Nile Therapeutics, Inc.
Form 8-K
September 21, 2007

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

FORM 8-K

CURRENT REPORT
Pursuant to Section 13 or 15(d) of
the Securities and Exchange Act of 1934

Date of Report (date of earliest event reported):
September 17, 2007

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

Delaware	**333-55166**	**88-0363465**
(State or other jurisdiction of incorporation)	(Commission File Number)	(IRS Employer Identification No.)

2850 Telegraph Avenue, Suite #310 **Berkeley, CA**	**94705**
(Address of principal executive offices)	(Zip Code)

Registrant's telephone number, including area code:
(510) 281-7700

(Former name or former address, if changed since last report)
SMI Products, Inc.
122 Ocean Park Blvd.
Suite 307
Santa Monica, California 90405

Check the appropriate box below if the Form 8-K filing is intended to simultaneously satisfy the filing obligation of the registrant under any of the following provisions (*see* General Instruction A.2. below):

o Written communications pursuant to Rule 425 under the Securities Act (17 CFR 230.425)

o Soliciting material pursuant to Rule 14a-12 under the Exchange Act (17 CFR 240.14a-12)

o Pre-commencement communications pursuant to Rule 14d-2(b) under the Exchange Act (17 CFR 240.14d-2(b))

o Pre-commencement communications pursuant to Rule 13e-4(c) under the Exchange Act (17 CFR 240.13e-4(c))

SAFE HARBOR STATEMENT UNDER THE PRIVATE SECURITIES LITIGATION REFORM ACT OF 1995

This current report on Form 8-K (this Report) contains "forward-looking statements" within the meaning of Section 27A of the Securities Act of 1933 (the Securities Act) and Section 21E of the Securities Exchange Act of 1934 (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," "intends," "may," "will" or "should" or, in each case, their neg 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, 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.

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. Examples of the risks and uncertainties include, but are not limited to:

- the risk that we may not successfully develop and market our products, and even if we do, we may not become profitable;
- risks relating to the progress of our research and development;
- risks relating to significant, time-consuming and costly research and development efforts, including pre-clinical studies, clinical trials and testing, and the risk that clinical trials may be delayed, halted or fail;
- risks relating to the rigorous regulatory approval process required for any products that we may develop independently, with our development partners or in connection with our collaboration arrangements;
- the risk that changes in the national or international political and regulatory environment may make it more difficult to gain U.S. Food and Drug Administration,(FDA) or other regulatory approval of our drug product candidates;
- risks that the FDA or other regulatory authorities may not accept any applications we file;
- risks that the FDA or other regulatory authorities may withhold or delay consideration of any applications that we file or limit such applications to particular indications or apply other label limitations;
- risks that, after acceptance and review of applications that we file, the FDA or other regulatory authorities will not approve the marketing and sale of our drug product candidates;

- risks relating to our drug manufacturing operations, including those of our third-party suppliers and contract manufacturers;

- risks relating to the ability of our development partners and third-party suppliers of materials, drug substance and related components to provide us with adequate supplies and expertise to support manufacture of drug product for initiation and completion of our clinical studies;

- risks relating to the transfer of our manufacturing technology to third-party contract manufacturers;

- the risk that recurring losses, negative cash flows and the inability to raise additional capital could threaten our ability to continue as a going concern;

- other risks and uncertainties detailed in “Risk Factors” and in the documents incorporated by reference in this report.

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. Except to the extent required by applicable laws or rules, we do not undertake to update any forward-looking statements or to publicly announce revisions to any of our forward-looking statements, whether resulting from new information, future events or otherwise.

ITEM 2.01

1. CHANGES IN CONTROL OF REGISTRANT

The disclosures set forth under Item 2 are incorporated by reference into this Item 1.

2. COMPLETION OF ACQUISITION OR DISPOSITION OF ASSETS

Closing of Merger

Pursuant to the merger agreement dated August 15, 2007 (Merger Agreement), between SMI Products, Inc. (SMI), Nile Merger Sub., Inc., a Delaware corporation and wholly-owned subsidiary of SMI (Nile Merger Sub), and Nile Therapeutics, Inc., a Delaware corporation (Old Nile), on September 17, 2007, Nile Merger Sub merged with and into Old Nile, with Old Nile remaining as the surviving entity and a wholly-owned operating subsidiary of SMI. SMI’s entry into the Merger Agreement was disclosed on SMI’s Current Report on Form 8-K filed with the SEC on August 17, 2007. On September 17, 2007, SMI filed a Certificate of Ownership with the Secretary of State of the State of Delaware pursuant to which Old Nile, SMI’s wholly-owned subsidiary by virtue of the Merger, merged with and into SMI with SMI 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 corporate name to “Nile Therapeutics, Inc.” (referred to throughout this Report as “Nile”). The Certificate of Ownership is filed with the Secretary of State of the State of Delaware. These two transactions are referred to throughout this Report as the “Merger.” Unless the context otherwise requires, hereafter in this report the terms the “Company,” “we,” “us,” or “our” refer to Nile, after giving effect to the Merger.

Each share of common stock, par value $0.001 per share of Old Nile (Old Nile Common Stock), that was outstanding immediately prior to the Merger was cancelled or exchanged for 2.758838 shares of SMI’s common stock, par value $0.001 per share (the SMI Common Stock), and one share of Old Nile Common Stock was issued to SMI. Simultaneously, SMI issued to the former holders of Old Nile Common Stock in exchange for their shares of Old Nile Common Stock, an aggregate of 22,849,716 shares of SMI Common Stock, making Old Nile a wholly-owned subsidiary of 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 for the

purchase of an aggregate of 3,572,350 shares of SMI Common Stock. In addition to the 755,100 shares of SMI Common Stock that were issued and outstanding prior to the effective time of the Merger, we also issued 494,900 shares of SMI Common Stock to Fountainhead Capital Partners Limited, or Fountainhead Capital, upon the conversion of $168,573 of convertible promissory notes and accrued interest.

At the effective time of the Merger, our board of directors was reconstituted by the resignation of Mr. Geoffrey Alison from his role as our sole director and the appointment of Mr. Peter Strumph, Mr. Peter Kash, Mr. Joshua Kazam, Mr. David Tanen, and Dr. Paul Mieyal as directors (all of whom were directors of Old Nile immediately prior to and after the Merger). Our executive management team also was reconstituted following the resignation of Mr. Alison as SMI's president, and new officers were appointed in place of our former officers. See "*Directors and Executive Officers, Promoters and Control Persons.*"

The former holders of Old Nile Common Stock now beneficially own approximately 95% of the outstanding shares of our capital stock. Accordingly, the Merger represents a change in control. As of the date of this report, there are 24,099,716 shares of SMI Common Stock outstanding. For accounting purposes, the Merger has been accounted for as an acquisition of SMI and a recapitalization of Old Nile, with Old Nile as the accounting acquirer (legal acquiree) and SMI as the accounting acquiree (legal acquiror). Unless the context otherwise requires, we refer to the SMI Common Stock following the Merger as Nile Common Stock.

Recent Financings

On March 28, 2006, Old Nile issued to certain qualified investors 6% Convertible Promissory Notes in the aggregate principal amount of approximately $4,000,000 (the 6% Notes). The 6% Notes provided that upon the closing of any equity financing in excess of $5,000,000 (a Qualified Financing), the 6% Notes would automatically convert into the same securities issued by Old Nile in the Qualified Financing (Conversion Shares), in an amount determined by dividing the principal amount of the 6% Notes, and all accrued interest thereon, by 90% of the price per share sold in the Offering (as such term is defined below) (the Offering Price). In addition, upon conversion, Old Nile agreed to issue to the holders of the 6% Notes five-year warrants (Conversion Warrants), to purchase a number of shares of Nile Common Stock equal to 10% of the Conversion Shares at an exercise price equal to the Offering Price.

On July 24, 2007, Old Nile issued to Iota Investors, LLC an 8% Promissory Note (the 8% Promissory Note) in the aggregate principal amount of $1,500,000, which has been repaid in full, together with a premium of $120,000. In addition, Old Nile paid the investor $30,000 (2%) out of the proceeds of that financing.

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 2,522,064 shares of Old Nile Common Stock in a private placement to certain qualified investors (the Offering). Contemporaneously with the Offering, the 6% Notes converted into 610,433 Conversion Shares and the 6% Noteholders received Conversion Warrants to purchase an aggregate of 61,028 shares of Old Nile Common Stock.

The issuance and sale of the promissory notes and other instruments described above were made pursuant to privately negotiated transactions that did not involve a public offering of securities and, accordingly, we believe that these transactions were exempt from the registration requirements of the Securities Act pursuant to Section 4(2) thereof and the rules promulgated thereunder. In addition, we believe that the 8% Promissory Note is commercial paper and is exempt from the registration requirements of the Securities Act under Section 3(a)3 thereof. Each of the above-referenced investors represented to us that they were "accredited investors" (as defined by Rule 501 under the Securities Act) and were acquiring the shares for investment and not distribution, that they could bear the risk of loss of the investment and could hold the securities for an indefinite period of time. The investors received written disclosures that the securities had not been registered under the Securities Act and that any resale must be made pursuant to a registration or an available exemption from such registration. All of the foregoing securities are deemed restricted securities for purposes of the Securities Act.

The issuance of the SMI Common Stock to the shareholders of Old Nile in the Merger was exempt from registration under the Securities Act pursuant to Section 4(2) thereof. We have made this determination based on the representations of the Old Nile shareholders and investors which included, in pertinent part, that such persons were either "accredited investors" or were acting through a "purchaser representative," each within the meaning of Rule 501 of

Regulation D promulgated under the Securities Act, that such persons were acquiring the shares of SMI Common Stock issued to them pursuant to the Merger, for investment purposes for their own respective accounts and not as nominees or agents, and not with a view to the resale or distribution thereof in violation of the Securities Act, and that each person understood that the shares of the SMI Common Stock issued in the Merger may not be sold or otherwise disposed of without registration under the Securities Act or an applicable exemption therefrom.

INFORMATION REQUIRED PURSUANT TO FORM 10-SB

See the "Glossary of Terms" included in this Report for definitions of certain technical terms used in this report that are commonly used in the pharmaceutical and biotechnology industries.

PART I

1. DESCRIPTION OF BUSINESS

Business of SMI

SMI was incorporated in the State of Nevada on June 17, 1996. On October 16, 2006, SMI changed its domicile to the State of Delaware. From inception through August 11, 2006, SMI was a development stage company in the business of internet real estate mortgage services. From and after August 11, 2006, SMI ceased its prior business. Upon completion of the Merger, we adopted Nile's business plan.

Employees

SMI had no employees at the time of the Merger.

