

Nile Therapeutics, Inc.  
Form SB-2  
October 22, 2007

As filed with the Securities and Exchange Commission  
on October 22, 2007

Registration No. \_\_\_\_\_

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

**FORM SB-2  
REGISTRATION STATEMENT UNDER THE SECURITIES ACT OF 1933**

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

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

**2850 Telegraph Ave.  
Berkeley, CA 94705  
(510) 281-7700**

(Address and telephone number of principal executive offices and principal place of  
business)

Mr. Peter M. Strumph  
Chief Executive Officer  
Nile Therapeutics, Inc.  
2850 Telegraph Ave., Suite 310  
Berkeley, CA 94705  
Telephone: (510) 281-7700  
Facsimile: (510) 288-1310

(Name and address of agent for service)

Copies to:  
Ira L. Kotel, Esq.  
Dickstein Shapiro, LLP  
1177 Avenue of the Americas  
New York, NY 10036  
Telephone: (212) 277-6686  
Facsimile: (212) 277-6501

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

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

Edgar Filing: Nile Therapeutics, Inc. - Form SB-2

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

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

If delivery of the prospectus is expected to be made pursuant to Rule 434, please check the following box.

1

---

## CALCULATION OF REGISTRATION FEE

Title of each class of securities to be registered	Number of shares to be registered <sup>(1)</sup>	Proposed maximum offering price per unit	Proposed maximum aggregate offering price	Amount of registration fee
Common stock, par value \$.001 per share	8,641,999	\$ 4.40(2)	\$ 38,024,796	\$ 1,167
Common stock, par value \$.001 per share	168,377(3)	\$ 4.40(2)	\$ 740,859	\$ 23
Total	8,810,376	\$ 4.40	\$ 38,765,655	\$ 1,190

- (1) This registration statement shall also cover any additional shares of common stock that shall become issuable by reason of any stock dividend, stock split, recapitalization or other similar transaction effected without the receipt of consideration that results in an increase in the number of the outstanding shares of common stock.
- (2) Estimated solely for the purpose of calculating the registration fee in accordance with Rule 457(c) of the Securities Act of 1933, as amended, based upon the average of the bid and asked price of our Common Stock on October 18, 2007, a date within five business days prior to the date of filing the registration statement, on the OTC Bulletin Board.
- (3) Represents shares of common stock issuable upon exercise of outstanding warrants.

**THE REGISTRANT HEREBY AMENDS THIS REGISTRATION STATEMENT ON SUCH DATE OR DATES AS MAY BE NECESSARY TO DELAY ITS EFFECTIVE DATE UNTIL THE REGISTRANT SHALL FILE A FURTHER AMENDMENT WHICH SPECIFICALLY STATES THAT THIS REGISTRATION STATEMENT SHALL THEREAFTER BECOME EFFECTIVE IN ACCORDANCE WITH SECTION 8(a) OF THE SECURITIES ACT OF 1933, AS AMENDED, OR UNTIL THE REGISTRATION STATEMENT SHALL BECOME EFFECTIVE ON SUCH DATE AS THE SEC, ACTING PURSUANT TO SAID SECTION 8(a), MAY DETERMINE.**

**The information in this prospectus is preliminary and incomplete and may be changed. Securities included in the registration statement of which this prospectus is a part may not be sold until the registration statement filed with the Securities and Exchange Commission becomes effective. This prospectus is not an offer to sell these securities and is not a solicitation of an offer to buy these securities in any state where the offer or sale is not permitted.**

**SUBJECT TO COMPLETION, DATED OCTOBER 22, 2007**

**NILE THERAPEUTICS, INC.**

**8,810,376 Shares  
Common Stock**

The selling stockholders identified on pages 40-43 of this prospectus are offering on a resale basis a total of 8,810,376 shares of our common stock, including 8,641,999 shares of our common stock and 168,377 shares issuable upon the exercise of outstanding warrants. We will not receive any proceeds from the sale of these shares by the selling stockholders.

Our common stock was formerly traded on the OTC Bulletin Board under the trading symbol "SPDU.OB," however, as of October 11, 2007, our common stock trades on the OTC Bulletin Board under the trading symbol "NILT.OB." On October 17, 2007, the closing price as reported on the OTC Bulletin Board was \$4.40 per share.

Brokers or dealers effecting transactions in these shares should confirm the registration of these securities under the securities laws of the states in which transactions occur or the existence of an exemption from registration.

**An investment in shares of our common stock involves a high degree of risk. We urge you to carefully consider the risk factors beginning on page 9.**

**NEITHER THE SECURITIES AND EXCHANGE COMMISSION ("SEC") NOR ANY STATE SECURITIES COMMISSION HAS APPROVED OR DISAPPROVED OF THESE SECURITIES OR DETERMINED IF THIS PROSPECTUS IS TRUTHFUL OR COMPLETE. ANY REPRESENTATION TO THE CONTRARY IS A CRIMINAL OFFENSE.**

The date of this prospectus is \_\_\_\_\_, 2007

In considering the acquisition of the common stock described in this prospectus, you should rely only on the information contained in this prospectus. We have not authorized anyone to provide you with information different from that contained in this prospectus. This prospectus is not an offer to sell, or a solicitation of an offer to buy, shares of common stock in any jurisdiction where offers and sales would be unlawful. The information contained in this prospectus is complete and accurate only as of the date on the front cover of this prospectus, regardless of the time of delivery of this prospectus or of any sale of the shares of common stock.

## Table of Contents

SUMMARY	5
THE OFFERING	8
RISK FACTORS	9
SAFE HARBOR STATEMENT UNDER THE PRIVATE SECURITIES LITIGATION REFORM ACT OF 1995	18
MANAGEMENT’S DISCUSSION AND PLAN OF OPERATIONS	20
DESCRIPTION OF BUSINESS	22
MANAGEMENT	28
SECURITY OWNERSHIP OF CERTAIN BENEFICIAL OWNERS AND MANAGEMENT	36
CERTAIN RELATIONSHIPS AND RELATED TRANSACTIONS	38
MARKET FOR COMMON EQUITY AND RELATED STOCKHOLDER MATTERS	38
USE OF PROCEEDS	40
DETERMINATION OF OFFERING PRICE	40
SELLING STOCKHOLDERS	40
PLAN OF DISTRIBUTION	45
DESCRIPTION OF SECURITIES	47
ANTI TAKEOVER EFFECTS OF CERTAIN PROVISIONS OF OUR CERTIFICATE OF INCORPORATION AND DELAWARE LAW	48
DISCLOSURE OF SEC POSITION ON INDEMNIFICATION FOR SECURITIES ACT LIABILITIES	48
CHANGES IN AND DISAGREEMENT WITH ACCOUNTANTS ON ACCOUNTING AND FINANCIAL DISCLOSURE	48
ABOUT THIS PROSPECTUS	49
VALIDITY OF COMMON STOCK	49
EXPERTS	49
TRANSFER AGENT	49
WHERE YOU CAN FIND MORE INFORMATION	49
GLOSSARY OF TERMS	50
FINANCIAL STATEMENTS	F-1

## SUMMARY

*This summary highlights information contained elsewhere in this prospectus. Because it is a summary, it may not contain all of the information that is important to you. Accordingly, you are urged to carefully review this prospectus in its entirety, including the risks of investing in our securities discussed under the caption “Risk Factors” and the financial statements and other information that is incorporated by reference into this prospectus before making an investment decision. 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 described below.*

### Company Overview

Our company develops and commercializes innovative products for the treatment of cardiovascular and metabolic diseases. 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 (NO) donating properties.

We were incorporated in the State of Nevada on June 17, 1996 and reincorporated in Delaware on February 9, 2006, at which time our name was SMI Products, Inc., which will hereinafter be referred to as “SMI.” From inception through August 11, 2006, SMI was a development stage company in the business of internet real estate mortgage services. On and after August 11, 2006, SMI ceased its prior business. On September 17, 2007, we completed a merger transaction whereby our wholly-owned subsidiary, Nile Merger Sub, Inc., a Delaware corporation hereinafter referred to as the “Merger Sub,” merged with and into Nile Therapeutics, Inc. a privately held Delaware corporation hereinafter referred to as “Old Nile,” with Old Nile becoming our wholly-owned subsidiary. Immediately following the Merger described above, we filed a Certificate of Ownership with the Secretary of State of the State of Delaware pursuant to which we merged Old Nile, our wholly-owned subsidiary by virtue of the merger described above, with and into us with us remaining as the surviving corporation to that merger. In connection with that short-form merger, and as set forth in the Certificate of Ownership, we changed our corporate name to “Nile Therapeutics, Inc.” (referred to throughout this Report as “Nile”). These two transactions are hereinafter referred to as the “Merger.” Upon completion of the Merger, we adopted Nile’s business plan.

Our executive offices are located at 2850 Telegraph Ave., Suite 310, Berkeley, CA 94705. Our telephone number is (510) 281-7700. Our website is [www.nilethera.com](http://www.nilethera.com). None of the information on our internet site is part of this prospectus.

*See the “Glossary of Terms” included in this prospectus for definitions of certain technical terms used in this report that are commonly used in the pharmaceutical and biotechnology industries.*

### **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<sub>B</sub> 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<sup>®</sup>, a natriuretic peptide currently marketed by Scios Inc. (a Johnson & Johnson company) to treat acute heart failure, including producing less hypotension than Natrecor<sup>®</sup> 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<sub>2</sub>), enhance the production of prostacyclin (PGI<sub>2</sub>) and supply pharmacological amounts of nitric oxide (NO) to the vasculature. TXA<sub>2</sub>, produced by activated platelets, is believed to have prothrombotic properties, stimulating activation of new platelets as well as increasing platelet aggregation. TXA<sub>2</sub> is implicated in a number of inflammatory and thrombotic conditions, particularly in diabetic populations. PGI<sub>2</sub> 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<sub>2</sub> *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 have initiated pre-clinical toxicology and manufacturing activities for 2NTX-99 and plan to file an investigational new drug application (IND) to enter human testing by the end of 2009.

## **Recent Developments**

### ***Acquisition and Reorganization***

On September 17, 2007, we completed the Merger described above. In accordance with the terms of 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 our common stock, par value \$0.001 per share, and one share of Old Nile Common Stock was issued to SMI. Simultaneously, we 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. 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 our Common Stock. In addition to the 755,100 shares of our 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 approximately \$168,573 of convertible promissory notes and accrued interest.

On September 17, 2007, we changed our name from SMI Products, Inc. to Nile Therapeutics, Inc.

### ***Private Placement Offering***

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, hereinafter referred to as the "Financing." Contemporaneously with the Financing, Old Nile converted \$4,351,333 of convertible debt and interest into 610,433 shares of Old Nile Common Stock, the "Conversion Shares", and warrants to purchase an aggregate of 61,028 shares of Old Nile Common Stock. The shares sold in the Financing were exchanged for 6,957,914 shares of our common stock and the Conversion Shares were exchanged for 1,684,085 shares of our common stock and the warrants were exchanged for five year warrants to purchase 168,377 shares of our common stock at an exercise price equal to \$2.71 per share.

### ***Changes in Board of Directors***

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 was also reconstituted following the resignation of Mr. Alison as our



president, and new officers were appointed in place of our former officers.

6

---

**Risk Factors**

For a discussion of some of the risks you should consider before purchasing shares of our common stock, you are urged to carefully review and consider the section entitled “Risk Factors” beginning on page 9 of this prospectus.

7

---

**THE OFFERING**

The selling stockholders identified on pages 40-43 of this prospectus are offering on a resale basis a total of 8,810,376 shares of our common stock, including 8,641,999 shares of our common stock and 168,377 shares issuable upon the exercise of outstanding warrants.

Common stock offered 8,810,376 shares

Common stock outstanding before the offering<sup>(1)</sup> 24,099,716 shares

Common stock outstanding after the offering<sup>(2)</sup> 24,268,053 shares

Use of Proceeds We will receive none of the proceeds from the sale of the shares by the selling stockholders, except for the warrant exercise price upon exercise of the warrants, which would be used for working capital and other general corporate purposes

OTC Bulletin Board Symbol NILT.OB

---

(1) Based on the number of shares outstanding as of September 30, 2007.

(2) Assumes the issuance of all shares offered hereby that are issuable upon exercise of warrants.

## RISK FACTORS

*You should carefully consider the following risk factors and all other information contained in this report before purchasing shares of our common stock. Investing in our 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 our common stock could decline and you may lose all or part of the money you paid to purchase our common stock.*

***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 Financing, cash on hand 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 and 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 our 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, and preparing for pre-clinical trials of 2NTX-99. 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 candidates for sale outside the U.S.



***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 candidates' 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 products 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 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 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 upon 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. Cesare 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.

14

---

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 maintain 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 between us and certain affiliates of Two River Group Holdings, LLC that may present potential conflicts of interest.***

Peter M. Kash, Joshua A. Kazam and David M. Tanen, each a director and substantial stockholder of our Company, are 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 and the Financial Operations Principal of Riverbank, 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.***

Our directors and principal stockholders beneficially own 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.

16

---

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

We 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 our common stock, if any, and ability to obtain any necessary equity or debt financing could suffer. In addition, in the event that our independent registered public accounting firm is unable to rely on our internal control over financial reporting in connection with its audit of our financial statements, and in the further event that it is unable to devise alternative procedures in order to satisfy itself as to the material accuracy of our financial statements and related disclosures, we may be unable to file our Annual Report on Form 10-K with the SEC. This would likely have an adverse affect on the trading price of our common stock, if any, and our ability to secure any necessary additional financing, and could result in the delisting of our common stock if we are listed on an exchange in the future. In such event, the liquidity of our common stock would be severely limited and the market price of our common stock would likely decline significantly.

