideration for their shares of our pre-merger common stock, our shareholders received an aggregate of 22,849,716 shares of SMI common stock. Immediately prior to the effective date of the Merger, 755,100 shares of SMI s common stock were issued and outstanding. In addition, prior to the effective date 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 our issued and outstanding common stock, assuming the exercise of all of the issued and outstanding common stock options and warrants.

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. The historical financial information prior to September 2007 in this Form 10-K is that of Old Nile.

Our results include non-cash compensation expense as a result of the issuance of stock, stock options, and warrants. We account for stock-based compensation in accordance with Statement of Financial Accounting Standards 123(R), *Share-Based Payment,* or SFAS 123(R). SFAS 123(R) requires us to expense the fair value of stock options and warrants over the vesting period. 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 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.

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Our Product Candidates

We currently have two product candidates: CD-NP, in clinical development for the treatment of heart failure; and CU-NP which is in pre-clinical development and has potential utility in a number of cardiovascular and renal indications. We recently terminated our 2NTX-99 program in order to focus on our natriuretic peptide programs.

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 current therapies while eliminating or attenuating the hypotensive response, and enhancing or preserving renal function. In addition to an initial indication for ADHF, CD-NP has potential utility in other indications which include preservation of cardiac function subsequent to acute myocardial infarction, and prevention of renal damage subsequent to cardiac surgery.

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

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

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

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

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

In 2009, we plan to initiate a Phase IIb study in acute heart failure patients to continue to assess the safety and tolerability of CD-NP, as well as to measure the effect of CD-NP on dyspnea and renal function. We expect to complete this Phase IIb study in 2010.

CU-NP Program CU-NP is a 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

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effects of CNP generated via NPR-B receptor agonism, with the beneficial renal effects of Urodilatin generated via NPR-A receptor agonism. In animal models, CU-NP was shown to increase natriuresis, diuresis, and glomerular filtration rate in a dose dependent manner, decrease cardiac filling pressure, and inhibit the renin-angiotensin system without inducing significant hypotension.

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

2NTX-99 Program 2NTX-99 is a small molecule anti-platelet, anti-atherothrombotic agent with NO donating properties that was in pre-clinical development. Mechanistically, 2NTX-99 inhibits the synthesis and action of thromboxane and enhances prostacyclin production. Prostacyclin and NO work together to inhibit platelet adhesion and aggregation, induce vasodilation, and protect the vascular wall from atherogenic stimuli.

We believe that the unique activity profile of 2NTX-99 has potential utility in a range of atherosclerotic, thrombotic, and microvascular diseases, including intermittent claudication and diabetic nephropathy. We performed pre-clinical toxicology and manufacturing activities for 2NTX-99 in 2008, with the intention of filing an IND and enter human testing in 2009.

On January 16, 2009, we provided notice to Dr. Casagrande that we were terminating the 2NTX-99 License Agreement effective 90 days from the date of the notice. We decided to end the 2NTX-99 program and to focus our resources on the development of our natriuretic peptides. Following the effectiveness of the termination, all rights to 2NTX-99 will revert to Dr. Casagrande.

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

Research and development 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. Research and development 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 research and development 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

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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 research and development 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 research and development 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 research and development 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 the Amended and Restated 2005 Stock Option Plan.

We account for employee stock-based compensation in accordance with SFAS 123(R) which requires us to expense the fair value of stock options over the vesting period on a straight-line basis. 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. Additional information on the variables and assumptions used in our stock-based compensation are described in Note 10 of the accompanying notes to our audited financial statements.

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 under SFAS 123, *Accounting for Stock-Based Compensation*, and Emerging Issues Task Force No. 96-18, *Accounting for Equity Instruments That Are Issued to Other Than Employees for Acquiring, or in Conjunction with Selling, Goods or Services* , 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.

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Research and Development Plan

In the first half of 2009, we expect to initiate a 30 patient, open-label study as part of a Phase IIb study CD-NP in patients with acute decompensated heart failure. Following the 30 patient lead-in, we plan to initiate another 330 patients in the Phase IIb study, which, if successful, would serve as the basis for dose selection for a Phase III program.

In addition to our own studies, in July 2008, Mayo dosed the first patient in a Phase Ib study, under an investigator-sponsored IND, to better understand CD-NP s renal properties. We expect Mayo to complete dosing of this trial in 2010.

For CU-NP, we have manufactured CU-NP API and expect to initiate work on pre-clinical pharmacology studies and chronic formulation development in 2009.

Results of Operations

The following analysis of our financial condition and results of operations should be read in conjunction with our audited financial statements and notes contained elsewhere in this Form 10-K.

Revenue. We had no product revenue during the years ended December 31, 2008 and 2007 as none of our product candidates have been approved for commercialization.

Research and Development Expenses. Research and development 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.

Research and development expenses for the year ended December 31, 2008 increased $4.4 million, or 85%, as compared to the same period in 2007. The change is primarily due to an increase of $2.7 million in clinical development expenses and $0.9 million in manufacturing expenses. In 2008, we conducted a Phase Ib and Phase IIa clinical trial with CD-NP, as compared to a single Phase Ia clinical trial with CD-NP in 2007. Manufacturing expenses, including formulation development and drug product manufacturing increased due to the increase in manufacturing activities for both CD-NP and 2NTX-99. In addition, in June 2008, we incurred a one-time expense of $0.5 million, including a mixture of issued stock and cash, pursuant to the CU-NP Mayo licensing agreement. The remaining increase resulted from an increase in salaries and related expenses resulting from the hiring of additional research and development personnel.

General and Administrative Expenses. General and administrative expenses consist primarily of salaries and related expenses for executive, finance and other administrative personnel, recruitment expenses, professional fees and other corporate expenses, including business development, rent and other office expense, and general legal activities.

General and administrative expenses for the year ended December 31, 2008 decreased by $0.6 million, or 12%, as compared to the same period in 2007. This decrease is primarily due to the one-time merger costs and the legal fees associated with the merger that occurred in 2007. These decreases were partially offset by increases in statutory representation, rent and insurance costs in 2008.

Interest Income. Interest income for the years ended December 31, 2008 and 2007 was approximately $333,000 and $288,000, respectively. In the third quarter of 2007, we completed a financing whereby we raised $20.0 million through the sale of 6,957,914 shares of common stock in a private placement. Cash balances in 2008 have decreased as we produce no revenue and have not raised any additional capital.

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Interest Expense. Interest expense for the years ended December 31, 2008 and 2007 was $0 and $1.1 million, respectively. We had no debt in 2008, and in September 2007 we had a conversion of 6% convertible promissory notes in September 2007 that were issued in March 2006 and had an aggregate principal amount of $4.0 million.