Business of Nile

Organization and Corporate History

Old Nile was incorporated in the State of Delaware on August 1, 2005, under the name Nile Pharmaceuticals, Inc. Old Nile changed its name to Nile Therapeutics, Inc. on January 18, 2007.

Business in General

Our company develops and commercializes innovative products for the treatment of cardiovascular and metabolic disease. Our lead compound is CD-NP, a chimeric natriuretic peptide in Phase I clinical studies for the treatment of heart failure. We are also developing 2NTX-99, a pre-clinical small molecule, anti-atherothrombotic agent with nitric oxide-donating properties.

CD-NP

CD-NP is a rationally-designed synthetic peptide developed by researchers at The Mayo Foundation for Medical Education and Research, or Mayo, to incorporate the optimal components of naturally occurring natriuretic peptides. CD-NP is a selective NPR_B agonist that has shown potent renal enhancement and cardiac unloading properties *in vivo.* Importantly, however, CD-NP appears to do so with minimal hypotensive effects as compared with competitive products. In multiple preclinical studies, including a large animal model of congestive heart failure, CD-NP demonstrated potent therapeutic activity compared to Natrecor®, a natriuretic peptide currently marketed by Scios Inc. (a Johnson & Johnson company) to treat acute heart failure, including producing less hypotension then Natrecor® and improving fluid unloading at equimolar doses.

We recently completed a Phase Ia 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, and identifying a dose for use in later stage studies. Data from this first in-human study confirmed several preclinical findings, including that CD-NP potently activated its target receptor in humans, preserved renal function and caused increases in natriuresis (sodium excretion) and diuresis (urine excretion) at doses associated with a minimal effect on mean arterial pressure. Two additional comprehensive Phase Ib studies to assess the safety and

pharmacodynamic profile of CD-NP in heart failure patients are planned for initiation in the fourth quarter of 2007.

2NTX-99

The second molecule in our pipeline is 2NTX-99, a novel small molecule that has been shown *in vivo* and *in vitro* to inhibit the synthesis and action of thromboxane (TXA_2), enhance the production of prostacyclin (PGI_2) and supply pharmacological amounts of nitric oxide (NO) to the vasculature. TXA_2, produced by activated platelets, is believed to have prothrombotic properties, stimulating activation of new platelets as well as increasing platelet aggregation. TXA_2 is implicated in a number of inflammatory and thrombotic conditions, particularly in diabetic populations. PGI_2 reverses many of these inflammatory and thrombotic processes, and acts chiefly to prevent platelet formation and clumping involved in blood clotting, and is also an effective vasodilator. NO-donation is hypothesized to act synergistically with PGI_2 *in vivo* to relax the vasculature and protect against atherosclerotic conditions.

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 intend to initiate pre-clinical toxicology and manufacturing activities for 2NTX-99 in the third quarter of 2007, and we plan to file an IND and enter human testing by the end of 2009.

Intellectual Property

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 U.S. 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 U.S. and abroad. However, even patent protection 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. See *"Risk Factors -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."*

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. See "*Risk Factors -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."*

License Agreements

On January 20, 2006, we entered into an exclusive, worldwide, royalty-bearing license agreement, or the Mayo License Agreement, with Mayo for the rights to issued patents, patent applications and know-how relating to CD-NP for all therapeutic uses. We also have the rights to improvements to CD-NP that arise out of the laboratory of Dr. John Burnett, the inventor of CD-NP, until January 20, 2009. We intend to continue to expand our patent portfolio by filing to protect any additional patents covering expanded uses for this technology.

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 500,000 shares of Old Nile Common Stock to Mayo. On August 31, 2007, Mayo transferred 200,000 shares to Miami Research Heart Institute (Miami Heart). Mayo's shares converted

into 827,651 shares of Nile Common Stock and Miami Heart's shares converted into 551,767 shares of Nile Common Stock at the effective time of the Merger. Additionally, Mayo will receive performance-based cash payments upon successful completion of clinical and regulatory milestones relating to CD-NP. We will make the first milestone payment to Mayo when the first patient is dosed in the first Company-sponsored Phase II clinical trial of CD-NP. 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. To the extent we enter into a sublicensing agreement relating to CD-NP, we will be responsible for each sub-licensee's adherence to the terms of the Mayo License Agreement and a breach of a sub-license agreement by a sub-licensee will constitute a breach of the Mayo License Agreement by us. 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. 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 Nile Common Stock to Mayo for an equivalent dollar amount of grant funding by Mayo of Dr. Burnett's CD-NP development program, above a threshold amount of grant funding not to exceed a specified amount of grant dollars. As of the date hereof, Mayo has funded a substantial portion of this amount of grant funding for CD-NP. Accordingly, following the closing of the Offering, Old Nile issued Mayo 23,009 shares of Old Nile Common Stock, which converted into 63,478 shares at the Merger. In addition, to the extent that Mayo funds up to an additional $92,765 in grant money, we are obligated to issue additional shares to Mayo contemporaneously with the closing of the first equity financing thereafter. See "*Risk Factors -If requirements under our license agreements are not met, we could suffer significant harm, including rights to our products*."

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 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 includes an issued U.S. patent and a pending European Patent Cooperative Treaty submission relating to its composition of matter, multiple methods of manufacturing, and method of use in treating a variety of atheroclerotic-thrombotic pathological conditions.

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 to Dr. Casagrande 126,904 shares of Old Nile Common Stock, which converted into 350,107 shares of Nile Common Stock at the effective time of the Merger. Additionally, the agreement provides for cumulative performance-based milestone payments to Dr. Casagrande upon completion of clinical and regulatory milestones relating to 2NTX-99 in the U.S., Europe and Japan. We will also be required to make certain milestones 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 will be due when the first patient is dosed in the first Company sponsored Phase I clinical trial of 2NTX-99 in the U.S. or the European Union. We also expect to be required to make quarterly royalty payments to Dr. Casagrande equal to a percentage of net sales of licensed products by us and our sub-licensees. The 2NTX-99 License Agreement also contains other customary clauses and terms as are common in similar agreements in the industry. See "*Risk Factors -If requirements under our license agreements are not met, we could suffer significant harm, including rights to our products.*"

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 2NTX-99. Our success will depend, in part, upon our ability to achieve market share at the expense of existing established 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 for new products to treat cardiovascular and metabolic 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 existing competitors include, without limitation Scios Inc. (a Johnson & Johnson company), Astellas Pharma, PDL Biopharma, Zealand Pharma, and NovaCardia.

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 (ACE) inhibitors, angiotensin receptor blockers (ARBs), beta-blockers, pentoxifylline and cilostazol. Some of our existing competitors include, without limitation, Brystol Myers Squibb Inc., Eli Lilly and Company, CardioVascular BioTherapeutics, Inc., and Keryx Biopharmaceuticals, Inc.

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Our competitors generally have substantially more resources than we do, including both financial and technical. In addition, many of these companies have more experience than Nile in preclinical 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. See *"Risk Factors Đevelopments by competitors may render our products or technologies obsolete or non-competitive."*

Government Regulation

The research, development, testing, manufacture, labeling, promotion, advertising, distribution, and marketing, among other things, of our products are extensively regulated by governmental authorities in the U.S. and other countries. In the U.S., the FDA, regulates drugs under the Federal Food, Drug, and Cosmetic Act, or the FDCA, and its implementing regulations. Failure to comply with the applicable U.S. 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 U.S. until the drug has received FDA approval. The steps required before a drug may be marketed in the U.S. include:

- preclinical 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.

Preclinical tests include laboratory evaluation of product chemistry, toxicity, and formulation, as well as animal studies. The conduct of the preclinical tests and formulation of the compounds for testing must comply with federal regulations and requirements. The results of the preclinical 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. The Company cannot be sure that submission of an IND will result in the FDA allowing clinical trials to begin.

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

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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 people 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, the Company 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 application. 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 preclinical 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. The Company cannot be sure that any of our drugs will qualify for any of these programs, or that, if a drug does qualify, that the review time will be reduced.

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

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

After approval, certain changes to the approved product, such as adding new indications, making certain manufacturing changes, or making certain additional labeling claims, are subject to further FDA review and approval. Before a company can market products for additional indications, it must obtain additional approvals from the FDA.

Obtaining approval for a new indication generally requires that additional clinical studies be conducted. The Company cannot be sure that any additional approval 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 conditions are not satisfied, the FDA may withdraw its approval of the drug. In addition, holders of an approved NDA are required to (i) report certain adverse reactions to the FDA; (ii) comply with certain requirements concerning advertising and promotional labeling for their products; and (iii) 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.

Research and Development

Our research and development expenses consist primarily of salaries and related personnel costs, fees paid to consultants and outside service providers for regulatory and quality assurance support, licensing of drug compounds, and other expenses relating to the manufacture, development, testing and enhancement of our product candidates. We expense our research and development costs as they are incurred.

Employees

As of the date of this Report, we have four employees, all of whom are full-time. We also retain several consultants who serve in various operational capacities. We expect to hire a full-time controller, as well as additional research and development and administrative staff in support of our existing product development.

RISK FACTORS

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

On September 17, 2007, the Merger was completed, and the business of Old Nile was adopted as our business. As such, the following Risk Factors are focused on the current and historical operations of Nile, and generally exclude the risks associated with the prior operations of SMI.

We currently have no product revenues and will need to raise substantial additional capital to operate our business.

To date, we have generated no 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. Therefore, for the foreseeable future, we will have to fund all of our operations and capital expenditures from the net proceeds of the Offering, cash on hand, licensing fees and grants.

The use of the proceeds from the Offering will depend on many factors, including among other things the course of the clinical and regulatory development of CD-NP and 2NTX-99 and the acquisition of new technologies and personnel. Based on our current development plans, we expect that our current resources will be sufficient to fund our operations until the first quarter of 2009. We will need to seek substantial additional financing in order to continue developing our current and any future product candidates, which additional financing may not be available on favorable terms, if at all.

If we do not succeed in raising additional funds on acceptable terms, we may be unable to complete planned pre-clinical testing and human clinical trials or obtain approval of our product candidates from the FDA and other regulatory authorities. In addition, we could be forced to discontinue product development, reduce or forego attractive business opportunities. Any additional sources of financing will likely involve the issuance of our equity securities, which will have a dilutive effect on our stockholders.

We are not currently profitable and may never become profitable.

We expect to incur substantial losses and negative operating cash flow for the foreseeable future, and we may never achieve or maintain profitability. For the six months ended June 30, 2007, we had a net loss of $2,237,825 and for the period from our inception on August 1, 2005, through the year ended December 31, 2006, we had a net loss of $2,592,015. Since our inception through June 30, 2007, we have an accumulated deficit of $4,829,840 and stockholders' equity (deficit) of ($4,817,673). 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 will need to generate significant revenues in order to achieve and maintain profitability. We may not be able to generate these revenues or achieve profitability in the future. Our failure to achieve or maintain profitability could negatively impact the value of Nile Common Stock.