***Our internal controls over financial reporting do not currently meet all of the standards contemplated by Section 404 of the Sarbanes-Oxley Act of 2002, and failure to achieve and maintain effective internal controls over financial reporting in accordance with Section 404 of the Sarbanes-Oxley Act of 2002 could have a material adverse effect on our business and common stock price.***

Our internal controls over financial reporting 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 our common stock.

***Our Common Stock is considered “a penny stock.”***

The SEC has adopted regulations which generally define “penny stock” to be an equity security that has a market price of less than \$5.00 per share, subject to specific exemptions. The market price of our common stock 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 our common stock. *See “Regulation of Penny Stocks” on page 39.*

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

***Upon the effective date of this registration statement, there will be a significant number of shares of our common stock eligible for sale, which could depress the market price of our common stock.***

Following the effective date of our next registration statement, up to 8,810,376 shares of our 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 our common stock. In general, a person who has held restricted shares for a period of one year may, upon filing with the SEC a notification on Form 144, sell into the market common stock in an amount equal to the greater of 1% of the outstanding shares or the average weekly number of shares sold in the last four weeks prior to such sale. Such sales may be repeated once every three months, and any of the restricted shares may be sold by a non-affiliate after they have been held two years.

***We cannot assure you that our 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 our common stock on either of those or any other stock exchange.

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

This registration statement on Form SB-2 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.

## Edgar Filing: Nile Therapeutics, Inc. - Form SB-2

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 any of 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 pre-clinical and 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 registration statement.

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.



## MANAGEMENT'S DISCUSSION AND PLAN OF OPERATIONS

*You should read the following discussion of our plan of operations in conjunction with the financial statements and accompanying notes included in this prospectus beginning on page F-1. 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, we completed the Merger and adopted the business of Old Nile as our business. Accordingly, the following Management Discussion is focused on the current and historical operations of Nile, and excludes the prior operations of SMI.

### **Overview**

We are in the business of commercially developing innovative biotechnologies 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. We are initially developing CD-NP 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 and warrant 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 and warrants 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.

20

---

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 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 \$3.7 million on clinical research and development activities, and approximately \$2.4 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***

During August 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.

### **Off Balance Sheet Arrangements**

There were no off-balance sheet arrangements as of October 22, 2007.

### **Future Financing Needs**

Our continued operations will depend on whether we are able to raise additional funds through various potential sources, such as equity and debt financing. Through the date of this Prospectus, all of our financing has been through private placements of common stock. We will continue to fund operations from cash on hand and through various sources of capital, including equity and debt instruments. We can give no assurances that any additional capital that we are able to obtain will be sufficient to meet our needs. Based on our resources, we believe that we have sufficient capital to fund our operations through 2009, but will need additional financing thereafter until we can achieve profitability, if ever.

We have incurred negative cash flows from operations since our inception. We expect to spend substantial amounts in connection with implementing our business strategy, including planned product development efforts, clinical trials, and research and discovery efforts. During 2007, we expect to spend approximately \$3.7 million on clinical research and development activities, and approximately \$2.4 million on general and administrative expenses.

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

- the progress of research activities;

- the number and scope of research programs;

21

---

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

We have based our estimate on assumptions that may prove to be wrong. We may need to obtain additional funds sooner than planned or in greater amounts than we currently anticipate. Potential sources of financing include strategic relationships, public or private sales of equity or debt and other sources. We may seek to access the public or private equity markets when conditions are favorable due to our long-term capital requirements. It is uncertain whether additional funding will be available when we need it on terms that will be acceptable to us, or at all. If we raise funds by selling additional shares of common stock or other securities convertible into common stock, the ownership interest of our existing stockholders will be diluted. If we are not able to obtain financing when needed, we may be unable to carry out our business plan. As a result, we may have to significantly limit our operations and our business, financial condition and results of operations would be materially harmed.

## 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<sub>B</sub> 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 Natreacor<sup>®</sup>, a natriuretic peptide currently marketed by Scios Inc. (a Johnson & Johnson company) to treat acute heart failure, including producing less hypotension than Natreacor<sup>®</sup> 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<sub>2</sub>), enhance the production of prostacyclin (PGI<sub>2</sub>) and supply pharmacological amounts of nitric oxide (NO) to the vasculature. TXA<sub>2</sub>, produced by activated platelets, is believed to have prothrombotic properties, stimulating activation of new platelets as well as increasing platelet aggregation. TXA<sub>2</sub> is implicated in a number of inflammatory and thrombotic conditions, particularly in diabetic populations. PGI<sub>2</sub> 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<sub>2</sub> *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**

### ***CD-NP***

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 our common stock and Miami Heart's shares converted into 551,767 shares of our 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 our 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 our 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."*

### ***2NTX-99***

On August 6, 2007, Old Nile entered into an exclusive, worldwide, royalty-bearing license agreement, or the 2NTX-99 License Agreement, with Dr. Cesare Casagrande for the rights to 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 atherosclerotic-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 our 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, inotropes, 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, antiplatelet 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, Bristol Myers Squibb Inc., Eli Lilly and Company, CardioVascular BioTherapeutics, Inc., and Keryx Biopharmaceuticals, Inc.

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 we do 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 - Developments 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 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;



## Edgar Filing: Nile Therapeutics, Inc. - Form SB-2

- 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. We cannot be sure that submission of an IND will result in the FDA allowing clinical trials to begin.

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

Clinical trials are typically conducted in three sequential “Phases”, although the Phases may overlap. The study protocol and informed consent information for study subjects in clinical trials must also be approved by an Institutional Review Board for each institution where the trials will be conducted. Study subjects must sign an informed consent form before participating in a clinical trial. Phase I usually involves the initial introduction of the investigational drug into 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, we or the FDA may suspend clinical trials at any time on various grounds, including a finding that the subjects or patients are being exposed to an unacceptable health risk.

The FDCA permits the FDA and the IND sponsor to agree in writing on the design and size of clinical studies intended to form the primary basis of an effectiveness claim in an NDA 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. We 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. We 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.

#### Employees

As of October 22, 2007, we have four (4) 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.

#### Description of Property

In March 2007, we entered into a three-year lease with Seagate Telegraph Associates, LLC. Under the terms of the lease, the monthly base rent is \$6,087 per month from May 1, 2007 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.



**Legal Proceedings**

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

**MANAGEMENT**

The following table sets forth the name and position of each of our directors and executive officers, and their ages as of October 22, 2007:

**Directors and Executive Officers**

<b><u>Name</u></b>	<b><u>Age</u></b>	<b><u>Positions</u></b>
Peter M. Strumph	42	Chief Executive Officer and Director
Daron Evans	34	Chief Financial Officer
Jennifer Hodge	39	Vice President, Development
Pedro Granadillo	60	Director
Peter M. Kash	46	Director
Joshua A. Kazam	30	Director
David M. Tanen	36	Secretary and Director
Paul Mieyal	38	Director
Scott L. Navins	36	Treasurer

**Peter M. Strumph.** Mr. Strumph served as Old Nile's Chief Executive Officer since June 4, 2007. Following the Merger, Mr. Strumph was elected to our board of directors and appointed our Chief Executive Officer. 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 joined Old Nile as its Chief Operating Officer in January 15, 2007, and following the Merger, was appointed as our Chief Financial Officer. 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 30, 2007, Ms. Hodge served as Old Nile's Vice President, Development, and following the Merger was appointed as our Vice President, Development. 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. .

**Pedro Granadillo.** Mr. Granadillo retired as senior vice president for Eli Lilly and Company (Lilly) on September 30, 2004 after 34 years of service. He was a member of Lilly's senior most committee, the Policy Committee, which was comprised of its top seven executives. As Lilly's top human resources, manufacturing and quality executive, he was responsible for policies affecting a global workforce of more than 45,000 employees, as well as a broad network of manufacturing facilities for its extensive line of products. Mr. Granadillo spent his first 22 years in manufacturing, including 13 years in international assignments. He became Lilly's Vice President of Human Resources in 1993, where he led initiatives that resulted in Lilly being named one of the best companies to work for by Working Mother magazine every year since 1995 and has been on the magazine's "top 10" list four times. In 1999, Lilly received the U.S. Department of Labor's "Opportunity 2000" award, the agency's highest ranking for affirmative action and diversity. Lilly has also been honored as a top employer in many other countries. In addition, the Harvard Business Review recently cited the excellence of Lilly's succession-management processes. In May 1998, Mr. Granadillo was awarded top leadership responsibilities for global manufacturing and quality, where he oversaw more than 20 sites and 13,000 employees, and doubled Lilly's line of first-in-class, best-in-class growth products that includes both conventional "small-molecule" pharmaceuticals and "large-molecule" biotech therapies. Mr. Granadillo currently serves as a member of the boards of directors of First Indiana Bank, Haemonetics Corporation, Noven Pharmaceuticals, Inc., and Purdue University Research Foundation. Mr. Granadillo received a B.S. in Industrial Engineering from Purdue University.

**Peter M. Kash.** In September 2004, Mr. Kash co-founded Two River Group Holdings, LLC or "Two River," a venture capital firm that specializes in the creation of new companies to acquire rights to commercially develop early stage biotechnology products, where he serves as 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 Capital Securities, Inc., a broker dealer registered with FINRA. From 1992 until 2004, Mr. Kash was a Senior Managing Director of Paramount BioCapital, Inc., a FINRA member broker dealer, specializing in conducting private financings for public and private development stage biotechnology companies as well as Paramount BioCapital Investments, LLC, a venture capital company. Mr. Kash also served as Director of Paramount Capital Asset Management, Inc. (the 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 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.

**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.

**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, a Connecticut limited liability company or “Wexford Capital,” 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.

**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 our small size and 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 we and our 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 our officers. The board of directors also determines and approves any non-cash compensation to any employee. We do not engage any compensation consultants to assist in determining or recommending the compensation to our officers or employees.

#### **Executive Compensation**

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 or acting in a similar capacity during our last completed fiscal year; and (ii) our two most highly compensated executive officers, other than our principal executive officer, who were serving as executive officers at the end of the last completed fiscal year; and (iii) up to two additional individuals for whom disclosure

would have been provided pursuant to clause (ii) but for the fact that the individual was not serving as an executive officer of the Company at the end of the last completed fiscal year (collectively, the Named Executive Officers).

30

---

**Summary Compensation Table**

Name and Principal Position	Year	Salary	Bonus (1)		Option Awards (2)	Total
Peter M. Strumph <i>Chief Executive Officer</i>	2006	\$ -0-	\$ -0-	(3)	\$ -0-	\$ -0-
Daron Evans <i>Chief Financial Officer</i>	2006	\$ -0-	\$ -0-	(4)	\$ -0-	\$ -0-
Jennifer Hodge <i>Vice President, Development</i>	2006	\$ -0-	\$ -0-	(5)	\$ -0-	\$ -0-
Allan Gordon (6) <i>Chief Executive Officer</i>	2006	\$ -0-	\$ -0-		\$ -0-	\$ -0-
Joshua Kazam (7) <i>President</i>	2006	\$ -0-	\$ -0-		\$ -0-	\$ -0-
Geoffrey Alison (8) <i>President</i>	2006	\$ -0-	\$ -0-		\$ -0-	\$ -0-

(1) Our Named Executive Officers are eligible for annual bonuses upon the successful achievement of agreed upon corporate and individual performance based milestones. See “Employment Agreements, Termination of Employment and Change-in-Control Arrangements” below.

(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 for stock option awards, and may include amounts from awards granted in and prior to fiscal year 2006.

(3) Mr. Strumph may annually earn up to \$150,000 in performance bonuses upon the successful completion of corporate and individual performance based milestones. See “*Employment Agreements, Termination of Employment and Change-in-Control Arrangements.*”

(4) Mr. Evans may annually earn up to \$38,344 in performance bonuses 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 may annually earn up to \$51,000 in performance bonuses 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, we will continue to pay Dr. Gordon his base salary, performance bonus and benefits until May 21, 2008. See “*Executive Compensation - Severance and Change of Control Agreements.*”

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

(8) Mr. 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 executive compensation plan is based on attracting and retaining qualified professionals who possess the skills and leadership necessary to enable us to achieve earnings and profitability growth to satisfy our stockholders. We must, therefore, create incentives for these executives to achieve both corporate 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.

### **Equity Compensation Plan Information**

Our Amended and Restated 2005 Stock Option Plan was approved by the unanimous written consent of our board of directors. In connection with our acquisition and recapitalization transaction, this plan was amended and restated on September 17, 2007 to, among other things, increase the number of shares reserved for awards pursuant to the plan to adjust for the exchange of shares of common stock pursuant to the Merger. 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 Executive Officers described herein.

As of December 31, 2006, there were no outstanding options, warrants or rights issued under our equity compensation plans.

## **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 we assumed pursuant to the Merger. Effective as of the closing of the Merger, Mr. Strumph was appointed as our Chief Executive Officer and a member of our Board of Directors. 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 premiums 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 our 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 our 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 our 2005 Stock Option Plan and are exercisable at \$2.71 per share of common stock. Additionally, in the event that we acquire 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 our 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 our 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, we 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 us for cause or by Mr. Strumph other than for good reason, then we 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 us except as provided in our 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 we 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 its Chief Operating Officer, which agreement we assumed 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 our Chief Financial Officer. 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.). We have also agreed to pay premiums 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 our 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 our 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 our 2005 Stock Option Plan and are exercisable at \$2.71 per share of common stock. Additionally, in the event that we acquire 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 our 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 our 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, we 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 us for cause or by Mr. Evans other than for good reason, then we 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 us except as provided in our 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 us for any other reason then we 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 Evans Employment 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 we assumed 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 our common stock at an exercise price equal to \$2.71 per share of common stock. 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 we acquire 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 our 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 our 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.

