Nile Therapeutics, Inc.
Form 10-K
June 21, 2013

UNITED STATES

SECURITIES AND EXCHANGE COMMISSION

WASHINGTON, D.C. 20549

FORM 10-K

x **Annual Report Pursuant to Section 13 or 15(d) of the Securities Exchange Act of 1934 for the fiscal year ended December 31, 2012**

or

¨ **Transition Report Under Section 13 or 15(d) of the Securities Exchange Act of 1934**

For the transition period from to

Commission File Number: 001-34058

NILE THERAPEUTICS, INC.

(Exact Name Of Registrant As Specified In Its Charter)

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

63 Bovet Rd., Suite 421, San Mateo, California

(Address of principal executive offices)

94402

(Zip Code)

(650) 918-7489
(Registrant's telephone number, including area code)

Not Applicable
(Former name, former address and former fiscal year, if changed since last report)

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

None

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

Common Stock, par value $0.001 per share

Warrants (expiring April 21, 2015)

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

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

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

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

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

Indicate by check mark whether the registrant is a large accelerated filer, an accelerated filer, a non-accelerated filer, or a smaller reporting company. See the definitions of "large accelerated filer," "accelerated filer" and "smaller reporting company" in Rule 12b-2 of the Exchange Act.

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

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

As of June 30, 2012: $3,763,041

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

As of June 19, 2013, there were 43,062,231 shares of the issuer's common stock, par value $0.001 per share, issued and outstanding.

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

FORWARD-LOOKING STATEMENTS

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

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

described in such statements or our objectives and plans will be achieved. Furthermore, past performance in operations and share price is not necessarily indicative of future performance. Except to the extent required by applicable laws or rules, we do not undertake to update any forward-looking statements or to announce publicly revisions to any of our forward-looking statements, whether resulting from new information, future events or otherwise.

PART I

ITEM 1. BUSINESS

Company Overview

We are a development stage, biopharmaceutical company developing innovative products for the treatment of cardiovascular and renal diseases, with an initial focus on heart failure. We currently have exclusive rights to develop two drug candidates:

- ***Cenderitide*** *(formerly CD-NP),* our lead product candidate, is a chimeric natriuretic peptide that we are developing for the treatment of heart failure. To date, we have developed cenderitide for the treatment of patients for up to 90 days following admission for acutely decompensated heart failure, or ADHF. We refer to this setting as the "post-acute" period. In 2011, we completed a 58-patient Phase 1 clinical trial of cenderitide in the post-acute setting. We conducted this clinical trial in collaboration with Medtronic, Inc., delivering cenderitide through continuous intravenous infusion using Medtronic's pump technology. Following that Phase 1 clinical trial, we had planned to initiate a Phase 2 clinical trial of cenderitide, pending availability of capital resources. However, to date we have been unable to raise the capital necessary to conduct the next phase of development of cenderitide. Any further development of cenderitide is subject to our ability to either raise additional capital or enter into a strategic transaction in which an acquirer or strategic partner provides the capital necessary to continue development activities. In addition to treating heart failure, we believe cenderitide may be useful in several other cardiovascular and renal indications.

- ***CU-NP***, is a pre-clinical rationally-designed natriuretic peptide that consists of amino acid chains identical to those produced by the human body, specifically the ring structure of C-type natriuretic peptide, or CNP, and the N- and C-termini of Urodilatin, or URO. All development of CU-NP is on hold pending the results of our efforts to pursue additional financing or strategic alternatives

We were originally incorporated under Delaware law in August 2005 under the name Nile Pharmaceuticals, Inc. and we changed our name to Nile Therapeutics, Inc. in January 2007. On September 17, 2007, we were acquired by SMI Products, Inc., or SMI, which was then a public shell company, in a reverse merger transaction whereby a wholly-owned subsidiary of SMI merged with, and into, Nile Therapeutics, with Nile Therapeutics remaining as the surviving corporation and a wholly-owned subsidiary of SMI. In accordance with the terms of this transaction, the stockholders of Nile Therapeutics exchanged all of their shares of Nile Therapeutics common stock for shares of SMI common stock, which immediately following the transaction represented approximately 95 percent of the issued and outstanding common stock of SMI. Upon completion of the merger, the sole officer and director of SMI resigned and was replaced by the officers and directors of Nile Therapeutics. Additionally, following the merger, Nile Therapeutics, or Old Nile, was merged into SMI, and SMI changed its name to Nile Therapeutics, Inc., or Nile, and adopted the business plan of Old Nile. We collectively refer to these two merger transactions in this Annual Report as the "Merger."

Because the Merger was accounted for as a reverse acquisition under generally accepted accounting principles, the financial statements for periods prior to September 17, 2007 reflect only the operations of Old Nile.

We do not currently own or lease any real property. Our mailing address is 63 Bovet Rd., Suite 421, San Mateo, California 94402. Our telephone number is 650-918-7489 and our Internet address is www.nilethera.com. The information on, or accessible through, our website is not part of this Form 10-K.

Our Product Candidates

The following table summarizes our product development programs:

Product	Indications	Commercial Rights	Ongoing Studies / Status
Cenderitide	Heart failure	Nile	Completed single-blind, placebo-controlled Phase 1 study of cenderitide in chronic heart failure patients in October 2011. The primary objective of the study was to assess the pharmacokinetics of cenderitide delivered through a subcutaneous micro-needle pump to patients in the post-acute heart failure setting. All future studies are on hold pending the results of our efforts to pursue additional financing or strategic alternatives.
CU-NP	Cardiovascular / Renal	Nile	Preclinical. All development is on hold pending the results of our efforts to pursue additional financing or strategic alternatives.

Background on Heart Failure

Heart failure, or HF, is a condition that exists when the heart cannot pump blood to the body as quickly as needed. Blood returning to the heart faster than the heart can eject it, congests the system behind it. Decreased blood flow to organs, such as the kidneys, causes the body to retain more fluid, which further complicates the problem. As a result, HF can often cause damage to the kidneys and other organs, which in turn can worsens the condition of the heart.

HF is the fastest-growing clinical cardiac disease in the United States according to the American Heart Association, affecting over 5 million Americans. Over 1.2 million patients in the U.S. each year are hospitalized with ADHF, an acute exacerbation of their condition. This hospitalization rate is almost double the rate seen 15 years ago. HF is the most frequent cause of hospital admission in the U.S. for patients older than 65 years, generating annual inpatient costs of more than $35 billion, according to the American Heart Association. We believe that approval of a novel agent with safety and efficacy improvements over existing therapies could significantly expand the HF market.

Patients with heart failure are treated with a combination of drugs in an attempt to improve cardiac output and reverse fluid overload. Diuretics, such as furosemide, are used as a first-line treatment to relieve the symptoms of ADHF patients by helping to remove excess fluid from the body, which then helps to increase cardiac output. However, some studies have correlated high doses of intravenous (i.v.) furosemide, a diuretic, with a decreased kidney function and some patients can become resistant to the effects of furosemide. Second-line treatments are often palliative, and can come at the cost of an increased mortality rate. Despite aggressive therapy, 1 in 3 patients die of the disease within a year of diagnosis, reflecting a substantial need for novel treatments.

Only one new treatment for ADHF patients has been approved by the FDA in over 20 years: nesiritide, which is also known as Natrecor®, or B-type natriuretic peptide, or BNP. Nesiritide, a drug marketed by Johnson & Johnson, is a natriuretic peptide that targets the A-type natriuretic peptide receptor and was approved in 2001 by the FDA.

Within 90 days following hospital admission for ADHF, which we refer to as the “post-acute” period, approximately 40% of patients with ADHF return to the hospital or pass away. To prevent a return to the hospital, post-acute patients need sustained cardiac and renal function support to prevent a recurrence of their acute symptoms. While this post-acute indication is a novel indication in the HF space, we believe that post-acute patients represent one of the greatest areas of unmet need in the HF market.

Cenderitide Program

Cenderitide is a novel chimeric natriuretic peptide in clinical development for the treatment of HF patients. Cenderitide was rationally designed by scientists at the Mayo Clinic's cardio-renal research labs. Current therapies for ADHF, including nesiritide, have been associated with favorable pharmacologic effects, but have also been associated with hypotension, which limit their utility outside the hospital setting. Cenderitide was designed to preserve the favorable effects of existing natriuretic peptide therapies while reducing or attenuating the hypotensive response and enhancing or preserving renal function. We believe that cenderitide has potential utility in multiple cardio-renal indications, including preservation of cardiac function following acute myocardial infarction and prevention of renal damage following cardiac surgery.

Prior Clinical Studies

In 2007, we completed a Phase 1 dose-escalation study in healthy volunteers to examine the safety and pharmacodynamic effects of various doses of cenderitide. The study placed particular emphasis on the effects of cenderitide on blood pressure and renal function. Data from the completed Phase 1 study in healthy volunteers was consistent with several pre-clinical findings, including that cenderitide was associated with increased levels of plasma cGMP, a secondary messenger of the target receptor, preserved renal function, increased urinary excretion of sodium, or natriuresis, and increased urination, or diuresis. The study also showed that cenderitide had a minimal effect on mean arterial pressure, a measurement of pumped blood flow in the arteries.

In 2008, we initiated two additional dose-escalation studies to assess the safety and pharmacodynamic profile of cenderitide in heart failure patients. The first study was a Phase 1 study in chronic heart failure patients with signs of fluid overload designed to understand the maximum tolerated dose of the product candidate. Patients with chronic heart failure with signs of fluid overload were enrolled into the study. The effects of 24 hours of cenderitide delivered through intravenous (i.v.) infusion was compared to the patient's baseline established in the 24 hours prior to cenderitide infusion. The patient's oral diuretic and vasoactive medications were withheld during the cenderitide infusion. While the study was not powered for statistical analysis, data from the Phase 1 study indicate the following:

- Cenderitide was tolerated at doses of up to 20 ng/kg/min;
- Cenderitide blood pressure effects were dose-dependent and well characterized;
- Cenderitide infusion resulted in increases in diuresis at doses of 3, 10 and 20 ng/kg/min as compared to each patient's base-line, which included oral diuretic medication;
- With a 24-hour infusion, cenderitide produced decreases in serum creatinine and cystatin-c in stable heart failure patients, consistent with enhanced renal function; and

- As expected, the limiting toxicity of cenderitide was shown to be symptomatic hypotension, which was experienced by one of six patients at the maximum tolerated dose of 20 ng/kg/min, and by two of two patients at a dose of 30 ng/kg/min.

The second study initiated in 2008 was a Phase 2 study in acute heart failure patients designed to better understand the hemodynamic properties of cenderitide, or how cenderitide affected blood circulation. The subjects were enrolled 24-48 hours after admission to the hospital for acute heart failure. In the first 24-48 hours after admission, subjects were treated with the standard of care. The subjects were enrolled into the study only after an investigator had determined that the patient needed a Swan-Ganz catheter to better monitor pulmonary capillary wedge pressure, or PCWP, and after the patient's acute condition had stabilized. All patients received a continuous i.v. infusion of furosemide throughout the administration of cenderitide. Data from this Phase 2 study indicate the following:

- Cenderitide was tolerated at all study doses, including 1, 3, 10 and 20 ng/kg/min;
- Cenderitide had minimal blood pressure effects at all doses;
- In the first cohort, where patients were dosed at 3 and then 10 ng/kg/min, the cenderitide infusions produced clinically relevant reductions in PCWP;
- In the second cohort, where patients were dosed at 1 and 20 ng/kg/min, the cenderitide infusions did not result in clinically relevant reductions in PCWP;
- Cenderitide produced a clinically relevant increase in diuresis at doses of 3, 10 and 20 ng/kg/min when administered concurrently with i.v. furosemide; and
- There was no clinically relevant change in serum creatinine and there were no cases of symptomatic hypotension in any subject.

In March 2009, the FDA placed a clinical hold on the cenderitide program. The FDA requested additional data on our Phase 2 clinical trial, which was finalized in March 2009, and modifications to cenderitide's current investigator brochure. We submitted a full response to the FDA in April 2009 and the cenderitide program was released from clinical hold in May 2009.

In June 2010, we completed dosing of a 77 patient, open-label, placebo controlled Phase 2 study of cenderitide in patients with ADHF and mild to moderate renal dysfunction. Cenderitide infusion at 1.25, 2.5 and 3.75 ng/kg/min appeared to be well tolerated. A dose-related effect on blood pressure was observed, with minimal or mild blood pressure reduction at 1.25 and 2.5 ng/kg/min, and moderate blood pressure reduction at 3.75 ng/kg/min. Dose escalation was limited by significant blood pressure reduction at 5 ng/kg/min. Secondary and exploratory analyses demonstrated favorable effects of cenderitide on renal function, particularly at the 1.25 and 2.5 ng/kg/min doses. At these doses, cenderitide appeared to preserve or enhance renal function compared to placebo, as evidenced by favorable trends in several biomarkers correlated with kidney function, including creatinine and cystatin-c.

In March 2011, the FDA granted Fast Track designation to our post-acute heart failure development program for cenderitide.

In October 2011, we completed dosing of a 58 patient, open-label, placebo controlled Phase I clinical trial that was designed to understand the doses required to achieve pre-determined plasma levels of cenderitide when delivered through a subcutaneous infusion pump. The target cenderitide plasma levels were based on our previous Phase 2 clinical trials, in which cenderitide was delivered through continuous i.v. infusion. The Phase 2 study enrolled patients in three parts. In Part A of the trial, 12 patients received two subcutaneous bolus injections of cenderitide. In Part B of the trial, 34 patients received a 24-hour continuous subcutaneous infusion of either of two fixed doses of cenderitide or placebo. In Part C, 12 patients received a 24-hour continuous subcutaneous infusion of either a weight-based dose of cenderitide, or placebo. All infusions were delivered through subcutaneous pump technology of Medtronic, Inc. pursuant to the parties' February 2011 collaboration agreement. In accordance with the terms of that agreement, Medtronic agreed to reimburse us for certain expenses of this Phase 1 study and provided the subcutaneous pumps used in the study.

The top line results from the Phase 1 trial are as follows:

- The primary end-point was met – cenderitide achieved target pharmacokinetic, or PK, levels when delivered through Medtronic's subcutaneous pump technology;
- 24 hour subcutaneous delivery of cenderitide through Medtronic's pump technology was well-tolerated, with no injection site irritation;
- Subcutaneously delivered cenderitide has an acceptable bioavailability profile;
- Cenderitide's PK profile achieved steady-state when delivered through subcutaneous infusion;
- Weight-based dosing reduced PK variability, as compared to a fixed dosing regimen.

In addition to our own studies, in July 2008, the Mayo Clinic initiated a Phase 1 study, under an investigator-sponsored investigational new drug application, or IND, to better understand cenderitide's renal properties.

Future Clinical Studies

We believe the next step in the clinical development of cenderitide is a Phase 2 single-blind, placebo-controlled, dose ranging study in post-acute patients, with the primary objective of ensuring that patients can tolerate subcutaneous infusion for up to 90 days in an outpatient setting. We estimate the costs to conduct this Phase 2 study, up to 296 patients, will be approximately $15 million to $20 million and will take approximately 30 months to complete. However, we have lacked the necessary capital to conduct any additional development activities of cenderitide, and until we obtain such capital, we will not proceed with any further development. During the last 12 months, we have been actively pursuing additional financing or other strategic transaction alternatives that would provide the capital necessary to continue development of cenderitide. Such alternatives could include collaborating with another biotechnology or pharmaceutical company to further develop cenderitide, or engaging in a merger or other corporate transaction in which the control of cenderitide's development would be assumed by a purchaser of our company. There can be no assurance that we will be able to successfully resolve our lack of capital resources or otherwise find a strategic alternative. See "Risk Factors – Risks Relating to Our Business – We need substantial additional funding before we can complete the development of our product candidates. If we are unable to obtain such additional capital, we will be forced to delay, reduce or eliminate our product development programs and may not have the capital required to otherwise operate our business."

CU-NP Program

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

Intellectual Property, License and Collaboration Agreement

Our goal is to obtain, maintain and enforce patent protection for our products, formulations, processes, methods and other proprietary technologies, preserve our trade secrets, and operate without infringing on the proprietary rights of other parties, both in the United States and abroad. Our policy is to actively seek to obtain, where appropriate, the broadest intellectual property protection possible for our current product candidates and any future product candidates, proprietary information and proprietary technology through a combination of contractual arrangements and patents, both in the United States and abroad. Even patent protection, however, may not always afford us with complete protection against competitors who seek to circumvent our patents. If we fail to adequately protect or enforce our intellectual property rights or secure rights to patents of others, the value of our intellectual property rights would

diminish.

We have depended upon the skills, knowledge and experience of scientific and technical personnel, as well as that of advisors, consultants and other contractors, none of which is patentable. To help protect such proprietary know-how, which is not patentable, and for inventions for which patents may be difficult to enforce, we have relied and will in the future rely on trade secret protection and confidentiality agreements to protect our interests. To this end, we require all of our employees, consultants, advisors and other contractors to enter into confidentiality agreements that prohibit the disclosure of confidential information and, where applicable, require disclosure and assignment to us of the ideas, developments, discoveries and inventions important to our business.

License Agreements

Cenderitide

On January 20, 2006, we entered into an exclusive, worldwide, royalty-bearing license agreement, or the Cenderitide License Agreement, with Mayo Foundation for Medical Education and Research, or the Mayo Foundation, for the rights to issued patents, patent applications and know-how relating to the use of cenderitide in all therapeutic uses. We were also entitled to rights to improvements to cenderitide that arose out of the laboratory of Dr. John Burnett, the co-inventor of cenderitide, until January 19, 2009.

Under the terms of the Cenderitide License Agreement, we paid the Mayo Foundation an up-front cash payment and reimbursed it for past patent expenses. We issued to the Mayo Foundation 1,379,419 shares of common stock. Additionally, we agreed to make contingent cash payments up to an aggregate of $31.9 million upon successful completion of specified clinical and regulatory milestones relating to cenderitide. This aggregate amount is subject to increase upon the receipt of regulatory approval for each additional indication of cenderitide as well as for additional compounds or analogues contained in the intellectual property. In July 2008, we made a milestone payment of $400,000 to the Mayo Foundation upon the dosing of the first patient in a Phase II trial. There were no such milestone payments due for the year ended December 31, 2012. Based on the current stage of research we do not expect to make any milestone payments for the year ending December 31, 2013. Pursuant to the Cenderitide License Agreement, we is required to pay the Mayo Foundation an annual maintenance fee and a percentage of net sales of licensed products, as well as $50,000 per year for the consulting services of Dr. Burnett while serving as chairman of the Company’s Scientific Advisory Board.