We have a limited operating history upon which to base an investment decision.

We are a development-stage company and have not demonstrated our ability to perform the functions necessary for the successful commercialization of any of our product candidates. The successful commercialization of our product candidates will require us to perform a variety of functions, including:

- continuing to undertake pre-clinical development and clinical trials for our product candidates;
- participating in regulatory approval processes;
- formulating and manufacturing products; and
- conducting sales and marketing activities.

Our operations have been limited to organizing our Company, acquiring, developing and securing our proprietary technology and preparing for pre-clinical and clinical trials of our lead product candidate, CD-NP. These operations provide a limited basis for you to assess our ability to commercialize our product candidates and the advisability of investing in our securities.

We may not obtain the necessary U.S. or worldwide regulatory approvals to commercialize our product candidates.

We will need FDA approval to commercialize our product candidates in the U.S. and approvals from the FDA equivalent regulatory authorities in foreign jurisdictions to commercialize our product candidates in those jurisdictions. In order to obtain FDA approval of any of our product candidates, we must submit to the FDA a 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. 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.

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.

In foreign jurisdictions, we must receive approval from the appropriate regulatory authorities before we can commercialize our drugs. Foreign regulatory approval processes generally include all of the risks associated with the FDA approval procedures described above. We cannot assure that we will receive the approvals necessary to commercialize our product candidate for sale outside the U.S.

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Each of our product candidates is in early stages of development.

Each of our product candidates, CD-NP and 2NTX-99, 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 U.S. 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 U.S. 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 therapeutic approaches and technologies 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.

The results of our clinical trials may not support our product candidate claims.

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. The 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.

Physicians and patients may not accept and use our drugs.

Even if the FDA approves our product candidates, physicians and patients may not accept and use them. Acceptance and use of our product will depend upon a number of factors including:

- perceptions by members of the health care community, including physicians, about the safety and effectiveness of our drugs;
- cost-effectiveness of our products relative to competing products;
- availability of reimbursement for our products from government or other healthcare payers; and
- effectiveness of marketing and distribution efforts by us and our licensees and distributors, if any.

Because we expect sales of our current product candidates, if approved, to generate substantially all of our product revenues for the foreseeable future, the failure of any of these drugs to find market acceptance would harm our business and could require us to seek additional financing.

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 needs and commercial needs, if any.

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

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

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

We have no experience selling, marketing or distributing products and no internal capability to do so.

We currently have no sales, marketing or distribution capabilities. We do not anticipate having resources in the foreseeable future to allocate to the sales and marketing of our proposed products. Our future success depends, in part, on our ability to enter into and maintain sales and marketing collaborative relationships, 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 U.S. or overseas.

If we cannot compete successfully for market share against other drug companies, we may not achieve sufficient product revenues and our business will suffer.

The market for our product candidates is characterized by intense competition and rapid technological advances. If our product candidates receive FDA approval, they will compete with a number of existing and future drugs and therapies developed, manufactured and marketed by others. Existing or future competing products may provide greater therapeutic convenience or clinical or other benefits for a specific indication than our products, or may offer comparable performance at a lower cost. If our products fail to capture and maintain market share, we may not achieve sufficient product revenues and our business will suffer.

We will compete against fully integrated pharmaceutical companies and smaller companies that are collaborating with larger pharmaceutical companies, academic institutions, government agencies and other public and private research organizations. Many of these competitors have technologies already approved or in development. In addition, many of these competitors, either alone or together with their collaborative partners, operate larger research and development programs and have substantially greater financial resources than we do, as well as significantly greater experience in:

- developing drugs;
- undertaking pre-clinical testing and human clinical trials;
- obtaining FDA and other regulatory approvals of drugs;
- formulating and manufacturing drugs; and
- launching, marketing and selling drugs.

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 U.S. 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 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 success, competitive position and future revenues will depend in part on our ability and the abilities of our licensors to obtain and maintain patent protection for our products, methods, processes and other technologies, to preserve our trade secrets, to prevent third parties from infringing on our proprietary rights and to operate without infringing upon the proprietary rights of third parties. Additionally, if any third-party manufacturer makes improvements in the manufacturing process for our products, we may not own, or may have to share, the intellectual property rights to the innovation.

To date, we hold certain exclusive rights under U.S. patents and patent applications as well as rights under foreign patent applications. We anticipate filing additional patent applications both in the U.S. and in other countries, as appropriate. However, we cannot predict:

- the degree and range of protection any patents will afford us against competitors including whether third parties will find ways to invalidate or otherwise circumvent our patents;

- if and when patents will issue;
- whether or not others will obtain patents claiming aspects similar to those covered by our patents and patent applications; or
- whether we will need to initiate litigation or administrative proceedings which may be costly whether we win or lose.

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.

If we infringe upon the rights of third parties we could be prevented from selling products, forced to pay damages, and defend against litigation.

If our products, methods, processes and other technologies infringe upon the proprietary rights of other parties, we could incur substantial costs and we may have to:

- obtain licenses, which may not be available on commercially reasonable terms, if at all;
- redesign our products or processes to avoid infringement;
- stop using the subject matter claimed in the patents held by others;
- pay damages; or
- defend litigation or administrative proceedings which may be costly whether we win or lose, and which could result in a substantial diversion of our valuable management resources.

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 and Dr. Casagrande. 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.

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.

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

Our ability to commercialize our drugs, alone or with collaborators, will depend in part on the extent to which reimbursement will be available from:

- government and health administration authorities;
- private health maintenance organizations and health insurers; and
- other healthcare payers.

Significant uncertainty exists as to the reimbursement status of newly approved healthcare products. Healthcare payers, including Medicare, are challenging the prices charged for medical products and services. Government and other healthcare payers 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 payers do not provide adequate coverage and reimbursement levels for any of our products, once approved, market acceptance of our products could be reduced.

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.

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 effect our business, financial condition and results of operations. In addition, the federal, state and local laws and regulations governing the use, manufacture, storage, handling and disposal of hazardous or radioactive materials and waste products may require us to incur substantial compliance costs that could materially adversely affect our business, financial condition and results of operations.

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

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

and sales and diversion of management resources, which could adversely affect our operating results.

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

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

We may incur substantial liabilities and may be required to limit commercialization of our products in response to product liability lawsuits.

The testing and marketing of medical products entail an inherent risk of product liability. If we cannot successfully defend ourselves against product liability claims, we may incur substantial liabilities or be required to limit commercialization of our products. Our inability to obtain sufficient product liability insurance at an acceptable cost to protect against potential product liability claims could prevent or inhibit the commercialization of pharmaceutical products we develop, alone or with corporate collaborators. Even if our agreements with any future corporate collaborators entitle us to indemnification against losses, such indemnification may not be available or adequate should any claim arise.

There are certain interlocking relationships among us and certain affiliates of Two River Group Holdings, LLC, which 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 the managing members of Two River Group Holdings, LLC, or Two River, a venture capital firm 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, formerly NASD). Mr. Tanen also serves as our Secretary and Scott Navins, the Vice President of Finance for Two River, serves as our Treasurer. Additionally, certain employees of Two River, who are also our stockholders, perform substantial operational activity for us, including without limitation 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 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 and principal stockholders.

After the Merger, our directors and principal stockholders beneficially owned approximately 34.51% of our outstanding voting securities. Accordingly, our executive officers, directors, principal stockholders and certain of their affiliates 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 file a registration statement for shares of Nile Common Stock received by stockholders who purchased shares of Old Nile Common Stock in the Offering.

We have agreed, at our expense, to prepare within 60 days of the closing of the Merger, a Securities Act registration statement covering the resale of shares of Nile Common Stock received by stockholders who purchased shares of Old Nile Common Stock in the Offering. In the event that such registration statement is not filed within 60 days after the Merger, we will be required to pay to each investor holding securities to be registered, as liquidated damages and not as a penalty, an amount, for each month (or portion of a month) in which such delay shall occur, equal to 1 percent of the purchase price paid by such investor, until we have cured the delay. Our financial condition and operating results will be harmed if we are required to pay such liquidated damages. Our obligation to register the shares of Nile Common Stock is subject to any limitation on our ability to register the full complement of such shares in accordance with Rule 415 under the Securities Act or other regulatory limitations. To the extent the number of such shares that can be registered is so limited, the Company will be obligated to use its commercially reasonable efforts to register additional tranches of registrable securities as soon as permissible thereafter under applicable laws, rules and regulations so that all of such registrable securities are registered as soon as reasonably practicable. The filing of a registration statement with the SEC can be costly and time-consuming, which could materially and adversely affect Nile.

We will be 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 will increase our costs and divert management's time and attention.

We are in a continuing process of establishing 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. 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 Nile 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 Annual Report on Form 10-K with the SEC. This would likely have an adverse affect on the trading price of Nile Common Stock, if any, and our ability to secure any necessary additional financing, and could result in the delisting of Nile Common Stock if we are listed on an exchange in the future. In such event, the liquidity of Nile Common Stock would be severely limited and the market price of Nile Common Stock would likely decline significantly.

Our internal controls over financial reporting do not currently meet all of the standards contemplated by Section 404 of the Sarbanes-Oxley Act, and failure to achieve and maintain effective internal controls over financial reporting in accordance with Section 404 of the Sarbanes-Oxley Act could have a material adverse effect on our business and common stock price.

Our internal controls over financial reporting do not currently meet all of the standards contemplated by Section 404 of the Sarbanes-Oxley Act that we will eventually be required to meet. We are in the process of addressing our internal controls over financial reporting and are establishing formal policies, processes and practices related to financial reporting and to the identification of key financial reporting risks, assessment of their potential impact and linkage of those risks to specific areas and activities within our organization.

Additionally, we expect to begin the process of documenting our internal control procedures to satisfy the requirements of Section 404, which requires annual management assessments of the effectiveness of our internal controls over financial reporting and a report by our independent registered public accounting firm addressing these assessments. Because we do not currently have comprehensive documentation of our internal controls and have not yet tested our internal controls in accordance with Section 404, we cannot conclude in accordance with Section 404 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. As a public entity, we will be required to complete our initial assessment in a timely manner. 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 Nile Common Stock.

Nile 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. Following the Merger, the market price of Nile Common Stock is likely to be less than $5.00 per share and therefore 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 Nile Common Stock.

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.

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

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

Upon the effective date of our next registration statement, there will be a significant number of shares of Nile Common Stock eligible for sale, which could depress the market price of Nile Common Stock.

Following the effective date of our next registration statement, up to 8,810,336 shares of Nile Common Stock will become available for sale in the public market, which could harm the market price. Further, 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 Nile 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 Nile Common Stock will ever be listed on NASDAQ or any other securities exchange.