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 our 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, which we assumed at the time of the Merger. Pursuant to the terms of the Separation Agreement, we will continue to pay Dr. Gordon his base salary, performance bonus and benefits until May 21, 2008. In addition, upon the closing of the Merger, Dr. Gordon exchanged options to purchase 215,215 shares of Old Nile Common Stock for options to purchase 593,743 shares of our common stock at an exercise price equal to \$2.71 per share of common stock. We will also provide Dr. Gordon 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.



**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 our outstanding common stock as of October 22, 2007 (after giving effect to the Merger) by (i) each person known by us to be the beneficial owner of more than 5% of our outstanding common stock, (ii) each of our directors, (iii) each of our named executive officers (as defined in Item 402(a)(2) 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 Our Common Stock Beneficially Owned (#) <sup>(1)</sup>	Percentage of Our Common Stock Beneficially Owned (%) <sup>(1)</sup>
Peter M. Strumph <sup>(2)</sup> 2850 Telegraph Avenue, Suite #310 Berkeley, CA 94705	0	*
Daron Evans <sup>(3)</sup> 2850 Telegraph Avenue, Suite #310 Berkeley, CA 94705	0	*
Wexford Capital LLC <sup>(4)</sup> 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 <sup>(5)</sup> 689 Fifth Avenue, 14th Floor New York, NY 10022	1,507,705	6.26%
Peter M. Kash <sup>(6)</sup> 689 Fifth Avenue, 14th Floor New York, NY 10022	1,492,796	6.19%
Joshua A. Kazam <sup>(7)</sup> 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	*
Pedro Granadillo 7218 Tory Lane Naples, FL 34108	27,588	*
Paul Mieyal 411 West Putnam Avenue Greenwich, CT 06830	0	*
Dr. Allan Gordon <sup>(8)</sup> 6936 Bristol Dr. Berkeley, CA 94705	593,743	2.46%
Directors and named executive officers as a group, 8 individuals <sup>(9)</sup>	4,853,652	19.65%

---

\* represents less than 1%.

(1) Assumes 24,099,716 shares of our 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.

36

---

(2) Excludes issued and outstanding options to purchase up to 1,876,491 shares of our 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 our 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 our common stock held by Iota Investors LLC, a Delaware limited liability company (“Iota Investors”); (ii) five year warrants to purchase 16,841 shares of our common stock at an exercise price of \$2.71 per share of common stock held by Iota Investors; and (iii) 696,675 shares of our common stock held by Wexford Spectrum Investors LLC, a Delaware limited liability company or “Wexford Spectrum.” 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 our 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 our common stock held by the Kash Family Foundation. Includes five year warrants to purchase 1,051 shares of our common stock at an exercise price equal to \$2.71 per share

(7) Includes 165,530 shares of our 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 our common stock held by the Kazam Family Trust and 165,530 shares of our 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 our common stock. See “*Severance and Change-in-Control Agreements.*”

(9) Includes 4,231,270 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.

**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 activities for us, including without limitation, financial, clinical and regulatory activities.

Messrs. Kash, Kazam and Tanen are also officers and directors of Riverbank and Mr. Navins is the Financial Operations Principal 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 \$1,500,000 to Iota Investors LLC, an affiliate of Wexford Capital, which note was repaid in full on September 11, 2007. Wexford Capital is a substantial stockholder of Nile, and Dr. Paul Mieyal, one of our directors, is a Vice President of Wexford Capital.

**MARKET FOR COMMON EQUITY AND RELATED STOCKHOLDER MATTERS**

Our common stock was formerly traded on the OTC Bulletin Board under the trading symbol "SPDU.OB," however, as of October 11, 2007 our common stock trades on the OTC Bulletin Board under the trading symbol "NILT.OB." Set forth below are the high and low bid prices for our common stock for the fiscal years ended December 31, 2005 and December 31, 2006, and the period ended September 30, 2007. Although our common stock is quoted on the OTC Bulletin Board, it has traded sporadically with no real volume. Consequently, the information provided below may not be indicative of our common stock price under different conditions.

**SMI HISTORICAL SHARE PRICE CHART**

<b>Quarter ended</b>	<b>High Bid</b>	<b>Low Bid</b>
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
September 28, 2007	4.30	1.15

These bid prices represent prices quoted by broker-dealers on the OTC Bulletin Board. The quotations reflect inter-dealer prices, without retail mark-up, mark-down or commissions, and may not represent actual transactions.



### **Record Holders**

As of September 30, 2007, there were approximately 215 holders of record of our common stock.

### **Dividend Policy**

We have not paid or declared any dividends on our common stock and we do not anticipate paying dividends on our common stock for the foreseeable future. The payment of dividends on our common stock is within the discretion of our board of directors, subject to our certificate of incorporation. We intend to retain any earnings for use in our operations and the expansion of our business. Payment of dividends in the future will depend on our future earnings, future capital needs and our operating and financial condition, among other factors.

### **Regulation of Penny Stocks**

Our common stock meets the definition of a “penny stock” under applicable SEC rules. Broker-dealers who sell penny stocks must satisfy several rules when recommending that their customers purchase penny stock. A summary of those rules is set forth below.

**Definition of a Penny Stock.** The SEC has adopted several rules regulating transactions involving “penny stocks.” As a general matter, the term “penny stock” means any equity security other than a security:

- that is a “reported security” as that term is defined by SEC rule, including securities listed on the Nasdaq Stock Market, the New York Stock Exchange or the American Stock Exchange,
- that is issued by an investment company,
- that is a put or call option issued by the Options Clearing House,
- that has a price of \$5.00 or more,
- that is registered, or approved for registration upon notice of issuance, on a national securities exchange that makes transaction reports available, subject to restrictions provided in the rule,
- that is authorized, or approved for authorization upon notice of issuance, for quotation on NASDAQ, subject to restrictions provided in the rule, or
- whose issuer has (i) net tangible assets of more than \$2,000,000 if the issuer has been in business for at least 3 continuous years, and \$5,000,000 if the issuer has been in business less than 3 years, or (ii) average revenue of at least \$6,000,000 for the last 3 years.

**Suitability Determination.** The SEC’s rules governing penny stock transactions are designed to ensure that brokers and dealers make a determination that a particular customer is appropriately suited to purchase penny stocks. Accordingly, prior to the sale of a penny stock recommended by the broker-dealer to a new customer who is not an institutional accredited investor, the broker-dealer must approve the customer’s account for transactions in penny stocks. The determination requires the broker-dealer to obtain from the customer information concerning the customer’s “financial situation, investment experience, and investment objectives.” Based on this information, the broker-dealer must then reasonably determine that transactions in penny stocks are suitable for the customer and that the customer has sufficient knowledge and experience in financial matters that the person reasonably may be expected

to be capable of evaluating the risks of penny stock transactions. The broker-dealer then must provide the customer with a written statement, to be signed by the customer, that sets forth the suitability determination made by the broker-dealer.

**Penny Stock Risk Disclosure Document.** At least two business days prior to the initial penny stock transaction with a customer, the broker-dealer must provide to the customer a risk disclosure document, which states clearly that transactions in penny stocks can be very risky and urges the customer to use caution before proceeding with the transaction. The document warns the customer of the lack of liquidity in many penny stocks, the possibility of losing the investment, the need to use caution, and not to rely on the salesperson. The document also sets forth the remedies available to customers in the event the broker-dealer violates the penny stock rules in connection with a transaction with the customer. The risk disclosure document also includes pricing information relating to the penny stock and the compensation paid to the broker-dealer in connection with the transaction.

**Monthly Statements.** The broker-dealer must also furnish to the customer a statement as of the last day of each month that describes for each penny stock held by the broker-dealer for the customer's account the price of the security, the number of shares of each penny stock security held for the customer, and the estimated market value of the security. The monthly statement must be sent to the customer within 10 days following the end of each month.

### USE OF PROCEEDS

We will receive none of the proceeds from the sale of the shares by the selling stockholders, except for the warrant exercise price upon exercise of the warrants, which would be used for working capital and other general corporate purposes.

### DETERMINATION OF OFFERING PRICE

The selling stockholders may sell their shares from time to time at prevailing market prices. The offering price of the securities for registration fee purposes was calculated pursuant to Rule 457(c) of the Securities Act and was not computed based on the assets, historical operating performance or other conventional means and should not be construed to indicate any relationship thereto. In establishing the offering price for registration fee purposes, we relied on the average of the high and low prices of our common stock on October 17, 2007 as reflected in the over-the-counter (OTC) marketplace, which was \$4.40 per share.

### SELLING STOCKHOLDERS

This prospectus covers the resale by the selling stockholders identified below of 8,810,376 shares of our common stock, including 168,377 shares issuable upon exercise of warrants.

The table and the corresponding footnotes set forth: (i) the selling stockholders, (ii) information regarding the beneficial ownership of shares of common stock by each of the selling stockholders, and (iii) any relationship between the Company, its predecessors and affiliates, and each of the selling stockholders during the past three years.

<b>Selling Stockholder</b>	<b>Shares Beneficially Owned Before Offering (a)</b>	<b>Maximum Number of Shares Sold Pursuant to this Prospectus</b>	<b>Number of Shares Offered by Selling Stockholder upon Exercise of Certain Warrants</b>	<b>Percentage Beneficial Ownership of Voting Securities After Offering (b)</b>
A. Lapidot Pharmaceuticals <sup>(1)</sup>	17,518	17,518	-	*
Alan Mendelson	11,576	10,524	1,052	*
Albert H. Keller	37,703	36,651	1,052	*
Albert Milstein	23,153	21,049	2,104	*
Albert Reichman	55,016	50,806	4,210	*
Arnold Feld	27,588	27,588	-	*
Aviv Raiz	34,734	31,577	3,157	*
Barry Goodman	11,576	10,524	1,052	*
Beck Family Partners, LP <sup>(2)</sup>	110,236	108,132	2,104	*

Edgar Filing: Nile Therapeutics, Inc. - Form SB-2

Beechwood Ventures, LLC <sup>(3)</sup>	40,570	38,466	2,104	*
Bonnie Kazam <sup>(4)</sup>	73,648	10,524	1,052	*
Bristol Investment Fund, Ltd. <sup>(5)</sup>	230,456	192,343	10,525	*
Bruce Lipnick	28,993	27,941	1,052	*
Clal Insurance, Ltd. <sup>(6)</sup>	174,157	174,157	-	*
Dana Freyer	11,576	10,524	1,052	*
Daniel Nissanoff	11,576	10,524	1,052	*
David and Susan Wilstein, TTEES of the Century Trust <sup>(7)</sup>	164,717	38,466	2,104	*
Dennis Lee Berman	17,416	17,416	-	*
Dikla Insurance Company Ltd. - Nostro <sup>(8)</sup>	3,481	3,481	-	*
Dikla Insurance Company Ltd. - Siudi <sup>(8)</sup>	10,447	10,447	-	*
Diversified Fund, Ltd. <sup>(9)</sup>	20,283	19,231	1,052	*
ECOrg, LLC <sup>(10)</sup>	104,205	94,732	9,473	*
Ed Steinberg	20,286	19,234	1,052	*
Ezra Kazam <sup>(11)</sup>	11,576	10,524	1,052	*
GMM Capital, LLC <sup>(12)</sup>	335,515	132,669	4,210	1.39%
Harel Insurance Company Ltd. - Clali <sup>(8)</sup>	13,932	13,932	-	*
Harel Insurance Company Ltd. - Mishtatfot <sup>(8)</sup>	104,499	104,499	-	*
Harel Insurance Company Ltd. - Nostro <sup>(8)</sup>	45,283	45,283	-	*
Harel Pension Fund Management Ltd. <sup>(8)</sup>	17,416	17,416	-	*
Harel Provident Funds, Ltd. - Taoz <sup>(8)</sup>	27,867	27,867	-	*
Harel Provident Funds, Ltd.-Gmisha <sup>(8)</sup>	10,447	10,447	-	*
Harel Provident Funds, Ltd.-Keren Hishtalmut <sup>(8)</sup>	10,447	10,447	-	*
Harel Provident Funds, Ltd.-Otzma <sup>(8)</sup>	104,499	104,499	-	*
Henry Rothman	23,153	21,049	2,104	*
High Glen Properties, Ltd. <sup>(13)</sup>	17,926	17,926	-	*
Hila Karah	11,576	10,524	1,052	*
HSBC Private Bank (Suisse) SA	348,336	348,336	-	1.45%
Inversiones Mirachonda, SL <sup>(14)</sup>	102,643	38,466	2,104	*
Iota Investors LLC <sup>(15)</sup>	1,926,944	1,910,103	16,841	7.99%
Irvin Kessler	133,395	129,185	4,210	*
Ivan and Lisa Kauffman Family Trust <sup>(16)</sup>	115,782	105,257	10,525	*
Jacob Gottlieb	194,117	126,310	12,631	*
JD Management Partners <sup>(17)</sup>	17,416	17,416	-	*