Liquidity and Capital Resources

Cash and cash flow

For the year ended December 31, 2008, we had a net loss of $13.1 million. From August 1, 2005 (inception) through December 31, 2008, we have incurred an aggregate net loss of $26.0 million, primarily through a combination of research and development activities related to the licensed technologies under our control and expenses supporting those activities. We expect to continue to incur substantial and increasing losses, which will continue to have 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.

Our total cash resources as of December 31, 2008 were $5.5 million compared to $16.2 million as of December 31, 2007. As of December 31, 2008, we had approximately $1.3 million in liabilities, and $4.7 million in net working capital. Our forecasted average monthly cash expenditures for the next six months are approximately $0.7 million, which is a decrease from our average monthly expenses from 2008.

From inception through December 31, 2008, we have financed our operations through private debt and equity financing. 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 before we exhaust our current cash resources 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 are seeking to raise additional funds through various potential sources, such as equity and debt financings, or though corporate collaboration 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 it such funds are available to us, that such additional financing will be sufficient to meet our needs.

Based on our resources at December 31, 2008, and our current plan of expenditure on continuing development of our current products, we believe that we have sufficient capital to fund our operations through the middle of 2009, depending largely on patient enrollment rates. 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.

In addition, 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.

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Recent global market and economic conditions have been unprecedented and challenging with tighter credit conditions and recession in most major economies continuing into 2009. 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 and consumer spending may adversely affect our liquidity and financial condition, and the liquidity and financial condition of our customers, including our ability to refinance maturing liabilities and access the capital markets to meet liquidity needs.

There is substantial doubt about our ability to continue as a going concern as the continuation of our business 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 is likely to result in a significant dilution in the equity interests of our current stockholders. Obtaining commercial loans, assuming those loans would be available, including on acceptable terms, will increase our liabilities and future cash commitments.

Off-Balance Sheet Arrangements

There were no off-balance sheet arrangements as of December 31, 2008.

Contractual Obligations

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.

Effective June 13, 2008, we entered into the CU-NP Mayo License Agreement with Mayo. 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, until June 12, 2011. In consideration for the CU-NP Mayo License Agreement, we agreed to expend reasonable amounts to conduct a research and commercial development program to commercialize a product developed from the patent, to pursue diligently the worldwide regulatory approval of a product, and to commence marketing within six months following regulatory approval of the product in the United States. In addition, under the terms of the agreement, we made an up-front cash payment to Mayo. Additionally, Mayo will receive performance-based cash payments upon successful completion of 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 a product. Additional milestone payments will be made upon the occurrence of other events. 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 the cash payments described above with respect to the CU-NP Mayo License Agreement, we have also agreed to issue certain amounts and types of equity to Mayo. In June 2008 we issued to Mayo 49,689 shares of common stock having a fair market value as of June 13, 2008 equal to $250,000. The shares issued to Mayo are not subject to anti-dilution protection and, like all of our shares of common stock, will be diluted over time if we issue additional shares. 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, we have agreed to grant to Mayo an equivalent dollar value in stock warrants to purchase our common stock. The number of warrants will be calculated using the Black-Scholes option-pricing model. The warrants will include a cashless exercise provision with language to be negotiated in good faith between the parties.

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In March 2008, we entered into a non-cancelable office lease agreement for office space in San Francisco, California. The lease expires in March 2011. Future minimum lease payments under the lease are approximately $112,000 in 2009, $116,000 in 2010, and $29,000 in 2011, not including annual operating cost escalations.

Financings

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, or the Financing. Issuance costs related to the Financing were $102,000.

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.

During March 2006, we completed a private placement offering for $4,000,000 aggregate 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 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, 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.

Related Party Transactions

As consideration for the performance of consulting and due diligence efforts related to the licensing of 2NTX-99, we have granted fully vested warrants to purchase 206,912 shares of our common stock at an exercise price of $2.71. Of the total amount of the warrants granted, 137,567 were granted to employees of Two River, a related party, and its affiliates (please see Note 13 of the financial statements). The remaining warrants were granted to outside consultants.

Inflation

We do not believe that inflation has had a material impact on our business and operating results during the periods presented.

ITEM 7A. QUANTITATIVE AND QUALITATIVE DISCLOSURES ABOUT MARKET RISK

Our exposure to market risk for changes in interest rates relates primarily to our cash and cash equivalents. The goal of our investment policy is to place our investments with highly rated credit issuers and limit the amount of credit exposure to any one issuer. We seek to improve the safety and likelihood of preservation of our invested funds by limiting default risk and market risk. Our policy is to mitigate default risk by investing in high credit quality securities and currently do not hedge interest rate exposure. Due to our policy to only make investments with short-term maturities, we do not believe that an increase in market rates would have any material negative impact on the value of our investment portfolio.

As of December 31, 2008, our portfolio consisted primarily of bank savings accounts with a certificate of deposit associated with our lease obligation, and we did not have any investments with significant exposure to the subprime mortgage market issues. Based on our investment portfolio and interest rates at December 31, 2008, we believe that a decrease in interest rates would not have a significant impact on the fair value of our cash and cash equivalents of approximately $5.5 million.

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ITEM 8. FINANCIAL STATEMENTS AND SUPPLEMENTARY DATA

FINANCIAL STATEMENTS

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REPORT OF INDEPENDENT REGISTERED PUBLIC ACCOUNTING FIRM

To the Board of Directors

Nile Therapeutics, Inc.

San Francisco, California

We have audited the accompanying balance sheets of Nile Therapeutics, Inc. (a development stage company) as of December 31, 2008 and 2007 and the related statements of operations, stockholders equity and cash flows for the years then ended and for the period from August 1, 2005 (inception) through December 31, 2008. These financial statements are the responsibility of the Company s management. Our responsibility is to express an opinion on these financial statements based on our audits.

We conducted our audits 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 audits 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. as of December 31, 2008 and 2007, and the results of its operations and its cash flows for the years then ended and for the period from August 1, 2005 (inception) through December 31, 2008, 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

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NILE THERAPEUTICS, INC.

(A DEVELOPMENT STAGE COMPANY)

BALANCE SHEETS

	December 31, 2008	December 31, 2007
ASSETS		
Current assets		
Cash and cash equivalents	$ 5,500,790	$ 16,233,464
Prepaid expenses and other current assets	544,834	526,303
Total current assets	6,045,624	16,759,767
Property and equipment, net	73,699	62,838
Intangible assets, net	209,549	252,723
Other non-current assets	106,597	14,000
Total assets	$ 6,435,469	$ 17,089,328
LIABILITIES AND STOCKHOLDERS EQUITY		
Current liabilities		
Accounts payable	$ 738,895	$ 658,773
Accrued expenses and other current liabilities	586,256	915,419
Due to related party	6,700	315,204
Total current liabilities	1,331,851	1,889,396
Commitments and contingencies		
Stockholders equity		
Preferred stock, $0.001 par value; 10,000,000 shares authorized		
Common stock, $0.001 par value; 100,000,000 shares authorized;		
24,149,405 and 24,099,716 shares issued and outstanding	24,150	24,100
Additional paid-in capital	31,105,874	28,070,642
Deficit accumulated during the development stage	(26,026,406)	(12,894,810)
Total stockholders equity	5,103,618	15,199,932
Total liabilities and stockholders equity	$ 6,435,469	$ 17,089,328

See accompanying notes to financial statements

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NILE THERAPEUTICS, INC.