We plan in the future to seek listing on NASDAQ or the American Stock Exchange. However, we cannot assure you that we will be able to meet the initial listing standards of either of those or any other stock exchange, or that we will be able to maintain a listing of Nile Common Stock on either of those or any other stock exchange.

2. MANAGEMENT'S DISCUSSION AND PLAN OF OPERATION

The following discussion and plan of operations should read in conjunction with the financial statements and the notes to those statements included in this 8-K. This discussion includes forward-looking statements that involve risk and uncertainties. As a result of many factors, such as those set forth under "*Risk Factors*," actual results may differ materially from those anticipated in these forward-looking statements.

Acquisition and Reorganization

On September 17, 2007, the Merger was completed, and the business of Old Nile was adopted as our business. As such, the following Management Discussion is focused on the current and historical operations of Nile, and excludes the prior operations of SMI.

Overview

Our company develops and commercializes innovative products for the treatment of cardiovascular and metabolic disease. Our efforts and resources are focused on acquiring and developing our pharmaceutical product candidates, raising capital and recruiting personnel. Our lead compound is CD-NP, a chimeric natriuretic peptide in Phase I clinical studies for the treatment of heart failure. We believe CD-NP may be useful in several cardiovascular and renal indications, and is initially being developed as a treatment for heart failure. We are also developing 2NTX-99, a pre-clinical, small molecule, anti-atherothrombotic agent with NO-donating properties.

We have no product sales to date and we will not receive any product revenue until we receive approval from the FDA or equivalent foreign regulatory bodies to begin selling our pharmaceutical candidates. Developing pharmaceutical products, however, 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. Currently, nearly all 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 2NTX-99, 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 various private financings, primarily private sales of Old Nile Common Stock and other equity securities and debt financings.

Our results include non-cash compensation expense as a result of the issuance of stock and stock option grants. Effective August 2005, we adopted Statement of Financial Accounting Standards No. 123R, *Share Based Payment*, or SFAS 123R. SFAS 123R requires us to expense the fair value of stock options over the vesting period. We determine the fair value of stock options using the Black-Scholes options 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. See "*Employment Agreements, Termination of Employment and Change-in-Control Arrangements."* Stock-based compensation expense is included in the respective

categories of expense in the statement of operations. We expect to record additional non-cash compensation expense in the future, which may be significant.

Plan of Operation

We expect our principal expenditures during the next 12 months to include, among other things:

· operating expenses, including expanded general and administrative expenses; and

· research and development expenses, including the costs incurred with respect to applications to conduct clinical trials in the U.S. for our lead product, CD-NP, and pre-clinical testing of 2NTX-99.

Our plan of operation for the year ending December 31, 2007 is to continue implementing our business strategy, including the clinical development of our product candidates. We also intend to expand our drug candidate portfolio by acquiring additional drug technologies for development.

As part of our planned expansion, we anticipate hiring up to four (4) additional full-time employees devoted to research and development activities and one or more additional full-time employees for general and administrative activities. In addition, we intend to use clinical research organizations and third parties to perform our clinical studies and manufacturing. During 2007, we expect to spend approximately $4.5 million on clinical research and development activities, and approximately $1.5 million on general and administrative expenses.

Research and Development Projects; Related Expenses

CD-NP

We plan to initiate a Phase Ib study of CD-NP in heart failure patients in the fourth quarter of 2007. The purpose of the study is to examine the safety, pharmacokinetics and pharmacologic activity of varying doses of CD-NP in patients with heart failure. In parallel, Mayo plans to initiate a Phase Ib study in cooperation with us, which is being sponsored by the National Institute of Health, or the NIH, to comprehensively evaluate the effects of CD-NP on renal hemodynamics and renal function in chronic heart failure patients.

2NTX-99

On August 6, 2007, Old Nile exclusively licensed the worldwide rights to 2NTX-99, a small molecule compound designed to improve on the efficacy and potency of picotamide, a generic anti-platelet therapy marketed in Italy. 2NTX-99 is in the pre-clinical stage of development and Nile expects to complete pre-clinical toxicology studies and manufacturing by the end of 2009. To date, we have not incurred any expenses in connection with the research and development of 2NTX-99 other than the initial licensing fees described herein.

Off Balance Sheet Arrangements

There were no off-balance sheet arrangements as of September 17, 2007.

3. DESCRIPTION OF PROPERTY

Following the Merger, our principal offices are located at 2850 Telegraph Avenue, Suite 310, Berkeley, CA 94705. Under the terms of a three-year lease with Seagate Telegraph Associates, LLC, the monthly base rent is $6,087 per month through April 30, 2008, $6,320 per month effective May 1, 2008 and $6,553 per month effective May 1, 2009. 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 $14,000 cash deposit. The lease expires on April 30, 2010. As our operations expand, we expect our space requirements and related expenses to increase.

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4. SECURITY OWNERSHIP OF CERTAIN BENEFICIAL OWNERS AND MANAGEMENT

The following table summarizes certain information regarding the beneficial ownership (as such term is defined in Rule 13d-3 under the Securities Exchange Act of 1934) of outstanding Nile Common Stock as of September 17, 2007 (after giving effect to the Merger) by (i) each person known by us to be the beneficial owner of more than 5% of the outstanding Nile Common Stock, (ii) each of our directors, (iii) each of our named executive officers (as defined in Item 402(a)(3) of Regulation S-B under the Securities Act), and (iv) all executive officers and directors as a group. Except as indicated in the footnotes below, the security and stockholders listed below possess sole voting and investment power with respect to their shares.

Name of Beneficial Owner	Shares of Nile Common Stock Beneficially Owned (#)(1)	Percentage of Nile Common Stock Beneficially Owned (%)(1)
Peter M. Strumph (2) 2850 Telegraph Avenue, Suite #310 Berkeley, CA 94705	0	*
Daron Evans (3) 2850 Telegraph Avenue, Suite #310 Berkeley, CA 94705	0	*
Wexford Capital LLC (4) 411 West Putnam Avenue Greenwich, CT 06830	2,623,619	10.88%
RIT Capital Partners, Plc 27 St. James Place London, UK SW1A 1NR	1,741,690	7.23%
David M. Tanen (5) 689 Fifth Avenue, 14th Floor New York, NY 10022	1,507,705	6.26%
Peter M. Kash (6) 689 Fifth Avenue, 14th Floor New York, NY 10022	1,492,796	6.19%
Joshua A. Kazam (7) 689 Fifth Avenue, 14th Floor New York, NY 10022	1,231,820	5.11%
Scott L. Navins 689 Fifth Avenue, 14th Floor New York, NY 10022	206,912	*
Paul Mieyal 411 West Putnam Avenue Greenwich, CT 06830	0	*
Dr. Allan Gordon (8) 6936 Bristol Dr. Berkeley, CA 94705	593,743	2.46%
Directors and named executive officers as a group, 8 individuals (9)	4,827,114	19.55%

* represents less than 1%.

(1) Assumes 24,099,716 shares of Nile Common Stock are outstanding. Beneficial ownership is determined in accordance with Rule 13d-3 under the Securities Act, and includes any shares as to which the security or stockholder has sole or shared voting power or investment power, and also any shares which the security or stockholder has the right to acquire within 60 days of the date hereof, whether through the exercise or conversion of any stock option, convertible security, warrant or other right. The indication herein that shares are beneficially owned is not an admission on the part of the security or stockholder that he, she or it is a direct or indirect beneficial owner of those shares.

(2) Excludes issued and outstanding options to purchase up to 1,876,491 shares of Nile Common Stock which are not exercisable within 60 days of the date hereof. See *"Employment Agreements, Termination of Employment and Change-in-Control Agreements."*

(3) Excludes issued and outstanding options to purchase 528,354 shares of Nile Common Stock which are not exercisable within 60 days of the date hereof. See *"Employment Agreements, Termination of Employment and Change-in-Control Agreements."*

(4) Includes (i) 1,910,103 shares of Nile Common Stock held by Iota Investors LLC, a Delaware limited liability company ("Iota Investors"); (ii) five year warrants to purchase 16,841 shares of Nile Common Stock at an exercise price of $2.71 per share held by Iota Investors; and (iii) 696,675 shares of Nile Common Stock held by Wexford Spectrum Investors LLC, a Delaware limited liability company ("Wexford Spectrum"). Wexford Capital LLC, a Connecticut limited liability company ("Wexford Capital") is a registered Investment Advisor and also serves as an investment advisor or sub-advisor to the members of Iota Investors and Wexford Spectrum. Mr. Charles E. Davidson is chairman, a managing member and a controlling member of Wexford Capital and Mr. Joseph M. Jacobs is chairman, a managing member and a controlling member of Wexford Capital.

(5) Excludes 137,941 shares of Common Stock held by Mr. Tanen's wife as custodian for the benefit of their minor daughter under the Uniform Gift to Minors Act (UGMA).

(6) Excludes 496,589 shares of Nile Common Stock held by Mr. Kash's wife as custodian for the benefit of each of their four minor children under the UGMA and 165,530 shares of Nile Common Stock held by the Kash Family Foundation. Includes five year warrants to purchase 1,051 shares of Nile Common Stock at an exercise price equal to $2.71 per share

(7) Includes 165,530 shares of Nile Common Stock held by the Kash Family Foundation, for which Mr. Kazam serves as Trustee. Mr. Kazam controls the right to vote and dispose of the shares held by the Kash Family Foundation, but has no pecuniary interest therein. Excludes 613,841 shares of Nile Common Stock held by the Kazam Family Trust and 165,530 shares of Nile Common Stock held by Mr. Kazam's wife as custodian for the benefit of their minor daughter under the UGMA. Mr. Kazam disclaims beneficial ownership of these shares, as well.

(8) Represents options to purchase 593,743 shares of Nile Common Stock. See *"Severance and Change-in-Control Agreements."*

(9) Includes 4,232,320 shares of common stock beneficially held by directors and officers, warrants to purchase 1,051 shares of common stock held by certain directors and officers, and options to purchase 593,743 shares of common stock held by certain directors and officers.

5. DIRECTORS AND EXECUTIVE OFFICERS, PROMOTERS AND CONTROL PERSONS

Changes in Control and Management

At the effective time of the Merger, our board of directors was reconstituted by the appointment of Mr. Peter Strumph, Mr. Peter Kash, Mr. Joshua Kazam, Mr. David Tanen and Mr. Paul Mieyal as directors (all of whom were directors of Old Nile immediately prior to and after the Merger), and the resignation of Geoffrey Alison from his role as our sole director. Our executive management team was also reconstituted following the resignation of Mr. Geoffrey Alison as SMI's president. The following table sets forth the name, age and position of each of our directors and executive officers after the Merger.