Edgar Filing: Nile Therapeutics, Inc. - Form SB-2

Jeff Berman	17,416	17,416	-	*
Jonathan Abodeely	17,416	17,416	-	*
Joseph Sitt	57,987	55,883	2,104	*
Jospeh Tabak	23,153	21,049	2,104	*
Kanfei Investments, LLC <sup>(18)</sup>	41,086	38,982	2,104	*
Larich Assoc. <sup>(19)</sup>	20,283	19,231	1,052	*
Leiden Overseas <sup>(20)</sup>	23,153	21,049	2,104	*
Leon Recanati	46,312	42,102	4,210	*
Leonard Grunstein	26,123	26,123	-	*
Leumi Overseas Trust Corporation Limited As TTEE for the BTL Trust <sup>(21)</sup>	81,145	76,935	4,210	*
Life Science Capital <sup>(22)</sup>	87,082	87,082	-	*
Linda Ann Hamilton TTEE, Linda Ann Hamilton Rev. Trust UAD 08-08-2000 <sup>(23)</sup>	20,286	19,234	1,052	*
Lyon Roth	17,416	17,416	-	*
Martin Granoff	115,782	105,257	10,525	*
Mehmet Oz	40,570	38,466	2,104	*
Michael Chisek	17,416	17,416	-	*
Michael Crockett	11,035	11,035	-	*
Millennium Partners	376,884	376,884	-	1.56%
Naftali Investments, Ltd. <sup>(24)</sup>	28,982	27,930	1,052	*
Norman Kraftchuk & Associates Ltd. (The Rose Corporation) <sup>(25)</sup>	8,704	8,704	-	*
Novatrust Ltd. As TTEES of the Sirius Trust <sup>(26)</sup>	451,160	192,340	10,525	1.87%
Pedro Granadillo <sup>(27)</sup>	27,588	27,588	-	*
Peter Kash <sup>(28)</sup>	1,492,796	10,524	1,052	8.94%
Peter Kiernan	174,168	174,168	-	*
Renato Negrin	34,833	34,833	-	*
RIT Capital Partners, Plc. <sup>(29)</sup>	1,741,690	1,741,690	-	7.23%
Robert I. Falk	119,712	55,535	2,104	*
Robert Israel	15,061	14,009	1,052	*
Robert Klein	23,153	21,049	2,104	*
Robert Koffman	20,283	19,231	1,052	*
Seymour and Star Sacks	9,655	9,655	-	*
Shimon Katz	33,647	32,595	1,052	*
Speisman Family 2000, LP <sup>(30)</sup>	20,283	19,231	1,052	*
Stahler Investments, LLC <sup>(31)</sup>	59,018	56,914	2,104	*
Stephen Evans	11,311	11,311	-	*
Stephen Thompson	27,588	27,588	-	*

Edgar Filing: Nile Therapeutics, Inc. - Form SB-2

Steve Warner	11,576	10,524	1,052	*
Steven Koffman	20,283	19,231	1,052	*
Troy W. and Allison K. Thacker	34,833	34,833	-	*
Wechsler & Co, Inc. <sup>(32)</sup>	46,312	42,102	4,210	*
Wexford Spectrum Investors, LLC <sup>(15)</sup>	696,675	696,675	-	2.89%
FCC Ltd. <sup>(33)</sup>	11,576	10,524	1,052	*
Yitzhak Dankner	156,544	150,229	6,315	*

---

\* Less than 1%

- (a) Assumes the exercise of all warrants held by such selling stockholder.
- (b) Assumes the exercise of all warrants outstanding.
- (1) Mr. Ami Lapidot, Chairman of the selling stockholder, holds voting and/or dispositive power over the shares held by the selling stockholder.
  - (2) Mr. Ronald Beck, general partner of the selling stockholder, holds voting and/or dispositive power over the shares held by the selling stockholder.
  - (3) Mr. Kalman Renov, managing member of the selling stockholder, holds voting and/or dispositive power over the shares held by the selling stockholder.
  - (4) The selling stockholder is the mother of Mr. Joshua Kazam, a director of the Company, and the spouse of Mr. Ezra Kazam, who is also a selling stockholder.
  - (5) Mr. Paul Kessler, managing member of the selling stockholder, holds voting and/or dispositive power over the shares held by the selling stockholder.
  - (6) Mr. Avigdor Kaplan, the CEO of the selling stockholder, holds voting and/or dispositive power over the shares held by the selling stockholder.
  - (7) Mr. David Wilstein, trustee of the selling stockholder, holds voting and/or dispositive power over the shares held by the selling stockholder.
  - (8) Harel Insurance Investments and Financial Services Ltd. owns each of the selling stockholders except for Dikla Insurance Company Ltd. - Nostro and Dikla Insurance Company Ltd. - Siudi, both in which Harel holds a 65% ownership interest in.
  - (9) Ms. Carlo Pagani, president of the selling stockholder, holds voting and/or dispositive power over the shares held by the selling stockholder.
  - (10) Ms. Linda A. Hamilton, Ms. Mary Tanner Hackney, Mr. Jeffrey L. Dymant and/or Ms. Lynn E. Coleman hold voting and/or dispositive power over the shares held by the selling stockholder.
  - (11) The selling stockholder is the father of Mr. Joshua Kazam, a director of the Company, and the spouse of Mrs. Bonnie Kazam, who is also listed as a selling stockholder.
  - (12) Mr. Isaac Dabah, managing member of the selling stockholder, holds voting and/or dispositive power over the shares held by the selling stockholder.
  - (13) Mr. John Ulmer, the President of the selling stockholder, holds voting and/or dispositive power over the shares held by the selling stockholder.
  - (14) Mr. Jose Luis Diaz-Rio, Director of the selling stockholder, holds voting and/or dispositive power over the shares held by the selling stockholder.

- (15) Wexford Capital is a registered Investment Advisor and also serves as an investment advisor or sub-advisor to the members of the selling stockholders. Mr. Charles E. Davidson and Mr. Joseph M. Jacobs are controlling members of Wexford Capital hold voting and/or dispositive power over the shares held by the selling stockholder. A Vice President of Wexford Capital, Dr. Paul Mieyal, is one of the Company's Directors.
- (16) Mr. Joseph Martello, Trustee of the selling shareholder, holds voting and/or dispositive power over the shares held by the selling stockholder.
- (17) Mr. Jeffrey L. Dymont, the President of the selling stockholder, holds voting and/or dispositive power over the shares held by the selling stockholder.
- (18) Mr. Dov Perlysky, managing member of the selling stockholder, holds voting and/or dispositive power over the shares held by the selling stockholder.
- (19) Mr. Lawrence Gross and Mr. Richard Hirsch, partners of the selling stockholder, hold voting and/or dispositive power over the shares held by the selling stockholder.
- (20) Mr. Shai Pilpel, the Chairman of the selling stockholder, holds voting and/or dispositive power over the shares held by the selling stockholder.
- (21) Mr. John Le M. Germain, Director of the selling stockholder, holds voting and/or dispositive power over the shares held by the selling stockholder.
- (22) Mr. Robert Sinclair, director of the selling stockholder, holds voting and/or dispositive power over the shares held by the selling stockholder.
- (23) Ms. Linda A. Hamilton, Trustee, holds voting and/or dispositive power over the shares held by the selling stockholder.
- (24) Mr. Meir Hadar, President and CEO of the selling stockholder, holds voting and/or dispositive power over the shares held by the selling stockholder.
- (25) Mr. Norman E. Kraftchuck, President of the selling stockholder, holds voting and/or dispositive power over the shares held by the selling stockholder.
- (26) Novatrust, Ltd., trustee of the selling stockholder, holds voting and/or dispositive power over the shares held by the selling stockholder.
- (27) The Selling Stockholder is a director of the Company.
- (28) The selling stockholder is a director and substantial stockholder of the Company and was a director of Old Nile, a predecessor of the Company. Excludes 496,589 shares of our 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 our common stock held by the Kash Family Foundation.
- (29) Mr. Duncan Budge, director of the selling stockholder, holds voting and/or dispositive power over the shares held by the selling stockholder.
- (30) Mr. Aaron Speisman, General Partner of the selling stockholder, holds voting and/or dispositive power over the shares held by the selling stockholder.
- (31) Ms. Esther Stahler, managing member of the selling stockholder, holds voting and/or dispositive power over the shares held by the selling stockholder.
- (32) Norman J. Wechsler holds voting and/or dispositive power over the shares held by the selling stockholder
- (33) Mr. Yacoz Reizman, Chairman of the selling stockholder, holds voting and/or dispositive power over the shares held by the selling stockholder.

#### **PLAN OF DISTRIBUTION**

We are registering the shares of our common stock covered by this prospectus for the selling shareholders. The selling stockholders, which as used herein includes donees, pledgees, transferees or other successors-in-interest selling shares of common stock or interests in shares of common stock received after the date of this prospectus from a selling stockholder as a gift, pledge, partnership distribution or other transfer, may, from time to time, sell, transfer or otherwise dispose of any or all of their shares of common stock or interests in shares of common stock on any stock

exchange, market or trading facility on which the shares are traded or in private transactions. These dispositions may be at fixed prices, at prevailing market prices at the time of sale, at prices related to the prevailing market price, at varying prices determined at the time of sale, or at negotiated prices.



## Edgar Filing: Nile Therapeutics, Inc. - Form SB-2

The selling stockholders may use any one or more of the following methods when disposing of shares or interests therein:

ordinary brokerage transactions and transactions in which the broker-dealer solicits purchasers;

block trades in which the broker-dealer will attempt to sell the shares as agent, but may position and resell a portion of the block as principal to facilitate the transaction;

purchases by a broker-dealer as principal and resale by the broker-dealer for its account;

an exchange distribution in accordance with the rules of the applicable exchange;

privately negotiated transactions;

short sales effected after the date the registration statement of which this prospectus is a part is declared effective by the SEC;

through the writing or settlement of options or other hedging transactions, whether through an options exchange or otherwise;

broker-dealers may agree with the selling stockholders to sell a specified number of such shares at a stipulated price per share; or

a combination of any such methods of disposition.

The selling stockholders may, from time to time, pledge or grant a security interest in some or all of the shares of common stock owned by them and, if they default in the performance of their secured obligations, the pledgees or secured parties may offer and sell the shares of common stock, from time to time, under this prospectus, or under an amendment to this prospectus under Rule 424(b)(3) or other applicable provision of the Securities Act amending the list of selling stockholders to include the pledgee, transferee or other successors in interest as selling stockholders under this prospectus. The selling stockholders also may transfer the shares of common stock in other circumstances, in which case the transferees, pledgees or other successors in interest will be the selling beneficial owners for purposes of this prospectus.

In connection with the sale of our common stock or interests therein, the selling stockholders may enter into hedging transactions with broker-dealers or other financial institutions, which may in turn engage in short sales of our common stock in the course of hedging the positions they assume. The selling stockholders may also sell shares of our common stock short and deliver these securities to close out their short positions, or loan or pledge our common stock to broker-dealers that in turn may sell these securities. The selling stockholders may also enter into option or other transactions with broker-dealers or other financial institutions or the creation of one or more derivative securities which require the delivery to such broker-dealer or other financial institution of shares offered by this prospectus, which shares such broker-dealer or other financial institution may resell pursuant to this prospectus (as supplemented or amended to reflect such transaction).

The aggregate proceeds to the selling stockholders from the sale of the common stock offered by them will be the purchase price of the common stock less discounts or commissions, if any. Each of the selling stockholders reserves the right to accept and, together with their agents from time to time, to reject, in whole or in part, any proposed purchase of common stock to be made directly or through agents. We will not receive any of the proceeds from this offering. Upon any exercise of the warrants by payment of cash, however, we will receive the exercise price of the warrants.



The selling stockholders and any underwriters, broker-dealers or agents that participate in the sale of our common stock or interests therein may be “underwriters” within the meaning of Section 2(11) of the Securities Act. Any discounts, commissions, concessions or profit they earn on any resale of the shares may be underwriting discounts and commissions under the Securities Act.

The selling stockholders also may resell all or a portion of the shares in open market transactions in reliance upon Rule 144 under the Securities Act, provided that they meet the criteria and conform to the requirements of that rule.

Because selling stockholders will be considered “underwriters” within the meaning of the Securities Act, they will be subject to the prospectus delivery requirements of the Securities Act including Rule 172 thereunder. In addition, any securities covered by this prospectus which qualify for sale pursuant to Rule 144 under the Securities Act may be sold under Rule 144 rather than under this prospectus. There is no underwriter or coordinating broker acting in connection with the proposed sale of the shares by the selling stockholders.

We agreed to keep this prospectus effective until the earlier of (i) the date on which the shares may be resold by the selling stockholders without registration and without regard to any volume limitations by reason of Rule 144(k) under the Securities Act or any other rule of similar effect, as determined by the counsel to the selling stockholder pursuant to a written opinion letter to such effect or (ii) all of the shares have been sold pursuant to this prospectus or Rule 144 under the Securities Act or any other rule of similar effect. The shares will be sold only through registered or licensed brokers or dealers if required under applicable state securities laws. In addition, in certain states, the shares may not be sold unless they have been registered or qualified for sale in the applicable state or an exemption from the registration or qualification requirement is available and is complied with.

To the extent required, the shares of our common stock to be sold, the names of the selling stockholders, the respective purchase prices and public offering prices, the names of any agent, dealer or underwriter, any applicable commissions or discounts with respect to a particular offer will be set forth in an accompanying prospectus supplement or, if appropriate, a post-effective amendment to the registration statement that includes this prospectus.

In order to comply with the securities laws of some states, if applicable, the common stock may be sold in these jurisdictions only through registered or licensed brokers or dealers. In addition, in some states the common stock may not be sold unless it has been registered or qualified for sale or an exemption from registration or qualification requirements is available and is complied with.

We have advised the selling stockholders that the anti-manipulation rules of Regulation M under the Exchange Act may apply to sales of shares in the market and to the activities of the selling stockholders and their affiliates. In addition, we will make copies of this prospectus (as it may be supplemented or amended from time to time) available to the selling stockholders for the purpose of satisfying the prospectus delivery requirements, if applicable, of the Securities Act. The selling stockholders may indemnify any broker-dealer that participates in transactions involving the sale of the shares against certain liabilities, including liabilities arising under the Securities Act.

We have agreed to indemnify the selling stockholders against liabilities, including liabilities under the Securities Act and state securities laws, relating to the registration of the shares offered by this prospectus.