(A DEVELOPMENT STAGE COMPANY)

STATEMENTS OF OPERATIONS

	Year ended December 31,		Period from August 1, 2005 (inception) through December 31, 2008
	2008	2007	
Grant income	$	$ 101,400	$ 482,235
Operating expenses:			
Research and development	9,477,823	5,124,292	17,311,520
General and administrative	3,922,164	4,477,567	8,579,588
Total operating expenses	13,399,987	9,601,859	25,891,108
Loss from operations	(13,399,987)	(9,500,459)	(25,408,873)
Other income (expense):			
Interest income	332,715	287,808	720,388
Interest expense	(137)	(1,090,144)	(1,273,734)
Other expense	(64,187)		(64,187)
Total other income (expense)	268,391	(802,336)	(617,533)
Net loss	$ (13,131,596)	$ (10,302,795)	$ (26,026,406)
Basic and diluted loss per share	$ (0.54)	$ (0.61)	
Weighted-average common shares outstanding	24,126,398	16,942,142	

See accompanying notes to financial statements

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NILE THERAPEUTICS, INC.

(A DEVELOPMENT STAGE COMPANY)

STATEMENT OF STOCKHOLDERS EQUITY (DEFICIT)

PERIOD FROM

AUGUST 1, 2005 (INCEPTION) THROUGH DECEMBER 31, 2008

	Common Stock				
	Shares	Amount	Additional Paid-in Capital	Deficit Accumulated During the Development Stage	Total Stockholders Equity (deficit)
Issuance of common shares to founders	13,794,132	$ 13,794	$ (8,794)	$	$ 5,000
Founders shares returned to treasury	(1,379,419)				
Net loss				(10,043)	(10,043)
Balance at December 31, 2005	12,414,713	13,794	(8,794)	(10,043)	(5,043)
Issuance of common shares pursuant to licensing agreement	1,379,419		500		500
Issuance of stock options for services			10,000		10,000
Net loss				(2,581,972)	(2,581,972)
Balance at December 31, 2006	13,794,132	13,794	1,706	(2,592,015)	(2,576,515)
Issuance of common shares pursuant to licensing agreement	63,478	64	182,172		182,236
Issuance of common shares pursuant to licensing agreement	350,107	350	999,650		1,000,000
Common shares sold in private placement, net of issuance costs of $102,000	6,957,914	6,958	19,865,789		19,872,747
Warrants issued in connection with note conversion			288,000		288,000
Conversion of notes payable upon event of merger	1,684,085	1,684	4,349,481		4,351,165
Note discount arising from beneficial conversion feature			483,463		483,463
Reverse merger transaction					
Elimination of accumulated deficit			(234,218)		(234,218)
Previously issued SMI stock	1,250,000	1,250	232,968		234,218
Employee stock-based compensation			1,902,298		1,902,298
Non-employee stock-based compensation			(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

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, 2008
	2008	2007	
Cash flows from operating activities			
Net loss	$ (13,131,596)	$ (10,302,795)	$ (26,026,406)
Adjustment to reconcile net loss to net cash used in operating activities			
Depreciation and amortization	113,289	26,984	140,626
Stock-based compensation	3,035,282	3,083,867	6,129,649
Warrants issued in connection with note conversion		288,000	288,000
Note discount arising from beneficial conversion feature		483,463	483,463
Loss on disposal of assets	11,654		11,654
Noncash interest expense		167,713	351,165
Changes in operating assets and liabilities			
Prepaid expenses and other current assets	(18,531)	(526,303)	(544,834)
Other non-current assets	(92,597)	1,000	(106,597)
Accounts payable	80,122	298,160	738,895
Accrued expenses and other current liabilities	(329,163)	797,919	586,256
Due to related party	(308,504)	309,375	6,700
Net cash used in operating activities	(10,640,044)	(5,372,617)	(17,941,429)
Cash flows from investing activities			
Purchase of property and equipment	(45,314)	(60,064)	(122,241)
Cash paid for intangible assets	(47,316)	(228,836)	(313,287)
Net cash used in investing activities	(92,630)	(288,900)	(435,528)
Cash flows from financing activities			
Proceeds from issuance of notes payable		1,500,000	5,500,000
Repayment of notes payable		(1,500,000)	(1,500,000)
Proceeds from sale of common stock to founders			5,000
Proceeds from sale of common stock in private placement		19,872,747	19,872,747
Net cash provided by financing activities		19,872,747	23,877,747
Net increase (decrease) in cash and cash equivalents	(10,732,674)	14,211,230	5,500,790
Cash and cash equivalents at beginning of period	16,233,464	2,022,234	
Cash and cash equivalents at end of period	$ 5,500,790	$ 16,233,464	$ 5,500,790
Supplemental schedule of cash flows information:			
Cash paid for interest	$	$ 150,000	$ 150,000
Supplemental schedule of non-cash investing and financing activities:			
Warrants issued in sastisfaction of accrued liability	$ 334,992	$	$ 334,992

Conversion of notes payable and interest to common stock	$		$	4,351,165	$ 4,351,165
Common shares of SMI issued in reverse merger transaction	$		$	1,250	$ 1,250

See accompanying notes to financial statements

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Nile Therapeutics, Inc.

(A Development Stage Company)

Notes to Financial Statements

1. DESCRIPTION OF BUSINESS

Nile Therapeutics, Inc. (Nile or the Company) commercially 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., or 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, the Company filed a Certificate of Ownership with the Secretary of State of the State of Delaware pursuant to which the Company merged Old Nile with and into the Company, with the Company remaining as the surviving corporation to that merger. In connection with that short-form merger, and as set forth in the Certificate of Ownership, the Company changed its name to Nile Therapeutics, Inc. These two transactions are hereinafter 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

The Company is a development stage enterprise since it has not yet generated any revenue from the sale of products and, through December 31, 2008, 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 Statement of Financial Accounting Standards (SFAS) No. 7, *Accounting and Reporting by Development Stage Enterprises.* 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 $26.0 million at December 31, 2008. 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, 2008 were $5.5 million, compared to $16.2 million as of December 31, 2007. Based on its resources at December 31, 2008, and the current plan of expenditure on continuing development of current products, the Company believes that it has sufficient capital to fund its operations through the middle of 2009 and will need 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

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Nile Therapeutics, Inc.