Executive Officers and Directors

Name	Age	Positions
Peter M. Strumph	42	Chief Executive Officer and Director
Daron Evans	34	Chief Financial Officer
Peter M. Kash	46	Director
Joshua A. Kazam	30	Director
Paul Mieyal	37	Director
David M. Tanen	36	Secretary and Director
Scott L. Navins	36	Treasurer
Jennifer Hodge	39	Vice President, Development

Peter M. Strumph. Mr. Strumph has served as Old Nile's Chief Executive Officer since June 4, 2007, and possesses over 10 years of cardiovascular drug development experience. Following the Merger, Mr. Strumph was elected a director of the Company and appointed Chief Executive Officer of the Company. Prior to joining Nile, from 1997 to 2007 Mr. Strumph worked for CV Therapeutics, Inc., or CVT, which discovers, develops, commercializes and sells cardiovascular therapeutic products. His latest position at CVT was Senior Vice President of Operations. At CVT, at various times, Mr. Strumph had responsibility for several functions including, pharmaceutical development and manufacturing, marketing, quality assurance/control, clinical trial operations, project management and alliance management. Additionally, Mr. Strumph was a member of the CEO Executive Staff, was the Project Team Leader for Ranexa™ and served as the Chair of the Product Development Committee. Prior to joining CVT in 1997, Mr. Strumph served as Manager, Operations Planning and Development at Biogen, Inc. where he played an active role in Biogen's transition from a research based company to a fully integrated profitable biotechnology company. Mr. Strumph received his M.B.A. in Finance and Healthcare Management from The Wharton School at the University of Pennsylvania and his B.S. in Systems Science and Engineering from The University of Pennsylvania. He also served as a Lieutenant in the United States Navy.

Daron Evans. Mr. Evans served as Old Nile's Chief Operating Officer since January 15, 2007. Following the Merger, Mr. Evans was appointed Chief Financial Officer of the Company. Mr. Evans has over 10 years of professional experience in drug development financial analysis and fiscal control. Prior to joining Nile, from 2006 to 2007, Mr. Evans served as Director of Business Assessment at Vistakon, a Johnson & Johnson company, where he led efforts to improve R&D efficiency and speed to market. Prior to that, from 2004 to 2006, he was a Director of Portfolio & Business Analytics for Scios R&D, a Johnson & Johnson company, where he was responsible for financial controls and reporting for portfolio of six clinical stage programs and five preclinical stage programs. While at Scios, Mr. Evans also served as Project Manager for the European registration trial of nesiritide. Mr. Evans also has experience as co-founder of a biotechnology diagnostic company, and has worked as a Management Consultant in the pharmaceutical industry with Booz Allen Hamilton. Mr. Evans received his M.B.A. from The Fuqua School of Business at the Duke University, his M.S. in Biomedical Engineering from Southwestern Medical School & University of Texas at Arlington and his B.S. in Chemical Engineering from Rice University.

Jennifer Hodge. Beginning August 31, 2007, Ms. Hodge has served as our Vice President, Development. Following the Merger, Ms. Hodge was appointed as Vice President, Development of the Company. Ms. Hodge has 18 years of international drug development experience spanning discovery through commercialization. Prior to joining Nile, from 2000 to 2007, Ms. Hodge worked at CVT where she most recently served as the Director of Project Management. While at CVT, Ms. Hodge held a variety of assignments of increasing scope and responsibility including; management of clinical trial operations staff, leadership of the project management function, starting and running CVT's alliance management function, Project Team Leader for two development projects, and membership on the CVT Product Development Committee. In addition, Ms. Hodge was responsible for critical special assignments to support CVT's commercial launch, to improve financial reporting and forecasting accuracy for development projects and to plan for the study start up for CVT's largest clinical trial. Prior to CVT, Ms Hodge was a Global Clinical Team Leader at Quintiles, had Clinical Research Associate positions at Otsuka and Solvay, and had pharmacologist and development management responsibilities at the James Black Foundation in London. Ms. Hodge received her B.S. in Biology with Honors in Pharmacology from the University of Edinburgh, UK. .

Peter M. Kash. In September 2004, Mr. Kash co-founded Two River, a venture capital firm that specializes in the creation of new companies to acquire rights to commercially develop early stage biotechnology products. He serves the President and Chairman of Two River's managing member, Two River Group Management, LLC. Mr. Kash is also the President and Chairman of Riverbank, a broker dealer registered with the Financial Industry Regulatory Authority (FINRA (formerly NASD) broker dealer. From 1992 until 2004, Mr. Kash was a Senior Managing Director of Paramount BioCapital, Inc., a FINRA (formerly NASD) member broker dealer, specializing in conducting private financings for public and private development stage biotechnology companies as well as Paramount BioCapital Investments, LLC, a venture capital company. Mr. Kash also served as Director of Paramount Capital Asset Management, Inc. (the Paramount companies are collectively referred to as Paramount), the general partner of several biotechnology-related hedge funds and as member of the General Partner of the Orion Biomedical Fund, LP, a private equity fund. Mr. Kash currently serves as a member of the board of directors of several privately held biotechnology companies. Mr. Kash received his B.S. in Management Science from SUNY Binghamton and his M.B.A. in Banking and International Finance from Pace University. Mr. Kash is currently seeking his doctorate in Jewish education at Yeshiva University. Mr. Kash will devote only a portion of his time to the business of the Company.

Joshua A. Kazam. In September 2004, Mr. Kazam co-founded Two River and currently serves as Vice President and Director of Two River's managing member, Two River Group Management, LLC. Mr. Kazam also serves as an Officer and Director of Riverbank. From 1999 to 2004, Mr. Kazam was a Managing Director of Paramount, where he was responsible for ongoing operations of venture investments, and as the Director of Investment for the Orion Biomedical Fund, LP. Mr. Kazam currently serves as a director of Velcera, Inc. a publicly reporting company, and an officer or director of several privately held companies. Mr. Kazam is a graduate of the Wharton School of the University of Pennsylvania. He will devote only a portion of his time to the business of the Company.

Paul Mieyal, Ph.D., CFA Dr. Mieyal was appointed to serve as a member of the board of directors on September 11, 2007. Since 2006 Dr. Mieyal has served as a Vice President of Wexford Capital LLC, or Wexford, an SEC registered investment advisor with over $5 billion of assets under management located in Greenwich, CT. Prior to that, from 2000 to 2006 he was Vice President in charge of healthcare investments for Wechsler & Co., Inc., a private investment firm and registered broker-dealer. Dr. Mieyal serves as a Director of Danube Pharmaceuticals, Inc., Tigris Pharmaceuticals, Inc., Epiphany Biosciences, Inc., Interventional Spine, Inc., GlobeImmune, Inc. and Microbiogen Pty Ltd. Dr. Mieyal received his Ph.D. in pharmacology from New York Medical College, a B.A. in chemistry and psychology from Case Western Reserve University, and is a Chartered Financial Analyst.

David M. Tanen. In September 2004, Mr. Tanen co-founded Two River and currently serves as Vice President and Director of Two River's managing member, Two River Group Management, LLC. Mr. Tanen also serves as an Officer and Director of Riverbank. Prior to founding Two River, from October 1996 to September 2004, Mr. Tanen was served as a Director of Paramount. Mr. Tanen also served as member of the General Partner of the Orion Biomedical Fund, LP. Mr. Tanen currently serves as an officer or director of several privately held biotechnology companies. Mr. Tanen received his B.A. from The George Washington University and his J.D. from Fordham University School of Law. He will devote only a portion of his time to the business of the Company.

Scott L. Navins. Mr. Navins served as Treasurer of Old Nile since its inception. Mr. Navins is the Vice President of Finance at Two River Group, where he is responsible for all accounting, finance and control activities. Mr. Navins joined Two River Group in 2005. Prior to joining Two River, from 2004 to 2005 Mr. Navins was the Senior Controller at Westbrook Partners, where he managed the accounting for a $560 million real estate private equity fund, including financial and partner reporting, tax coordination, maintaining internal controls and overseeing a $300 million credit facility, among other things. Before that, from 2002 to 2004 Mr. Navins was a Senior Manager at Morgan Stanley, where he managed the accounting for a $2.4 billion real estate private equity fund. Prior to that Mr. Navins was an Associate in the Finance Group at BlackRock, Inc. and the controller for a high-tech venture capital fund. Mr. Navins graduated with honors from The George Washington University in 1993, where he earned a Bachelor of Accountancy degree. Mr. Navins passed the Uniform Certified Public Accounting examination in 1993. Mr. Navins will devote only a portion of his business time to the Company's business. Effective as of the closing of the

Merger, Mr. Navins has been elected Treasurer of the Company.

Audit Committee

We do not currently have a separate Audit Committee. Our full board performs the functions normally designated to an Audit Committee. When acting in this capacity, the Board does not have a charter.

Compensation Committee

Our board of directors does not have a standing compensation committee responsible for determining executive and director compensation. Instead, the entire board of directors fulfills this function, and each member of the Board participates in the determination. Given the small size of the Company and its Board and the Company's limited resources, locating, obtaining and retaining additional independent directors is extremely difficult. In the absence of independent directors, the Board does not believe that creating a separate compensation committee would result in any improvement in the compensation determination process. Accordingly, the board of directors has concluded that the Company and its stockholders would be best served by having the entire board of directors act in place of a compensation committee. When acting in this capacity, the Board does not have a charter.

In considering and determining executive and director compensation, our board of directors reviews compensation that is paid by other similar public companies to its officers and takes that into consideration in determining the compensation to be paid to the Company’s officers. The board of directors also determines and approves any non-cash compensation to any employee. The Company does not engage any compensation consultants to assist in determining or recommending the compensation to the Company’s officers or employees.

6. EXECUTIVE COMPENSATION

Summary Compensation Table

The following table sets forth all of the compensation awarded to, earned by or paid to (i) each individual serving as our principal executive officer during our last completed fiscal year; and (ii) each other individual that served as an executive officer at the conclusion of the fiscal year ended December 31, 2006 and who received in excess of $100,000 in the form of salary and bonus during such fiscal year (collectively, the Named Executives).

Name and Principal Position	Year	Salary	Bonus (1)	Option Awards (2)	Non-Equity Incentive Plan Compensation	All Other Compensation	Total
Peter M. Strumph *Chief Executive Officer*	2006	$ -0-	$ -0-(3)	$ -0-	-0-	$ -0-	$ -0-
Daron Evans *Chief Financial Officer*	2006	$ -0-	$ -0-(4)	$ -0-	-0-	$ -0-	$ -0-
Jennifer Hodge *Vice President, Development*	2006	$ -0-	$ -0-(5)	$ -0-	-0-	$ -0-	$ -0-
Allan Gordon (6) *Chief Executive Officer*	2006	$ -0-	$ -0-	$ -0-	-0-	$ -0-	$ -0-
Joshua Kazam (7) *President*	2006	$ -0-	$ -0-	$ -0-	-0-	$ -0-	$ -0-
Geoffrey Alison (8) *President*	2006	$ -0-	$ -0-	$ -0-	-0-	$ -0-	$ -0-

(1) Our Named Executives are eligible for annual bonuses upon the successful achievement of agreed upon corporate and individual performance based milestones.