### **Shares Eligible For Future Sale**

Upon completion of this offering and assuming the issuance of all of the shares covered by this prospectus that are issuable upon the exercise of the warrants, there will be 24,268,053 shares of our common stock issued and outstanding. The shares purchased in this offering will be freely tradable without registration or other restriction under the Securities Act, except for any shares purchased by an “affiliate” of our company (as defined in the Securities Act).



Our currently outstanding shares have been issued in reliance upon the “private placement” exemptions provided by the Act are deemed “restricted securities” within the meaning of Rule 144. Restricted securities may not be sold unless they are registered under the Securities Act or are sold pursuant to an applicable exemption from registration, including an exemption under Rule 144 of the Securities Act.

In general, under Rule 144 as currently in effect, any person (or persons whose shares are aggregated) including persons deemed to be affiliates, whose restricted securities have been fully paid for and held for at least one year from the later of the date of issuance by us or acquisition from an affiliate, may sell such securities in broker’s transactions or directly to market makers, provided that the number of shares sold in any three month period may not exceed the greater of 1% of the then-outstanding shares of our common stock or the average weekly trading volume of our shares of common stock in the over-the-counter market during the four calendar weeks preceding the sale. Sales under Rule 144 are also subject to certain notice requirements and the availability of current public information about our company. After two years have elapsed from the later of the issuance of restricted securities by us or their acquisition from an affiliate, such securities may be sold without limitation by persons who are not affiliates under the rule.

Following the date of this prospectus, we cannot predict the effect, if any, that sales of our common stock or the availability of our common stock for sale will have on the market price prevailing from time to time. Nevertheless, sales by existing stockholders of substantial amounts of our common stock could adversely affect prevailing market prices for our stock.

### **Other Matters**

Any FINRA member participating in the distribution of the shares offered under this prospectus will be subject to compliance with FINRA rules and regulations, including rules governing the timely filing of documents and disclosures with the Corporate Finance Department of the FINRA.

## **DESCRIPTION OF SECURITIES**

We currently have authorized 110,000,000 shares of capital stock, of which 100,000,000 are designated as common stock, par value \$.001 per share, and 10,000,000 are designated as preferred stock, par value \$.001 per share. We have 24,099,716 shares of common stock outstanding. Additionally, there are outstanding warrants to purchase an aggregate of 168,377 shares of our common stock and have issued options to purchase an aggregate 3,404,013 shares of our common stock, of which 731,641 options are currently exercisable.

### **Common Stock**

The holders of our 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 up, holders of our 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 our common stock have no preemptive, subscription, redemption or conversion rights.

## **ANTI TAKEOVER EFFECTS OF CERTAIN PROVISIONS OF OUR CERTIFICATE OF INCORPORATION AND DELAWARE LAW**

We are subject to Section 203 of the Delaware General Corporation Law, an anti takeover law. In general, Section 203 prohibits a publicly held Delaware corporation from engaging in a “business combination” with an “interested stockholder” for a period of three years following the date the person became an interested stockholder, unless (with certain exceptions) the “business combination” or the transaction in which the person became an “interested stockholder” is approved in a prescribed manner. Generally, a “business combination” includes a merger, asset or stock sale, or other transaction resulting in a financial benefit to the interested stockholder. Generally, an “interested stockholder” is a

person who, together with affiliates and associates, owns (or within three years prior to the determination of interested stockholder status, did own) 15% or more of the corporation's voting stock. The existence of this provision would be expected to have an anti takeover effect with respect to transactions not approved in advance by the board of directors, including discouraging takeover attempts that might result in a premium over the market price for the shares of common stock held by stockholders.

## **DISCLOSURE OF SEC POSITION ON INDEMNIFICATION FOR SECURITIES ACT LIABILITIES**

Pursuant to our amended and restated 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.

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

## **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, LLP 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.

## **ABOUT THIS PROSPECTUS**

This prospectus is not an offer or solicitation in respect to these securities in any jurisdiction in which such offer or solicitation would be unlawful. This prospectus is part of a registration statement that we filed with the SEC. The registration statement that contains this prospectus (including the exhibits to the registration statement) contains additional information about our company and the securities offered under this prospectus. That registration statement

can be read at the SEC web site or at the SEC's offices mentioned under the heading "Where You Can Find More Information." We have not authorized anyone else to provide you with different information or additional information. You should not assume that the information in this prospectus, or any supplement or amendment to this prospectus, is accurate at any date other than the date indicated on the cover page of such documents.



## **VALIDITY OF COMMON STOCK**

Legal matters in connection with the validity of the shares offered by this prospectus will be passed upon by Dickstein Shapiro, LLP, New York, NY.

### **EXPERTS**

Our financial statements as of June 30, 2007, and for the period from inception to June 30, 2007, included in this prospectus, have been included herein in reliance on the report of Hays & Company, L.L.P., independent registered public accounting firm, given on the authority of that firm as experts in accounting and auditing.

### **TRANSFER AGENT**

The transfer agent for our common stock is American Stock Transfer & Trust Company, and its address is Operations Center, 6201 15th Avenue, Brooklyn, NY 11219.

### **WHERE YOU CAN FIND MORE INFORMATION**

We have filed a registration statement on Form SB-2 with the SEC, to register the shares of our common stock being offered by this prospectus. In addition, we file annual, quarterly and current reports, proxy statements and other information with the SEC. You may read and copy any reports, statements or other information that we file at the SEC's public reference facilities at 100 F Street, N.E., Washington, D.C. 20549. Please call the SEC at 1-800-SEC-0330 for further information regarding the public reference facilities. The SEC maintains a website, <http://www.sec.gov>, that contains reports, proxy statements and information statements and other information regarding registrants that file electronically with the SEC, including us. Our SEC filings are also available to the public from commercial document retrieval services. Information contained on our website should not be considered part of this prospectus.

You may also request a copy of our filings at no cost by writing or telephoning us at:

Nile Therapeutics, Inc.  
2850 Telegraph Ave.  
Berkeley, CA 94705  
Telephone: (510) 281-7700  
Attn: Chief Financial Officer

## GLOSSARY OF TERMS

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

<b>agonist</b>	A drug that can combine with a receptor on a cell to produce a physiological reaction.
<b>atherothrombotic</b>	The formation of a clot in an artery that is characterized by a thickening and fatty degeneration of that vessel's inner coat.
<b>atherosclerotic</b>	A thickening and hardening of the artery walls characterized by fatty deposits in and fibrosis of the inner layer of the arteries.
<b>cardiovascular</b>	Of, relating to, or involving the heart and blood vessels.
<b>chimeric</b>	Of or related to an individual, organ, or part consisting of pieces of diverse genetic constitution.
<b>claudication</b>	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.
<b>natriuretic</b>	Of or related to the excretion of sodium in the urine.
<b>congestive heart failure</b>	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.
<b>diabetic nephropathy</b>	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.
<b>equimolar</b>	Of or relating to an equal number of moles.
<b>hypotension</b>	Abnormally low pressure of the blood.
<b>in vitro</b>	Outside the living body and in an artificial environment.
<b>in vivo</b>	In the living body of a plant or animal.
<b>mean arterial pressure</b>	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.
<b>metabolic disease</b>	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.
<b>microvascular disease</b>	An illness related to or constituting the part of the circulatory system made up of minute vessels.
<b>nitric oxide</b>	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.
<b>nitric oxide-donating properties</b>	The ability to release nitric oxide.
<b>pathological peptide</b>	Altered or caused by disease
<b>pharmacodynamics</b>	Two or more amino acids formed by combination of the amino group of one acid with the carboxyl group of another.

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.

<b>platelet aggregation</b>	The clumping of many small blood-based bodies that generally assists in blood clotting by adhering to each other and epithelium.
<b>prostacyclin</b>	A cyclic fatty acid that inhibits aggregation of platelets, and dilates blood vessels.
<b>prothrombotic</b>	Of or related to the promotion of blood clot formation.
<b>renal</b>	Relating to, involving, affecting, or located in the region of the kidneys.
<b>synthetic</b>	Of, relating to, or produced by chemical or biochemical synthesis; produced artificially.
<b>thrombotic</b>	Of or related to blood clot formation.
<b>thromboxane</b>	A substance that is produced by platelets, causes constriction of vascular and bronchial smooth muscle, and promotes blood clotting.
<b>vasculature</b>	The disposition or arrangement of blood vessels in an organ or part of the body.
<b>vasodilator</b>	An agent that widens the lumen of blood vessels.

**FINANCIAL STATEMENTS**

**NILE THERAPEUTICS, INC.**  
**(A Development Stage Enterprise)**

INDEX

	Page
Independent Auditor's Report	F-1
Balance Sheet as of June 30, 2007	F-2
Statements of Operations for the six month period ended June 30, 2007 and the period from August 1, 2005 (inception) to June 30, 2007	F-3
Statement of Stockholders' Equity (Deficit) for the period from August 1, 2005 (inception) to June 30, 2007	F-4
Statements of Cash Flows for the six month period ended June 30, 2007 and the period from August 1, 2005 (inception) to June 30, 2007	F-5
Notes to Financial Statements	F-6

To the Stockholders  
Nile Therapeutics, Inc.

### INDEPENDENT AUDITOR'S REPORT

We have audited the accompanying balance sheet of Nile Therapeutics, Inc. (a development stage company) (the "Company") as of June 30, 2007, the related statements of operations, changes in stockholders' equity (deficit), and cash flows for the six months ended June 30, 2007 and the period from August 1, 2005 (inception) through June 30, 2007. These financial statements are the responsibility of the Company's management. Our responsibility is to express an opinion on these financial statements based on our audit.

We conducted our audit in accordance with auditing standards generally accepted in the United States of America. Those standards require that we plan and perform the audit to obtain reasonable assurance about whether the financial statements are free of material misstatement. An audit includes consideration of internal control over financial reporting as a basis for designing audit procedures that are appropriate in the circumstances, but not for the purpose of expressing an opinion on the effectiveness of the Company's internal control over financial reporting. Accordingly, we express no such opinion. An audit also includes examining, on a test basis, evidence supporting the amounts and disclosures in the financial statements, assessing the accounting principles used and significant estimates made by management, as well as evaluating the overall financial statement presentation. We believe that our audit provides a reasonable basis for our opinion.

In our opinion, the financial statements referred to above present fairly, in all material respects, the financial position of Nile Therapeutics, Inc. (a development stage company) as of June 30, 2007, and the results of its operations and its cash flows for the six months ended June 30, 2007 and for the period from August 1, 2005 (inception) to June 30, 2007 in conformity with accounting principles generally accepted in the United States of America.

The accompanying financial statements have been prepared assuming that the Company will continue as a going concern. As discussed in Note 1 to the financial statements, the Company has incurred a significant working capital deficiency and recurring losses from operations that raise substantial doubt about its ability to continue as a going concern. Management's plans in regard to these matters are also described in Note 1. The financial statements do not include any adjustments that might result from the outcome of this uncertainty.

/s/ Hays & Company L.L.P.

August 14, 2007  
New York, New York

F-1

---

**NILE THERAPEUTICS, INC.**  
**(a development stage company)**

**BALANCE SHEET**

**JUNE 30, 2007**

**ASSETS**

**Current assets**

Cash and cash equivalents	\$	165,194
Note receivable - employee, current portion		15,559
Prepaid expenses		26,760
		207,513

Property and equipment, net of accumulated depreciation of \$4,774		59,674
Note receivable - employee, net of current portion		31,117
Intangible assets, net of accumulated amortization of \$1,807		41,511
Deposits		33,400
	\$	373,215

**LIABILITIES AND STOCKHOLDERS' EQUITY (DEFICIT)**

**Current liabilities**

Accounts payable and accrued expenses	\$	804,313
Accrued interest - convertible notes payable		302,466
Due to related party		84,109
		1,190,888

Convertible notes payable		4,000,000
		5,190,888

**Commitments and contingencies**

(Notes 1, 3, 4, 5, 6, 7, 8, 9, 10, 11 and 12)

**Stockholders' equity (deficit)**

Common stock, \$.001 par value; 25,000,000 shares authorized, 5,000,000 issued and outstanding		5,000
Additional paid-in capital		7,167
Deficit accumulated during the development stage		(4,829,840)
		(4,817,673)
	\$	373,215

The accompanying notes are an integral part of these financial statements.

**NILE THERAPEUTICS, INC.**  
**(a development stage company)**

**STATEMENTS OF OPERATIONS**

	Six months ended June 30, 2007	Period from August , 2005 (inception) through June 30, 2007
<b>Revenues</b>	\$ -	\$ 380,835
Grant income		
<b>Operating expenses</b>		
Research and development	1,421,277	4,130,683
General and administrative	721,496	901,353
	2,142,773	5,032,036
<b>Loss from operations</b>	(2,142,773)	(4,651,201)
Interest income	23,962	123,827
Interest expense	(119,014)	(302,466)
<b>Net loss</b>	\$ (2,237,825)	\$ (4,829,840)

The accompanying notes are an integral part of these financial statements.



**NILE THERAPEUTICS, INC.**  
**(a development stage company)**

**STATEMENT OF STOCKHOLDERS' EQUITY (DEFICIT)**

**PERIOD FROM AUGUST 1, 2005 (INCEPTION)  
TO JUNE 30, 2007**

	Common Stock		Additional paid-in capital	Deficit accumulated during the development stage	Total
	Shares	Amount			
Issuance of common stock to founders at \$0.001 per share	5,000,000	\$ 5,000	\$ -	\$ -	5,000
Founders' shares returned to treasury	(500,000)	-	-	-	-
Issuance of common stock to licensor at \$0.001 per share	500,000	-	500	-	500
Issuance of stock options for services at \$0.25	-	-	10,000	-	10,000
Net loss, period from August 1, 2005 (inception) to December 31, 2006	-	-	-	(2,592,015)	(2,592,015)
Balance at December 31, 2006	5,000,000	5,000	10,500	(2,592,015)	(2,576,515)
Net loss, period from January 1, 2007 to June 30, 2007	-	-	-	(2,237,825)	(2,237,825)
Cancellation of stock options issued in 2006 at \$0.25	-	-	(3,333)	-	(3,333)
Balance at June 30, 2007	5,000,000	\$ 5,000	\$ 7,167	\$ (4,829,840)	\$ (4,817,673)

The accompanying notes are an integral part of these financial statements.