(A Development Stage Company)

Notes to Financial Statements (Continued)

to finance the continued operating and capital requirements of the Company. Amounts raised will be used to further develop the Company s products, acquire additional product licenses and for other working capital purposes. While the Company will extend its best efforts to raise additional capital to fund all operations for the next 12 to 24 months, management can provide no assurances that the Company will be able to raise such sufficient funds. 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.

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 $2.71 per 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,

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Nile Therapeutics, Inc.

(A Development Stage Company)

Notes to Financial Statements (Continued)

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. The historical financial statements (prior to September 2007) in this Annual Report are those of Old Nile.

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).

4. SUMMARY OF SIGNIFICANT ACCOUNTING POLICIES

(a) Use of Estimates

The preparation of financial statements in conformity with generally accepted accounting principles 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 and consultants, and estimates of the probability and potential magnitude of contingent liabilities. Actual results could differ from those estimates.

(b) Cash and Cash Equivalents

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

(c) Restricted Cash

In March 2008, the Company entered into a non-cancelable three year office lease agreement. In connection with the lease, the Company delivered 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 shall be restricted for the entire period of the three year lease agreement. Restricted cash is included in other noncurrent assets on the accompanying Balance Sheets.

(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
Leaseholder improvements	3 years
Computer equipment	3 years

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Nile Therapeutics, Inc.

(A Development Stage Company)

Notes to Financial Statements (Continued)

(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. The 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. There have been no impairment charges recorded to date. 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 will record an impairment of the intangibles related to 2NTX-99 of approximately $48,000 in the first quarter of 2009.

(g) Fair Value of Financial Instruments

The Company adopted SFAS No. 157, *Fair Value Measurements* (SFAS 157) on January 1, 2008. SFAS 157 defines fair value, establishes a framework for measuring fair value in accordance with generally accepted accounting principles, and expands disclosures about fair value measurements. SFAS 157 does not require any new fair value measurements; rather, it applies under other accounting pronouncements that require or permit fair value measurements. The provisions of SFAS 157 are to be applied prospectively as of the beginning of the fiscal year in which it is initially applied, 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.

(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 fees associated with operational consultants, contract clinical research organizations, contract manufacturing

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Nile Therapeutics, Inc.

(A Development Stage Company)

Notes to Financial Statements (Continued)

organizations, clinical site fees, contract laboratory research organizations, contract central testing laboratories, licensing activities, and allocated office, insurance, depreciation, and costs for employees who oversee such activities. The Company accrues for costs incurred as the services are being provided by monitoring the status of the project 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 and patents 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

The Company accounts for stock-based compensation in accordance with SFAS No. 123(R), *Share-Based Payment,* (SFAS 123(R)) which requires the Company to record as an expense in its financial statements the fair value of all stock-based compensation awards. The terms and vesting schedules for stock-based awards vary by type of grant. Generally, the awards vest based on time-based (immediate to five years) and/or performance-based conditions. Performance-based vesting conditions generally include the attainment of goals related to the Company s development performance.

The Company accounts for stock-based compensation arrangements for non-employees under Emerging Issues Task Force No. 96-18, *Accounting for Equity Instruments That Are Issued to Other Than Employees for Acquiring, or in Conjunction with Selling, Goods or Services* (EITF 96-18) and SFAS No. 123, *Accounting for Stock-Based Compensation* (SFAS 123). As such, those transactions are measured on the grant date at either the fair value of the equity instruments issued or the consideration received, whichever is more reliably measurable.

(l) Loss per Common Share

The Company calculates loss per share in accordance with SFAS No. 128, *Earnings per 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, 2008	December 31, 2007
Warrants to purchase common stock	375,249	375,249
Options to purchase common stock	4,571,519	3,506,424
Total potentially dilutive securities	4,946,768	3,881,673

(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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Nile Therapeutics, Inc.

(A Development Stage Company)

Notes to Financial Statements (Continued)

(n) Income Taxes

The Company accounts for income taxes in accordance with SFAS No. 109, *Accounting for Income Taxes,* which requires the recognition of 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.

The Company adopted FASB Interpretation No. 48 (FIN 48), *Accounting for Uncertainty in Income Taxes* as of January 1, 2007, as required, and determined that the adoption of FIN 48 did not have a material impact on the Company s financial position and results of operations. The Company had no material unrecognized tax benefits before or after the adoption of FIN 48. There was no effect on the Company s financial position, results of operations or cash flows as a result of adopting FIN 48. The Company s policy is to recognize accrued interest and penalties for unrecognized tax benefits as a component of tax expense. As of December 31, 2008, there was no accrued interest and penalties for unrecognized tax benefits. During 2008, there was no interest or penalties included as a component of tax expense for unrecognized tax benefits.

(o) Recently Issued Accounting Standards

In June 2008, the Financial Accounting Standards Board, (FASB), issued FASB Staff Position, (FSP) Emerging Issuers Task Force (EITF) 03-6-1, *Determining Whether Instruments Granted in Share-Based Transactions Are Participating Securities*. This standard provides guidance in determining whether unvested instruments granted under share-based payment transactions are participating securities and, therefore, should be included in earnings per share calculations under the two-class method provided under SFAS No. 128, *Earnings per Share*. FSP EITF 03-6-1 is effective for fiscal years beginning after December 15, 2008, and interim periods within those fiscal years. The Company does not expect that the adoption of FSP EITF 03-6-1 will have a significant impact on its financial statements.

In April 2008, the FASB issued FSP FAS 142-3, *Determination of the Useful Life of Intangible Assets.* FSP FAS 142-3 amends the factors that should be considered in developing renewal or extension assumptions used to determine the useful life of a recognized intangible asset under SFAS No. 142, *Goodwill and Other Intangible Assets*. FSP FAS 142-3 aims to improve the consistency between the useful life of a recognized intangible asset under SFAS No. 142 and the period of expected cash flows used to measure the fair value of the asset under SFAS No. 141(R) and other applicable accounting literature. FSP FAS 142-3 is effective for financial statements issued for fiscal years beginning after December 15, 2008 and must be applied prospectively to intangible assets acquired after the effective date. The Company does not expect that the adoption of FSP FAS 142-3 will have a significant impact on its financial statements.

In December 2007, the Securities and Exchange Commission (SEC) issued Staff Accounting Bulletin (SAB) No. 110. SAB 110 expresses the views of the SEC regarding the use of a simplified or shortcut method, as discussed in SAB No. 107, Share-Based Payment , in developing an estimate of expected term of plain vanilla share options in accordance with SFAS No. 123(R). The guidance in SAB 110 is effective as of January 1, 2008. The adoption of SAB 110 did not have a material effect on the Company s financial statements.