(2) Amount reflects the dollar amount recognized for financial statement reporting purposes for the fiscal year ended December 31, 2006 in accordance with SFAS 123R of stock option awards, and may include amounts from awards granted in and prior to fiscal year 2006.

(3) Mr. Strumph is entitled to an annual performance based bonus of up to $150,000 upon the successful completion of annual corporate and individual performance based milestones. See "*Employment Agreements, Termination of Employment and Change-in-Control Arrangements*."

(4) Mr. Evans is entitled to an annual performance based bonus of up to $38,344 upon the successful completion of annual corporate and individual performance based milestones. See "*Employment Agreements, Termination of Employment and Change-in-Control Arrangements*."

(5) Ms. Hodge is entitled to an annual performance based bonus of up to $51,000 upon the successful completion of annual corporate and individual performance based milestones. See "*Employment Agreements, Termination of Employment and Change-in-Control Arrangements*."

(6) Pursuant to the terms of the Separation Agreement, the Company will continue to pay Dr. Gordon his base salary, performance bonus and benefits until May 21, 2008. In addition, Old Nile granted Dr. Gordon options to purchase approximately 215,217 shares of Old Nile Common Stock following the closing of the Offering, which were exchanged at the effective time of the Merger into options to purchase 593,750 shares of Nile Common Stock. See *"Executive Compensation - Severance and Change of Control Agreements."*

(7) Joshua Kazam served as President of Old Nile until January 15, 2007. During this time, he did not receive any compensation.

(8) Geoffrey Alison served as President of SMI Products, Inc. until September 17, 2007, when he resigned and was replaced by Mr. Strumph, in connection with the Merger. During this time, Mr. Alison did not receive any compensation.

Compensation Policy. Our Company's executive compensation plan is based on attracting and retaining qualified professionals who possess the skills and leadership necessary to enable our Company to achieve earnings and profitability growth to satisfy our stockholders. We must, therefore, create incentives for these executives to achieve both Company and individual performance objectives through the use of performance-based compensation programs. No one component is considered by itself, but all forms of the compensation package are considered in total. Wherever possible, objective measurements will be utilized to quantify performance, but many subjective factors still come into play when determining performance.

Compensation Components. As an early-stage development company, the main elements of our compensation package consist of base salary, stock options and bonus.

Base Salary. As we continue to grow and financial conditions improve, these base salaries, bonuses and incentive compensation will be reviewed for possible adjustments. Base salary adjustments will be based on both individual and Company performance and will include both objective and subjective criteria specific to each executive's role and responsibility with the Company.

Executive Compensation under the Amended and Restated 2005 Stock Option Plan

Following the Merger, we have outstanding 3,404,013 stock options issued under our Amended and Restated 2005 Stock Option Plan at exercise prices ranging from $0.09 to $2.71 per share, of which 3,238,484 have been issued to the Named Executives.

Compensation of Directors

We currently do not compensate any non-employee member of our board of directors for serving as a board member, although we may, in our sole discretion, decide to compensate certain of our non-employee members of our board of directors in the future. No fees are paid to Peter Strumph, our Chief Executive Officer, for serving on our board of directors.

Employment Agreements, Termination of Employment and Change-in-Control Arrangements

Peter M. Strumph
Chief Executive Officer

On May 16, 2007, Old Nile entered into a three-year employment agreement with Mr. Strumph to serve as Old Nile's Chief Executive Officer, which agreement was assumed by SMI, and later by Nile, pursuant to the Merger. Effective as of the closing of the Merger, Mr. Strumph was appointed a director and Chief Executive Officer of the Company. Mr. Strumph will receive a base salary equal to $310,000 per annum. In addition, Mr. Strumph is eligible to receive an annual performance based bonus, or the Strumph Performance Bonus, of up to $150,000 upon the successful completion of annual corporate and individual milestones at an exemplary metric (i.e., ahead of schedule, under budget, etc.). Mr. Strumph is also entitled to a cash bonus upon the successful completion of a merger or acquisition transaction. Mr. Strumph may also receive a variable cash bonus upon a change of control depending upon the valuation ascribed to the company at the change of control. We have also agreed to pay for up to $1,000,000 of life insurance for Mr. Strumph. He will be entitled to up to four weeks of vacation per year and may participate in Company sponsored benefit plans (i.e., health, dental, etc.).

We have granted to Mr. Strumph stock options or the Strumph Employment Options, to purchase 1,876,491 shares of Nile Common Stock. Of the Strumph Employment Options, 989,572 shall vest, if at all, and become exercisable in three equal installments on the day before each anniversary of Mr. Strumph's employment agreement. In addition, up to 886,919 options, or the Strumph Performance Options, shall vest, if at all, and become exercisable upon the successful completion of annual corporate and individual milestones in an exemplary manner (e.g., ahead of schedule, under budget, etc.). The options shall be governed by the Company's 2005 Stock Option Plan and are exercisable at a $2.71 per share. Additionally, in the event that the Company acquires by license, acquisition or otherwise, an additional biotechnology product or series of biotechnology products for development that is first identified by Mr. Strumph, then we shall grant to Mr. Strumph options, or the Strumph Technology Options, to purchase additional shares of Nile Common Stock based upon the stage of development of the licensed technology. The Strumph Technology Options shall be exercisable for five years at an exercise price equal to the fair market value of the Nile Common Stock on the date of the grant.

In the event that Mr. Strumph's employment is terminated as a result of his death or disability, the Company will pay him or his estate (a) his base salary for a period of six months thereafter; (b) expense reimbursement amounts through the date of his death or disability, (c) any accrued but unpaid performance bonus for a year prior to the year in which the Executive's employment is terminated; (d) a *pro rata* performance bonus for the year in which the Executive's employment is terminated; and (e) all Strumph Employment Options shall vest immediately and become exercisable. In the event that Mr. Strumph's employment is terminated by the Company for cause or by Mr. Strumph other than for good reason, then the Company shall pay to him his base salary, accrued but unpaid Performance Bonus and expense reimbursement through the date of his termination. He shall have no further entitlement to any other compensation or benefits from the Company except as provided in the Company's compensation and benefit plans. All stock options, other than any Strumph Technology Options, that have not previously vested shall expire immediately. In the event that Mr. Strumph's employment is terminated upon a change of control, by Mr. Strumph for good reason, or by the Company for any other reason then the Company will (a) continue to pay to Mr. Strumph his base salary, Performance Bonus (based on the assumption that a realistic metric is achieved) and benefits for a period of one year following such termination; (b) pay Mr. Strumph any accrued but unpaid Performance Bonus for the year in which the Executive's employment is terminated; (c) pay Mr. Strumph any expense reimbursement amounts owed through the date of termination; and (d) all unvested Strumph Employment Options shall vest and become exercisable immediately and shall remain exercisable for a period of not less than five years.

Daron Evans
Chief Financial Officer

On January 19, 2007, Old Nile entered into a three-year employment agreement with Daron Evans, to serve as our Chief Operating Officer, which agreement was assumed by SMI, and later by Nile, pursuant to the Merger. Mr. Evans received a $25,000 signing bonus and Nile agreed to reimburse him for qualified moving expenses incurred in connection with his relocation to California. Mr. Evans's employment agreement was amended on August 28, 2007. Effective as of the closing of the Merger, Mr. Evans was appointed as Chief Financial Officer of the Company. Mr. Evans will receive a base salary equal to $175,000 per annum. In addition, Mr. Evans is eligible to receive an annual performance based bonus, or the Evans Performance Bonus, of up to $38,344 based upon the successful completion of annual corporate and individual milestones at an exemplary metric (i.e., ahead of schedule, under budget, etc.). The Company has also agreed to pay for up to $1,000,000 of life insurance for Mr. Evans. He will be entitled to up to three weeks of vacation per year and may participate in Company sponsored benefit plans (i.e., health, dental, etc.).

Pursuant to the amendment to Mr. Evans' employment contract, Old Nile paid Mr. Evans a bonus in the amount of $64,969. A portion of this bonus, $47,785, was used to satisfy a loan from Old Nile to Mr. Evans.

We have granted to Mr. Evans stock options, or the Evans Employment Options, to purchase 528,354 shares of Nile Common Stock. Of the Evans Employment Options, 239,896 shall vest, if at all, and become exercisable in three equal installments on the day before each anniversary of Mr. Evans's employment agreement. In addition, up to 288,458 options, or the Evans Performance Options, shall vest, if at all, and become exercisable upon the successful completion of annual corporate and individual milestones in an exemplary manner (e.g., ahead of schedule, under budget, etc.). The options granted to Mr. Evans shall be governed by the Company's 2005 Stock Option Plan and are exercisable at a $2.71 per share. Additionally, in the event that the Company acquires by license, acquisition or otherwise, an additional biotechnology product or series of biotechnology products for development that is first identified by Mr. Evans, then we shall grant to Mr. Evans options, or the Evans Technology Options, to purchase additional shares of Nile Common Stock based upon the stage of development of the licensed technology. The Evans Technology Options shall be exercisable for five years at an exercise price equal to the fair market value of the Nile Common Stock on the date of the grant.

In the event that Mr. Evans' employment is terminated as a result of his death or disability, the Company will pay him or his estate (a) his base salary for a period of six months thereafter; (b) expense reimbursement amounts through the date of his death or disability, (c) any accrued but unpaid Performance Bonus for a year prior to the year in which the Executive's employment is terminated; (d) a *pro rata* performance bonus for the year in which the Executive's employment is terminated; and (e) all Evans Employee Options shall vest immediately and become exercisable. In the event that Mr. Evans' employment is terminated by the Company for cause or by Mr. Evans other that for good reason, then the Company shall pay to him his base salary, accrued but unpaid Performance Bonus and expense reimbursement through the date of his termination. He shall have no further entitlement to any other compensation or benefits from the Company except as provided in the Company's compensation and benefit plans. All Evans Employee Options and Evans Performance Options that have not previously vested shall expire immediately. In the event that Mr. Evans employment is terminated upon a change of control, by Mr. Evans for good reason (which shall include relocation outside of the San Francisco metropolitan area), or by the Company for any other reason then that the Company will (a) continue to pay to Mr. Evans his base salary, performance bonus and benefits for a period of one year following such termination; (b) pay Mr. Evans any accrued but unpaid performance bonus for the year prior to the year in which the Executive's employment is terminated; (c) pay Mr. Evans any expense reimbursement amounts owed through the date of termination; and (d) all unvested stock options shall vest and become exercisable immediately and shall remain exercisable for a period of not less than five years.