**NILE THERAPEUTICS, INC.**  
**(a development stage company)**

**STATEMENTS OF CASH FLOWS**

	Six months ended June 30, 2007	Period from August 1, 2005 (inception) through June 30, 2007
<b>Cash flows from operating activities</b>		
Net loss	\$ (2,237,825)	\$ (4,829,840)
<b>Adjustments to reconcile net loss to net cash used in operating activities</b>		
Depreciation and amortization	6,227	6,581
Stock based compensation	(3,333)	7,167
<b>Changes in operating assets and liabilities</b>		
Increase in prepaid expenses	(26,760)	(26,760)
Increase in deposits	(18,400)	(33,400)
Increase in accounts payable and accrued expenses	326,200	804,313
Increase in accrued interest - notes payable	119,014	302,466
Increase in due to related party	78,280	84,109
<b>Net cash used in operating activities</b>	<b>(1,756,597)</b>	<b>(3,685,364)</b>
<b>Cash flows from investing activities</b>		
Purchase of property and equipment	(47,585)	(64,448)
Investment in notes receivable - employee	(46,676)	(46,676)
Cash paid for intangible assets	(6,183)	(43,318)
<b>Net cash used in investing activities</b>	<b>(100,444)</b>	<b>(154,442)</b>
<b>Cash flows from financing activities</b>		
Proceeds from sale of common stock	-	5,000
Proceeds from sale of convertible notes payable	-	4,000,000
<b>Net cash provided by financing activities</b>	<b>-</b>	<b>4,005,000</b>
Net (decrease) increase in cash and cash equivalents	(1,857,041)	165,194
Cash and cash equivalents, beginning of period	2,022,235	-
Cash and cash equivalents, end of period	\$ 165,194	\$ 165,194

The accompanying notes are an integral part of these financial statements.

**NILE THERAPEUTICS, INC.**  
**(a development stage company)**

**NOTES TO FINANCIAL STATEMENTS**

**PERIOD FROM AUGUST 1, 2005 (INCEPTION)**  
**TO JUNE 30, 2007**

**1 Organization and business activities**

**The Company**

Nile Therapeutics, Inc. (the "Company"), a Delaware corporation, was incorporated on August 1, 2005. The Company is a biopharmaceutical company that develops and commercializes innovative products for the treatment of important unmet medical needs, including without limitation, in cardiovascular disease. The Company is initially focusing its efforts on developing, testing and commercializing its lead compound, known as CD-NP, for the treatment of heart failure.

The Company's primary activities since incorporation have been organizational; including recruiting personnel, establishing office facilities, acquiring a technology license, performing business and financial planning, conducting research and development activities and raising capital and have not generated any revenues other than certain grants. Accordingly, the Company is considered to be in the development stage.

**Going concern**

The accompanying financial statements have been prepared assuming that the Company will continue as a going concern. The Company has incurred a significant working capital deficiency and recurring losses from operations that raise substantial doubt about its ability to continue as a going concern. Management's plans with regard to this uncertainty are discussed below.

On July 19, 2007, the Company entered into a Confidential Term Sheet with SMI Products, Inc., a Delaware corporation ("SMI") pursuant to which the Company will enter into a Merger Agreement with SMI and its wholly-owned subsidiary, Nile Merger Sub, Inc., also a Delaware corporation, pursuant to which Nile Merger Sub, Inc. shall be merged with and into the Company (the "Merger"), the separate corporate existence of Nile Merger Sub, Inc. shall cease and the Company shall continue as the surviving corporation and shall become a wholly-owned subsidiary of SMI. SMI is subject to the reporting requirements of the Securities Exchange Act of 1934, as amended, and is publicly traded on the OTC Bulletin Board. SMI does not operate any business.

**NILE THERAPEUTICS, INC.**  
**(a development stage company)**

**NOTES TO FINANCIAL STATEMENTS**

**PERIOD FROM AUGUST 1, 2005 (INCEPTION)**  
**TO JUNE 30, 2007**

As a condition of the Merger, the Company must obtain gross proceeds from an equity financing equal to at least \$15,000,000 (the "Financing"). As discussed in Note 5, upon the closing of the Financing, the outstanding balance of the Notes will automatically convert into shares of the Company's common stock. The Company expects to use the proceeds from the Financing to satisfy its current outstanding obligations, including the Promissory Note discussed in Note 12, and to provide sufficient funds in order to continue its business plan over the next year or more. Management can provide no assurances that the Company will be able to raise sufficient funds in order to complete the Merger or satisfy its current outstanding obligations. The accompanying financial statements do not include any adjustments that might result from this uncertainty.

At the effective time of the Merger, each of the Company's then issued and outstanding shares of common stock, including shares purchased in the Financing, will be exchanged for shares of SMI common stock, \$0.001 par value per share, so that, after giving effect to the Merger, the holders of the Company's common stock on a fully-diluted basis, will hold approximately 95% of the issued and outstanding shares of SMI common stock and holders of SMI common stock immediately prior to the Merger shall hold approximately 5% of the outstanding shares of SMI common stock on a fully-diluted basis. All outstanding warrants, options and other rights to purchase or acquire shares of the Company's common stock outstanding immediately prior to the Merger shall convert into to the right to purchase that number of shares of SMI common stock at the exchange ratio at adjusted exercise prices.

Upon completion of the Merger, SMI will adopt and continue implementing the Company's business plan. Further, upon completion of the Merger, the current officers and directors of SMI will resign and the current officers and directors of the Company will be appointed officers and directors of SMI. For accounting purposes, the Merger will be accounted for as an acquisition of SMI and recapitalization of the Company with the Company as the accounting acquirer (legal acquiree) and SMI as the accounting acquiree (legal acquirer). Also at the effective date of the Merger, the Company will pay to Fountainhead Capital Partners Limited ("Fountainhead") a consulting fee of \$500,000 for their work in connection with the Merger. Fountainhead holds approximately 73.5% of SMI's issued and outstanding common shares and also holds various convertible promissory notes from SMI in the aggregate amount of \$165,901. These convertible promissory notes by Fountainhead will convert into shares of SMI common stock as a condition to the Merger.

As a result of the Merger, the Company expects to incur increased operating costs primarily related to public company regulatory compliance.

**2**

**Significant accounting policies**

**Estimates**

The preparation of financial statements in conformity with generally accepted accounting principles in the United States of America requires management to make estimates and assumptions that affect the reported amounts of assets and liabilities and disclosures of contingent assets and liabilities at the date of the financial statements and reported amounts of revenue and expenses during the reporting period. Accordingly, actual results could differ from those estimates.



**NILE THERAPEUTICS, INC.**  
**(a development stage company)**

**NOTES TO FINANCIAL STATEMENTS**

**PERIOD FROM AUGUST 1, 2005 (INCEPTION)**  
**TO JUNE 30, 2007**

**Cash and cash equivalents**

For purposes of the statement of cash flows, cash equivalents include time deposits, money market accounts, and all highly liquid debt instruments with original maturities of three months or less. The Company maintains cash in bank deposit accounts which, at times, exceed federally insured limits. The Company has not experienced any losses on these accounts.

**Property and equipment**

Property and equipment, which consists principally of furnishings and fixtures and computer and related equipment, are stated at cost. Maintenance and repairs are charged to expense as incurred. Additions, improvements and replacements are capitalized.

Depreciation of property and equipment is provided for by the straight line method over the estimated useful lives of the related assets which are five to seven years for furnishings and fixtures and three years for computer and related equipment.

**Intangible assets**

Intangible assets consist of costs related to acquiring patents and are amortized over the estimated patent life. Pending patent applications will be amortized when the patents are issued.

**Impairment of long lived assets**

The Company reviews long-lived assets for impairment whenever events or changes in circumstances indicate that the carrying amount of an asset may not be recoverable. An asset is considered to be impaired when the sum of the undiscounted future net cash flows expected to result from the use of the asset and its eventual disposition is less than its carrying amount. The amount of impairment loss, if any, is measured as the difference between the net book value of the asset and its estimated fair value.

**Grant revenue**

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

**Research and development**

Research and development costs are expensed as incurred. Clinical trial costs incurred by third parties are expensed as the contracted work is performed. Where contingent milestone payments are due to third parties under research and development arrangements, the milestone payment obligations are expensed when the milestone results are achieved.

**NILE THERAPEUTICS, INC.**  
**(a development stage company)**

**NOTES TO FINANCIAL STATEMENTS**

**PERIOD FROM AUGUST 1, 2005 (INCEPTION)**  
**TO JUNE 30, 2007**

**Income taxes**

In accordance with Statement of Financial Accounting Standards (“SFAS”) No. 109, Accounting for Income Taxes, deferred tax assets and liabilities are recognized based on temporary differences between the financial statement and the tax bases of assets and liabilities. Deferred tax assets and liabilities are measured using enacted tax rates expected to apply to taxable income in the years in which these assets and liabilities are expected to be recovered or settled. The Company provides a valuation allowance when it appears more likely than not that some or all of the net deferred tax assets will not be realized.

**Share based payments**

Effective August 2005, the Company adopted Statement of Financial Accounting Standards No. 123R, Share-Based Payment, (“SFAS 123R”). SFAS 123R requires the recognition of stock-based compensation expense in the financial statements. 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 vesting conditions generally include the attainment of goals related to the Company's financial and development performance.

**3 License agreement**

In January 2006 the Company entered into an exclusive, worldwide, royalty bearing license agreement (the “License Agreement”) with Mayo Foundation for Medical Education and Research (“Mayo”), including the right to grant sublicenses, for the rights to intellectual property and know-how relating to CD-NP, a chimeric natriuretic peptide, for all therapeutic uses. Under the terms of the License Agreement, the Company paid Mayo an up-front cash payment and reimbursed it for past patent expenses. In addition, the Company issued to Mayo 500,000 shares of its common stock. The Company is also required to make performance-based cash payments upon successful completion of clinical and regulatory milestones relating to CD-NP. The Company will not owe any milestone payment to Mayo until the first patient is dosed in the first Company sponsored Phase II clinical trial of its lead product in the U.S. The Company has also agreed to pay Mayo 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.

In addition to the potential milestone payments discussed above, the License Agreement requires the Company to issue common shares to Mayo for an equivalent dollar amount of grants received in excess of \$300,000, but not exceeding \$575,000. The shares are to be issued upon the completion of an additional equity financing completed by the Company. For the period from August 1, 2005 (inception) through June 30, 2007, the Company received \$380,835 in grant income. Accordingly, the Company has recorded a liability of \$80,835 in the accompanying financial statements in connection with this obligation. On July 3, 2007, the Company received an additional \$101,400 of grant revenue and will be required to issue shares of an equivalent dollar amount upon the completion of an additional equity financing.

**NILE THERAPEUTICS, INC.**  
**(a development stage company)**

**NOTES TO FINANCIAL STATEMENTS**

**PERIOD FROM AUGUST 1, 2005 (INCEPTION)**  
**TO JUNE 30, 2007**

Under the License Agreement, the Company is also obligated to pay Mayo royalty payments based on sales of licensed products, as defined.

**4 Note receivable - employee**

In January 2007, the Company advanced \$46,676 to one of its executive employees and issued a promissory note which accrues interest at a rate of 4.75% per annum and matures in February 2010. The note requires three equal annual installment re-payments due from the future performance bonuses earned by the executive.

**5 Convertible notes payable**

During March 2006, the Company completed a private placement offering for \$4,000,000 aggregate principal amount of 6% convertible promissory notes (the "Notes") due on March 28, 2008.

The Notes are unsecured obligations convertible into the Company's common stock. Interest on the Notes accrues at 6% per year and is payable in full on maturity. The Notes mandatorily convert upon the closing of the Company's next equity financing ("Subsequent Financing") in which the Company sells newly-issued shares of its equity securities or securities convertible into equity securities, of one or more series (the "Equity Securities") for cash proceeds of \$5,000,000 or more. At conversion, the outstanding principal and accrued but unpaid interest shall automatically convert into validly issued, fully paid and non-assessable Equity Securities of the same kind issued in the Subsequent Financing at a conversion price equal to 90% of the per share or unit purchase price of the Subsequent Financing.

In addition, upon conversion, the Company shall issue warrants entitling the holder to purchase, for a period of five years from the effective date of the conversion, a number of shares of common stock of the Company computed by dividing 10% of the principal amount of the Note by either (a) the price per share paid by investors in the Subsequent Financing or (b) if a Subsequent Financing does not occur on or before the maturity date, the price per share paid by the most recent investor in the common stock of the Company.

At June 30, 2007, \$302,466 in interest has been accrued on the Notes.



**NILE THERAPEUTICS, INC.**  
**(a development stage company)**

**NOTES TO FINANCIAL STATEMENTS**

**PERIOD FROM AUGUST 1, 2005 (INCEPTION)**  
**TO JUNE 30, 2007**

**6** **Stockholder's equity**

In August 2005, the Company issued 5,000,000 shares of common stock to its founders for \$5,000 or \$0.001 per share. The founders subsequently returned 500,000 of these shares to the Company for issuance to the licensor.

In January 2006, the Company issued 500,000 shares of common stock to its licensor in accordance with the terms of the License Agreement. The fair value of the shares at the time of issuance was estimated by management to be \$0.001 and the Company recorded \$500 of stock based compensation which has been charged to research and development expense.