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Nile Therapeutics, Inc.

(A Development Stage Company)

Notes to Financial Statements (Continued)

In December 2007, the FASB issued SFAS No. 141 (R), *Business Combinations* (SFAS 141(R)), which replaces SFAS 141. SFAS 141(R) establishes principles and requirements for how an acquirer recognizes and measures in its financial statements the identifiable assets acquired, the liabilities assumed, any non-controlling interest in the acquiree and the goodwill acquired. SFAS 141(R) also establishes disclosure requirements which will enable users to evaluate the nature and financial effects of the business combination. SFAS 141(R) is effective for business combinations for which the acquisition date is on or after the beginning of the first annual reporting period beginning on or after December 15, 2008. The Company does not anticipate that the adoption of this new standard will have any significant effect on its financial statements.

In December 2007, the FASB issued SFAS No. 160, *Noncontrolling Interests in Consolidated Financial Statements an Amendment of Accounting Research Bulletin No. 51* (SFAS 160) , which establishes accounting and reporting standards for ownership interests in subsidiaries held by parties other than the parent, the amount of consolidated net income attributable to the parent and to the noncontrolling interest, changes in a parent s ownership interest and the valuation of retained noncontrolling equity investments when a subsidiary is deconsolidated. SFAS 160 also establishes reporting requirements that provide sufficient disclosures that clearly identify and distinguish between the interests of the parent and the interests of the noncontrolling owners. SFAS 160 is effective for fiscal years, and interim periods within those fiscal years, beginning on or after December 15, 2008. The adoption of this new standard did not have any significant effect on the Company s financial statements.

In June 2007, the Emerging Issues Task Force (EITF) issued Issue 07-3, *Accounting for Nonrefundable Advance Payments for Goods or Services To Be Used in Future Research and Development Activities* (EITF 07-3), which concluded that nonrefundable advance payments for goods or services to be received in the future for use in research and development activities should be deferred and capitalized. The capitalized amounts should be expensed as the related goods are delivered or services are performed. Such capitalized amounts should be charged to expense if expectations change such that the goods will not be delivered or services will not be performed. The provisions of EITF 07-3 are effective for new contracts entered into during fiscal years beginning after December 15, 2007. The consensus may not be applied to earlier periods and early adoption is not permitted. The adoption of this new standard did not have any significant effect on the Company s financial statements.

In February 2007, the FASB issued SFAS No.159, *The Fair Value Option for Financial Assets and Financial Liabilities* (SFAS 159), including an Amendment of FASB Statement 115, which permits the measurement of many financial instruments and certain other asset and liabilities at fair value on an instrument-by-instrument basis (the fair value option). The guidance is applicable for fiscal years beginning after November 15, 2007. The adoption of this new standard did not have any significant effect on the Company s financial statements.

(p) Reclassifications

Certain prior period amounts have been reclassified in order to conform to current period presentation.

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Nile Therapeutics, Inc.

(A Development Stage Company)

Notes to Financial Statements (Continued)

5. PROPERTY AND EQUIPMENT

Property and equipment as of December 31, 2008 and 2007 consist of the following:

	2008	2007
Computer equipment	$ 33,930	$ 29,342
Office furniture and equipment	64,469	47,585
Leasehold improvements	9,528	
Total property and equipment	107,927	76,927
Accumulated depreciation	(34,228)	(14,089)
Total property and equipment, net	$ 73,699	$ 62,838

Depreciation expense related to property and equipment for the years ended December 31, 2008 and 2007 totaled $22,798 and $13,736, respectively, and $36,887 for the period from August 1, 2005 (inception) through December 31, 2008.

6. INTANGIBLE ASSETS AND INTELLECTUAL PROPERTY

Patents

At December 31, 2008, intangible assets consisted of patents and patent applications acquired from third parties for the CD-NP, CU-NP, and 2NTX-99 compounds with a cost basis of $313,288 and $265,971 at December 31, 2008 and 2007. Amortization expense was $ 90,491 and $13,248 for the years ended December 31, 2008 and 2007, respectively, and $ 103,739 for the period from August 1, 2005 (inception) through December 31, 2008. Estimated aggregate amortization expense of the Company s current intellectual property is approximately $80,000 for each of the next two fiscal years. In addition, there will be a onetime charge of approximately $48,000 in 2009 for the impairment of patents and patent applications associated with 2NTX-99.

License Agreements

CD-NP

On January 16, 2006, the Company entered into an exclusive, worldwide, royalty-bearing license agreement, or the Mayo 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 uses. The Company also holds the rights to improvements to CD-NP that arise out of the laboratory of Dr. John Burnett, the inventor of CD-NP, until January 19, 2009. Under the terms of the Mayo License Agreement, the Company paid Mayo an up-front cash payment and reimbursed it for past patent expenses. In addition, the Company issued 1,379,419 shares of common stock to Mayo. Mayo will receive performance-based cash payments upon successful completion of clinical and regulatory milestones relating to CD-NP. 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. The Company will also pay substantial milestone payments to Mayo 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. Pursuant to the Mayo 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 Mayo License Agreement requires the Company to issue shares of common stock to Mayo for an equivalent dollar amount of grants received in excess

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Notes to Financial Statements (Continued)

of $300,000, but not to exceed $575,000. For the period from August 1, 2005 (inception) through December 31, 2008, the Company received $482,235 in grant income for which it has issued to Mayo 63,478 shares (representing $182,236) of common stock.

CU-NP

Effective as of June 13, 2008, the Company entered into an exclusive, worldwide, royalty-bearing license agreement, or the CU-NP Mayo 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 13, 2011.

Under the terms of the CU-NP Mayo License Agreement, the Company paid Mayo an up-front cash payment. Additionally, Mayo will receive performance-based cash payments upon successful completion of 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 a product. Additional milestone payments will occur upon certain other events. Pursuant to the agreement, Nile must also pay Mayo an annual maintenance fee and a percentage of net sales of licensed products.

In addition to the cash payments described above with respect to the CU-NP Mayo License Agreement, the Company has also agreed to issue certain amounts and types of equity 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 has agreed to grant to Mayo an equivalent dollar value in stock warrants to purchase the Company s common stock. The number of warrants will be calculated using the Black-Scholes option-pricing model and will include a cashless exercise provision with language to be negotiated in good faith between the parties.

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. The intellectual property portfolio for 2NTX-99 included an issued United States patent and an issued European patent relating to its composition of matter, multiple methods of manufacturing, and method of use in treating a variety of atherothrombotic pathological conditions. Patent applications were filed in other major markets around the world.