Jennifer Hodge
Vice President, Development

On August 8, 2007, Old Nile entered into a Letter Agreement, or the Hodge Letter, with Ms. Jennifer Hodge to serve as our Vice President, Development, which Letter Agreement was assumed by SMI, and later by Nile, pursuant to the Merger. Ms. Hodge commenced her employment on August 30, 2007. Effective as of the closing of the Merger, Ms. Hodge was appointed Vice President, Development. Ms. Hodge will be employed at-will and will receive an annual base salary equal to $170,000, and will be eligible to receive an annual discretionary bonus of up to 30% of her base salary based upon the successful accomplishment of individual and corporate performance goals to be agreed upon annually between Ms. Hodge and our Chief Executive Officer, which amount shall be pro-rated for the year 2007. Ms. Hodge will also be entitled to up to four weeks of vacation per year and may participate in company sponsored benefit plans (i.e., health, dental, etc.).

We also granted Ms. Hodge stock options pursuant to the Company's 2005 Stock Option Plan, or the Hodge Employment Options, to purchase 239,896 shares of Nile Common Stock at an exercise price equal to $2.71. One quarter of the Hodge Employment Options shall vest and become exercisable on the first anniversary of the Hodge Letter. Thereafter, the Hodge Employment Options shall vest in equal amounts and become exercisable on the last day of each calendar month until all remaining Hodge Employment Options are fully vested and exercisable. Additionally, in the event that the Company acquires by license, acquisition or otherwise, an additional biotechnology product or series of biotechnology products for development that is first identified by Ms. Hodge, then Nile shall grant to Ms. Hodge options, or the Hodge Technology Options, to purchase additional shares of Nile Common Stock based upon the stage of development of the licensed technology. The Hodge Technology Options shall be exercisable for five years at an exercise price equal to the fair market value of the Nile Common Stock on the date of the grant.

Executive Bonus Compensation

As described above, Mr. Strumph and Mr. Evans are annually eligible for a proportionate share of their respective Performance Bonuses based upon the assigned weight of agreed upon annual corporate or individual performance milestones , or the Performance Milestones, to be granted upon completion of such Performance Milestones. These executives will receive 100% of their contractual Performance Bonus for Performance Milestones achieved at a "Baseline" metric and 120% of such contractual Performance Bonus for Performance Milestones achieved at an "Exemplary" metric. If Performance Milestones are achieved at a "Pessimistic" metric, the executives will receive 80% of such contractual Performance Bonus. The Performance Milestones shall be amended each subsequent year during the

term of their respective employment agreements upon the mutual agreement of our board of directors and the executive no later than 30 days following the beginning of such year.

Separately, Ms. Hodge will be eligible to receive an annual discretionary bonus of up to 30% of her base salary based upon the successful accomplishment of individual and corporate performance goals to be agreed upon annually between Ms. Hodge and our Chief Executive Officer, which amount shall be pro-rated for the year 2007.

Aggregated Option Exercises in Last Fiscal Year and Fiscal Year End Option Values

No options to purchase shares of Nile Common Stock were exercised by any of the Named Executives during the fiscal year ended December 31, 2006. For a discussion of option arrangements relating to our Named Executive Officers, see "*Employment Agreements, Termination of Employment and Change-in-Control Arrangements*."

Severance and Change of Control Arrangements

See "*Employment Agreements*" above for a description of the severance and change of control arrangement with members of management.

On August 10, 2007, Old Nile entered into a Separation Agreement with Dr. Allan Gordon, a former executive of Nile. Pursuant to the terms of the Separation Agreement, the Company will continue to pay Dr. Gordon his base salary, performance bonus and benefits until May 21, 2008. In addition, Old Nile granted options to Dr. Gordon to purchase 215,215 shares of Old Nile Common Stock following the closing of the Offering, which converted at the time of the Merger into options to purchase 593,743 Nile Shares at an exercise price equal to $2.71 per share. The Company will also provide the executive with limited "piggy-back" registration rights and will reimburse Dr. Gordon for attorney's fees in an amount up to $12,500. In addition, Dr. Gordon agreed to release Old Nile from any claims arising out of Dr. Gordon's employment with Nile.

Our board of directors, or a committee thereof, serving as plan administrator of our 2005 Stock Option Plan, has the authority pursuant to Section 6.3 of the Plan to provide for accelerated vesting of the options granted to our named executive officers and any other person in connection with changes of control.

7. CERTAIN RELATIONSHIPS AND RELATED TRANSACTIONS

Old Nile was incorporated in August 2005 by Two River. Messrs. Peter M. Kash, Joshua A. Kazam and David M. Tanen, each a director and substantial stockholder of Nile, are the managing members of Two River. Mr. Tanen also serves as our Secretary, and Mr. Scott Navins, the Vice President of Finance for Two River, serves as our Treasurer. Additionally, certain employees of Two River, who are also stockholders of Nile, perform substantial operational activity for us, including without limitation, financial, clinical and regulatory activities.

Messrs. Kash, Kazam and Tanen are also officers and directors of Riverbank. Riverbank acted as placement agent on a best-efforts basis for Old Nile in connection with the sale of shares of Old Nile Common Stock on September 11, 2007. Riverbank did not receive any selling commission for its services in connection with such services, but received a non-accountable expense allowance of $100,000 for its expenses incurred in connection with its service. Nile also agreed to indemnify Riverbank against any claims that may arise out of the services provided in connection with the Offering.

On July 24, 2007, Old Nile issued an 8% Promissory Note in the aggregate principal amount of $1.5 million to Iota Investors LLC, an affiliate of Wexford Capital LLC, which note was repaid in full on September 11, 2007. See *"Item 2.01—Recent Financings."* Wexford is a substantial stockholder of Nile, and Dr. Paul Mieyal, one of our directors, is a Vice President of Wexford.

8. DESCRIPTION OF SECURITIES

The certificate of incorporation of Nile authorizes it to issue 110 million shares of capital stock, par value $0.001 per share comprised of 100 million shares of Nile Common Stock, and 10 million shares of preferred stock, par value $0.001 per share.

Following the Merger, we will have approximately: (i) 24,099,716 shares of Nile Common Stock issued, (ii) options to purchase 3,404,103 shares of Nile Common Stock at exercise prices ranging from $0.09 to $2.71 per share, and (iii) warrants to purchase 168,337 shares of Nile Common Stock. There are no shares of preferred stock issued or outstanding.

The holders of Nile Common Stock are entitled to one vote for each share held of record on all matters submitted to a vote of the stockholders and do not have cumulative voting rights. Upon our liquidation, dissolution or winding, holders of Nile Common Stock will be entitled to share ratably in all of our assets that are legally available for distribution, after payment of all debts and other liabilities. The holders of Nile Common Stock have no preemptive, subscription, redemption or conversion rights.

Holders of Nile Common Stock are entitled to receive such dividends, as the board of directors may from time to time declare out of funds legally available for the payment of dividends. The Company seeks growth and expansion of its business through the reinvestment of profits, if any, and does not anticipate that it will pay dividends in the foreseeable future.

Authority to Issue Stock

Our board of directors has the authority to issue the authorized but unissued shares of Nile Common Stock without action by the shareholders. The issuance of such shares would reduce the percentage ownership held by current shareholders.

Our board of directors also has the authority to issue up to 10 million shares of preferred stock, none of which are issued or currently outstanding. The board of directors has the authority to fix and determine the relative rights and preferences of preferred shares, as well as the authority to issue such shares, without further stockholder approval. As a result, the board of directors could authorize the issuance of a series of preferred stock that is senior to the Nile Common Stock and that would grant to holders preferred rights to our assets upon liquidation, the right to receive dividend, additional registration rights, anti-dilution protection, the right to the redemption to such shares, together with other rights, none of which will be afforded holders of Nile Common Stock. See *"Risk Factors - There may be additional issuances of shares of blank check preferred stock in the future."*

PART II.

1. MARKET INFORMATION

Nile Common Stock is quoted on the OTC Bulletin Board, or the OTCBB, under the symbol "SPDU.OB." We expect to change our symbol. Set forth below are the high and low bid prices for Nile Common Stock for the fiscal years ended December 31, 2005 and December 31, 2006, and the period ended June 30, 2007. Although Nile Common Stock is quoted on the OTCBB, it has traded sporadically with no real volume. Consequently, the information provided below my not be indicative of Nile Common Stock price under different conditions.

SMI HISTORICAL SHARE PRICE CHART

Quarter ended	High Bid	Low Bid
March 31, 2005	6.00	5.10
June 30, 2005	6.00	5.00
September 30, 2005	NA	NA
December 30, 2005	6.50	4.10
March 31, 2006	6.90	3.50
June 30, 2006	NA	NA
September 29, 2006	7.50	3.50
December 29, 2006	6.50	3.50
March 30, 2007	3.50	0.77
June 29, 2007	2.05	2.00

All prices listed herein reflect inter-dealer prices, without retail mark-up, mark-down or commissions, and may not represent actual transactions.

Since our inception, we have not paid any dividends on the Nile Common Stock, and we do not anticipate that we will pay any dividends in the foreseeable future. We intend to retain any future earnings for use in our business. At September 17, 2007, we had approximately 215 shareholders of record.

2. LEGAL PROCEEDINGS

We are not currently involved in any material legal proceedings.

3. CHANGES IN AND DISAGREEMENT WITH ACCOUNTANTS ON ACCOUNTING AND FINANCIAL DISCLOSURE

On or about October 31, 2006, SMI dismissed its former accountant, Amisano Hanson Chartered Accountants, Vancouver, Canada, as our principal accountant effective October 31, 2006. Amisano Hanson had served SMI since 1996.

On or about September 21, 2007, and effective upon the completion of the Merger, Old Nile dismissed Paritz & Co., Hackensack, New Jersey, as the our principal accountants effective as of September 21, 2007.

Under Item 304 of Regulation S-K, the reasons for the changes in the accountants listed above is dismissal, not resignation or declining to stand for re-election. During the two most recent fiscal years and the interim period through the date of the dismissal, there were no disagreements with any of the accountants listed above on any matter of accounting principles or practices, financial statement disclosure or auditing scope or procedure, which disagreements, if not resolved to these accountants satisfaction, would have caused the accountants to make reference to the subject matter of the disagreements in connection with its reports. During the two most recent fiscal years through the date of dismissal, the reports of these accountants did not contain any adverse opinion or disclaimer of opinion, or were modified as to uncertainty, audit scope, or accounting principles other than the issuance of a “going concern” opinion with respect to its reports issued with respect to the Company’s financial statements dated December 31, 2006, and December 31, 2005, respectively.