In addition to the potential milestone payments discussed above, the Cenderitide License Agreement requires us to issue shares of common stock to the Mayo Foundation for an equivalent dollar amount of grants received in excess of $300,000, but not to exceed $575,000. For the period from August 1, 2005 (inception) through December 31, 2011, the Company received $482,235 in grant income for which it has issued to the Mayo Foundation 63,478 shares (representing $182,236) of common stock. No such shares have been issued since the year ended December 31, 2008.

The Cenderitide License Agreement, unless earlier terminated, will continue in full force and effect until January 20, 2026. However, to the extent any patent covered by the license is issued with an expiration date beyond January 20, 2026, the term of the agreement will continue until such expiration date. Mayo may terminate the agreement earlier (i) for our material breach of the agreement that remains uncured after 90 days' written notice to us, (ii) our insolvency or bankruptcy, or (iii) if we challenge the validity or enforceability of any of the patents in any manner. We may terminate the agreement without cause upon 90 days' written notice.

Pursuant to the Cenderitide License Agreement, we have exclusive rights to 3 issued U.S. patents and 3 pending U.S. patent applications, 16 issued foreign patents and 3 pending foreign applications, covering composition of matter and methods of use. These patents and patent applications cover cenderitide, and other similar natriuretic peptides, as well as methods of use of the peptides in the treatment of multiple cardiovascular and renal indications. The issued composition of matter patent expires in 2019 and, if allowed, the last of the pending U.S. patents would expire in 2028.

As of the end of 2012, we were not in compliance with several terms of the Cenderitide License Agreement, including, but not limited to, provisions requiring us to pay the Mayo Foundation an annual maintenance fee and actively pursue the development of cenderitide. We are in discussions with the Mayo Foundation to amend the agreement, but we cannot guarantee that we will be able to reach an agreement with Mayo that allows us to maintain our rights to cenderitide. See "Risk Factors – Risks Relating to Our Business – We are not in compliance with various provisions of our license agreements with the Mayo Foundation. If we are unable to renegotiate these agreements, then we will lose our rights to cenderitide and CU-NP."

CU-NP

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

Under the terms of the CU-NP License Agreement, we made an up-front cash payment to the Mayo Foundation and agreed to make future contingent cash payments up to an aggregate of $24.3 million upon achievement of specific clinical and regulatory milestones relating to CU-NP, including a milestone payment due in connection with the initiation of the first Phase 2 clinical trial of the licensed product. This aggregate amount of $24.3 million is subject to increase upon the receipt of regulatory approval for each additional indication of CU-NP, as well as for additional compounds or analogues contained in the intellectual property. There were no such milestone payments due for the year ended December 31, 2012. Based on the current stage of research, we do not expect to make any milestone payments for the year ending December 31, 2013. Pursuant to the agreement, we must also pay the Mayo Foundation an annual maintenance fee and a percentage of net sales of licensed products.

In addition to these cash payments payable with respect to the CU-NP License Agreement, we also agreed to issue shares of our common stock and warrants to the Mayo Foundation. In June 2008, we issued 49,689 shares of common stock to the Mayo Foundation having a fair market value as of June 13, 2008 equal to $250,000.

The CU-NP License Agreement, unless earlier terminated, will continue in full force and effect until June 13, 2028. However, to the extent any patent covered by the license is issued with an expiration date beyond June 13, 2028, the term of the agreement will continue until such expiration date. The Mayo Foundation may terminate the agreement earlier (i) for our material breach of the agreement that remains uncured after 90 days' written notice to us, (ii) our insolvency or bankruptcy, (iii) if we challenge the validity or enforceability of any of the patents in any manner, or (iv) or upon receipt of notice from us that we have terminated all development efforts under the agreement. We may terminate the agreement without cause upon 90 days' written notice.

Pursuant to our CU-NP license agreement with Mayo Foundation, we have exclusive rights to 1 U.S. patent and 3 pending foreign applications, covering composition of matter and methods of use. These patents and patent applications cover CU-NP, and other similar natriuretic peptides, as well as methods of use of the peptides in the treatment of multiple cardiovascular and renal indications. If allowed, the pending U.S. patent would expire in 2028.

As of the end of 2012, we were not in compliance with several terms of the CU-NP license agreement, including, but not limited to, provisions requiring us to pay the Mayo Foundation an annual maintenance fee and actively pursue the development of CU-NP. We are in discussions with the Mayo Foundation to amend the agreement, but we cannot guarantee that we will be able to reach an agreement with Mayo that allows us to maintain our rights to CU-NP. See "Risk Factors – Risks Relating to Our Business – We are not in compliance with various provisions of our license agreements with the Mayo Foundation. If we are unable to renegotiate these agreements, then we will lose our rights to cenderitide and CU-NP."

Collaboration Agreement

In February 2011, we entered into a Clinical Trial Funding Agreement with Medtronic, Inc. Pursuant to the agreement, Medtronic provided the funding and equipment necessary for us to conduct our Phase 1 clinical trial to assess the pharmacokinetics and pharmacodynamics of cenderitide when delivered to heart failure patients through continuous subcutaneous infusion using Medtronic's diabetes pump technology.

Under the agreement, we agreed not to enter into an agreement with a third party to develop or commercialize cenderitide or any drug/device combination developed under the agreement until the earlier of: (i) three months following delivery to Medtronic of a final database with respect to the Phase 1 trial; and (ii) 15 months after the date of the agreement. The final database was delivered to Medtronic on November 19, 2011.

The agreement provides that intellectual property conceived in or otherwise resulting from the performance of the Phase I clinical trial shall be jointly owned by us and Medtronic (the "Joint Intellectual Property"), and that we shall pay royalties to Medtronic based on the net sales of any Nile product, the manufacture, use or sale of which is covered or claimed in one or more issued patents constituting Joint Intellectual Property. The agreement further provides that, if the parties fail to enter into a definitive commercial license agreement with respect to cenderitide, then each party shall have a right of first negotiation to license exclusive rights to any Joint Intellectual Property.

Pursuant to its terms, the agreement expired in February 2012, following the completion of the Phase 1 clinical trial and the delivery of data and reports related to such study.

Government Regulation

The research, development, testing, manufacture, labeling, promotion, advertising, distribution, and marketing, among other things, of our product candidates are extensively regulated by governmental authorities in the United States and other countries. In the United States, the Food and Drug Administration, or FDA, regulates drugs under the Federal Food, Drug, and Cosmetic Act, or the FDCA, and it's implementing regulations. Failure to comply with the applicable United States requirements may subject us to administrative or judicial sanctions, such as FDA refusal to approve a pending NDA, warning letters, product recalls, product seizures, total or partial suspension of production or distribution, injunctions, and/or criminal prosecution.

Drug Approval Process

A drug or drug candidate may not be marketed or sold in the United States until it has received FDA approval. The process to receiving such approval is long, expensive and risky, and includes the following steps:

- pre-clinical laboratory tests, animal studies, and formulation studies;
- submission to the FDA of an IND for human clinical testing, which must become effective before human clinical trials may begin;
- adequate and well-controlled human clinical trials to establish the safety and efficacy of the drug for each indication;
- submission to the FDA of an NDA;
- satisfactory completion of an FDA inspection of the manufacturing facility or facilities at which the drug is produced to assess compliance with current good manufacturing practices, or cGMPs; and
- FDA review and approval of the NDA.

Pre-clinical tests include laboratory evaluation of product chemistry, toxicity, and formulation, as well as animal studies. The conduct of the pre-clinical tests and formulation of the compounds for testing must comply with federal regulations and requirements. The results of the pre-clinical tests, together with manufacturing information and analytical data, are submitted to the FDA as part of an IND, which must become effective before human clinical trials may begin. An IND will automatically become effective 30 days after receipt by the FDA, unless before that time the FDA raises concerns or questions about issues such as the conduct of the trials as outlined in the IND. In such a case, the IND sponsor and the FDA must resolve any outstanding FDA concerns or questions before clinical trials can proceed. There can be no assurance that submission of an IND will result in the FDA allowing clinical trials to begin.

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

Clinical trials are typically conducted in three sequential “Phases”, although the Phases may overlap. The study protocol and informed consent information for study subjects in clinical trials must also be approved by an Institutional Review Board for each institution where the trials will be conducted. Study subjects must sign an informed consent form before participating in a clinical trial. Phase I usually involves the initial introduction of the investigational drug into human patients to evaluate its short-term safety, dosage tolerance, metabolism, pharmacokinetics and pharmacologic actions, and, if possible, to gain an early indication of its effectiveness. Phase II usually involves trials in a limited patient population to (i) evaluate dosage tolerance and appropriate dosage; (ii) identify possible adverse effects and safety risks; and (iii) evaluate preliminarily the efficacy of the drug for specific indications. Phase III trials usually further evaluate clinical efficacy and test further for safety by using the drug in its final form in an expanded patient population. There can never be any assurance that Phase I, Phase II, or Phase III testing will be completed successfully within any specified period of time, if at all. Furthermore, clinical trials may be suspended at any time on various grounds, including a finding that the subjects or patients are being exposed to an unacceptable health risk.

The FDCA permits the FDA and the IND sponsor to agree in writing on the design and size of clinical studies intended to form the primary basis of an effectiveness claim in an NDA. This process is known as Special Protocol Assessment. These agreements may not be changed after the clinical studies begin, except in limited circumstances.

Assuming successful completion of the required clinical testing, the results of the pre-clinical studies and of the clinical studies, together with other detailed information, including information on the manufacture and composition of the drug, are submitted to the FDA in the form of an NDA requesting approval to market the product for one or more indications. The testing and approval process requires substantial time, effort, and financial resources. The FDA reviews the application and may deem it to be inadequate to support the registration, and companies cannot be sure that any approval will be granted on a timely basis, if at all. The FDA may also refer the application to the appropriate advisory committee, typically a panel of clinicians, for review, evaluation, and a recommendation as to whether the application should be approved. The FDA is not bound by the recommendations of the advisory committee.

The FDA has various programs, including fast track, priority review, and accelerated approval, that are intended to expedite or simplify the process for reviewing drugs, and/or provide for approval on the basis of surrogate endpoints. Generally, drugs that may be eligible for one or more of these programs are those for serious or life-threatening conditions, those with the potential to address unmet medical needs, and those that provide meaningful benefit over existing treatments. There can be no assurance that a drug will qualify for any of these programs, or that, if a drug does qualify, the review time will be reduced.

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

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

After approval, certain changes to the approved product, such as adding new indications, making certain manufacturing changes, or making certain additional labeling claims, are subject to further FDA review and approval. Before we can market our product candidates for additional indications, we must obtain additional approvals from the FDA. Obtaining approval for a new indication generally requires that additional clinical studies be conducted. We cannot be sure that any additional approvals for new indications for any product candidate will be approved on a timely basis, or at all.

Post-Approval Requirements

Often times, even after a drug has been approved by the FDA for marketing and sales of the approved product, the FDA may require that certain post-approval requirements be satisfied, including the conduct of additional clinical studies. If such post-approval requirements are not satisfied, the FDA may withdraw its approval of the drug. In addition, holders of an approved NDA are required to report certain adverse reactions to the FDA, comply with certain requirements concerning advertising and promotional labeling for their products, and continue to have quality control and manufacturing procedures conform to cGMP after approval. The FDA periodically inspects the sponsor's records related to safety reporting and/or manufacturing facilities; this latter effort includes assessment of compliance with cGMP. Accordingly, manufacturers must continue to expend time, money, and effort in the area of production and quality control to maintain cGMP compliance. If we obtain the capital necessary for us to continue the development of our product candidates, whether through a strategic transaction or otherwise, we intend to use third-party manufacturers to produce our products in clinical and commercial quantities, and future FDA inspections may identify compliance issues at the facilities of our contract manufacturers that may disrupt production or distribution, or require substantial resources to correct. In addition, discovery of problems with a product after approval may result in restrictions on a product, manufacturer, or holder of an approved NDA, including withdrawal of the product from the market.

Manufacturing

We do not currently have our own manufacturing facilities. If we obtain the capital necessary for us to continue the development of our product candidates, whether through a strategic transaction or otherwise, we intend to continue to use our financial resources to accelerate development of our product candidates rather than diverting resources to establish our own manufacturing facilities. To date, we have met our pre-clinical and clinical trial manufacturing requirements by establishing relationships with third-party manufacturers and other service providers to perform these services for us. We have historically relied on individual proposals and purchase orders to meet our needs and have typically relied on terms and conditions proposed by the third party or us to govern our rights and obligations under each order (including provisions with respect to intellectual property, if any). We do not have any long-term agreements or commitments for these services. Likewise, we do not have any long-term agreements or commitments with vendors to supply the underlying component materials of our product candidates, some of which are available from only a single supplier.

Competition

Even if we obtain the capital necessary for us to continue the development of our product candidates, whether through a strategic transaction or otherwise, we will face significant competition from companies with substantial financial, technical, and marketing resources, which could limit our future revenues from sales of cenderitide and CU-NP. Our success will depend, in part, upon our ability to achieve market share at the expense of existing and future products in the relevant target markets. Existing and future products, therapies, technologies, technological innovations, and delivery systems will likely compete directly with our products.

The development and commercialization of new products to treat cardiovascular diseases is highly competitive, and there will be considerable competition from major pharmaceutical, biotechnology, and other companies. With respect to cenderitide, many therapeutic options are available for patients with ADHF, including, without limitation, nitroglycerine, inotropic agents, diuretics, as well as Natrecor®. Some of our competitors include, without limitation, Scios (a Johnson & Johnson company), Bayer, Merck, Zealand Pharma, and Novartis. We are not currently aware of other compounds being developed to treat ADHF patients in the post-acute period.

With respect to CU-NP, competitors would include many of the same companies included as competitors for cenderitide. If CU-NP demonstrates a potential for chronic administration, additional competitors could include, without limitation, Teva Pharmaceuticals and Palatin Technologies.

Our competitors generally have substantially more resources than we do, including both financial and technical resources. In addition, many of these companies have more experience than Nile in pre-clinical and clinical

development, manufacturing, regulatory, and global commercialization. We also face competition academic institutions, governmental agencies, and private organizations that are conducting research in the field of cardiovascular disease. In addition to competition with respect to our product candidates, competition for highly qualified employees is intense.

Research and Development Expenses

Research and development, or R&D, expenses consist primarily of salaries and related personnel costs, fees paid to consultants and outside service providers for pre-clinical, clinical, and manufacturing development, legal expenses resulting from intellectual property prosecution, contractual review, and other expenses relating to the design, development, testing, and enhancement of our product candidates R&D expenses for the years ended December 31, 2012 and 2011 were approximately $1.0 million and $4.1 million, respectively.

Employees

As of December 31, 2012, we had two full-time employees. None of our employees are covered by a collective bargaining agreement. We believe our relations with our employees are satisfactory.

We have historically retained several consultants to serve in various operational and administrative capacities, and have utilized clinical research organizations and third parties to perform our pre-clinical studies, clinical studies, and manufacturing.

ITEM 1A. RISK FACTORS

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

Risks Relating to Our Business

We need substantial additional funding in order to continue our business operations and the further development of our product candidates. If we are unable to obtain such additional capital, whether through a strategic transaction or otherwise, we will be forced to cease operations altogether.

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As of December 31, 2012, we only had approximately $0.05 million in cash and cash resources, and negative net working capital of approximately $0.2 million. We believe that our currently available cash resources, together with the net proceeds of our March 2013 offering of convertible notes, are only sufficient to fund our minimal operating expenses until the end of the second quarter of 2013. As a result, our financial statements reflect a substantial uncertainty about our ability to continue as a going concern, which is also reflected in the report from our auditors on the audit of our financial statements as of and for the year ended December 31, 2012 included elsewhere in this report. Accordingly, we are in immediate need of additional capital to fund our general corporate activities.

Further, beyond funding our basic corporate activities, we need substantial additional capital in order to continue the development of cenderitide, for which the next step is a Phase 2 trial. We estimate that this Phase 2 trial will cost approximately $15 million to $20 million and take approximately 30 months to complete. During the last 12 months, we have attempted, unsuccessfully, to complete a financing transaction that would provide us with the capital necessary to fund the Phase 2 trial, and it is doubtful that we will ever be able to complete such a financing transaction. We have also pursued, and continue to pursue, alternative strategic transactions that would provide for the means to continue development of cenderitide. Such alternatives could include collaborating with another biotechnology or pharmaceutical company to further develop cenderitide, or engaging in a merger or other corporate transaction in which the control of cenderitide's development would be assumed by a purchaser of our company. However, we do not have any agreement or commitment from any collaboration partner, and there is no assurance we will be able to reach any such agreement. All of further clinical and other development activities for our cenderitide and CU-NP programs are on hold until we obtain the additional capital needed to fund such activities, whether through a financing, strategic transaction or otherwise. If we are not able to obtain such additional capital, we will likely be forced to cease operating altogether and wind down our company, in which case you will lose your entire investment in our common stock.

We are not in compliance with various provisions of our license agreements with the Mayo Foundation. If we are unable to renegotiate these agreements, then we will lose our rights to cenderitide and CU-NP.

Our rights to our cenderitide and CU-NP drug candidates are both derived from separate license agreements between us and the Mayo Foundation, an affiliate of Mayo Clinic. While our business depends substantially on these agreements to maintain the intellectual property rights to both our product candidates, we are not in compliance with several terms of these agreements, including, but not limited to, the requirements that we pay the Mayo Foundation an annual maintenance fee and actively pursue the development of cenderitide and CU-NP. We are in discussions with the Mayo Foundation to amend the agreement, but we cannot guarantee that we will be able to reach an agreement with Mayo that allows us to maintain our rights to cenderitide and CU-NP. Under the license agreements, we currently owe the Mayo Foundation an aggregate of approximately $XX, which we are unable to pay.