As discussed in Note 3, the Company is obligated to issue shares of common stock to Mayo equal to \$80,835 upon completion of additional equity financing by the Company.

**7** **Stock based compensation**

In 2005, the Company established a stock option plan (the "Plan") under which incentives may be granted to officers, employees, directors, consultants and advisors. Incentives under the Plan may be granted in any one or a combination of the following forms: (a) incentive stock options and non-statutory stock options; (b) stock appreciation rights; (c) stock awards; (d) restricted stock; and (e) performance shares. The number of shares of common stock, which may be issued under the Plan, shall not exceed 1,500,000. Since inception, the Company granted a total of 75,000 stock options to advisors with an exercise price of \$0.25 per share, of which, 25,000 were subsequently canceled during the six months ended June 30, 2007.

The stock-based compensation expense in connection with stock option grants amounted to \$6,667 for the period from August 1, 2005 (inception) to June 30, 2007 and is included in research and development expense.

The fair value of each stock option granted has been determined using the Black-Scholes model. The material factors incorporated in the Black-Scholes model in estimating the value of the options reflected in the following table include:

Risk-free interest rate	4.70 %
Volatility	62.67 %
Estimated life in years	4 years
Dividends paid	None

**NILE THERAPEUTICS, INC.**  
**(a development stage company)**

**NOTES TO FINANCIAL STATEMENTS**

**PERIOD FROM AUGUST 1, 2005 (INCEPTION)  
TO JUNE 30, 2007**

A summary of option activity under the Plan since inception and changes during the period from December 31, 2006 to June 30, 2007 is as follows:

Options	Shares	Weighted-Average Exercise Price
<b>2006 and prior</b>		
Options granted	75,000	\$ 0.25
Options exercised	-	\$ -
Outstanding at December 31, 2006	75,000	\$ 0.25
Exercisable at December 31, 2006	75,000	\$ 0.25
<b>2007</b>		
Options granted	-	\$ -
Options exercised	-	\$ -
Options cancelled	(25,000)	\$ 0.25
Outstanding at June 30, 2007	50,000	\$ 0.25
Exercisable at June 30, 2007	50,000	\$ 0.25

As of June 30, 2007, the aggregate fair value of options outstanding was \$6,667, with a weighted-average remaining term of two years. The aggregate fair value of stock options exercisable at that same date was \$6,667, with a weighted-average remaining term of two years. As of June 30, 2007, the Company has 1,450,000 shares available for future stock option grants.

As discussed in Note 6, the Company recorded stock based compensation expense of \$500 during 2006 in connection with the issuance of 500,000 shares of common stock to the licensor.

**NILE THERAPEUTICS, INC.**  
**(a development stage company)**

**NOTES TO FINANCIAL STATEMENTS**

**PERIOD FROM AUGUST 1, 2005 (INCEPTION)**  
**TO JUNE 30, 2007**

**7** **Stock based compensation (Cont.)**

Immediately following the closing of the Financing as discussed in Note 1, the Company will grant stock options (the "Employment Options") to its Chief Executive Officer ("CEO") pursuant to the Plan to purchase that number of shares representing 4% of the Company's outstanding common stock on a fully diluted basis as of the grant date. The Employment Options shall vest, if at all, and become exercisable in three equal installments on the day before each anniversary of the CEO's employment agreement. At the same time, the Company will grant to its CEO performance-based stock options (the "Performance Options") to purchase up to that number of shares representing 3.6% of the Company's outstanding common stock on a fully diluted basis as of the grant date. A pro-rata portion of the Performance Options shall vest, if at all, and become exercisable upon the successful completion of annual corporate and individual milestones.

Also immediately following the closing of the Financing as discussed in Note 1, the Company will grant Employment Options to its Chief Operating Officer ("COO") pursuant to the Plan to purchase that number of shares representing 1% of the Company's outstanding common stock on a fully diluted basis as of the grant date. The Employment Options shall vest, if at all, and become exercisable in three equal installments on the day before each anniversary of the COO's employment agreement. At the same time, the Company will grant to its COO Performance Options to purchase up to that number of shares representing 1.2% of the Company's outstanding common stock on a fully diluted basis as of the grant date. A pro-rata portion of the Performance Options shall vest, if at all, and become exercisable upon the successful completion of annual corporate and individual milestones.

**8** **Pension plan**

On April 1, 2007 the Company established a defined contribution 401(k) plan (the "401(k) Plan") for the benefit of its employees. Substantially all of the employees of the Company are eligible to participate in the 401 (k) Plan which permits employees to make voluntary contributions up to the dollar limit allowed under the Internal Revenue Code. The 401(k) Plan also provides for matching contributions by the Company of up to a combined total of 3% of an employee's annual compensation. The Company has recorded \$773 of matching contributions for the six months ended June 30, 2007

**9** **Related parties**

From time-to-time, some of the Company's expenses are paid for by Two River Group Holdings, LLC ("Two River"), accompany owned by several of the Company's founders. The Company reimburses Two River for these expenses and no interest is charged on the outstanding balance. For six months ended June 30, 2007, reimbursable expenses amounted to \$83,133. At June 30, 2007, \$84,109 is unpaid.

The Company utilized the services of Riverbank Capital Securities, Inc., ("Riverbank"), an entity owned by several of the Company's officers, directors and founders, for investment banking and other investment advisory services in connection with the Company's private placement issuance of the Notes. Riverbank did not charge any fees to the Company in connection with this private placement.



**NILE THERAPEUTICS, INC.**  
**(a development stage company)**

**NOTES TO FINANCIAL STATEMENTS**

**PERIOD FROM AUGUST 1, 2005 (INCEPTION)**  
**TO JUNE 30, 2007**

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

**10** **Income taxes**

At December 31, 2006, the Company has federal tax net operating loss and credit carry forwards of approximately \$2,580,000. During the six months ended June 30, 2007, the Company has generated an additional estimated net operating loss and credit carry forward of approximately \$1,828,000. The federal net operating loss and credit carry forwards will begin to expire in 2026, unless previously utilized. Pursuant to Internal Revenue Code Sections 382 and 383, use of the Company's net operating loss and credit carry forwards may be limited if a cumulative change in ownership of more than 50% occurs within a three-year period. No assessment has been made as to whether such a change in ownership has occurred.

Significant components of the Company's net deferred tax assets at June 30, 2007 are shown below. A valuation allowance of \$1,899,000 has been established to offset the net deferred tax asset at June 30, 2007, as realization of such assets is uncertain.

Noncurrent net operating loss carry forwards	\$ 1,895,000
Other noncurrent	4,000
<b>Total noncurrent</b>	<b>1,899,000</b>
Other current	-
<b>Total deferred tax assets</b>	<b>1,899,000</b>
Deferred tax valuation allowance	(1,899,000)
<b>Net deferred taxes-</b>	<b>\$ -</b>

**11** **Commitments and contingencies**

The Company is obligated under noncancelable operating leases for office space and office equipment expiring in April 2010. The aggregate minimum future payments under the leases are payable as follows:

<u>Year ending December 31,</u>	
2007 (six month period)	\$ 38,786
2008	79,437
2009	82,233
2010	27,722
	<b>\$ 228,178</b>



**NILE THERAPEUTICS, INC.**  
**(a development stage company)**

**NOTES TO FINANCIAL STATEMENTS**

**PERIOD FROM AUGUST 1, 2005 (INCEPTION)**  
**TO JUNE 30, 2007**

Rent expense charged to operations, including escalation charges for real estate taxes and other expenses, amounted to \$14,524 for the six months ended June 30, 2007.

The Company has entered into various contracts with third parties in connection with the development of the licensed technology as described in Note 3. Future minimum commitments under these agreements amounted to approximately \$256,000 at June 30, 2007 and are scheduled to be incurred during the next year.

The Company has entered into various agreements with third party consultants which expire at various dates through 2008 for which the Company is obligated to pay for services based upon hourly rates or completion of services as defined.

As of June 30, 2007 the Company has two employment agreements with executives expiring through June 2010. The agreements provide for base salaries plus additional incentive compensation, as defined.

Future minimum commitments under this agreement as of June 30, 2007 are as follows:

<u>Year ending December 31,</u>		
2007 (six month period)	\$	242,500
2008		485,000
2009		485,000
2010		151,042
	\$	1,363,542

A former executive of the Company terminated his employment agreement with the Company on May 21, 2007. On August 10, 2007, the Company entered into a Separation Agreement and General Release (the "Separation Agreement") with the executive. Pursuant to the terms of the Separation Agreement, the Company will continue to pay the executive's base salary, performance bonus and benefits until May 21, 2008. In addition, the Company will grant stock options to purchase a number of shares of the Company's common stock immediately following the closing of the Financing. The Company will also provide the executive with limited "piggyback" registration rights and will reimburse him for attorney's fees in an amount up to \$12,500. In addition, the parties agree to release each other from any claims arising out of the executive's employment with the Company.

In the normal course of business, the Company enters into contracts that contain a variety of indemnifications with its employees, licensors, suppliers and service providers. Further, the Company indemnifies its directors and officers who are, or were, serving at the Company's request in such capacities. The Company's maximum exposure under these arrangements is unknown as of June 30, 2007. The Company does not anticipate recognizing any significant losses relating to these arrangements.

**NILE THERAPEUTICS, INC.**  
**(a development stage company)**

**NOTES TO FINANCIAL STATEMENTS**

**PERIOD FROM AUGUST 1, 2005 (INCEPTION)**  
**TO JUNE 30, 2007**

**12**

**Subsequent events**

On July 24, 2007, the Company issued an 8% Promissory Note to an investor in the aggregate amount of \$1,500,000. This Promissory Note matures on the November 24, 2007. The Company also paid the investor a \$30,000 fee at closing, which was netted from the gross proceeds.

On July 19, 2007, the Company signed a non-binding letter of intent to enter into an additional license agreement relating to certain intellectual property. Pursuant to the letter of intent, the Company would acquire the worldwide, exclusive rights to research, develop and commercialize a novel therapeutic technology. If this transaction is completed, the Company would be required to (a) pay an initial license fee, (b) reimburse the licensor for past patent expenses and (c) issue to the licensor a number of shares of common stock.

In addition, the Company would be obligated to make additional cash payments upon the successful completion of clinical, regulatory and commercial milestones. If the Company is able to obtain regulatory approval in the U.S., Europe and Japan and to thereafter make substantial sales of licensed product(s), such milestone payments could be significant.

The Company would also be obligated to pay the licensor royalty payments based on sales of the licensed product(s).

Upon completion of the license agreement, the Company may also pay to certain employees of Two River a cash finder's fee and issue them warrants to purchase the Company's common stock exercisable at fair market value.

F-16

---



## Part II

**INFORMATION NOT REQUIRED IN PROSPECTUS****Item 24. Indemnification of Directors and Officers.**

Pursuant to our amended and restated 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.

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

**Item 25. Other Expenses of Issuance and Distribution.**

The following table sets forth the costs and expenses, other than underwriting discounts and commissions, payable by us in connection with the sale of common stock being registered. All amounts, other than the SEC registration fee, are estimates. We will pay all these expenses.

	<b>Amount to be Paid</b>
SEC Registration Fee	\$ 1,167
Printing Fees and Expenses	\$ 5,000
Legal Fees and Expenses	\$ 50,000
Accounting Fees and Expenses	\$ 5,000
Blue Sky Fees and Expenses	\$ 5,000
Miscellaneous	\$ 0.00
<b>Total</b>	<b>\$ 66,167</b>

**Item 26. Recent Sales of Unregistered Securities.**

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 our common stock as of the closing of the Merger.

**Recent Financings**

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 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

Edgar Filing: Nile Therapeutics, Inc. - Form SB-2

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 our common stock equal to 10% of the Conversion Shares at an exercise price equal to the Offering Price.

II-1

---

## Edgar Filing: Nile Therapeutics, Inc. - Form SB-2

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.

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.

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 at a conversion price equal \$7.128 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.

On September 17, 2007, we exchanged stock options of Old Nile held by Mr. Peter Strumph for stock options to purchase 1,876,491 shares of our common stock. See *“Employment Agreements, Termination of Employment and Change-in-Control Arrangements.”*

On September 17, 2007, we exchanged stock options of Old Nile held by Mr. Daron Evans for stock options to purchase 528,354 shares of our common stock. See *“Employment Agreements, Termination of Employment and Change-in-Control Arrangements.”*

On September 17, 2007, we exchanged stock options of Old Nile held by Ms. Jennifer Hodge stock for options to purchase 239,896 shares of our common stock. See *“Employment Agreements, Termination of Employment and Change-in-Control Arrangements.”*

On September 17, 2007, we exchanged stock options of Old Nile held by Dr. Allan Gordon for stock options to purchase 593,743 shares of our common stock. See *“Employment Agreements, Termination of Employment and Change-in-Control Arrangements.”*

On September 17, 2007, we also issued 494,900 shares of our common stock to Fountainhead Capital Partner Limited, upon the conversion of \$168,573 of convertible promissory notes, and accrued interest.

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 our 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.