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.

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.

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Nile Therapeutics, Inc.

(A Development Stage Company)

Notes to Financial Statements (Continued)

7. ACCRUED LIABILITIES

Accrued liabilities as of December 31, 2008 and 2007 consist of the following:

	2008	2007
Accrued compensation and related benefits	$ 205,919	$ 447,720
Accrued research and development expense	364,143	438,104
Accrued other expense	16,194	29,595
Total accrued liabilities	$ 586,256	$ 915,419

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 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 purchase 168,337 shares of common stock to the holders of the Notes. The warrants were valued at $288,000 using the Black-Scholes option-pricing model and the following assumptions: exercise price $2.71, a 3.98% risk-free interest rate, a 5 year contractual term, a dividend rate of 0%, and 68% expected volatility. The cost of the warrants was included in interest expense in the accompanying Statements of Operations, and as an increase in additional paid-in capital.

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

9. STOCKHOLDERS EQUITY

(a) Common Stock

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

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

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

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Notes to Financial Statements (Continued)

As a condition to the closing of the Merger, on September 11, 2007, Old Nile completed the 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 Mayo 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.

(b) Warrants

In conjunction with the conversion of the Notes, the Company issued fully vested warrants to purchase 168,337 shares of common stock to the holders of the Notes. The warrants were issued with an exercise price of $2.71 and expire in September 2012. As discussed in Note 8, the fair value of the warrants was determined to be $288,000. No 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: exercise price $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 (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.

10. STOCK-BASED COMPENSATION

(a) Stock Option Plan

The Company s 2005 Stock Option Plan (the Plan) was 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. 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.

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.

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.

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Nile Therapeutics, Inc.

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Notes to Financial Statements (Continued)

A summary of the status of the options issued under the Plan at December 31, 2008, and information with respect to the changes in options outstanding is as follows:

	Options Available for Grant	Options Outstanding	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	$
Exercisable at December 31, 2008		964,555	$ 2.59	$

The following table summarizes information about stock options outstanding at December 31, 2008:

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	317,940	6.56	$ 0.57	137,940	$ 0.09
$2.71 to $4.45	2,907,241	8.77	$ 2.89	705,323	$ 2.71
$4.50 to $5.75	752,588	9.21	$ 4.89	121,292	$ 4.71
Total	3,977,769	8.67	$ 3.08	964,555	$ 2.59

The weighted-average contractual term of options outstanding and options exercisable is 8.67 years and 2.59 years, respectively.

Employee stock-based compensation costs for the years ended December 31, 2008 and 2007 and for the cumulative period from August 1, 2005 (inception) through December 31, 2008 is as follows:

	Year ended December 31,		Period from August 1, 2005 (inception) through December 31, 2008
	2008	2007	
General and administrative	$ 1,990,438	$ 1,862,454	$ 3,852,892

Research and development	563,917	39,844	603,761
Total	$ 2,554,355	$ 1,902,298	$ 4,456,653

Included in the 2008 amounts is $74,520 for general and administrative and $43,232 for research and development expenses related to 2008 bonuses that were accrued but not granted until January 16, 2009.

The fair value of shares vested under the Plan for the years ended December 31, 2008 and 2007 and for the period from August 1, 2005 through December 31, 2008 were $1,689,762, $0 and $1,699,762, respectively.

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Notes to Financial Statements (Continued)

At December 31, 2008, total unrecognized estimated employee compensation cost related to stock options granted prior to that date was $4,859,223, which is expected to be recognized over a weighted-average vesting period of 2.19 years.

The weighted-average fair value on the grant date of options granted to employees during the year ended December 31, 2008 and 2007 and from August 1, 2005 (inception) through December 31, 2008 were $3.02, $1.83 and $2.06 per share, respectively. The fair value of options granted to employees during the years ended December 31, 2008 and 2007 was estimated using the Black-Scholes option-pricing model with the following range of assumptions:

	2008	2007
Expected volatility	75% to 137%	68% to 81%
Expected terms	5.50 to 6.25 years	5.00 to 6.25 years
Dividend yield	0%	0%
Risk-free interest rates	1.60% to 3.44%	3.70% to 4.28%

As allowed by SFAS 123(R) for companies with a 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. As the Company has so far only awarded plain vanilla options as defined by SAB 107, the Company used the simplified method for determining the expected life of the options granted.

The Company has no historical basis for determining expected forfeitures and as such, compensation expense for stock-based awards does not include an estimate for forfeitures. The Company adjusts share-based compensation on a quarterly basis for actual equity award forfeitures.

In accordance with the provisions of SFAS 123, and EITF No. 96-18, common stock, 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.

Stock-based compensation costs incurred for services by non-employees for the years ended December 31, 2008 and 2007, respectively, and for the cumulative period from August 1, 2005 (inception) through December 31, 2008 totaled $13,687, ($667), and $23,020. These amounts were included in research and development expense in the accompanying Statements of Operations.

(b) Other stock option grants

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. The options expire on September 17, 2012. The former executive was provided with limited piggy-back registration rights and was reimbursed for approximately $12,000 in attorney s fees. The fair value of the options on the grant date was $1.62 per share.

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Notes to Financial Statements (Continued)

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. For the year ended December 31, 2008, the Company has fully funded the 401(k) Plan. For the years ended December 31, 2008 and 2007, the costs associated with this plan were approximately $9,000 and $8,000, respectively.

12. INCOME TAXES

The Company adopted FIN 48 as of January 1, 2007, as required, and determined that the adoption of FIN 48 did not have a material impact on the Company s financial position and results of operations. The Company did not recognize interest or penalties related to income tax during the periods ended December 31, 2008 or 2007 and did not accrue for interest or penalties as of December 31, 2008 or 2007. The Company does not have an accrual for uncertain tax positions as of December 31, 2008. Tax returns for all years 2002 and thereafter are subject to future examination by tax authorities.

At December 31, 2008, the Company had no federal income tax expense or benefit but did have federal tax net operating loss carry-forwards of approximately $5,902,875. 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, 2007 are shown below. A valuation allowance of $8,488,217 has been established to offset the net deferred tax assets at December 31, 2008, as realization of such assets is uncertain.

	For Years Ended December 31,	
	2008	2007
Current deferred tax asset		
Non-cash stock issue	$	$
Others		
Non-current deferred tax assets		
Research tax credit	661,882	147,001
Net operating loss carry forwards	5,902,875	1,623,994
Others	1,923,460	819,202
Total deferred tax asset	8,488,217	2,590,197
Non-current deferred tax liability		
Total net deferred tax asset	8,488,217	2,590,197
Loss valuation allowance	(8,488,217)	(2,590,197)
Net deferred tax asset	$	$

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Nile Therapeutics, Inc.