If we are unable to renegotiate the license agreements, then we will lose our rights to cenderitide and CU-NP. Even if we are able to renegotiate the license agreements, there is no guarantee that we will be able to obtain the capital necessary for us to continue the development of our product candidates, whether through a strategic transaction or otherwise.

We are largely dependent on the viability of cenderitide, our lead product candidate, and we cannot be certain it will receive regulatory approval to be commercialized.

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

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

Each of our product candidates is in an early stage of development, and we currently lack the resources to continue the development of our product candidates.

Each of our two product candidates, cenderitide and CU-NP, is in an early stage of development and requires extensive clinical testing before it will be approved by the FDA or another regulatory authority in a jurisdiction outside the United States, which could take several years to complete, if ever. The development of our product candidates is currently on hold until we obtain the capital necessary for us to continue such clinical testing, whether through a financing, strategic or other transaction. Even if we obtain the necessary capital, we cannot predict with any certainty the results of such clinical testing, including the results of our planned Phase 2 clinical trial of cenderitide in the post-acute heart failure setting. We cannot predict with any certainty if, or when, we might commence any such clinical trials or whether such trials will yield sufficient data to permit us to proceed with additional clinical development and ultimately submit an application for regulatory approval of our product candidates in the United States or abroad, or whether such applications will be accepted by the appropriate regulatory agency.

Our estimates of the amount of capital required to fund the further development of cenderitide are subject to assumptions that may prove to be wrong.

Our forecasts regarding the sufficiency of our financial resources to support our current and planned operations are forward-looking statements and involve significant risks and uncertainties, and actual results could vary as a result of a number of factors, including the factors discussed elsewhere in this "Risk Factors" section. We have based this estimate on assumptions that may prove to be wrong, and we could utilize our available capital resources sooner than we currently expect. Our future funding requirements will depend on many factors, including, but not limited to:

- the scope, rate of progress, cost and results of our research and development activities, especially our planned Phase 2 clinical trial of cenderitide;
- the costs and timing of regulatory approval;
- the costs of filing, prosecuting, defending and enforcing any patent claims and other intellectual property rights;
- the effect of competing technological and market developments;
- the terms and timing of any collaboration, licensing or other arrangements that we may establish;
- the cost and timing of completion of clinical and commercial-scale outsourced manufacturing activities; and
- the costs of establishing sales, marketing and distribution capabilities for any product candidates for which we may receive regulatory approval.

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

Our operations to date have been primarily limited to organizing and staffing our company, developing our technology, and undertaking pre-clinical studies and clinical trials of our product candidates. We have not yet obtained regulatory approvals for any of our product candidates and further development of our product candidates is currently on hold pending the results of our efforts to pursue strategic alternatives. Consequently, any predictions you make about our future success or viability may not be as accurate as they could be if we had a longer operating history. Specifically, our financial condition and operating results have varied significantly in the past and will

continue to fluctuate from quarter-to-quarter and year-to-year in the future due to a variety of factors, many of which are beyond our control. Factors relating to our business that may contribute to these fluctuations include the following factors, as well as other factors described elsewhere in this Annual Report:

- our ability to secure financing or a strategic partnership to fund the next phase of development of our product candidates;
- delays in the commencement, enrollment, and timing of clinical testing;
- the success of our clinical trials through all phases of clinical development;
- the success of clinical trials of our cenderitide and CU-NP product candidates or future product candidates;
- any delays in regulatory review and approval of our product candidates in clinical development;
- our ability to receive regulatory approval or commercialize our two product candidates, cenderitide and CU-NP, within and outside the United States;
- potential side effects of our current or future products and product candidates that could delay or prevent commercialization or cause an approved treatment drug to be taken off the market;
- regulatory difficulties relating to products that have already received regulatory approval;
- market acceptance of our product candidates;
- our ability to establish an effective sales and marketing infrastructure once our products are commercialized;
- competition from existing products or new products that may emerge;
- the impact of competition in the market in which we compete on the commercialization of cenderitide and CU-NP;
- guidelines and recommendations of therapies published by various organizations;

- Ÿ the ability of patients to obtain coverage of or sufficient reimbursement for our products;
- Ÿ our ability to maintain adequate insurance policies;
- Ÿ our dependency on third parties to formulate and manufacture our product candidates;
- Ÿ our ability to establish or maintain collaborations, licensing or other arrangements;
- Ÿ our ability and third parties' abilities to protect intellectual property rights;
- Ÿ costs related to and outcomes of potential intellectual property litigation;
- Ÿ compliance with obligations under intellectual property licenses with third parties;
- Ÿ our ability to adequately support future growth;
- Ÿ our ability to attract and retain key personnel to manage our business effectively; and
- Ÿ the level of experience in running a public company of our senior management who are relatively new to their current roles as managers of a public company.

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

For the years ended December 31, 2012 and 2011, respectively, we had a net loss of $1.9 million and $4.9 million. Since our inception on August 1, 2005, through December 31, 2012, we have an accumulated a deficit of $46.7 million and have a stockholders' deficit of $0.2 million. We expect to incur substantial losses and negative operating cash flow for the foreseeable future, and we may never achieve or maintain profitability. Even if we succeed in developing and commercializing one or more of our product candidates, we expect to incur substantial losses for the foreseeable future, as we:

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

- Ÿ seek regulatory approvals for our product candidates;
- Ÿ in-license or otherwise acquire additional products or product candidates;
- Ÿ implement additional internal systems and infrastructure; and
- Ÿ hire additional personnel.

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

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

The relationships between Two River Consulting, Riverbank Capital Securities and certain of our officers and directors may present potential conflicts of interest.

Arie S. Belldegrun and Joshua A. Kazam, each of whom are currently directors of our company, and David M. Tanen, a co-founder, director and secretary of our company until September 2009, are the managing members of Two River Consulting, LLC, or TRC. From June 2009 to August 2012, Mr. Kazam served as our President and Chief Executive Officer. In June 2009, we entered into a services agreement with TRC pursuant to which it performs various management, clinical development, operational and administrative activities and services for us, including the services of Mr. Kazam as our President and Chief Executive Officer. The terms of the services agreement were reviewed and approved by a special committee of our Board of Directors consisting of independent, disinterested directors. As consideration for the services provided under the services agreement, we paid TRC a monthly cash fee of $65,000 through March 2011, which was thereafter reduced to $30,082 per month due to reduced services being provided by TRC. In August 2012, upon the appointment of a full-time President and Chief Executive Officer, we further reduced the monthly fee to $6,600 to reflect the termination of Mr. Kazam's services as our President and Chief Executive Officer. In addition, upon entering into the services agreement, we issued to designees of TRC (excluding Dr. Belldegrun and Messrs. Kazam and Tanen) stock options to purchase an aggregate of 750,000 shares of our common stock at an exercise price of $0.89 per share. Twenty-five percent of the stock options vested immediately and the remaining 75% were scheduled to vest pursuant to the achievement of certain milestones relating to the clinical development of cenderitide. On January 3, 2011, the final block of stock options vested. Of the 750,000 stock options issued, 535,172 stock options vested and the remaining 214,828 stock options were forfeited. Also, in connection with an August 2010 amendment extending the term of the services agreement with TRC, we issued to designees of TRC (excluding Dr. Belldegrun and Messrs. Kazam and Tanen) fully-vested and immediately-exercisable stock options to purchase an aggregate of 250,000 shares of our common stock at an exercise price of $0.38 per share. Additional operational and clinical development services may be provided by TRC, and billed to us, on an hourly basis. Each of Messrs. Kazam and Tanen, as well as Peter M. Kash, a director of our company, are also officers and directors of Riverbank Capital Securities, Inc., or Riverbank, a registered broker-dealer, which served as placement agent in connection with our July 2009 private placement. Scott L. Navins, the Financial and Operations Principal of Riverbank, serves as our Treasurer pursuant to the TRC services agreement.

Generally, Delaware corporate law requires that any transactions between us and any of our affiliates be on terms that, when taken as a whole, are substantially as favorable to us as those then reasonably obtainable from a person who is not an affiliate in an arms-length transaction. We believe that the terms of the agreements that we have entered into with TRC and Riverbank satisfy the requirements of Delaware law, but in the event one or more parties challenges the fairness of such terms we may have to expend substantial resources in resolving such challenges and can make no guarantees of the result. Further, none of our affiliates or TRC 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 TRC 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 substantially dependent on the services of our CEO, CFO and certain consultants.

We currently have only two employees – Darlene Horton, our Chief Executive Officer and Daron Evans, our Chief Financial Officer. Due to our lack of financial resources, each of Dr. Horton and Mr. Evans are currently being paid only $100 per month, with the balance of their salaries being deferred and becoming payable only upon an acquisition event. While we are substantially dependent on their services, there can be no assurance that we will be able to retain Dr. Horton and Mr. Evans as employees.

We currently rely on TRC, an entity affiliated with certain of our directors, to render various administrative activities and services for us. We have also relied in substantial part, and, assuming we obtain the capital needed to continue operations, for the foreseeable future will continue to rely, on certain independent organizations and consultants to provide other important services, including substantially all aspects of regulatory guidance, clinical management, and manufacturing. Even if we obtain sufficient capital to fund these activities, 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 not be able to manage our growth.

Should we achieve our near-term milestones, such as obtaining the capital necessary for us to continue the development of our product candidates, whether through a strategic transaction or otherwise, and, thereafter, completing our planned Phase 2 clinical trial of cenderitide with positive data, of which no assurance can be given, our long-term viability will depend upon the expansion of our operations and the effective management of our growth, which will place a significant strain on our management and on our administrative, operational and financial resources. To manage this growth, we may need to expand our facilities, augment our operational, financial and management systems and hire and train additional qualified personnel. If we are unable to manage our growth effectively, our business would be harmed.

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

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

Ÿ withdrawal of clinical trial participants;

- termination of clinical trial sites or entire trial programs;
- costs of related litigation;
- substantial monetary awards to patients or other claimants;

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- Ÿ decreased demand for our product candidates;
- Ÿ impairment of our business reputation;
- Ÿ loss of revenues; and
- Ÿ the inability to commercialize our product candidates.

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

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

Our directors, officers, and principal stockholders beneficially own approximately 19% of our outstanding common stock. Accordingly, our executive officers, directors, and principal stockholders will have the ability to exert substantial influence over the election of our Board of Directors and the outcome of issues submitted to our stockholders.

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

Recent global market and economic conditions have been unprecedented and challenging with tighter credit conditions leading to decreased spending by businesses and consumers alike. Continued turbulence in the U.S. and international markets and economies and prolonged declines in business and consumer spending may adversely affect our liquidity and financial condition, including our ability to access the capital markets to meet our liquidity needs. If the conditions in the U.S. and world economic markets remain uncertain or continue to be volatile, or if they deteriorate further, our industry and business may be adversely affected.

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

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

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

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

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

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

Further delays in the commencement, enrollment, and completion of clinical testing could also significantly affect our product development costs. The commencement and completion of clinical trials requires us to identify and maintain a sufficient number of trial sites, many of which may already be engaged in other clinical trial programs for the same indication as our product candidates, may be required to withdraw from a clinical trial as a result of changing

standards of care, or may become ineligible to participate in clinical studies.

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

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

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

- failure to conduct the clinical trial in accordance with regulatory requirements or our clinical protocols;
- inspection of the clinical trial operations or trial sites by the FDA or other regulatory authorities resulting in the imposition of a clinical hold;
- unexpected delays in approvals of protocol amendments by regulatory authorities;

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

- lack of adequate funding to continue the clinical trial, including the incurrence of unforeseen costs due to enrollment delays; or

- requirements to conduct additional trials and studies, and increased expenses associated with the services of our CROs and other third parties.

If we are required to conduct additional clinical trials or other testing of our product candidates beyond those that we currently contemplate, we or our development partners, if any, may be delayed in obtaining, or may not be able to obtain, marketing approval for these product candidates. We may not be able to obtain approval for indications that are as broad as intended, or we may be able to obtain approval only for indications that are entirely different than those indications for which we sought approval.

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

Any delays in obtaining regulatory approvals may:

- delay commercialization of, and our ability to derive product revenues from, our product candidates;

- impose costly procedures on us; or

- diminish any competitive advantages that we may otherwise enjoy.

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

Even if we obtain the capital necessary for us to continue the development of our product candidates, whether through a strategic transaction or otherwise, including our planned Phase 2 clinical trial of cenderitide, we cannot be certain that their results will support the claims of our product candidates. Positive results in pre-clinical testing and early clinical trials does not ensure that results from later clinical trials will also be positive, and we cannot be sure that the results of later clinical trials will replicate the results of prior clinical trials and pre-clinical testing. A number of companies in the pharmaceutical industry, including those with greater resources and experience, have suffered significant setbacks in Phase 3 clinical trials, even after seeing promising results in earlier clinical trials.

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

Despite the results reported in earlier clinical trials for our product candidates, we do not know whether any Phase 2, Phase 3 or other clinical programs we may conduct will demonstrate adequate efficacy and safety to result in regulatory approval to market our product candidates.

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

A key element of our short-term viability and long-term success includes potentially partnering with pharmaceutical, biotechnology and other companies to obtain assistance for the development and potential commercialization of our product candidates, including the cash and other resources we need for such development and potentially commercialization. We intend to enter into potential strategic partnerships with third parties to develop and commercialize our product candidates, including, as discussed elsewhere in this report, our planned development of cenderitide. We also intend to enter into strategic partnerships to commercialize our product candidates that are intended for larger markets, and we may enter into strategic partnerships for product candidates that are targeted toward specialty markets. We face significant competition in seeking appropriate strategic partners, and these potential strategic partnerships can be intricate and time consuming to negotiate and document. In addition, the early development stage of our product candidates may make it more difficult for us to identify and secure a strategic partner because of the additional risks inherent in early stage technologies. We may not be able to negotiate strategic

partnerships on acceptable terms, or at all. We are unable to predict when, if ever, we will enter into any potential strategic partnerships because of the numerous risks and uncertainties associated with establishing strategic partnerships. If we are unable to negotiate strategic partnerships for our product candidates we will be required to undertake development or commercialization activities at our own expense, for which we currently lack adequate resources. In addition, we will bear all the risk related to the development of that product candidate. If we elect to fund development or commercialization activities on our own, we will need to obtain substantial additional capital, which may not be available to us on acceptable terms, or at all. If we do not have sufficient funds, we will not be able to bring our product candidates to market and generate product revenue.

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

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

- we may not be able to control the amount and timing of resources that our strategic partners devote to the development or commercialization of product candidates;
- strategic partners may delay clinical trials, provide insufficient funding, terminate a clinical trial or abandon a product candidate, repeat or conduct new clinical trials or require a new version of a product candidate for clinical testing;
- strategic partners may not pursue further development and commercialization of products resulting from the strategic partnering arrangement or may elect to discontinue research and development programs;
- strategic partners may not commit adequate resources to the marketing and distribution of any future products, limiting our potential revenues from these products;
- disputes may arise between us and our strategic partners that result in the delay or termination of the research, development or commercialization of our product candidates or that result in costly litigation or arbitration that diverts management's attention and consumes resources;
- strategic partners may experience financial difficulties;
- strategic partners may not properly maintain or defend our intellectual property rights or may use our proprietary information in a manner that could jeopardize or invalidate our proprietary information or expose us to potential litigation;

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

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

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

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

Our drug development programs depend upon third-party researchers who are outside our control.

Assuming we obtain the capital necessary for us to continue the development of our product candidates, 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 have historically, and, subject to our continued development of cenderitide and CU-NP, intend in the future to, contract with one or more manufacturers to manufacture, supply, store, and distribute drug supplies for our clinical trials. If any of our product candidates receive FDA approval, we will rely on one or more third-party contractors to manufacture supplies of our drug candidates. Our current and anticipated future reliance on a limited number of third-party manufacturers exposes us to the following risks:

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

- Some of the raw materials needed to manufacture our product candidates are available from a very limited number of suppliers. Although we believe we have good relationships with these suppliers, we may have difficulty identifying alternative suppliers if our arrangements with our current suppliers are disrupted or terminated.

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

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

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

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

Our product candidates may be associated with undesirable or serious side effects and may cause a delay in the completion of the clinical trials.

If any of our product candidates lead to sufficiently undesirable or serious side effects in clinical trials, this could lead to a significant delay or termination of the development program for the following reasons:

- A data safety monitoring committee that is evaluating the data intermittently during the course of the trial could stop a trial due to significant risk or recommend a change to the clinical trial which would lead to a delay in the completion of the clinical trial.

- Investigators and study staff who have seen subjects in the clinical trials experience the serious side effects may alter their recruiting of patients for the trial or cease to enroll further patients into the trial
- The company or FDA could place a clinical hold on a trial due to significant safety concerns
- The company may need to amend the trial leading to a delay in the completion of the clinical trial
- The company could decide that the side effect profile no longer supports further development of the product candidate.

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

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

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

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

generating significant revenues from its sale.

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

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

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

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

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

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

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

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

As a result of these factors, our competitors may obtain regulatory approval of their products more rapidly than we are able to or may obtain patent protection or other intellectual property rights that limit our ability to develop or

commercialize our product candidates. Our competitors may also develop drugs that are more effective, useful, and less costly than ours, and may also be more successful than us in manufacturing and marketing their products.

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

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

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

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

Ÿ limitations or warnings contained in a product's FDA-approved labeling;

Ÿ changes in the standard of care for the targeted indications for any of our product candidates, which could reduce the marketing impact of any claims that we could make following FDA approval;

Ÿ limitations inherent in the approved indication for any of our product candidates compared to more commonly understood or addressed conditions;

- Ÿ lower demonstrated clinical safety and efficacy compared to other products;
- Ÿ prevalence and severity of adverse effects;
- Ÿ ineffective marketing and distribution efforts;
- Ÿ lack of availability of reimbursement from managed care plans and other third-party payors;
- Ÿ lack of cost-effectiveness;
- Ÿ timing of market introduction and perceived effectiveness of competitive products;
- Ÿ availability of alternative therapies at similar costs; and
- Ÿ potential product liability claims.