The decision to change principal accountants was approved by the board of directors. On September 17, 2007, the Company engaged Hays & Company, LLP as successor to Partitz & Co. Hays & Company, LLP was Old Nile's principal accountants for its fiscal year ending December 31, 2006 and the six months ended June 30, 2007. During the Company's two most recent fiscal years or subsequent interim period, the Company has not consulted with the entity of Hays & Company LLP regarding the application of accounting principles to a specific transaction, either completed or proposed, or the type of audit opinion that might be rendered on the Nile's financial statements, nor did the entity of Hays & Company, L.L.P. provide advice to Nile, either written or oral, that was an important factor considered by Nile in reaching a decision as to the accounting, auditing or financial reporting issue. Further, during Nile's two most recent fiscal years or subsequent interim period, the Company has not consulted the entity of Hays & Company, L.L.P. on any matter that was the subject of a disagreement or a reportable event.

4. RECENT ISSUANCES OF UNREGISTERED SECURITIES BY NILE

The following summarizes all sales of unregistered securities by Old Nile since inception in August 2005. Each issued and outstanding share of Old Nile Common Stock converted to 2.758838 shares of Nile Common Stock as of the Closing of the Merger.

In August 2005, in connection with Old Nile's incorporation, Old Nile issued an aggregate of 5,000,000 shares of Old Nile Common Stock for aggregate consideration of $5,000. 500,000 shares were returned to treasury and subsequently issued to Mayo in January 2006, as partial consideration for the Mayo License Agreement granting us rights to commercially develop CD-NP.

In February 2006, Old Nile issued options to purchase 25,000 shares of Old Nile Common Stock at an exercise price of $0.25 per share to each of two members of Old Nile's Scientific Advisory Board. The options expire in February 2011.

On March 28, 2006, Old Nile issued the 6% Notes to certain qualified investors. See *"Item 2.01—Recent Financings."*

On July 24, 2007, Old Nile issued $1,500,000 in face amount of an 8% Promissory Note, which note was repaid on September 11, 2007. See *"Item 2.01—Recent Financings."*

On August 6, 2007, Old Nile issued 126,904 shares of Old Nile Common Stock to Dr. Cesare Casagrande as partial payment for the 2NTX-99 License Agreement. See *"Item 2.01—Recent Financings."*

As a condition to the closing of the Merger, on September 11, 2007, Old Nile completed a private placement offering whereby it received gross proceeds of approximately $19,974,747 through the sale of 2,522,064 shares of Old Nile Common Stock in a private placement to certain qualified investors. Old Nile also issued 23,009 shares of Nile Common Stock to Mayo pursuant to the terms of the Mayo License Agreement. See *"Item 2.01—Recent Financings."*

On September 17, 2007, we granted to Mr. Peter Strumph stock options to purchase 1,876,491 shares of Nile Common Stock. See "*Employment Agreements, Termination of Employment and Change-in-Control Arrangements."*

On September 17, 2007, we granted to Mr. Daron Evans stock options to purchase 528,354 shares of Nile Common Stock. See "*Employment Agreements, Termination of Employment and Change-in-Control Arrangements."*

On September 17, 2007, we granted to Ms. Jennifer Hodge stock options to purchase 239,896 shares of Nile Common Stock. See "*Employment Agreements, Termination of Employment and Change-in-Control Arrangements."*

On September 17, 2007, we granted to Dr. Allan Gordon stock options to purchase 593,743 shares of Nile Common Stock. . See "*Employment Agreements, Termination of Employment and Change-in-Control Arrangements."*

On September 17, 2007, we also issued 494,900 shares of Nile Common Stock to Fountainhead Capital, upon the conversion of $168,573 of convertible promissory notes, and accrued interest. See *"Item 2.01- Completion of Acquisition or Disposition of Assets.*"

Except as noted above, the sales of the securities identified above were made pursuant to privately negotiated transactions that did not involve a public offering of securities and, accordingly, we believe that these transactions were exempt from the registration requirements of the Securities Act pursuant to Section 4(2) thereof and rules promulgated thereunder. In addition, we believe that the 8% Promissory Note is commercial paper and is exempt from the registration requirements of the Securities Act under Section 3(a)3 thereof. Each of the above-referenced investors in our stock represented to us in connection with their investment that they were "accredited investors" (as defined by Rule 501 under the Securities Act) and were acquiring the shares for investment and not distribution, that they could bear the risks of the investment and could hold the securities for an indefinite period of time. The investors received written disclosures that the securities had not been registered under the Securities Act and that any resale must be made pursuant to a registration or an available exemption from such registration. All of the foregoing securities are deemed restricted securities for purposes of the Securities Act.

Recent Issuances of Securities by SMI

The issuance of the SMI Common Stock to the shareholders of Old Nile in the Merger was exempt from registration under the Securities Act pursuant to Section 4(2) thereof. Nile has made this determination based on the representations of the Old Nile shareholders and investors which included, in pertinent part, that such persons were either "accredited investors" or represented by a purchaser representative, within the meaning of Rule 501 of Regulation D promulgated under the Securities Act, that such persons were acquiring the Nile Common Stock, and the shares of SMI Common Stock issued to them pursuant to the Merger, for investment purposes for their own respective accounts and not as nominees or agents, and not with a view to the resale or distribution thereof in violation of the Securities Act, and that each person understood that the shares of the SMI Common Stock issued in the Merger, may not be sold or otherwise disposed of without registration under the Securities Act or an applicable exemption therefrom.

5. INDEMNIFICATION OF OFFICERS AND DIRECTORS

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

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

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ITEM 4.01 CHANGES IN REGISTRANT'S CERTIFYING ACCOUNTANT.

See "Information Required Pursuant to Form 10-SB" II(3) "*Changes In and Disagreements with Accountants*," which discussion is incorporated herein by reference.

ITEM 5.01 CHANGES IN CONTROL OF REGISTRANT.

Please see the discussion of "*Closing of Merger*" and "*Recent Financings*" in Item 2.01, which discussion is incorporated herein by reference.

ITEM 5.02 DEPARTURE OF DIRECTORS OR PRINCIPAL OFFICERS; ELECTION OF DIRECTORS; APPOINTMENT OF PRINCIPAL OFFICERS.

See "Information Required Pursuant to Form 10-SB" item 5 "*Directors and Executive Officers, Promoters and Control Persons*," which discussion is incorporated herein by reference.

ITEM 5.03 AMENDMENTS TO ARTICLES OF INCORPORATION OR BYLAWS; CHANGE IN FISCAL YEAR.

On September 17, 2007, the Company filed a Certificate of Ownership with the Secretary of State of the State of Delaware pursuant to which Old Nile, a wholly-owned subsidiary of SMI by virtue of the Merger, merged with and into SMI with SMI remaining as the surviving corporation to the merger (the "Short-Form Merger"). In connection with the Short-Form Merger, and as set forth in the Certificate of Ownership, SMI changed its corporate name to "Nile Therapeutics, Inc." The Certificate of Ownership is filed as Exhibit 3.1 to this current report.

ITEM 5.06 CHANGE IN SHELL COMPANY STATUS.

As described in Item 2.01 above, which is incorporated by reference into this Item 5.06, we ceased being a shell company (as defined in Rule 12b-2 under the Exchange Act of 1934, as amended) upon completion of the Merger.

PART III.

ITEM 9.01 FINANCIAL STATEMENTS AND EXHIBITS.

(a) As a result of the Merger described in Item 2.01, the registrant is filing Nile's audited financial information as Exhibit 99.2 to this current report.

(b) Pro forma financial information has not been included, as it would not be materially different from the financial information of Nile as referenced above.

(c) Exhibits.

Exhibit	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. [1]
3.1	Articles of Incorporation of SMI Products, Inc.[2]
3.2	By-laws of SMI Products, Inc.[2]
4.1	Specimen Common Stock Certificate.
10.1	Form of Nile Therapeutics, Inc. Common Stock Purchase Warrant.
10.2	Employment Agreement between Nile Therapeutics, Inc. and Peter M. Strumph dated May 11, 2007.
10.3	Employment Agreement between Nile Therapeutics, Inc. and Daron Evans dated January 19, 2007.
10.4	Amendment No. 1 to Employment Agreement between Nile Therapeutics, Inc. and Daron Evans dated August 19, 2007.
10.5	Letter Agreement between Nile Therapeutics, Inc. and Jennifer L. Hodge, dated August 31, 2007.
10.6	License Agreement between The Mayo Foundation for Medical Education and Research and Nile Therapeutics, Inc., dated January 20, 2006.*
10.7	License Agreement between Nile Therapeutics, Inc. and Dr. Cesare Casagrande, dated August 6, 2007.*
10.8	Lease Agreement between Nile Therapeutics, Inc. and Seagate Telegraph Associates, LLC for office space located at 2850 Telegraph Avenue, Suite #310, Berkeley, CA 94705 dated March 21, 2007.
10.9	Amended and Restated 2005 Stock Option Plan.
10.10	Form of Stock Option Agreement.
10.11	Form of Incentive Stock Option Agreement.

10.12 Separation Agreement and General Release between Nile Therapeutics, Inc. and Allan Gordon dated August 10, 2007.

16.1 Letter from Paritz & Co dated September 20, 2007 regarding change in certifying accountants.

16.2 Letter from Amisano Hanson Chartered Accountants dated February 5, 2007, regarding change in certifying accountants.[3]

23.1 Consent from Hays & Company LLP.

99.1 Press Release dated September 17, 2007.

99.2 Audited financial statements of Nile Therapeutics, Inc. for the period ended June 30, 2007 (pro forma financial information is not included, as the pro-forma information would not be materially different from Nile's historical financial statements).

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[1] Incorporated by reference from SMI's current report on Form 8-K filed with the Commission dated August 18, 2007, SEC file no. 333-55166.
[2] Incorporated by reference from SMI's current report on Form 8-K filed with the Commission dated February 9, 2007, SEC file no. 333-55166.
[3] Incorporated by reference from SMI's current report on Form 8-K filed with the Commission dated December 8, 2006, SEC file no. 333-55166.
[*] Confidential treatment requested as to certain portions of this exhibit. Such portions have been redacted and filed separately with the SEC.

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.
atherothromboticg	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 the formation of scar-like tissue (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.
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.
equimolar	Of or relating to an equal number of moles. A mole is a unit of measurement that is determined as "6.2 x 10^{23} atoms or molecules of a substance.
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.
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

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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 the tissues lining the blood vessels (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 cavity of the blood vessels.

SIGNATURE

Pursuant to the requirements of the Securities Exchange Act of 1934, the registrant has duly caused this report to be signed on its behalf by the undersigned hereunto duly authorized.

NILE THERAPEUTICS, INC.

Date: September 17, 2007 By: /s/ Peter M. Strumph

Peter M. Strumph
Chief Executive Officer