(A Development Stage Company)

Notes to Financial Statements (Continued)

13. RELATED PARTIES

On occasion, some of the Company s expenses are paid by Two River, a company owned by several 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, 2008 and 2007, respectively, and for the period from August 1, 2005 (inception) through December 31, 2008, reimbursable expenses totaled $22,364, $96,290, and $154,840. In addition, during 2007 the Company paid $70,245 to Two River for consulting and due diligence efforts related to the licensing of 2NTX-99. As of December 31, 2008 the Company owes Two River approximately $6,700.

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

The Company utilized the services of Riverbank Capital Securities, Inc. (Riverbank), an entity owned by several of the Company s directors and founders, for investment banking and other investment advisory services in connection with the Financing. Fees charged by Riverbank totaled $100,000 for the financing and have been paid in full. There are no amounts outstanding to Riverbank as of December 31, 2008 and 2007.

The financial condition and results of operations of the Company, as reported, are not necessarily indicative of results that would have been reported had the Company operated completely independently.

14. COMMITMENTS AND CONTINGENCIES

The Company relocated its principal offices effective April 1, 2008 from Berkeley, California to San Francisco, California. The Company leased its office facility in Berkeley, California under a non-cancelable operating lease that was due to expire in April 2010. The total undiscounted future lease payments due under this lease as of March 31, 2008 were approximately $162,000. The Company recorded a loss liability of approximately $138,500, which was equal to the total future lease payments through the end of the lease, discounted at 16%. In June 2008, the Company entered into a lease termination and surrender of premises agreement with the landlord, under which the Company paid $57,000 and surrendered the $14,000 security deposit to terminate the lease.

On March 3, 2008 the Company signed a non-cancelable operating lease agreement to lease office space in San Francisco, California. The lease expires in March 2011. Future non-cancelable minimum lease payments under this lease are approximately $112,000 in 2009, $116,000 in 2010, and $29,000 in 2011, not including annual operating cost escalations. In connection with this lease, the Company delivered 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 shall be restricted for the entire period of the three-year lease agreement. Restricted cash is included in other noncurrent assets in the accompanying Balance Sheets.

Total rent expense in the years ended December 31, 2008 and 2007 was approximately $194,000 and $51,073, respectively.

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ITEM 9. CHANGES IN AND DISAGREEMENTS WITH ACCOUNTANTS ON ACCOUNTING AND FINANCIAL DISCLOSURE
None.

ITEM 9A. CONTROLS AND PROCEDURES
Management s Annual Report on Internal Control Over Financial Reporting

We maintain disclosure controls and procedures, as such term is defined in Rule 13a-15(e) under the Securities Exchange Act of 1934, as amended, or the Exchange Act, that are designed to ensure that information required to be disclosed by us in reports that we file or submit under the Exchange Act is recorded, processed, summarized and reported within the time periods specified in SEC rules and forms, and that such information is accumulated and communicated to our management, including our Chief Executive Officer and Chief Financial Officer, as appropriate to allow timely decisions regarding required disclosure. In designing and evaluating our disclosure controls and procedures, management recognized that disclosure controls and procedures, no matter how well conceived and operated, can provide only reasonable, not absolute, assurance that the objectives of the disclosure controls and procedures are met. Additionally, in designing disclosure controls and procedures, our management necessarily was required to apply its judgment in evaluating the cost-benefit relationship of possible disclosure controls and procedures. The design of any disclosure controls and procedures also is based in part upon certain assumptions about the likelihood of future events, and there can be no assurance that any design will succeed in achieving its stated goals under all potential future conditions.

Our management is responsible for establishing and maintaining adequate internal control over financial reporting as defined in Rule 13a-15(f) of the Exchange Act. Because of its inherent limitations, internal control over financial reporting may not prevent or detect misstatements. Also, projections of any evaluation of effectiveness to future periods are subject to the risk that controls may become inadequate because of changes in conditions, or that the degree of compliance with the policies or procedures may deteriorate.

As of December 31, 2008, we carried out an evaluation, under the supervision and with the participation of our Chief Executive Officer and the 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 Exchange). 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, 2008 that have materially affected, or are likely to materially affect, our internal controls over financial reporting. In making this assessment, we used the criteria set forth by the Committee of Sponsoring Organizations of the Treadway Commission in Internal Control Integrated Framework.

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, 2009. 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, 2009, 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.

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Changes in Internal Control Over Financial Reporting

There were no changes in our internal control over financial reporting during the quarter ended December 31, 2008 that have materially affected, or are reasonably likely to materially affect, our internal control over financial reporting.

ITEM 9B. OTHER INFORMATION

On March 10, 2009, the Compensation Committee of our Board of Directors approved certain amendments to the Employment Agreement, dated as of May 11, 2007, as amended to date, between Peter Strumph, our Chief Executive Officer, and us, the Offer Letter, dated February 22, 2008, between Hsiao D. Lieu, M.D., F.A.C.C., our Vice President of Clinical Research, and us, and the Offer Letter, dated April 25, 2008, between Jane Moffitt, our Vice President of Regulatory Affairs, and us, to change the definition of change of control in those agreements. The full details of the amendments described herein are set forth in the amendments, which are attached as Exhibits 10.18 through 10.20 to this Annual Report on Form 10-K.

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Part III

ITEM 10. DIRECTORS, EXECUTIVE OFFICERS AND CORPORATE GOVERNANCE

The information to be provided under the captions Management and Election of Directors, each to be contained in the Definitive Proxy Statement and required to be disclosed in this Item 10, is hereby incorporated by reference in this Item 10; and the information to be provided under the caption Section 16(a) Beneficial Ownership Reporting Compliance, to be contained in the Definitive Proxy Statement and required to be disclosed pursuant to Section 16(a) of the Exchange Act, is also hereby incorporated by reference in this Item 10.

We have adopted a written code of business conduct and ethics that applies to our principal executive officer, principal financial officer, principal accounting officer or controller, or persons serving similar functions. The code of business conduct and ethics is attached as an exhibit to this Annual Report and is also available on our corporate website (www.nilethera.com).

ITEM 11. EXECUTIVE COMPENSATION

The information to be provided under the caption Compensation of Directors and Executive Officers, to be contained in the Definitive Proxy Statement and required to be disclosed in this Item 11, is hereby incorporated by reference in this Item 11.

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

The information to be provided under the captions Equity Compensation Plan Information and Security Ownership of Certain Beneficial Owners and Management, each to be contained in the Definitive Proxy Statement and required to be disclosed in this Item 12, is hereby incorporated by reference in this Item 12.