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

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

Even if United States regulatory approval is obtained, the FDA may still impose significant restrictions on a product's indicated uses or marketing, or impose ongoing requirements for potentially costly post-approval studies. Given the number of recent high-profile adverse safety events with certain drug products, the FDA may require, as a condition of approval, costly risk management programs which may include safety surveillance, restricted distribution and use, patient education, enhanced labeling, special packaging or labeling, expedited reporting of certain adverse events, pre-approval of promotional materials, and restrictions on direct-to-consumer advertising. Furthermore, heightened

Congressional scrutiny on the adequacy of the FDA's drug approval process and the agency's efforts to assure the safety of marketed drugs has resulted in the proposal of new legislation addressing drug safety issues. If enacted, any new legislation could result in delays or increased costs during the period of product development, clinical trials, and regulatory review and approval, as well as increased costs to assure compliance with any new post-approval regulatory requirements. Any of these restrictions or requirements could force us to conduct costly studies or increase the time for us to become profitable. For example, any labeling approved for cenderitide, CU-NP, or any other product candidates may include a restriction on the term of its use, or it may not include one or more of our intended indications.

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

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

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

Our ability to generate significant sales of our products depend on the availability of adequate coverage and reimbursement from third-party payors. Healthcare providers that purchase medicine or medical products for treatment of their patients generally rely on third-party payors to reimburse all or part of the costs and fees associated with the products. Adequate coverage and reimbursement from governmental, such as Medicare and Medicaid, and commercial payors is critical to new product acceptance. Patients are unlikely to use our products if they do not receive reimbursement adequate to cover the cost of our products.

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

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

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

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

Risks Related to Our Intellectual Property

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

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

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

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

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

- others may be able to make compounds that are similar to our product candidates but that are not covered by the claims of any of our patents;
- we might not have been the first to make the inventions covered by any issued patents or patent applications we may have (or third parties from whom we license intellectual property may have);

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- we might not have been the first to file patent applications for these inventions;
- it is possible that any pending patent applications we may have will not result in issued patents;
- any issued patents may not provide us with any competitive advantages, or may be held invalid or unenforceable as a result of legal challenges by third parties;
- we may not develop additional proprietary technologies that are patentable; or
- the patents of others may have an adverse effect on our business.

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

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

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

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

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

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

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

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

A significant delay in the development of our product candidates could jeopardize the commercial viability of our product candidates due to the anticipated expiry date of our composition of matter patents.

For a company to continue to make substantial investments in the development of a product candidate through approval and commercialization, the company must be assured that its investment will be protected from competition by generic or biosimilar drug manufacturers for some period of time after the approval of the product candidate. Every additional month or year of development of the product that may occur if the program's development has been delayed for whatever reason reduces the time that a company may commercial the product without direct competition by a generic or biosimilar competition.

Risks Relating to Our Securities

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

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

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

- failure or delays in entering additional drug candidates into clinical trials;
- failure or discontinuation of any of our research programs;
- issuance of new or changed securities analysts' reports or recommendations;
- developments in establishing new strategic alliances;
- market conditions in the pharmaceutical, biotechnology and other healthcare related sectors;
- actual or anticipated fluctuations in our quarterly financial and operating results;
- developments or disputes concerning our intellectual property or other proprietary rights;
- introduction of technological innovations or new commercial products by us or our competitors;
- issues in manufacturing our drug candidates or drugs;
- market acceptance of our drugs;
- third-party healthcare coverage and reimbursement policies;
- FDA or other United States or foreign regulatory actions affecting us or our industry;
- litigation or public concern about the safety of our drug candidates or drugs;
- additions or departures of key personnel; or
- volatility in the stock prices of other companies in our industry.

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

Because our common stock is primarily traded on the OTC Pink tier of the OTC Markets, the volume of shares traded and the prices at which such shares trade may result in lower prices than might otherwise exist if our common stock was traded on a national securities exchange.

Trading of our common stock on the Nasdaq Capital Market was suspended in May 2011 and trading in our common stock has since been conducted on the OTC Markets, an automated quotation system. Beginning in May 2011, our common stock traded on the OTCQB tier of the OTC Markets; however, as a result of our failure to file our Form 10-Q for the quarter ended September 30, 2012 and subsequent periodic reports on a timely basis, trading in our common stock was moved to the lower OTC Pink tier of the OTC Markets. Stocks traded on the OTC Pink tier of the OTC Markets are often less liquid than stocks traded on national securities exchanges, not only in terms of the number of shares that can be bought and sold at a given price, but also in terms of delays in the timing of transactions and reduced coverage of us by security analysts and the media. This may result in lower prices for our common stock than might otherwise be obtained if our common stock were traded on a national securities exchange, and could also result in a larger spread between the bid and asked prices for our common stock.

Due to our extremely limited resources, we may be unable to become and remain current in our filing obligations with the SEC, which means you may not have current information about our business.

Due to our extremely limited resources, we may be unable to become and remain current in our filing obligations with the SEC. If we are unable to obtain additional capital, whether through a financing, strategic or other transaction, we will be unable to pay the professional fees and other expenses required to prepare and file periodic reports with the SEC. In that event, investors in our securities would not have current information about our business, which would significantly increase the risk of trading in our securities. and trading in our common stock would continue to be conducted on the OTC Pink tier of the OTC Markets, if at all.

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. Because the market price of our common stock is

currently less than $5.00 per share, and none of the specific exemptions are applicable, our common stock is considered a “penny stock” according to SEC rules. This designation requires any broker or dealer selling our common stock or our outstanding publicly-traded warrants to purchase common stock to disclose certain information concerning the transaction, obtain a written agreement from the purchaser and determine that the purchaser is reasonably suitable to purchase our common stock, subject to certain exceptions. These rules may restrict the ability of brokers or dealers to sell shares of our common stock, which may make adversely affect the market for our securities.

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

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

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

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

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

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

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

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

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

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

Our certificate of incorporation and by-laws contain provisions that may discourage, delay or prevent a change in our management team that stockholders may consider favorable.

Our certificate of incorporation, our bylaws and Delaware law contain provisions that may have the effect of preserving our current management, such as:

- Ÿ authorizing the issuance of "blank check" preferred stock without any need for action by stockholders;

- eliminating the ability of stockholders to call special meetings of stockholders; and

- establishing advance notice requirements for nominations for election to the board of directors or for proposing matters that can be acted on by stockholders at stockholder meetings.

These provisions could make it more difficult for our stockholders to affect our corporate policies, make changes in our Board of Directors and for a third party to acquire us, even if doing so would benefit our stockholders.

ITEM 1B. UNRESOLVED STAFF COMMENTS

None.

ITEM 2. PROPERTIES

As of December 31, 2012, our principal offices were located at 4 West 4th, Ave. Suite 400, San Mateo, CA, 94402. We moved out of the offices as of February 28, 2013, and do not currently own or lease any real property. Our mailing address is 63 Bovet Rd., Suite 421, San Mateo, California 94402.

ITEM 3. LEGAL PROCEEDINGS

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

ITEM 4. MINE SAFETY DISCLOSURES

Not applicable.

PART II

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

Market Information

Prior to May 12, 2011, our common stock traded on the NASDAQ Capital Market under the symbol "NLTX." Since May 12, 2011, our common stock has traded on the OTC Markets under the symbol "NLTX." The following table lists the high and low sale price for our common stock as quoted, in U.S. dollars, by the NASDAQ Capital Market and the OTC Markets, as applicable, during each quarter within the last two completed fiscal years.

	High	Low
Year ended December 31, 2012		
First Quarter	$0.59	$0.44
Second Quarter	0.50	0.07
Third Quarter	0.15	0.09
Fourth Quarter	0.11	0.02
Year ended December 31, 2011		
First Quarter	$0.97	$0.50
Second Quarter	1.02	0.53
Third Quarter	0.82	0.59
Fourth Quarter	0.64	0.45

Holders

According to the records of our transfer agent, American Stock Transfer & Trust Company, as of May XX, 2013, we had 152 holders of record of common stock, not including those held in "street name."

Dividends

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

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

None.

Issuer Purchases of Equity Securities

None.

ITEM 6. SELECTED FINANCIAL DATA

Not Applicable.

ITEM 7. MANAGEMENT'S DISCUSSION AND ANALYSIS OF FINANCIAL CONDITION AND RESULTS OF OPERATIONS

The following discussion of our financial condition and results of operations should be read in conjunction with the financial statements and the notes to those statements included elsewhere in this Annual Report. This discussion includes forward-looking statements that involve risks and uncertainties. As a result of many factors, such as those set forth under "Risk Factors" in Item 1A of this Annual Report, our actual results may differ materially from those anticipated in these forward-looking statements.

Overview

We are a development stage, biopharmaceutical company developing innovative products for the treatment of cardiovascular and renal diseases, with an initial focus on heart failure. We currently have exclusive rights to develop two drug candidates:

- ***Cenderitide*** *(formerly CD-NP),* our lead product candidate, is a chimeric natriuretic peptide that we are developing for the treatment of heart failure. To date, we have developed cenderitide for the treatment of patients for up to 90 days following admission for acutely decompensated heart failure, or ADHF. We refer to this setting as the "post-acute" period. In 2011, we completed a 58-patient Phase 1 clinical trial of cenderitide in the post-acute setting. We conducted this clinical trial in collaboration with Medtronic, Inc., delivering cenderitide through continuous intravenous infusion using Medtronic's pump technology. Following that Phase 1 clinical trial, we had planned to initiate a Phase 2 clinical trial of cenderitide, pending availability of capital resources. However, to date we have been unable to raise the capital necessary to conduct the next phase of development of cenderitide. Any further development of cenderitide is subject to our ability to either raise additional capital or enter into a strategic transaction in which an acquirer or strategic partner provides the capital necessary to continue development activities. In addition to treating heart failure, we believe cenderitide may be useful in several other cardiovascular and renal indications.

- ***CU-NP***, is a pre-clinical rationally designed natriuretic peptide that consists of amino acid chains identical to those produced by the human body, specifically the ring structure of C-type natriuretic peptide, or CNP, and the N- and C-termini of Urodilatin, or URO. All development of CU-NP is on hold pending the results of our efforts to pursue strategic alternatives

We have no product sales to date and we will not generate any product revenue until we receive approval from the U.S. Food and Drug Administration, or the FDA, or equivalent foreign regulatory bodies to begin selling our pharmaceutical product candidates. Developing pharmaceutical products is a lengthy and very expensive process. Even if we obtain the capital necessary for us to continue the development of our product candidates, whether through a strategic transaction or otherwise, we do not expect to complete the development of a product candidate for several years, if ever. To date, most of our development expenses have related to our lead product candidate, cenderitide. To the extent we proceed with the clinical development of cenderitide and if we further develop CU-NP, our second product candidate, our research and development expenses will continue increasing. Accordingly, our success depends not only on the safety and efficacy of our product candidates, but also on our ability to finance the development of the products. Our major sources of working capital have been proceeds from public and private sales of our equity and debt securities.

Research and development, or R&D, expenses consist primarily of salaries and related personnel costs, fees paid to consultants and outside service providers for pre-clinical, clinical, and manufacturing development, legal expenses resulting from intellectual property prosecution, contractual review, and other expenses relating to the design, development, testing, and enhancement of our product candidates. We expense our R&D costs as they are incurred.

General and administrative, or G&A, expenses consist primarily of salaries and related expenses for executive, finance and other administrative personnel, personnel recruiting fees, accounting, legal and other professional fees, business development expenses, rent, business insurance and other corporate expenses.

Our results include non-cash compensation expense as a result of the issuance of stock, stock options, and warrants. We expense the fair value of stock options and warrants over the vesting period. When more precise pricing data is

unavailable, we determine the fair value of stock options using the Black-Scholes option-pricing model. The terms and vesting schedules for share-based awards vary by type of grant and the employment status of the grantee. Generally, the awards vest based upon time-based or performance-based conditions. Performance-based conditions generally include the attainment of goals related to our financial performance and product development. Stock-based compensation expense is included in the respective categories of expense in the statements of operations. We expect to record additional non-cash compensation expense in the future, which may be significant.

Results of Operations

General and Administrative Expenses. G&A expenses for the years ended December 31, 2012 and 2011 were approximately $1.6 million and $2.1 million, respectively. This decrease of approximately $0.5 million compared to the same period of 2011 is primarily attributable to a decrease of approximately $0.2 million in compensation costs, primarily from reduced stock compensation expense. Additionally, there was a reduction in professional fees of approximately $0.2 compared to the same period of 2011 from requiring less services from outside consultants due to limited operations. Additionally, there was an approximately $0.1 million savings compared to the same period in 2011 as a result of no longer being listed on the NASDAQ as of May 2011.

Research and Development Expenses. R&D expenses for the years ended December 31, 2012 and 2011 were approximately $1.0 million and $4.1 million, respectively. This decrease of approximately $3.1 million over the same period of 2011 is primarily due to the fact that during 2011, the Company was actively conducting clinical development activities of cenderitide and in 2012, the Company was winding down clinical activities and had almost no development activities for most of the year. This resulted in a decrease of approximately $2.4 million in development costs. Additionally, we had a reduction of approximately $0.5 million in compensation costs, including stock compensation, compared to 2011 due to having no R&D employees for approximately half of 2012, compared to one employee during all of 2011. There was also a reduction in R&D professional fees of approximately $0.2 million compared to 2011 as a result of the decrease in R&D activities.

Cenderitide (formerly CD-NP). All development of cenderitide is on hold pending the results of our efforts to pursue strategic alternatives for the Company.

CU-NP. Since acquiring our rights to CU-NP in June 2008, we have incurred a total of approximately $0.6 million through December 31, 2011. All development of CU-NP is on hold pending the results of our efforts to pursue strategic alternatives for the Company.

Our expenditures on current and future clinical development programs, particularly our cenderitide program, are expected to be substantial, particularly in relation to our available capital resources, and to increase. However, these planned expenditures are subject to many uncertainties, including the results of clinical trials and whether we develop any of our drug candidates with a partner or independently. As a result of such uncertainties, we cannot predict with any significant degree of certainty the duration and completion costs of our research and development projects or whether, when and to what extent we will generate revenues from the commercialization and sale of any of our product candidates. The duration and cost of clinical trials may vary significantly over the life of a project as a result of unanticipated events arising during clinical development and a variety of factors, including:

- the number of trials and studies in a clinical program;
- the number of patients who participate in the trials;
- the number of sites included in the trials;
- the rates of patient recruitment and enrollment;
- the duration of patient treatment and follow-up;
- the costs of manufacturing our drug candidates; and
- the costs, requirements, timing of, and the ability to secure regulatory approvals.

Collaboration income. Collaboration income for the years ended December 31, 2012 and 2011 were approximately $0.2 million and $1.4 million, respectively, all of which represents the funds paid to us by Medtronic as reimbursement of expenses we incurred in connection with our Phase 1 clinical trial of cenderitide in accordance with the terms of our February 2011 clinical trial funding agreement with Medtronic. All amounts due under the agreement were paid as of February 2012 at which time the agreement expired.

Interest Income. Interest income for the years ended December 31, 2012 and 2011 was approximately $1,227 and $6,006, respectively. This decrease in interest income over 2011 is due to lower interest rates earned on cash in bank accounts, and lower average cash balances in 2012 than 2011 levels.

Other Income. Other income for the years ended December 31, 2012 and 2011 was approximately $0.5 million and $8,338, respectively. This increase is attributed to changes in the fair value of the warrant liability associated with the warrants issued in conjunction with the April 2012 Financing.

Liquidity and Capital Resources

The following table summarizes our liquidity and capital resources as of and for each of the last two fiscal years, and is intended to supplement the more detailed discussion that follows. The amounts stated are expressed in thousands.

	December 31,	
Liquidity and capital resources	2012	2011
Cash and cash equivalents	$47	$1,039
Working capital (deficit)	(159)	769
Stockholders' (deficit) equity	(167)	831

	Year ended December 31,		Period from Aug. 1, 2005 (inception)
Cash flow data	2012	2011	to Dec. 31, 2012
Cash provided by (used in):			
Operating activities	$ (2,187)	$ (4,649)	$ (34,891)
Investing activities	-	(2)	(474)
Financing activities	1,194	2,312	35,412
Net increase (decrease) in cash and cash equivalents	$ (993)	$ (2,339)	$ 47

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Our total cash resources as of December 31, 2012 were $0.05 million, compared to $1.0 million as of December 31, 2011. As of December 31, 2012, we had approximately $0.4 million in liabilities, of which, approximately $0.1 relates to the non-cash warrant liability, and $0.2 million in net working capital deficit. We incurred a net loss of $1.9 million and had negative cash flow from operating activities of $2.2 million for the year ended December 31, 2012. Since August 1, 2005 (inception) through December 31, 2012, we have incurred an aggregate net loss of approximately $46.7 million, while negative cash flow from operating activities has amounted to $34.9 million. To the extent we obtain sufficient capital and are able to continue developing our product candidates, we expect to continue to incur substantial and increasing losses, which will continue to generate negative net cash flows from operating activities as we expand our technology portfolio and engage in further research and development activities, particularly the conducting of pre-clinical studies and clinical trials.

We need substantial additional capital in order to continue the development of cenderitide, for which the next step is a Phase 2 trial. We estimate that this Phase 2 trial will cost approximately $15 million to $20 million and take approximately 30 months to complete. During the last 12 months, we have attempted, unsuccessfully, to complete a financing transaction that would provide us with the capital necessary to fund the Phase 2 trial, and it is doubtful that we will ever be able to complete such a financing transaction. We have also pursued, and continue to pursue, alternative strategic transactions that would provide for the means to continue development of cenderitide. Such alternatives could include collaborating with another biotechnology or pharmaceutical company to further develop cenderitide, or engaging in a merger or other corporate transaction in which the control of cenderitide’s development would be assumed by a purchaser of our company. However, we do not have any agreement or commitment from any collaboration partner, and there is no assurance we will be able to reach any such agreement. All of further clinical and other development activities for our cenderitide and CU-NP programs are on hold until we obtain the additional capital needed to fund such activities, whether through a financing, strategic transaction or otherwise. If we are not able to obtain such additional capital, we will likely be forced to cease operating altogether and wind down our company.