II-2

---

**Item 27. Exhibits.**

The following exhibits are filed as part of this registration statement:

Exhibit No.	Description
2.1	Agreement and Plan of Merger, by and among SMI Products, Inc. (SMI), Nile Merger Sub, Inc., and Nile Therapeutics, Inc. dated as of August 15, 2007 (incorporated by reference to Exhibit 2.1 of SMI's current report on Form 8-K filed on August 15, 2007).
3.1	Amended and Restated Certificate of Incorporation (incorporated by reference to Exhibit 3.1 of SMI's current report on Form 8-K filed on February 9, 2007).
3.2	Certificate of Merger relating to the merger of Nile Merger Sub, Inc. with and into Nile Therapeutics, Inc.
3.3	Certificate of Ownership and Merger Merging Nile Therapeutics, Inc. into SMI Products, Inc.
3.4	Bylaws (incorporated by reference to Exhibit 3.2 of SMI's current report on Form 8-K filed on February 9, 2007).
4.1	Form of Nile Therapeutics, Inc. Common Stock Purchase Warrant issued on September 11, 2007 (incorporated by reference to Exhibit 10.1 of our current report on Form 8-K filed on September 21, 2007).
4.2	Specimen Common Stock Certificate (incorporated by reference to Exhibit 4.1 of our current report on Form 8-K filed on September 21, 2007).
5.1	Opinion of Dickstein Shapiro, LLP dated October 22, 2007
10.1	Form of Subscription Agreement dated September 11, 2007 entered into with investors in the September 11, 2007 private placement offering (incorporated by reference to Exhibit 10.12 of our current report on Form 8-K filed on September 21, 2007)
10.2	License Agreement between The Mayo Foundation for Medical Education and Research and Nile Therapeutics, Inc., dated January 20, 2006 (incorporated by reference to Exhibit 10.6 of our current report on Form 8-K filed on September 21, 2007).
10.3	License Agreement between Nile Therapeutics, Inc. and Dr. Cesare Casagrande, dated August 6, 2007 (incorporated by reference to Exhibit 10.7 of our current report on Form 8-K filed on September 21, 2007).
10.4	Amended and Restated 2005 Stock Option Plan (incorporated by reference to Exhibit 10.9 of our current report on Form 8-K filed on September 21, 2007).
10.5	

Edgar Filing: Nile Therapeutics, Inc. - Form SB-2

Employment Agreement dated as of May 11, 2007 between Nile Therapeutics, Inc. and Peter M. Strumph (incorporated by reference to Exhibit 10.2 of our current report on Form 8-K filed on September 21, 2007).

II-3

---

Edgar Filing: Nile Therapeutics, Inc. - Form SB-2

- 10.6 Employment Agreement dated as of January 19, 2007 between Nile Therapeutics, Inc. and Daron G. Evans (incorporated by reference to Exhibit 10.3 of our current report on Form 8-K filed on September 21, 2007).
- 10.7 Amendment No. 1 to Employment Agreement, dated as of August 19, 2007, between Nile Therapeutics, Inc. and Daron G. Evan.
- 10.8 Letter Agreement, dated as of August 31, 2007, between Nile Therapeutics, Inc. and Jennifer L. Hodge (incorporated by reference to Exhibit 10.5 of our current report on Form 8-K filed on September 21, 2007).
- 10.9 Form of Stock Option Agreement (incorporated by reference to Exhibit 10.10 of our current report on Form 8-K filed on September 21, 2007)
- 10.10 Form of Incentive Stock Option Agreement (incorporated by reference to Exhibit 10.11 of our current report on Form 8-K filed on September 21, 2007)
- 10.11 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. (incorporated by reference to Exhibit 10.8 of our current report on Form 8-K filed on September 21, 2007).
- 10.12 Separation Agreement and General Release between Nile Therapeutics, Inc. and Allan Gordon dated August 10, 2007 (incorporated by reference to Exhibit 10.13 of our current report on Form 8-K filed on September 21, 2007).
- 16.1 Letter from Paritz & Co dated September 20, 2007 regarding change in certifying accountants (incorporated by reference to Exhibit 16.1 of our current report on Form 8-K filed on September 21, 2007).
- 16.2 Letter from Amisano Hanson Chartered Accountants dated February 5, 2007, regarding change in certifying accountants (incorporated by reference to Exhibit 16.1 of SMI's current report on Form 8-K filed on December 8, 2006).
- 23.1 Consent of Hays & Company LLP
- 23.2 Consent of Dickstein Shapiro, LLP (included in Exhibit 5.1).
- 24.1 Powers of Attorney (included in Signature Pages to this Registration Statement on Form SB-2).

II-4

---

**Item 28. Undertakings.**

The undersigned registrant hereby undertakes:

- (1) To file, during any period in which it offers or sells securities, a post-effective amendment to this registration statement to: (i) Include any prospectus required by section 10(a)(3) of the Securities Act; (ii) Reflect in the prospectus any facts or events which, individually or together, represent a fundamental change in the information in the registration statement. Notwithstanding the foregoing, any increase or decrease in volume of securities offered (if the total dollar value of the securities offered would not exceed that which was registered) and any deviation from the low or high end of the estimated maximum offering range may be reflected in the form of prospectus filed with the SEC pursuant to Rule 424(b) under the Securities Act if, in the aggregate, the changes in volume and price represent no more than a 20% change in the maximum aggregate offering price set forth in the "Calculation of Registration Fee" table in the effective registration statement; and (iii) Include any additional or changed material information on the plan of distribution.
- (2) For determining liability under the Securities Act, treat each post-effective amendment as a new registration statement of the securities offered, and the offering of the securities at that time to be the initial bona fide offering; and
- (3) File a post-effective amendment to remove from registration any of the securities that remain unsold at the end of the offering.
- (4) For determining liability of the Company under the Securities Act to any purchaser in the initial distribution of the securities, the Company undertakes that in a primary offering of securities of the Company pursuant to this registration statement, regardless of the underwriting method used to sell the securities to the purchaser, if the securities are offered or sold to such purchaser by means of any of the following communications, the Company will be a seller to the purchaser and will be considered to offer or sell such securities to such purchaser: (i) Any preliminary prospectus or prospectus of the Company relating to the offering required to be filed pursuant to Rule 424; (ii) Any free writing prospectus relating to the offering prepared by or on behalf of the Company or used or referred to by the Company; (iii) The portion of any other free writing prospectus relating to the offering containing material information about the Company or its securities provided by or on behalf of the Company; and (iv) Any other communication that is an offer in the offering made by the Company to the purchaser.
- (5) For determining any liability under the Securities Act, treat the information omitted from the form of prospectus filed as part of this registration statement in reliance upon Rule 430A and contained in a form of prospectus filed by the Company under Rule 424(b)(1), or (4) or 497(h) under the Securities Act as part of this registration statement as of the time the SEC declared it effective.
- (6) For determining any liability under the Securities Act, treat each post-effective amendment that contains a form of prospectus as a new registration statement for the securities offered in the registration statement, and that offering of the securities at that time as the initial bona fide offering of those securities.

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

In the event that a claim for indemnification against such liabilities (other than the payment by the Company of expenses incurred or paid by a director, officer or controlling person of the Company in the successful defense of any action, suit or proceeding) is asserted by such director, officer or controlling person in connection with the securities being registered, the Company will, unless in the opinion of its counsel the matter has been settled by controlling precedent, submit to a court of appropriate jurisdiction the question whether such indemnification by it is against



public policy as expressed in the Securities Act and will be governed by the final adjudication of such issue.

II-5

---

**SIGNATURES**

Pursuant to the requirements of the Securities Act of 1933, the registrant hereby certifies that it has reasonable grounds to believe that it meets all of the requirements for filing on Form SB-2 and has duly caused this Registration Statement to be signed on its behalf by the undersigned, thereunto duly authorized, in the city of San Francisco, California, on October 22, 2007.

**NILE THERAPEUTICS, INC.**

By: /s/ Peter M. Strumph

\_\_\_\_\_  
Name: Peter M. Strumph  
Title: Chief Executive Officer

**POWER OF ATTORNEY**

KNOW ALL MEN BY THESE PRESENTS, that each person whose signature appears below constitutes and appoints each of Peter M. Strumph and Daron Evans, or any of them, each acting alone, his true and lawful attorney-in-fact and agent, with full power of substitution and resubstitution, for such person in his name, place and stead, in any and all capacities, in connection with the Registrant's Registration Statement on Form SB-2 under the Securities Act, including, without limiting the generality of the foregoing, to sign the Registration Statement in the name and on behalf of the Registrant or on behalf of the undersigned as a director or officer of the Registrant, and any and all amendments or supplements to the Registration Statement, including any and all stickers and post-effective amendments to the Registration Statement, and to sign any and all additional registration statements relating to the same offering of securities as the Registration Statement that are filed pursuant to Rule 462(b) under the Securities Act of 1933, as amended, and to file the same, with all exhibits thereto, and other documents in connection therewith, with the SEC and any applicable securities exchange or securities self-regulatory body, granting unto said attorneys-in-fact and agents, each acting alone, full power and authority to do and perform each and every act and thing requisite and necessary to be done in and about the premises, as fully to all intents and purposes as he might or could do in person, hereby ratifying and confirming all that said attorneys-in-fact and agents, or their substitutes or substitute, may lawfully do or cause to be done by virtue hereof.

Pursuant to the requirements of the Securities Exchange Act of 1933, the Registration Statement has been signed as of the dates indicated by the following persons in the capacities indicated.

<b>Signature</b>	<b>Title</b>	<b>Date</b>
<u>/s/ Daron G. Evans</u>	Chief Financial Officer	October 22, 2007
<u>/s/ Peter M. Strumph</u>	Director	October 22, 2007
<u>/s/ Pedro Granadillo</u>	Director	October 22, 2007



Edgar Filing: Nile Therapeutics, Inc. - Form SB-2

/s/ Peter M. Kash Director October 22, 2007

/s/ Paul Mieyal Director October 22, 2007

/s/ Joshua A. Kazam Director October 22, 2007

/s/ David M. Tanen Director October 22, 2007

II-7

---

**Exhibit Index**

Exhibit No.	Description
2.1	Agreement and Plan of Merger, by and among SMI Products, Inc. (SMI), Nile Merger Sub, Inc., and Nile Therapeutics, Inc. dated as of August 15, 2007 (incorporated by reference to Exhibit 2.1 of SMI's current report on Form 8-K filed on August 15, 2007).
3.1	Amended and Restated Certificate of Incorporation (incorporated by reference to Exhibit 3.1 of SMI's current report on Form 8-K filed on February 9, 2007).
3.2	Certificate of Merger relating to the merger of Nile Merger Sub, Inc. with and into Nile Therapeutics, Inc.
3.3	Certificate of Ownership and Merger Merging Nile Therapeutics, Inc. into SMI Products, Inc.
3.4	Bylaws (incorporated by reference to Exhibit 3.2 of SMI's current report on Form 8-K filed on February 9, 2007).
4.1	Form of Nile Therapeutics, Inc. Common Stock Purchase Warrant issued on September 11, 2007 (incorporated by reference to Exhibit 10.1 of our current report on Form 8-K filed on September 21, 2007).
4.2	Specimen Common Stock Certificate (incorporated by reference to Exhibit 4.1 of our current report on Form 8-K filed on September 21, 2007).
5.1	Opinion of Dickstein Shapiro, LLP dated October 22, 2007
10.1	Form of Subscription Agreement dated September 11, 2007 entered into with investors in the September 11, 2007 private placement offering (incorporated by reference to Exhibit 10.12 of our current report on Form 8-K filed on September 21, 2007)
10.2	License Agreement between The Mayo Foundation for Medical Education and Research and Nile Therapeutics, Inc., dated January 20, 2006 (incorporated by reference to Exhibit 10.6 of our current report on Form 8-K filed on September 21, 2007).
10.3	License Agreement between Nile Therapeutics, Inc. and Dr. Cesare Casagrande, dated August 6, 2007 (incorporated by reference to Exhibit 10.7 of our current report on Form 8-K filed on September 21, 2007).
10.4	Amended and Restated 2005 Stock Option Plan (incorporated by reference to Exhibit 10.9 of our current report on Form 8-K filed on September 21, 2007).
10.5	Employment Agreement dated as of May 11, 2007 between Nile Therapeutics, Inc. and Peter M. Strumph (incorporated by reference to Exhibit 10.2 of our

Edgar Filing: Nile Therapeutics, Inc. - Form SB-2

current report on Form 8-K filed on September 21, 2007).

- 10.6 Employment Agreement dated as of January 19, 2007 between Nile Therapeutics, Inc. and Daron G. Evans (incorporated by reference to Exhibit 10.3 of our current report on Form 8-K filed on September 21, 2007).
  - 10.7 Amendment No. 1 to Employment Agreement, dated as of August 19, 2007, between Nile Therapeutics, Inc. and Daron G. Evan.
  - 10.8 Letter Agreement, dated as of August 31, 2007, between Nile Therapeutics, Inc. and Jennifer L. Hodge (incorporated by reference to Exhibit 10.5 of our current report on Form 8-K filed on September 21, 2007).
-

Edgar Filing: Nile Therapeutics, Inc. - Form SB-2

- 10.9 Form of Stock Option Agreement (incorporated by reference to Exhibit 10.10 of our current report on Form 8-K filed on September 21, 2007)
  - 10.10 Form of Incentive Stock Option Agreement (incorporated by reference to Exhibit 10.11 of our current report on Form 8-K filed on September 21, 2007)
  - 10.11 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. (incorporated by reference to Exhibit 10.8 of our current report on Form 8-K filed on September 21, 2007).
  - 10.12 Separation Agreement and General Release between Nile Therapeutics, Inc. and Allan Gordon dated August 10, 2007 (incorporated by reference to Exhibit 10.13 of our current report on Form 8-K filed on September 21, 2007).
  - 16.1 Letter from Paritz & Co dated September 20, 2007 regarding change in certifying accountants (incorporated by reference to Exhibit 16.1 of our current report on Form 8-K filed on September 21, 2007).
  - 16.2 Letter from Amisano Hanson Chartered Accountants dated February 5, 2007, regarding change in certifying accountants (incorporated by reference to Exhibit 16.1 of SMI's current report on Form 8-K filed on December 8, 2006).
  - 23.1 Consent of Hays & Company LLP
  - 23.2 Consent of Dickstein Shapiro, LLP (included in Exhibit 5.1).
  - 24.1 Powers of Attorney (included in Signature Pages to this Registration Statement on Form SB-2).
-