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

The information to be provided under the caption Certain Relationships and Related Transactions, and Director Independence, to be contained in the Definitive Proxy Statement and required to be disclosed in this Item 13, is hereby incorporated by reference in this Item 13.

ITEM 14. PRINCIPAL ACCOUNTING FEES AND SERVICES

The information to be provided under the caption Principal Accounting Fees and Services, to be contained in the Definitive Proxy Statement and required to be disclosed in this Item 14, is hereby incorporated by reference in this Item 14.

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PART IV

ITEM 15. EXHIBITS, 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 from the Company s current report on Form 8-K filed with the Commission dated August 18, 2007).
3.1	Certificate of Incorporation of SMI Products, Inc. (incorporated by reference from the Company s current report on Form 8-K filed with the Commission dated September 9, 2007).
3.2	Bylaws of SMI Products, Inc. (incorporated by reference from the Company s current report on Form 8-K filed with the Commission dated September 9, 2007).
4.1	Specimen Common Stock Certificate (incorporated by reference from the Company s current report on Form 8-K filed with the Commission dated September 21, 2007).
4.2	Form of Nile Therapeutics, Inc. Common Stock Purchase Warrant (incorporated by reference from the Company s current report on Form 8-K filed with the Commission dated September 21, 2007).
10.1	Employment Agreement between Nile Therapeutics, Inc. and Peter M. Strumph dated May 11, 2007 (incorporated by reference from the Company s current report on Form 8-K filed with the Commission dated September 21, 2007).
10.2	Amendment of Employment Agreement, by and between Nile Therapeutics, Inc. and Peter Strumph, dated March 4, 2008 (incorporated by reference from the Company s current report on Form 8-K filed with the Commission dated March 5, 2008).
10.3	Amendment of Incentive Stock Option Agreement, by and between Nile Therapeutics, Inc. and Peter Strumph, dated March 4, 2008 (incorporated by reference from the Company s current report on Form 8-K filed with the Commission dated March 5, 2008).
10.4	Employment Agreement between Nile Therapeutics, Inc. and Daron Evans dated January 19, 2007 (incorporated by reference from the Company s current report on Form 8-K filed with the Commission dated September 21, 2007).
10.5	Amendment No. 1 to Employment Agreement between Nile Therapeutics, Inc. and Daron Evans dated August 19, 2007 (incorporated by reference from the Company s current report on Form 8-K filed with the Commission dated September 21, 2007).
10.6	Amendment of Employment Agreement, by and between Nile Therapeutics, Inc. and Daron Evans, dated March 4, 2008 (incorporated by reference from the Company s current report on Form 8-K filed with the Commission dated March 5, 2008).
10.7	Amendment of Incentive Stock Option Agreement, by and between Nile Therapeutics, Inc. and Daron Evans, dated March 4, 2008 (incorporated by reference from the Company s current report on Form 8-K filed with the Commission dated March 5, 2008).
10.8	Letter Agreement between Nile Therapeutics, Inc. and Jennifer L. Hodge, dated August 31, 2007 (incorporated by reference from the Company s current report on Form 8-K filed with the Commission dated September 21, 2007).
10.9	Offer Letter between the Company and Hsiao Dee Lieu, M.D., F.A.C.C. entered into on February 22, 2008 (incorporated by reference from the Company s current report on Form 8-K filed with the Commission dated February 27, 2008).
10.10	Offer Letter between the Company and Jane Moffitt entered into on April 25, 2008 (incorporated by reference from the Company s current report on Form 8-K filed with the Commission dated April 25, 2008).

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Exhibit No.	Description
10.11	License Agreement between Nile Therapeutics, Inc., dated August 6, 2007 (incorporated by reference from the Company s current report on Form 8-K filed with the Commission dated September 21, 2007).*
10.12	License Agreement between Nile Therapeutics, Inc. and Dr. Cesare Casagrande, dated August 6, 2007 (incorporated by reference from the Company s current report on Form 8-K filed with the Commission dated September 21, 2007).
10.13	Lease Agreement between Nile Therapeutics, Inc. and AG/SIC-115 Sansome, LLC, dated January 25, 2008 (incorporated by reference from the Company s current report on Form 8-K filed with the Commission dated March 5, 2008).
10.14	Amended and Restated 2005 Stock Option Plan (incorporated by reference from the Company s current report on Form 8-K filed with the Commission dated March 5, 2008).
10.15	Form of Stock Option Plan (incorporated by reference from the Company s current report on Form 8-K filed with the Commission dated September 21, 2007).
10.16	Form of Stock Option Agreement (incorporated by reference from the Company s current report on Form 8-K filed with the Commission dated September 21, 2007).
10.17	Form of Incentive Stock Option Agreement (incorporated by reference from the Company s current report on Form 8-K filed with the Commission dated September 21, 2007).
10.18	Amendment of Employment Agreement, dated as of March 10, 2009, by and between Nile Therapeutics, Inc. and Peter M. Strumph.
10.19	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.
10.20	Amendment to Offer Letter, dated as of March 10, 2009, by and between Nile Therapeutics, Inc. and Jane Moffitt.
14.1	Code of Business Conduct and Ethics, as amended to date (incorporated by reference from the Company s current report on Form 8-K filed with the Commission dated December 14, 2007).
16.1	Letter from Paritz & Co dated September 20, 2007 regarding change in certifying accountants (incorporated by reference from the Company s current report on Form 8-K filed with the Commission dated September 21, 2007).
23.1	Consent of Hays & 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 requested as to certain portions of this exhibit. Such portions have been redacted and filed separately with the SEC.

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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 11, 2009.

NILE THERAPEUTICS, INC.

BY: /s/ PETER M. STRUMPH
Peter M. Strumph
Chief Executive Officer

KNOW ALL MEN BY THESE PRESENTS, that we, the undersigned officers and directors of Nile Therapeutics, Inc., hereby severally constitute Peter Strumph 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/ PETER M. STRUMPH	Chief Executive Officer and Director	March 11, 2009
Peter M. Strumph	*(Principal Executive Officer)*	
/s/ DARON EVANS	Chief Financial Officer	March 11, 2009
Daron Evans	*(Principal Financial and Accounting Officer)*	
/s/ PETER M. KASH	Chairman of the Board of Directors	March 11, 2009
Peter M. Kash		
/s/ PEDRO GRANADILLO	Director	March 11, 2009
Pedro Granadillo		
/s/ JOSHUA A. KAZAM	Director	March 11, 2009
Joshua A. Kazam		
/s/ GREGORY W. SCHAFER	Director	March 11, 2009
Gregory W. Schafer		
/s/ PAUL A. MIEYAL, PH.D.	Director	March 11, 2009
Paul A. Mieyal, Ph.D.		

/s/ DAVID M. TANEN	Director	March 11, 2009

David M. Tanen