From inception through December 31, 2012, we have financed our operations through public and private sales of our equity and debt securities. As we have not generated any revenue from operations to date, and we do not expect to generate revenue for several years, if ever, we will need to raise substantial additional capital in order to fund our immediate general corporate activities and, thereafter, to fund our research and development, including our long-term plans for clinical trials and new product development. We may seek to raise additional funds through various potential sources, such as equity and debt financings, or through strategic collaborations and license agreements. We can give no assurances that we will be able to secure such additional sources of funds to support our operations, or if such funds are available to us, that such additional financing will be sufficient to meet our needs. Moreover, to the extent that we raise additional funds by issuing equity securities, our stockholders may experience additional significant dilution, and debt financing, if available, may involve restrictive covenants. To the extent that we raise additional funds through collaboration and licensing arrangements, it may be necessary to relinquish some rights to our technologies or our product candidates, or grant licenses on terms that may not be favorable to us.

On March 15, 2013, we entered into a convertible note purchase agreement certain purchasers under which we agreed to sell secured convertible promissory notes to such purchasers in consideration for an aggregate purchase price of $382,500. See “—Financing Activities,” below. We believe that the net proceeds from this offering, together with our

existing cash resources, only provides us with sufficient capital to fund our minimal operating expenses until the end of the second quarter of 2013. Further, beyond our general corporate activities, we need substantial additional capital to fund our planned Phase 2 clinical trial of cenderitide. If we are unable to obtain the capital necessary for us to continue the development of our product candidates, whether through a financing, strategic or other transaction, we will be forced to cease operations altogether.

Our estimates regarding the sufficiency of our financial resources are based 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. The actual amount of funds we will need to operate is subject to many factors, some of which are beyond our control. These factors include the following:

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

Financing Activities

March 2013 Financing. On March 15, 2013, we entered into a convertible note purchase agreement with certain accredited investors pursuant to which we agreed to sell an aggregate principal amount of up to $500,000 of secured convertible promissory notes (the “Notes”) for an aggregate original issue price of $425,000, representing a 15% original issue discount. The closing of the private placement also occurred on March 15, 2013, and resulted in the sale of Notes in the aggregate principal amount of $450,000 for an aggregate original issue price of $382,500.

The Notes, which have a maturity date of March 15, 2014, do not bear interest and may be prepaid by us without penalty upon 30 days' written notice, on the terms set forth in the Notes. The Notes are secured by a blanket lien on our assets pursuant to a security agreement dated March 15, 2013.

Upon a Change of Control (as defined in the Notes) in which either (i) the outstanding shares of our common stock are exchanged for securities of another corporation, or (ii) we issue shares of common stock, with no securities or other consideration paid or payable to holders of our common stock (e.g., a merger transaction in which we acquire another corporation in exchange for shares of our common stock), then (A) the entire unpaid principal under the applicable Note shall automatically convert, as of immediately prior to the effective time of the Change of Control, into shares of our common stock at a conversion price per share equal to the Closing Price (as defined in the Notes) on the effective date of the Change of Control, and (B) we shall also issue to each Note holder a five-year warrant entitling the holder to purchase, at an exercise price equal to the Closing Price on the effective date of the Change of Control, that number of shares of our common stock obtained by dividing (a) the sum of the outstanding principal under the applicable Note by (b) the Closing Price on the effective date of the Change of Control.

Upon a Change of Control other than as described in the preceding paragraph, we shall pay to each Note holder an amount in cash equal to 175% of the principal amount then outstanding under the applicable Note. Upon payment of such amount to the Note holders, all of the obligations under the Notes shall be deemed paid and satisfied in full.

April 2012 Financing. On March 30, 2012, we entered into subscription agreements with certain purchasers pursuant to which we agreed to sell an aggregate of 3,350,000 shares of our common stock to such purchasers for a purchase price of $0.40 per share. In addition, for each share purchased, each purchaser also received three-fourths of a five-year warrant to purchase an additional share of common stock at an exercise price of $0.50 per share, resulting in the issuance of warrants to purchase an aggregate of 2,512,500 shares of our common stock. The total gross proceeds from the offering were $1.34 million, before deducting anticipated selling commissions and expenses of approximately $0.2 million. The offer and sale of these securities was registered under our Form S-3 shelf registration statement declared effective in March 2010. The closing of the offering occurred April 4, 2012. In connection with the offering, we engaged Roth Capital Partners, LLC, or Roth, to serve as placement agent. Pursuant to the terms of the placement agent agreement, we agreed to pay Roth a cash fee equal to seven percent of the gross proceeds received by us, or approximately $93,800, plus a non-accountable expense allowance of $35,000. Richard B. Brewer, our former Executive Chairman, Joshua A. Kazam, our former President and Chief Executive Officer and a director, Daron Evans, our Chief Financial Officer, and Hsiao Lieu, M.D., our former Executive VP of Clinical Development, participated in the offering on the same terms as the unaffiliated purchasers, and collectively purchased 275,000 shares of our common stock and warrants to purchase 206,250 shares of our common stock for an aggregate purchase price of $110,000.

June 2011 Financing. On June 20, 2011, we sold in a private placement offering a total of 5,000,000 units of our securities at an offering price of $0.50 per unit. Each unit contained one share of common stock and 0.50 warrants to purchase one share of common stock at an exercise price of $0.60 per share. We may call the warrants for redemption upon 30 days' notice if the volume weighted average price of the common stock for any 20 consecutive business days

is equal to or greater than $1.50 per share. The total gross proceeds from the 2011 Offering were $2.5 million, before deducting selling commissions and expenses, which were approximately $0.2 million. The closing of the private placement occurred on June 23, 2011. Pursuant to the Purchase Agreement, the Company agreed to file a registration statement with the Securities and Exchange Commission seeking to register the resale of the Shares and Warrant Shares. The registration statement was filed on July 22, 2011. In connection with the private placement offering, we engaged Riverbank Capital Securities, Inc. (or "Riverbank") to serve as placement agent, and Ladenburg Thalmann & Co. Inc. served as a sub-placement agent. Pursuant to the terms of the engagement agreement, we paid the placement agents a cash fee of $175,000 and issued warrants to purchase 250,000 shares of common stock, valued at $99,100. Peter M. Kash, a director, and Joshua A. Kazam, our former President and Chief Executive Officer and a director, are each officers of Riverbank. Dr. Kash was allocated a portion of the warrants issuable to the placement agents. In light of the relationship between Dr. Kash, Mr. Kazam and Riverbank, the selection of Riverbank as a placement agent and the terms of the engagement were reviewed and approved by a special committee of the our Board consisting of disinterested directors with no affiliation to Riverbank or its affiliates.

April 2010 Financing. On April 21, 2010, we sold, in an underwritten public offering, a total of 6,500,000 units of our securities at a public offering price of $0.70 per unit. Each unit contained one share of common stock and 0.30 warrants to purchase common stock, each whole warrant representing the right to purchase one share of common stock at an exercise price of $0.94 per share. We may call the warrants for redemption upon 30 days' notice if the price of our common stock is at least $3.00 per share for any 20 trading days within a period of 30 consecutive trading days. The units separated immediately and the common stock and warrants were issued separately. The warrants are approved for trading on the Nasdaq Capital Market under the symbol "NLTXW" and began trading on April 22, 2010. The sale of these 6,500,000 units closed on April 27, 2010. Pursuant to the terms of the underwriting agreement, we granted the underwriters an option for a period of 45 days to purchase up to an additional 975,000 units to cover over-allotments, if any. We also issued the underwriters a five-year warrant to purchase 390,000 shares of our common stock at an exercise price of $0.94 per share. On May 6, 2010, the underwriters exercised their option to purchase the maximum amount of 975,000 over-allotment units. The sale of the over-allotment units closed on May 10, 2010. The net proceeds to us from the sale of the units, after deducting underwriting discounts and commissions, was approximately $4.5 million when including the proceeds from the sale of the 975,000 over-allotment units.

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

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

- A warrant representing the right to purchase 25% of the warrant shares at an exercise price equal to $1.25, which represented 110% of the $1.14 consolidated closing bid price of our common stock on the date of the securities purchase agreement;
- A warrant representing the right to purchase 25% of the warrant shares at an exercise price equal to $1.71, which represented 150% of the closing bid price of our common stock on the date of the securities purchase agreement; and
- A warrant representing the right to purchase 50% of the warrant shares at an exercise price equal to $2.28, which represented 200% of the closing bid price of our common stock on the date of the securities purchase agreement.

These warrants are redeemable by us, at a redemption price of $0.001 per warrant share, upon 30 days' notice, if at any time, the volume weighted average price of our common stock for any 20 consecutive business days is equal to or greater than 200% of the then applicable exercise price of the warrants.

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

License Agreement Commitments

Cenderitide License Agreement

Pursuant to our license agreement with the Mayo Foundation for cenderitide (formerly CD-NP), in July 2008 we made a milestone payment of $400,000 to Mayo upon the dosing of the first patient in a Phase II trial. Subsequent milestones achieved will require us to make additional milestone payments to Mayo. We agreed to make contingent cash payments up to an aggregate of $31.9 million upon successful completion of specified clinical and regulatory milestones relating to cenderitide. This aggregate amount is subject to increase upon the receipt of regulatory approval for each additional indication of cenderitide as well as for additional compounds or analogues contained in the intellectual property.

The cenderitide license agreement, unless earlier terminated, will continue in full force and effect until January 20, 2026. However, to the extent any patent covered by the license is issued with an expiration date beyond January 20, 2026, the term of the agreement will continue until such expiration date. Mayo may terminate the agreement earlier (i) for our material breach of the agreement that remains uncured after 90 days' written notice to us, (ii) our insolvency or bankruptcy, or (iii) if we challenge the validity or enforceability of any of the patents in any manner. We may terminate the agreement without cause upon 90 days' written notice.

As of the end of 2012, we were not in compliance with several terms of the cenderitide license agreement, including, but not limited to, provisions requiring us to pay Mayo an annual maintenance fee and actively pursue the development of cenderitide. We are in discussions with the Mayo Foundation to amend the agreement, but we cannot guarantee that we will be able to reach an agreement with Mayo that allows us to maintain our rights to cenderitide. See "Risk Factors – Risks Relating to Our Business – We are not in compliance with various provisions of our license agreements with the Mayo Foundation. If we are unable to renegotiate these agreements, then we will lose our rights to cenderitide and CU-NP."

CU-NP License Agreement

On June 13, 2008, we entered into a second license agreement with Mayo pursuant to which we acquired our rights to CU-NP. Under the terms of the agreement, Mayo granted to us a worldwide, exclusive license for the rights to commercially develop CU-NP for all therapeutic indications. We were also entitled to rights to improvements to CU-NP and know-how that arose out of the laboratory of Dr. John Burnett and Dr. Candace Lee, the inventors of CU-NP and employees of the Mayo Clinic, until June 12, 2011.

Under the terms of the CU-NP license agreement, we made an up-front cash payment to Mayo and agreed to make future contingent cash payments up to an aggregate of $24.3 million upon achievement of specific clinical and regulatory milestones relating to CU-NP, including a milestone payment due in connection with the initiation of the first Phase II clinical trial of the licensed product. This aggregate amount of $24.3 million is subject to increase upon the receipt of regulatory approval for each additional indication of CU-NP, as well as for additional compounds or analogues contained in the intellectual property. Pursuant to the agreement, we must also pay Mayo an annual maintenance fee and a percentage of net sales of licensed products.

In addition to these cash payments payable with respect to the CU-NP license agreement, we also agreed to issue shares of our common stock and warrants to Mayo. In June 2008, we issued 49,689 shares of common stock to Mayo having a fair market value as of June 13, 2008 equal to $250,000. This amount has been recorded in research and development expenses in the accompanying Statements of Operations.

The CU-NP License Agreement, unless earlier terminated, will continue in full force and effect until June 13, 2028. However, to the extent any patent covered by the license is issued with an expiration date beyond June 13, 2028, the term of the agreement will continue until such expiration date. Mayo may terminate the agreement earlier (i) for our material breach of the agreement that remains uncured after 90 days' written notice to us, (ii) our insolvency or bankruptcy, (iii) if we challenge the validity or enforceability of any of the patents in any manner, or (iv) or upon receipt of notice from the Company that we have terminated all development efforts under the agreement. We may terminate the agreement without cause upon 90 days' written notice.

As of the end of 2012, we were not in compliance with several terms of the CU-NP license agreement, including, but not limited to, provisions requiring us to pay Mayo an annual maintenance fee and actively pursue the development of CU-NP. We are in discussions with the Mayo Foundation to amend and the agreement, but we cannot guarantee that we will be able to reach an agreement with Mayo that allows us to maintain our rights to cenderitide. See "Risk Factors – Risks Relating to Our Business – We are not in compliance with various provisions of our license agreements with the Mayo Foundation. If we are unable to renegotiate these agreements, then we will lose our rights to cenderitide and CU-NP."

Off -Balance Sheet Arrangements

There were no off-balance sheet arrangements as of December 31, 2012.

Critical Accounting Policies and Estimates

Our financial statements are prepared in accordance with generally accepted accounting principles. The preparation of these financial statements requires us to make estimates and assumptions that affect the reported amounts of assets, liabilities, revenues, expenses and related disclosures. We evaluate our estimates and assumptions on an ongoing basis, including research and development and clinical trial accruals, and stock-based compensation estimates. Our estimates are based on historical experience and various other assumptions that we believe to be reasonable under the circumstances. Our actual results could differ from these estimates. We believe the following critical accounting policies reflect the more significant judgments and estimates used in the preparation of our financial statements and accompanying notes.

Research and Development Expenses and Accruals

R&D expenses consist primarily of salaries and related personnel costs, fees paid to consultants and outside service providers for pre-clinical, clinical, and manufacturing development, legal expenses resulting from intellectual property prosecution, contractual review, and other expenses relating to the design, development, testing, and enhancement of our product candidates. Except for capitalized patent expenses, R&D costs are expensed as incurred. Amounts due under such arrangements may be either fixed fee or fee for service, and may include upfront payments, monthly payments, and payments upon the completion of milestones or receipt of deliverables.

Our cost accruals for clinical trials and other R&D activities are based on estimates of the services received and efforts expended pursuant to contracts with numerous clinical trial centers and CROs, clinical study sites, laboratories, consultants, or other clinical trial vendors that perform the activities. Related contracts vary significantly in length, and may be for a fixed amount, a variable amount based on actual costs incurred, capped at a certain limit, or for a combination of these elements. Activity levels are monitored through close communication with the CRO's and other clinical trial vendors, including detailed invoice and task completion review, analysis of expenses against budgeted amounts, analysis of work performed against approved contract budgets and payment schedules, and recognition of any changes in scope of the services to be performed. Certain CRO and significant clinical trial vendors provide an estimate of costs incurred but not invoiced at the end of each quarter for each individual trial. The estimates are reviewed and discussed with the CRO or vendor as necessary, and are included in R&D expenses for the related period. For clinical study sites, which are paid periodically on a per-subject basis to the institutions performing the clinical study, we accrue an estimated amount based on subject screening and enrollment in each quarter. All estimates may differ significantly from the actual amount subsequently invoiced, which may occur several months after the related services were performed.

In the normal course of business we contract with third parties to perform various R&D activities in the on-going development of our product candidates. The financial terms of these agreements are subject to negotiation and vary from contract to contract and may result in uneven payment flows. Payments under the contracts depend on factors such as the achievement of certain events, the successful enrollment of patients, and the completion of portions of the clinical trial or similar conditions. The objective of our accrual policy is to match the recording of expenses in our financial statements to the actual services received and efforts expended. As such, expense accruals related to clinical trials and other R&D activities are recognized based on our estimate of the degree of completion of the event or events specified in the specific contract.

No adjustments for material changes in estimates have been recognized in any period presented.

Stock-Based Compensation

Our results include non-cash compensation expense as a result of the issuance of stock, stock options and warrants. We have issued stock options to employees, directors, consultants and Scientific Advisory Board members under our Amended and Restated 2005 Stock Option Plan.

We expense the fair value of stock-based compensation over the vesting period. When more precise pricing data is unavailable, we determine the fair value of stock options using the Black-Scholes option-pricing model. This valuation model requires us to make assumptions and judgments about the variables used in the calculation. These variables and assumptions include the weighted-average period of time that the options granted are expected to be outstanding, the volatility of our common stock, the risk-free interest rate and the estimated rate of forfeitures of unvested stock options.

Stock options or other equity instruments to non-employees (including consultants and all members of the Company's Scientific Advisory Board) issued as consideration for goods or services received by the Company are accounted for based on the fair value of the equity instruments issued (unless the fair value of the consideration received can be more reliably measured). The fair value of stock options is determined using the Black-Scholes option-pricing model. The fair value of any options issued to non-employees is recorded as expense over the applicable vesting periods.

The terms and vesting schedules for share-based awards vary by type of grant and the employment status of the grantee. Generally, the awards vest based upon time-based or performance-based conditions. Performance-based conditions generally include the attainment of goals related to our financial and development performance. Stock-based compensation expense is included in the respective categories of expense in the Statements of Operations. We expect to record additional non-cash compensation expense in the future, which may be significant.

In the quarter ending March 31, 2009, with two years of employee performance and forfeiture history, we began to estimate forfeitures of performance-based stock options. Prior to December 31, 2008, we did not include an estimate for forfeitures in our compensation expenses on a quarterly basis. Instead, adjustments to the performance-based stock compensation expense for the full year were made in the fourth quarter at the time of performance assessment. Forfeiture rates for performance stock options vested in 2008 through 2012 were between 0% and 55%.

Warrant Liability

We account for the warrants issued in connection with the April 2012 financing in accordance with the guidance on Accounting for Certain Financial Instruments with Characteristics of both Liabilities and Equity, which provides that we classify the warrant instrument as a liability at its fair value and adjusts the instrument to fair value at each reporting period. This liability is subject to re-measurement at each balance sheet date until exercised, and any change in fair value is recognized as a component of other income or expense. The fair value of warrants issued in connection with offerings of securities, has been estimated by management using a binomial options pricing model. The binomial option pricing model is a generally accepted valuation model used to generate a defined number of stock price paths in order to develop a reasonable estimate of the range of our future expected stock prices, and their resulting probabilistic valuation.

ITEM 7A. QUANTITATIVE AND QUALITATIVE DISCLOSURES ABOUT MARKET RISK

Not applicable.

ITEM 8. FINANCIAL STATEMENTS AND SUPPLEMENTARY DATA

Financial Statements Index

REPORT OF INDEPENDENT REGISTERED PUBLIC ACCOUNTING FIRM

To the Board of Directors and stockholders

Nile Therapeutics, Inc.

San Mateo, California

We have audited the accompanying balance sheets of Nile Therapeutics, Inc. as of December 31, 2012 and 2011, and the related statements of operations, stockholders' equity (deficit), and cash flows for the years then ended and the period from August 1, 2005 (inception) through December 31, 2012. These financial statements are the responsibility of the Company's management. Our responsibility is to express an opinion on these financial statements based on our audits.

We conducted our audits in accordance with the standards of the Public Company Accounting Oversight Board (United States). Those standards require that we plan and perform the audit to obtain reasonable assurance about whether the financial statements are free of material misstatement. The Company is not required to have, nor were we engaged to perform, an audit of its internal control over financial reporting. Our audit included consideration of internal control over financial reporting as a basis for designing audit procedures that are appropriate in the circumstances, but not for the purpose of expressing an opinion on the effectiveness of the Company's internal control over financial reporting. Accordingly, we express no such opinion. An audit includes examining, on a test basis, evidence supporting the amounts and disclosures in the financial statements. An audit also includes assessing the accounting principles used and significant estimates made by management, as well as evaluating the overall financial statement presentation. We believe that our audits provide a reasonable basis for our opinion.

In our opinion, the financial statements referred to above present fairly, in all material respects, the financial position of the Company as of December 31, 2012 and 2011 and the results of its operations and its cash flows for the years then ended and the period from August 1, 2005 (inception) through December 31, 2012, in conformity with U.S. generally accepted accounting principles.

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

/s/ Crowe Horwath LLP

New York, New York

June 21, 2013

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NILE THERAPEUTICS, INC.

(A DEVELOPMENT STAGE COMPANY)

BALANCE SHEETS

	December 31, 2012	December 31, 2011
ASSETS		
Current assets		
Cash and cash equivalents	$ 46,716	$ 1,039,190
Prepaid expenses and other current assets	124,912	271,298
Total current assets	171,628	1,310,488
Property and equipment, net	3,488	9,744
Deposits	51,938	51,938
Total assets	$ 227,054	$ 1,372,170
LIABILITIES AND STOCKHOLDERS' EQUITY		
Current liabilities		
Accounts payable	$ 182,916	$ 437,837
Accrued expenses and other current liabilities	131,928	64,718
Due to related party	16,139	38,892
Total current liabilities	330,983	541,447
Warrant liability	63,384	-
Total liabilities	394,367	541,447
Commitments and contingencies		
Stockholders' (deficit) equity		
Preferred stock, $0.001 par value, 10,000,000 shares authorized, none issued and outstanding	-	-
Common stock, $0.001 par value, 100,000,000 shares authorized, 43,062,231 and 39,712,231 shares issued and outstanding	43,062	39,712
Additional paid-in capital	46,497,642	45,605,991
Deficit accumulated during the development stage	(46,708,017)	(44,814,980)
Total stockholders' (deficit) equity	(167,313)	830,723
Total liabilities and stockholders' equity	$ 227,054	$ 1,372,170

See accompanying notes to financial statements

NILE THERAPEUTICS, INC.

(A DEVELOPMENT STAGE COMPANY)

STATEMENTS OF OPERATIONS

	Year ended December 31,		Period from August 1, 2005 (incpetion) through December 31, 2012
	2012	2011	
Income:			
Grant income	$-	$-	$ 482,235
Collaboration income	195,500	1,354,500	1,550,000
Total income	195,500	1,354,500	2,032,235
Operating expenses:			
Research and development	1,023,929	4,136,951	31,019,820
General and administrative	1,611,711	2,116,729	17,937,871
Total operating expenses	2,635,640	6,253,680	48,957,691
Loss from operations	(2,440,140)	(4,899,180)	(46,925,456)
Other income (expense):			
Interest income	1,227	6,006	795,192
Interest expense	-	-	(1,273,734)
Other income	545,876	8,388	695,981
Total other income	547,103	14,394	217,439
Net loss	$(1,893,037)	$(4,884,786)	$ (46,708,017)
Basic and diluted loss per share	$(0.04)	$(0.13)	
Weighted-average common shares outstanding	42,201,848	37,328,519	

See accompanying notes to financial statements

NILE THERAPEUTICS, INC.

(A DEVELOPMENT STAGE COMPANY)

STATEMENT OF STOCKHOLDERS' (DEFICIT) EQUITY

Period from

August 1, 2005 (inception) through December 31, 2012

	COMMON STOCK				
	SHARES	AMOUNT	ADDITIONAL PAID-IN CAPITAL	DEFICIT ACCUMULATED DURING THE DEVELOPMENT STAGE	TOTAL STOCKHOLDERS' (DEFICIT) EQUITY
Issuance of common shares to founders	13,794,132	$ 13,794	$ (8,794)	$ -	$ 5,000
Founders shares returned to treasury	(1,379,419)	-	-	-	-
Net loss	-	-	-	(10,043)	(10,043)
Balance at December 31, 2005	12,414,713	13,794	(8,794)	(10,043)	(5,043)
Issuance of common shares pursuant to licensing agreement	1,379,419	-	500	-	500
Issuance of stock options for services	-	-	10,000	-	10,000
Net loss	-	-	-	(2,581,972)	(2,581,972)
Balance at December 31, 2006	13,794,132	13,794	1,706	(2,592,015)	(2,576,515)
Issuance of common shares pursuant to licensing agreement	63,478	64	182,172	-	182,236
Issuance of common shares pursuant to licensing agreement	350,107	350	999,650	-	1,000,000
Common shares sold in private placement, net of issuance costs of $102,000	6,957,914	6,958	19,865,789	-	19,872,747
Warrants issued in connection with note conversion	-	-	288,000	-	288,000

Conversion of notes payable upon event of merger	1,684,085	1,684	4,349,481	-	4,351,165
Note discount arising from beneficial conversion feature	-	-	483,463	-	483,463
Reverse merger transaction					
Elimination of accumulated deficit	-	-	(234,218)	-	(234,218)
Previously issued SMI stock	1,250,000	1,250	232,968	-	234,218
Employee stock-based compensation	-	-	1,902,298	-	1,902,298
Non-employee stock-based compensation	-	-	(667)	-	(667)
Net loss	-	-	-	(10,302,795)	(10,302,795)
Balance at December 31, 2007	24,099,716	24,100	28,070,642	(12,894,810)	15,199,932
Warrants issued in satisfaction of accrued liabilities	-	-	334,992	-	334,992
Employee stock-based compensation	-	-	2,436,603	-	2,436,603
Non-employee stock-based compensation	-	-	13,687	-	13,687
Issuance of common shares pursuant to licensing agreement	49,689	50	249,950	-	250,000
Net loss	-	-	-	(13,131,596)	(13,131,596)
Balance at December 31, 2008	24,149,405	24,150	31,105,874	(26,026,406)	$ 5,103,618
Employee stock-based compensation	-	-	1,772,597	-	1,772,597
Non-employee stock-based compensation	-	-	473,584	-	473,584
Units sold in private placement, net of issuance costs of $282,773	2,691,394	2,691	3,284,484	-	3,287,175
Stock option and warrant exercises	245,025	245	217,228	-	217,473
Net loss	-	-	-	(7,872,297)	(7,872,297)
Balance at December 31, 2009	27,085,824	27,086	36,853,767	(33,898,703)	2,982,150

Employee stock-based compensation	-	-	1,142,552	-	1,142,552
Non-employee stock-based compensation	-	-	(19,249)	-	(19,249)
Units sold in private placement, net of issuance costs of $715,801	7,475,000	7,475	4,509,224	-	4,516,699
Stock option and warrant exercises	68,970	69	6,138	-	6,207
Net loss	-	-	-	(6,031,491)	(6,031,491)
Balance at December 31, 2010	34,629,794	34,630	42,492,432	(39,930,194)	2,596,868
Employee stock-based compensation	-	-	785,587	-	785,587
Non-employee stock-based compensation	-	-	20,740	-	20,740
Stock option and warrant exercises	82,437	82	13,666	-	13,748
Units sold in private placement, net of issuance costs of $201,434	5,000,000	5,000	2,293,566	-	2,298,566
Net loss	-	-	-	(4,884,786)	(4,884,786)
Balance at December 31, 2011	39,712,231	39,712	45,605,991	(44,814,980)	830,723
Employee stock-based compensation	-	-	312,690	-	312,690
Units sold in private placement, net of issuance costs of $145,793	3,350,000	3,350	1,190,857	-	1,194,207
Warrants issued in connection with offering	-	-	(611,896)	-	(611,896)
Net loss	-	-	-	(1,893,037)	(1,893,037)
Balance at December 31, 2012	43,062,231	$ 43,062	$ 46,497,642	$ (46,708,017)	$ (167,313)

See accompanying notes to financial statements

NILE THERAPEUTICS, INC.

(A DEVELOPMENT STAGE COMPANY)

STATEMENTS OF CASH FLOWS

	Year ended December 31,		Period from August 1, 2005 (inception) through December 31, 2012
	2012	2011	
Cash flows from operating activities			
Net loss	$(1,893,037)	$(4,884,786)	$ (46,708,017)
Adjustment to reconcile net loss to net cash used in operating activities			
Depreciation and amortization	6,256	7,507	326,904
Stock-based compensation	312,690	806,327	10,618,150
Warrant liability	(548,512)	-	(548,512)
Write-off of intangible assets	-	-	106,830
Warrants issued in connection with note conversion	-	-	288,000
Note discount arising from beneficial conversion feature	-	-	483,463
Loss on disposal of assets	-	1,501	36,724
Noncash interest expense	-	-	351,165
Changes in operating assets and liabilities			
Prepaid expenses and other current assets	146,386	(52,203)	(124,912)
Other non-current assets	-	-	(51,938)
Accounts payable	(254,921)	105,457	182,916
Accrued expenses and other current liabilities	67,210	(587,557)	131,928
Due to related party	(22,753)	(45,538)	16,139
Net cash used in operating activities	(2,186,681)	(4,649,292)	(34,891,160)
Cash flows from investing activities			
Purchase of property and equipment	-	(1,987)	(130,855)
Proceeds from sale of assets	-	-	2,500
Cash paid for intangible assets	-	-	(345,591)
Net cash used in investing activities	-	(1,987)	(473,946)
Cash flows from financing activities			
Proceeds from issuance of notes payable	-	-	5,500,000
Repayment of notes payable	-	-	(1,500,000)
Proceeds from exercise of stock options and warrants	-	13,748	237,428
Proceeds from sale of common stock to founders	-	-	5,000
Proceeds from sale of common stock in private placement, net	1,194,207	2,298,566	31,169,394

Net cash provided by financing activities	1,194,207	2,312,314	35,411,822
Net (decrease) increase in cash and cash equivalents	(992,474)	(2,338,965)	46,716
Cash and cash equivalents at beginning of period	1,039,190	3,378,155	-
Cash and cash equivalents at end of period	$46,716	$1,039,190	$ 46,716
Supplemental schedule of cash flows information:			
Cash paid for interest	$-	$-	$ 150,000
Supplemental schedule of non-cash investing and financing activities:			
Warrants issued in satisfaction of accrued liability	$-	$-	$ 334,992
Warrants issued to placement agent and investors in connection with private placements		$1,083,700	$ 5,721,000
Warrants issued to investors in connection with registered direct offering	$611,896	$-	$ 611,896
Conversion of notes payable and interest to common stock	$-	$-	$ 4,351,165
Common shares of SMI issued in reverse merger transaction	$-	$-	$ 1,250

See accompanying notes to financial statements

Nile Therapeutics, Inc

(A Development Stage Company)

Notes to Financial Statements

1. DESCRIPTION OF BUSINESS

Nile Therapeutics, Inc. ("Nile" or the "Company") engages in research and development of innovative products for the treatment of cardiovascular diseases. Nile's lead compound is cenderitide (formerly CD-NP), a chimeric natriuretic peptide currently in clinical studies for the treatment of heart failure. The Company also has exclusive rights to develop CU-NP, a pre-clinical rationally designed natriuretic peptide that consists of amino acid chains identical to those produced by the human body, specifically the ring structure of C-type Natriuretic Peptide ("CNP") and the N- and C-termini of Urodilatin ("URO").

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

2. BASIS OF PRESENTATION, CAPITAL RESOURCES AND MANAGEMENT'S PLANS

The Company is a development stage enterprise since it has not yet generated any revenue from the sale of products and, through December 31, 2012, its efforts have been principally devoted to developing its licensed technologies, recruiting personnel, establishing office facilities, and raising capital. Accordingly, the accompanying financial statements have been prepared in accordance with the provisions of Accounting Standards Codification ("ASC") 915, "*Development Stage Entities*." The Company's financial statements have been prepared on a going concern basis, which contemplates the realization of assets and the settlement of liabilities and commitments in the normal course of business. The Company has experienced net losses since its inception and has an accumulated deficit of approximately $46.7 million at December 31, 2012. The Company expects to incur substantial and increasing losses and have negative net cash flows from operating activities as it expands its technology portfolio and engages in further research and development activities, particularly the conducting of pre-clinical and clinical trials.

Cash resources as of December 31, 2012 were approximately $0.05 million, compared to $1.0 million as of December 31, 2011. Based on its resources at December 31, 2012, together with the net proceeds of the Company's March 2013 offering of convertible notes (Note 16), and the current plan of expenditure, the Company believes that it has sufficient capital to fund its operations until the end of the second quarter of 2013. The Company will need to raise additional capital to fund any clinical development and to otherwise continue operations beyond the second quarter of 2013. Additionally, the Company will need substantial additional financing in the future until it can achieve profitability, if ever. The Company's continued operations will depend on its ability to raise additional funds through various potential sources, such as equity and debt financing, or to license its compounds to another pharmaceutical company. The Company will continue to fund operations from cash on hand and through sources of capital similar to those previously described. The Company cannot assure that it will be able to secure such additional financing, or if available, that it will be sufficient to meet its needs.

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

In addition, to the extent that the Company raises additional funds by issuing shares of its common stock or other securities convertible or exchangeable for shares of common stock, stockholders may experience significant additional dilution. In the event the Company raises additional capital through debt financings, the Company may incur significant interest expense and become subject to covenants in the related transaction documentation that may affect the manner in which the Company conducts its business. To the extent that the Company raises additional funds through collaboration and licensing arrangements, it may be necessary to relinquish some rights to its technologies or product candidates, or grant licenses on terms that may not be favorable to the Company.

Nile Therapeutics, Inc

(A Development Stage Company)

Notes to Financial Statements

These factors raise substantial doubt about the Company's ability to continue as a going concern. The Company's financial statements have been prepared on a going concern basis, which contemplates the realization of assets and the settlement of liabilities and commitments in the normal course of business. The financial statements do not include any adjustments that might result from the inability of the Company to continue as a going concern.

3. THE MERGER

(a) Description of the Merger and Private Placement Offering

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

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

As a condition to the closing of the Merger, on September 11, 2007, Old Nile completed a financing whereby it received gross proceeds of $19,974,747 through the sale of 6,957,914 shares of common stock in a private placement to certain qualified investors (the "Financing"). Contemporaneously with the Financing, the Company converted

$4,351,165 of convertible debt and interest into 1,684,085 shares of common stock, and issued five-year warrants to purchase an aggregate of 168,337 shares of common stock at an exercise price of $2.71per share.

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

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

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

SMI’s historical accumulated deficit for periods prior to September 17, 2007, in the amount of $234,218, was eliminated against additional-paid-in-capital, and the accompanying financial statements present the previously issued shares of SMI common stock as having been issued pursuant to the Merger on September 17, 2007. The shares of common stock of the Company issued to the Old Nile stockholders in the Merger are presented as having been outstanding since August 2005 (the month when Old Nile first sold its equity securities).

Because the Merger was accounted for as a reverse acquisition under U.S. generally accepted accounting principles (“GAAP”), the financial statements for periods prior to September 17, 2007 reflect only the operations of Old Nile.

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4. SUMMARY OF SIGNIFICANT ACCOUNTING POLICIES

(a) Use of Estimates

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

(b) Cash and Cash Equivalents

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

(c) Property and Equipment

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

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

Computer equipment	3 years

(d) Intangible Assets and Intellectual Property

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

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

(e) Concentration of Credit Risk

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

(f) Research and Development

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

(g) Grant and Collaboration Income

The Company has entered into a collaboration agreement under which the Company is reimbursed for development work performed on behalf of the collaborator and upon the achievement of certain milestones. The Company records all of these expenses as research and development expenses and the reimbursements upon the achievement of the milestones as income.

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The Company recognizes milestone payments as income upon achievement of the milestone only if (1) the milestone payment is non-refundable, (2) substantive effort is involved in achieving the milestone, (3) the amount of the milestone is reasonable in relation to the effort expended or the risk associated with achievement of the milestone, and (4) the milestone is at risk for both parties. If any of these conditions are not met, the Company defers the milestone payment and recognizes it as income over the remaining estimated period of performance under the contract as the Company completes its performance obligations.

(h) Stock-Based Compensation

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

Common stock, stock options or other equity instruments issued to non-employees (including consultants and all members of the Company’s Scientific Advisory Board) as consideration for goods or services received by the Company are accounted for based on the fair value of the equity instruments issued (unless the fair value of the consideration received can be more reliably measured). The fair value of stock options is determined using the Black-Scholes option-pricing model. The fair value of any options issued to non-employees is recorded as expense over the applicable service periods.

(i) Loss per Common Share

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

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

Potentially dilutive securities include:

	December 31, 2012	December 31, 2011
Warrants to purchase common stock	-	3,096,533
Options to purchase common stock	-	2,750,000
Total potentially dilutive securities	-	5,846,533

For the years ended December 31, 2012 and 2011, 15,382,331 and 11,300,285 warrants and options have been excluded from the computation of the dilutive earnings per share, respectively, as their exercise prices are greater than the average market price per common share for the three months ended December 31, 2012, and December 31, 2011, respectively.

(j) Comprehensive Loss

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

(k) Income Taxes

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

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

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The Company's policy is to include interest and penalties related to unrecognized tax benefits within the Company's provision for (benefit from) income taxes. The Company recognized no amounts for interest and penalties related to unrecognized tax benefits in 2012 and 2011 respectively. In addition, the Company had no amounts accrued for interest and penalties as of December 31, 2012 and 2011, respectively.

(l) Fair Value Measurement

The Company measures fair value in accordance with generally accepted accounting principles. Fair value measurements are applied under other accounting pronouncements that require or permit fair value measurements. Financial instruments included in the Company's balance sheets consist of cash and cash equivalents, accounts payable, accrued expenses due to related parties, and warrant liability. The carrying amounts of these instruments reasonably approximate their fair values due to their short-term maturities.

(m) Warrant Liability

The Company accounts for the warrants issued in connection with the April 2012 financing (Note 10b) in accordance with the guidance on Accounting for Certain Financial Instruments with Characteristics of both Liabilities and Equity, which provides that the Company classifies the warrant instrument as a liability at its fair value and adjusts the instrument to fair value at each reporting period. This liability is subject to re-measurement at each balance sheet date until exercised, and any change in fair value is recognized as a component of other income or expense. The fair value of warrants issued by the Company, in connection with offerings of securities, has been estimated by management using a binomial options pricing model. The binomial option pricing model is a generally accepted valuation model used to generate a defined number of stock price paths in order to develop a reasonable estimate of the range of the Company's future expected stock prices, and their resulting probabilistic valuation.

(n) Recently Issued Accounting Pronouncements

In May 2011, the Financial Accounting Standards Board ("FASB") issued additional guidance relating to fair value measurement and disclosure requirements. For fair value measurements categorized in Level 3 of the fair value hierarchy, the new guidance requires (1) disclosure of quantitative information about unobservable inputs; (2) a description of the valuation processes used by the entity; and (3) a qualitative discussion about the sensitivity of the fair value measurements to changes in unobservable inputs and interrelationships between those unobservable inputs, if any. Entities must report the level in the fair value hierarchy of assets and liabilities that are not recorded at fair value in the statement of financial position but for which fair value is disclosed. The new requirements clarify that the concepts of highest and best use and valuation premise only apply to measuring fair value of nonfinancial assets. The new requirements also specify that in the absence of a Level 1 input, a reporting entity should incorporate a premium or discount in a fair value measurement if a market participant would take into account such an input in pricing an asset or liability. Additionally, the new guidance introduces an option to measure certain financial assets and financial liabilities with offsetting positions on a net basis if certain criteria are met. For public entities, these new requirements become effective for interim and annual periods beginning on or after December 15, 2011. These requirements are applicable to our fiscal year end beginning January 1, 2012. This guidance did not affect the Company's financial statements.

5. PROPERTY AND EQUIPMENT

Property and equipment as of December 31, 2012 and 2011 consist of the following:

	2012	2011
Computer equipment	$11,834	$11,834
Office furniture and equipment	38,521	38,521
Total property and equipment	50,355	50,355
Accumulated depreciation	(46,867)	(40,611)
Total property and equipment, net	$3,488	$9,744

Depreciation expense related to property and equipment for the years ended December 31, 2012 and 2011 totaled $6,256 and $7,507, respectively, and $75,217 for the period from August 1, 2005 (inception) to December 31, 2012.

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6. INTANGIBLE ASSETS AND INTELLECTUAL PROPERTY

License Agreements

Cenderitide (formerly CD-NP)

On January 20, 2006, the Company entered into an exclusive, worldwide, royalty-bearing license agreement, or the Cenderitide License Agreement, with Mayo Foundation for Medical Education and Research ("Mayo") for the rights to issued patents, patent applications and know-how relating to the use of cenderitide in all therapeutic indications. The Company was also entitled to rights to improvements to cenderitide that arose out of the laboratory of Dr. John Burnett, the co-inventor of cenderitide, until January 19, 2009.

Under the terms of the Cenderitide License Agreement, the Company paid Mayo an up-front cash payment, reimbursed it for past patent expenses and issued to Mayo 1,379,419 shares of common stock. Additionally, the Company agreed to make contingent cash payments up to an aggregate of $31.9 million upon successful completion of specified clinical and regulatory milestones relating to cenderitide. This aggregate amount is subject to increase upon the receipt of regulatory approval for each additional indication of cenderitide as well as for additional compounds or analogues contained in the intellectual property. In July 2008, the Company made a milestone payment of $400,000 to Mayo upon the dosing of the first patient in a Phase II trial. Based on the current stage of research the Company does not expect to make any milestone payments for the year ending December 31, 2013. Pursuant to the Cenderitide License Agreement, the Company is required to pay Mayo an annual maintenance fee and a percentage of net sales of licensed products, as well as $50,000 per year for the consulting services of Dr. Burnett while serving as chairman of the Company's Scientific Advisory Board.

In addition to the potential milestone payments discussed above, the Cenderitide License Agreement requires the Company to issue shares of common stock to Mayo for an equivalent dollar amount of grants received in excess of $300,000, but not to exceed $575,000. For the period from August 1, 2005 (inception) through December 31, 2012, the Company received $482,235 in grant income for which it has issued to Mayo 63,478 shares (representing $182,235) of common stock. No such shares have been issued since the year ended December 31, 2008.

The Cenderitide License Agreement, unless earlier terminated, will continue in full force and effect until January 20, 2026. However, to the extent any patent covered by the license is issued with an expiration date beyond January 20, 2026, the term of the agreement will continue until such expiration date. Mayo may terminate the agreement earlier (i) for the Company's material breach of the agreement that remains uncured after 90 days' written notice, (ii) the Company's insolvency or bankruptcy, or (iii) if the Company challenges the validity or enforceability of any of the patents in any manner. The Company may terminate the agreement without cause upon 90 days' written notice.

As of the end of 2012, the Company was not in compliance with several terms of the Cenderitide License Agreement, including, but not limited to, provisions requiring the Company to pay the Mayo Foundation an annual maintenance fee and actively pursue the development of cenderitide. The Company is in discussions with the Mayo Foundation to amend the agreement, but the Company cannot guarantee that it will be able to reach an agreement with Mayo that allows the Company to maintain its rights to cenderitide. As of December 31, 2012, the Company owed Mayo $132,600 in annual maintenance fees and other expense reimbursements related to the Cenderitide License Agreement, all of which is included in accounts payable.

CU-NP

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

Under the terms of the CU-NP License Agreement, the Company made an up-front cash payment to Mayo and agreed to make future contingent cash payments up to an aggregate of $24.3 million upon achievement of specific clinical and regulatory milestones relating to CU-NP, including a milestone payment due in connection with the initiation of the first Phase II clinical trial of the licensed product. This aggregate amount of $24.3 million is subject to increase upon the receipt of regulatory approval for each additional indication of CU-NP, as well as for additional compounds or analogues contained in the intellectual property. Based on the current stage of research the Company does not expect to make any milestone payments for the year ending December 31, 2013. Pursuant to the agreement, the Company must also pay Mayo an annual maintenance fee and a percentage of net sales of licensed products.

In addition to these cash payments payable with respect to the CU-NP License Agreement, the Company also agreed to issue shares of its common stock to Mayo. In June 2008, the Company issued 49,689 shares of common stock to Mayo having a fair market value as of June 13, 2008 equal to $250,000. This amount has been recorded as research and development expense in the accompanying Statements of Operations.

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The CU-NP License Agreement, unless earlier terminated, will continue in full force and effect until June 13, 2028. However, to the extent any patent covered by the license is issued with an expiration date beyond June 13, 2028, the term of the agreement will continue until such expiration date. Mayo may terminate the agreement earlier (i) for the Company's material breach of the agreement that remains uncured after 90 days written notice, (ii) the Company's insolvency or bankruptcy, (iii) if the Company challenges the validity or enforceability of any of the patents in any manner, or (iv) or upon receipt of notice from the Company that it has terminated all development efforts under the agreement. The Company may terminate the agreement without cause upon 90 days' written notice.

As of the end of 2012, the Company was not in compliance with several terms of the CU-NP License Agreement, including, but not limited to, provisions requiring the Company to pay the Mayo Foundation an annual maintenance fee and actively pursue the development of CU-NP. The Company is in discussions with the Mayo Foundation to amend the agreement, but the Company cannot guarantee that it will be able to reach an agreement with Mayo that allows the Company to maintain its rights to CU-NP. As of December 31, 2012, the Company owed Mayo $35,000 in annual maintenance fees and other expense reimbursements related to the CU-NP License Agreement, all of which is included in accounts payable.

Collaboration Agreement

In February 2011, the Company entered into a Clinical Trial Funding Agreement with Medtronic, Inc. Pursuant to the agreement, Medtronic provided the funding and equipment necessary for the Company to conduct its Phase 1 clinical trial to assess the pharmacokinetics and pharmacodynamics of cenderitide when delivered to heart failure patients through continuous subcutaneous infusion using Medtronic's diabetes pump technology.

Under the agreement, the Company agreed not to enter into an agreement with a third party to develop or commercialize cenderitide or any drug/device combination developed under the agreement until the earlier of: (i) three months following delivery to Medtronic of a final database with respect to the Phase 1 trial; and (ii) 15 months after the date of the agreement. The final database was delivered to Medtronic on November 19, 2011.

The agreement provides that intellectual property conceived in or otherwise resulting from the performance of the Phase I clinical trial shall be jointly owned by the Company and Medtronic (the "Joint Intellectual Property"), and that

the Company shall pay royalties to Medtronic based on the net sales of any Nile product, the manufacture, use or sale of which is covered or claimed in one or more issued patents constituting Joint Intellectual Property. The agreement further provides that, if the parties fail to enter into a definitive commercial license agreement with respect to cenderitide, then each party shall have a right of first negotiation to license exclusive rights to any Joint Intellectual Property.

Pursuant to its terms, the agreement expired in February 2012, following the completion of the Phase 1 clinical trial and the delivery of data and reports related to such study.

7. ACCRUED LIABILITIES

Accrued liabilities as of December 31, 2012 and 2011 consist of the following:

	2012	2011
Accrued compensation and related benefits	$56,428	$39,718
Accrued research and development expense	75,500	25,000
Total accrued liabilities	$131,928	$64,718

8. CONVERTIBLE AND OTHER NOTES PAYABLE

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

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

On March 15, 2013, the Company entered into a convertible note purchase agreement with certain accredited investors pursuant to which the Company agreed to sell an aggregate principal amount of up to $500,000 of secured convertible promissory notes (the “2013 Notes”) for an aggregate original issue price of $425,000, representing a 15% original issue discount. The closing of the private placement also occurred on March 15, 2013, and resulted in the sale of the 2013 Notes in the aggregate principal amount of $450,000 for an aggregate original issue price of $382,500.

The 2013 Notes, which have a maturity date of March 15, 2014, do not bear interest and may be prepaid without penalty upon 30 days’ written notice, on the terms set forth in the Notes. The 2013 Notes are secured by a blanket lien on our assets pursuant to a security agreement dated March 15, 2013.

Upon a Change of Control (as defined in the 2013 Notes) in which either (i) the outstanding shares of the Company’s common stock are exchanged for securities of another corporation, or (ii) the Company issues shares of common stock, with no securities or other consideration paid or payable to holders of our common stock (e.g., a merger transaction in which the Company acquires another corporation in exchange for shares of our common stock), then (A) the entire unpaid principal under the applicable 2013 Note shall automatically convert, as of immediately prior to the effective time of the Change of Control, into shares of the Company’s common stock at a conversion price per share equal to the Closing Price (as defined in the Notes) on the effective date of the Change of Control, and (B) the Company shall also issue to each 2013 Note holder a five-year warrant entitling the holder to purchase, at an exercise price equal to the Closing Price on the effective date of the Change of Control, that number of shares of our common stock obtained by dividing (a) the sum of the outstanding principal under the applicable Note by (b) the Closing Price on the effective date of the Change of Control.

Upon a Change of Control other than as described in the preceding paragraph, the Company shall pay to each 2013 Note holder an amount in cash equal to 175% of the principal amount then outstanding under the applicable Note. Upon payment of such amount to the 2013 Note holders, all of the obligations under the Notes shall be deemed paid and satisfied in full.

9. FAIR VALUE OF FINANCIAL INSTRUMENTS

The Company defines fair value as the amount at which an asset (or liability) could be bought (or incurred) or sold (or settled) in a current transaction between willing parties, that is, other than in a forced or liquidation sale. The fair value estimates presented in the table below are based on information available to the Company as of December 31, 2012.

The accounting standard regarding fair value measurements discusses valuation techniques, such as the market approach (comparable market prices), the income approach (present value of future income or cash flow), and the cost approach (cost to replace the service capacity of an asset or replacement cost). The standard utilizes a fair value hierarchy that prioritizes the inputs to valuation techniques used to measure fair value into three broad levels. The following is a brief description of those three levels:

· Level 1: Observable inputs such as quoted prices (unadjusted) in active markets for identical assets or liabilities.

· Level 2: Inputs other than quoted prices that are observable for the asset or liability, either directly or indirectly. These include quoted prices for similar assets or liabilities in active markets and quoted prices for identical or similar assets or liabilities in markets that are not active.

· Level 3: Unobservable inputs that reflect the reporting entity's own assumptions.

The Company has determined the fair value of certain liabilities using the market approach: the following tables present the Company's fair value hierarchy for these assets measured at fair value on a recurring basis as of December 31, 2012:

	Fair Value December 31, 2012	Quoted Market Prices in Active Markets (Level 1)	Significant Other Observable Inputs (Level 2)	Significant Unobservable Inputs (Level 3)
Warrant Liability	$ 63,384	$ -	$ -	$ 63,384

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The fair value of the warrant liability relating to the warrants issued in conjunction with the April 2012 financing (Note 10b) was estimated by management using a binomial option pricing model. The binomial option pricing model is a generally accepted valuation model used to generate a defined number of stock price paths in order to develop a reasonable estimate of the range of the Company's future expected stock prices, and their resulting probabilistic valuation. The changes in the fair value of the warrant liability are recorded in other income (expense) on the statement of operations.

The following table provides a summary of changes in fair value of the Company's liabilities, as well as the portion of losses included in income attributable to unrealized appreciation that relate to those liabilities held at December 31, 2012:

Fair Value Measurements Using Significant Unobservable Inputs (Level 3)	
	Warrant Liability
Balance at January 1, 2012	$ -
Purchases, sales and settlements:	
Warrants and other derivatives issued	611,896
Total gains or losses:	
Unrealized depreciation	(548,512)
Balance at December 31, 2012	$ 63,384

Significant assumptions used at December 31, 2012 for the warrants are as follows:

	December 31, 2012	
Weighted average term	4.25 years	
Volatility	101	%
Risk-free interest rate	0.72	%

10. STOCKHOLDERS' EQUITY

(a) Common Stock

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

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

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

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

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

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

Pursuant to the terms of a Securities Purchase Agreement dated July 7, 2009, among the Company and certain investors, on July 15, 2009, the Company issued and sold to such investors 2,691,394 units of its securities in a private placement in exchange for an aggregate gross purchase price of $3,368,748. Each unit included one share of common stock and one warrant to purchase a share of common stock. See Note 9(b). Issuance costs related to the financing were $282,773, including the issuance of warrants to purchase 218,300 shares of common stock to designees of Riverbank Capital Securities, Inc. ("Riverbank"), a FINRA member broker dealer that acted as placement agent for the Company in connection with the private placement. See Note 14.

On April 21, 2010, the Company entered into an underwriting agreement (the "Underwriting Agreement"), providing for the offer and sale in a firm commitment underwritten public offering of 6,500,000 units of its securities at a public offering price of $0.70 per unit (less an underwriting discount of $0.063 per unit). The offering closed on April 27, 2010. Pursuant to the Underwriting Agreement, the Company granted the underwriters an option for a period of 45 days to purchase up to an additional 975,000 units to cover over-allotments. On May 6, 2010, the underwriters exercised their option to purchase the maximum amount of 975,000 over-allotment units. The sale of the over-allotment units closed on May 10, 2010. Each unit sold in the Offering consisted of one share of the Company's common stock and 0.30 warrants to purchase common stock (the "Unit Warrants"). Each whole Unit Warrant has a term of five years and represents the right to purchase one share of the Company's common stock at an exercise price of $0.94 per share. The units separated immediately and the common stock and Unit Warrants were issued separately. Among other terms and conditions of the Unit Warrants, the agreement provides that, in the event the closing sale price of the Company's common stock is at least $3.00 per share for any 20 trading days within a period of 30 consecutive trading days, the Company may call the Unit Warrants for redemption, at a redemption price of $0.01 per Unit Warrant, by providing at least 30 days' notice to each Unit Warrant holder. In total, the Company sold 7,475,000 units under the terms of the Underwriting Agreement, consisting of an aggregate of 7,475,000 shares of common stock and 2,242,500 Unit Warrants. In addition, the Company issued the underwriters a five-year warrant to purchase 390,000 shares of the Company's common stock at an exercise price of $0.94 per share, which had a fair value of $271,900 and was accounted for as a cost of the offering and charged to stock holder's equity. The net proceeds to the Company from the sale of all units, after deducting underwriting discounts, commissions and professional fees of $715,801, was $4,516,699.

On June 20, 2011, the Company entered into a securities purchase agreement (the "2011 Purchase Agreement") with certain investors pursuant to which it sold 5,000,000 units of its securities, each unit consisting of (i) one share of

common stock and (ii) a five-year warrant to purchase one-half share of common stock at an exercise price of $0.60 per share, for a purchase price of $0.50 per Unit (the "2011 Offering"). The warrants issued to investors may be exercised immediately and are redeemable by the Company, at a redemption price of $0.001 per warrant share, upon 30 days' notice, if at any time, the volume weighted average price of the common stock for any 20 consecutive business days is equal to or greater than 250% of the then applicable exercise price of the warrants. The gross proceeds from the 2011 Offering, which closed on June 23, 2011, were $2.5 million, before deducting selling commissions and expenses, which were approximately $0.2 million.

In connection with the 2011 Offering, the Company engaged Riverbank to serve as placement agent, and Ladenburg Thalmann & Co. Inc. served as a sub-placement agent (together with Riverbank, the "Placement Agents"). The Company agreed to pay the Placement Agents a cash fee equal to 7% of the gross proceeds resulting from the private placement, plus issue a five-year warrant to purchase a number of shares equal to 5% of the shares sold to investors in the private placement. Pursuant to such terms, the Company paid the Placement Agents a cash fee of $175,000 and issued to the Placement Agents warrants to purchase 250,000 shares of common stock valued at $99,100. The warrants issued to the Placement Agents are in substantially the same form as the warrants issued to the investors in the 2011 Offering, except that the Placement Agents' warrants include provisions allowing for cashless (net) exercise.

Peter M. Kash, Ed.D., a director of the Company, and Joshua A. Kazam, the Company's former President and Chief Executive Officer and a director of the Company, are each officers of Riverbank. Dr. Kash was allocated a portion of the Agent Warrants. In light of the relationship between Dr. Kash, Mr. Kazam and Riverbank, the selection of Riverbank as a placement agent and the terms of the engagement were reviewed and approved by a special committee of the Company's Board consisting of disinterested directors with no affiliation to Riverbank or its affiliates.

On April 4, 2012, the Company closed an offering with certain purchasers pursuant to which it sold an aggregate of 3,350,000 shares of the Company's common stock to such purchasers for a purchase price of $0.40 per share. In addition, for each share purchased, each purchaser also received three-fourths of a five-year warrant to purchase an additional share of common stock at an exercise price of $0.50 per share, which resulted in the issuance of warrants to purchase an aggregate of 2,512,500 shares of the Company's common stock. The warrants contain non-standard anti-dilution features (Note 7b) and as result will be classified as a liability on the Company's balance sheet.

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The total gross proceeds from the offering were $1.34 million, before deducting selling commissions and other offering expenses of approximately $0.14 million. In connection with the offering, the Company engaged Roth Capital Partners, LLC, or Roth, to serve as placement agent. Pursuant to the terms of the placement agent agreement, the Company paid Roth a cash fee equal to seven percent of the gross proceeds received by the Company, or approximately $0.1 million, plus a non-accountable expense allowance of $35,000. Richard B. Brewer, the Company's Executive Chairman, Joshua A. Kazam, the Company's former President and Chief Executive Officer and a director, Daron Evans, the Company's Chief Financial Officer, and Hsiao Lieu, M.D., the Company's former Executive VP of Clinical Development, participated in the offering on the same terms as the unaffiliated purchasers, and collectively purchased 275,000 shares of common stock and warrants to purchase 206,250 shares of common stock for an aggregate purchase price of $110,000.

(b) Warrants

In conjunction with the conversion of $4,351,165 of convertible debt prior to the Merger, the Company issued fully vested warrants to purchase 168,337 shares of common stock to the holders of such debt. The warrants were issued with an exercise price of $2.71 and expired in September 2012, at which time none of the warrants had been exercised.

In 2007, as consideration for the performance of consulting and due diligence efforts related to the licensing of 2NTX-99, the Company granted and accrued for fully vested warrants to purchase 206,912 shares of its common stock. The warrants were valued at $334,992 using the Black-Scholes option-pricing model and the following assumptions: an exercise price of $2.71, a 4.02% risk-free interest rate, a 5 year contractual term, a dividend rate of 0%, and 68% expected volatility. Of the total warrants granted, 137,567 warrants with an aggregate value of $222,770 were granted to employees of Two River Group Holdings, LLC ("Two River"), a related party, and its affiliates (Note 14). The remaining warrants were granted to outside consultants. The warrants were recorded as an expense and a liability during the year ended December 31, 2007. In March 2008, these warrants were issued in satisfaction of the accrued liability.

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

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

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

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

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

In connection with the 2011 Offering discussed above, the Company issued a total of 2,500,000 warrants, each of which has a term of five years and represents the right to purchase one share of the Company's common stock at an exercise price of $0.60 per share. In addition, the Company issued to the Placement Agents a five-year warrant to purchase 250,000 shares of the Company's common stock at an exercise price of $0.60 per share.

In connection with the April 2012 financing, the Company issued a total of 2,512,500 warrants, each of which has a term of five years and represents the right to purchase one share of the Company's common stock at an exercise price of $0.50 per share. The warrants contain non-standard anti-dilution features, such that, in the event the Company issues common shares at a price below the current exercise price of the warrants, the exercise price of the warrants will be adjusted based on the lower issuance price. Because of this anti-dilution provision and the inherent uncertainty as to the probability of future common share issuances, the Black-Scholes option pricing model the Company uses for valuing stock options could not be used. Management used a binomial option pricing model to determine the warrant liability to be approximately $0.6 million on the date of issuance and $0.2 million at September 30, 2012. The binomial option pricing model is a generally accepted valuation model used to generate a defined number of stock price paths in order to develop a reasonable estimate of the range of the Company's future expected stock prices, and their resulting probabilistic valuation. This valuation will be revised on a quarterly basis until the warrants are exercised or they expire with the changes in fair value recorded in other expense on the statement of operations.

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The table below summarizes all outstanding warrants to purchase shares of the Company's common stock as of December 31, 2012.

Grant Date	Warrants Issued	Exercise Price Range	Weighted Average Exercise Price	Expiration Date	Exercised	Warrants Outstanding
7/15/2009	2,909,695	$1.25-2.28	$ 1.84	7/14/2014	5,000	2,904,695
4/21/2010	2,632,500	$0.94	$ 0.94	4/20/2015	-	2,632,500
6/20/2011	2,750,000	$0.60	$ 0.60	6/19/2016	-	2,750,000
4/4/2012	2,512,500	$0.50	$ 0.50	4/3/2017	-	2,512,500
	10,804,695		$ 0.99		5,000	10,799,695

11. STOCK-BASED COMPENSATION

The Company's Amended and Restated 2005 Stock Option Plan (the "Plan") was initially adopted by the Board of Directors on August 10, 2005. The Plan authorized a total of 2,000,000 shares of common stock for issuance. On September 17, 2007, pursuant to the Merger, the Plan was amended and each share of common stock then subject to the Plan was substituted with 2.758838 shares of common stock, resulting in an aggregate of 5,517,676 shares available under the Plan. On July 26, 2010, the Company's stockholders approved an amendment to the Plan increasing the total number of shares authorized for issuance thereunder to 9,500,000, which was an increase of 3,982,324 shares to the Plan. Under the Plan, incentives may be granted to officers, employees, directors, consultants, and advisors. Incentives under the Plan may be granted in any one or a combination of the following forms: (a) incentive stock options and non-statutory stock options, (b) stock appreciation rights, (c) stock awards, (d) restricted stock and (e) performance shares.

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

A summary of the status of the options issued under the Plan at December 31, 2012, and information with respect to the changes in options outstanding is as follows:

		Options Outstanding		
	Shares Available for Grant	Outstanding Stock Options	Weighted-Average Exercise Price	Aggregate Intrinsic Value
Balance at December 31, 2010	2,279,441	6,911,564	$ 1.52	
Options granted under the Plan	(1,110,000)	1,110,000	$ 0.68	
Options exercised	-	(82,437)	$ 0.17	
Options forfeited	60,133	(60,133)	$ 0.93	
Balance at December 31, 2011	1,229,574	7,878,994	$ 1.52	
Options granted under the Plan	-	-	$ -	
Options exercised	-	-	$ -	
Options expired	30,000	(30,000)		
Options forfeited	3,277,948	(3,277,948)	$ 1.67	
Balance at December 31, 2012	4,537,522	4,571,046	$ 1.24	$ -
Exercisable at December 31, 2012		4,496,046	$ 1.25	$ -

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The Company estimated the fair value of each option award granted to employees using the Black-Scholes option-pricing model. No stock options were issued in 2012. The following assumptions we used for stock options issued in the year ended December 31, 2011:

	December 31, 2011	
Stock price	$0.56 to $0.78	
Expected volatility	97	%
Expected term	3-5 years	
Dividend yield	0	%
Risk-free interest rates	1-2%	

The valuation assumptions were determined as follows:

- *Expected volatility* – Management calculated the 200 day volatility from historical NLTX.QB stock prices.

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

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

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

Share-based compensation is recognized only for those awards that are ultimately expected to vest. Only 4,726 performance options vested in 2012. The Company has applied an estimated forfeiture rate of 0% for those remaining performance options. These estimates will be revised, if necessary, in future periods if actual forfeitures differ from estimates. Changes in forfeiture estimates impact compensation cost in the period in which the change in estimate occurs.

Employee stock-based compensation costs for the year ended December 31, 2012 and 2011 and for the cumulative period from August 1, 2005 (inception) through December 31, 2012, are as follows:

	Year ended December 31,		Period from August 1, 2005 (inception)
	2012	2011	through December 31, 2012
General and administrative	$ 245,404	$ 375,518	$ 6,807,950
Research and development	67,286	410,070	1,551,203
Total	$ 312,690	$ 785,588	$ 8,359,153

The following table summarizes information about stock options outstanding at December 31, 2012:

	Outstanding			Exercisable	
Range of Exercise Prices	Shares	Weighted-Average Remaining Contractual Life	Weighted-Average Exercise Price	Total Shares	Weighted-Average Exercise Price
$0.09 to $0.57	1,586,533	6.01	$ 0.40	1,511,533	$ 0.40
$0.68 to $0.93	1,549,820	5.28	$ 0.82	1,549,820	$ 0.82
$1.46 to $2.71	1,104,693	5.68	$ 2.05	1,104,693	$ 2.05
$4.45	330,000	4.71	$ 4.50	330,000	$ 4.50
Total	4,571,046	5.59	$ 1.23	4,496,046	$ 1.25

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The fair value of shares vested under the Plan for the year ended December 31, 2012 and 2011 and for the period from August 1, 2005 (inception) through December 31, 2012 were $633,391, $864,844, and $7,626,292 respectively.

Certain employees have been granted performance-based stock options that are subject to forfeiture based on the failure to achieve specified goals. The Company analyzed two years of annual performance measurements, and, based on that analysis, estimated forfeiture rates on performance-based stock options for future periods. For the cumulative period from August 1, 2005 (inception) through December 31, 2012, employees forfeited 396,797 shares related to performance-based options, which had a fair value of $655,532.

At December 31, 2012, total unrecognized estimated employee (including directors) compensation cost related to stock options granted prior to that date was $14,777, which is expected to be recognized over a weighted-average vesting period of 0.5 years.

Common stock, stock options or other equity instruments issued to non-employees (including consultants and all members of the Company’s Scientific Advisory Board) as consideration for goods or services received by the Company are accounted for based on the fair value of the equity instruments issued (unless the fair value of the consideration received can be more reliably measured). The fair value of stock options is determined using the Black-Scholes option-pricing model and is periodically re-measured as the underlying options vest. The fair value of any options issued to non-employees is recorded as expense over the applicable vesting periods.

On August 3, 2012, the Company entered into an Option Termination Agreement with Peter M. Strumph, who served as the Company’s Chief Executive Officer and as a director of the Company from June 2007 to June 2009, pursuant to which the Company paid Mr. Strumph $2,000 in exchange for the forfeiture and termination of options to purchase an aggregate of 1,232,054 shares of the Company’s common stock at an exercise price of $2.71, which stock options had previously been granted to Mr. Strumph pursuant to the Plan.

Stock-based compensation costs incurred for services by non-employees for the year ended December 31, 2012 and 2011, and for the cumulative period from August 1, 2005 (inception) through December 31, 2012 totaled $0, $20,740, and $ 498,095, respectively. These amounts were included in research and development expense in the accompanying Statements of Operations.

12. 401(k) SAVINGS PLAN

On April 1, 2007, the Company adopted a 401(k) savings plan (the "401(k) Plan") for the benefit of its employees. Under the 401(k) Plan the Company is required to make contributions equal to 3% of eligible compensation for each eligible employee whether or not the employee contributes to the 401(k) Plan. The Company recorded compensation expenses of $0, $0 and $21,947 for the years ended December 31, 2012 and 2011 and for the cumulative period from August 1, 2005 (inception) through December 31, 2012, respectively. As of December 31, 2012, the Company has fully funded the 401(k) Plan.

13. INCOME TAXES

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

The Company's policy is to include interest and penalties related to unrecognized tax benefits within the Company's provision for (benefit from) income taxes. The Company recognized no amounts for interest and penalties related to unrecognized tax benefits in 2012, 2010 and the period from August 1, 2005 (inception) through December 31, 2012 and as of December 31, 2012 and 2011, had no amounts accrued for interest and penalties.

At December 31, 2012, the Company had no federal income tax expense or benefit but did have federal tax net operating loss carry-forwards of approximately $34,053,994, and an R&D credit carry-forward of $1,353,859. The federal net operating loss carry-forwards will begin to expire in 2026, unless previously utilized.

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Deferred income taxes reflect the net effect of temporary difference between the carrying amounts of assets and liabilities for financial reporting purposes and the amounts used for income tax purposes. Significant components of the Company's net deferred tax assets at December 31, 2012 and 2011 are shown below. A valuation allowance of $16,348,179 has been established to offset the net deferred tax assets at December 31, 2012, as realization of such assets is uncertain.

	For Years Ended December 31,	
	2012	2011
Deferred tax assets		
Research tax credit	$ 1,353,859	$ 1,388,835
Net operating loss carry forwards	13,621,597	12,766,139
Others	1,372,723	3,189,587
Total deferred tax asset	16,348,179	17,344,561
Deferred tax liability	-	-
Total net deferred tax asset	16,348,179	17,344,561
Valuation allowance	(16,348,179)	(17,344,561)
Net deferred tax asset	$ -	$ -

The Company files income tax returns in the U.S. federal and California state jurisdictions, which returns are generally subject to examination by federal authorities for all tax years from 2009 to present and by California authorities from 2008 to present.

A reconciliation of the statutory tax rates and the effective tax rates for the years ended December 31, 2012 and 2011.

	Year ended December 31, 2012		Year ended December 31, 2011	
	Amount	**Rate**	**Amount**	**Rate**

Federal Tax	$ (643,633)	34.0	%	$ (1,660,827)	34.0	%
State Tax	(110,447)	5.8	%	(284,998)	5.8	%
R&D Credit	(2,119)	3.3	%	(14,700)	5.5	%
Incentive Stock Options	(12,123)	8.0	%	(20,360)	6.5	%
Valuation Allowance	768,322	-51.2	%	1,980,885	-51.8	%
Net	$ -	$ -		$ -	$ -	

14. RELATED PARTIES

On June 24, 2009, the Company entered into a services agreement with TRC to provide various clinical development, operational and administrative services to the Company for a period of one year. Joshua A. Kazam, the Company's President and Chief Executive Officer and director, and Arie S. Belldegrun, who was appointed to serve as a member of the Company's Board of Directors on September 24, 2009, are each partners of TRC. David M. Tanen, who served as the Company's Secretary and director until his resignation from both positions on September 24, 2009, is also a partner of TRC. The terms of the services agreement were reviewed and approved by a special committee of the Company's Board of Directors consisting of independent directors. None of the members of the special committee has any interest in TRC or the services agreement. As compensation for the services contemplated by the services agreement, the Company paid TRC a monthly cash fee of $65,000 and issued stock options to purchase up to an aggregate of 750,000 shares of the Company's common stock at a price per share equal to $0.89, the closing sale price of the Company's common stock on June 24, 2009. Twenty-five percent of the stock options vested immediately and the remaining 75% were scheduled to vest pursuant to the achievement of certain milestones relating to the clinical development of cenderitide. On January 3, 2011, the final block of stock options vested. Of the 750,000 original stock options issued, 535,172 stock options vested with a total fair value of $353,976. On August 12, 2010, the special committee of the Company's Board of Directors consisting of independent directors approved an extension of the services agreement with TRC and the issuance of fully-vested and immediately-exercisable stock options to purchase 250,000 shares of the Company's common stock at an exercise price of $0.38 per share, which had an estimated fair value of $82,200 that was expensed on the date of grant. On March 17, 2011, the Special Committee approved an amendment of the services agreement, pursuant to which the level of services to be provided by TRC was reduced and the monthly cash fee payable to TRC was reduced to $30,082 starting in July 2011 when certain services were eliminated. In August of 2012 the fee was reduced to $6,600 per month when additional services were eliminated. Additional operational and clinical development services may be provided by TRC, and billed to the Company, on an hourly basis.

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On occasion, some of the Company's expenses are paid by TRC. No interest is charged by TRC on any outstanding balance owed by the Company. For the years ended December 31, 2012 and 2011 and for the period from August 1, 2005 (inception) through December 31, 2012, total cash services and reimbursed expenses totaled $238,346, $529,218 and $2,107,176, respectively. As of December 31, 2012 the Company has a payable to TRC of $16,139, all of which was paid during the first quarter of 2013.

15. COMMITMENTS AND CONTINGENCIES

On August 15, 2009, the Company relocated its primary office space to San Mateo, California. Under the terms of an open-ended lease, cancellable upon 60 days' notice, the base rent is $2,000 per month. The office space is approximately 1,200 square feet. In connection with this lease, the Company made a $2,000 cash security deposit.

On June 18, 2012, the Company appointed Darlene Horton, M.D. to serve as its Chief Medical Officer. The terms of Dr. Horton's appointment are set forth in a Consulting Agreement (the "Agreement"). The Agreement provides for a month-to-month term until terminated by either party upon 30 days' written notice. Pursuant to the Agreement, Dr. Horton will serve as an independent contractor and will receive a monthly fee of $30,000 for her services as the Company's Chief Medical Officer. The Agreement also provides that the Company will reimburse Dr. Horton for all reasonable, pre-approved expenses incurred in connection with her services to the Company. The Agreement includes customary confidentiality, assignment of inventions, and non-solicitation provisions.

On November 5, 2012, the Company entered into a letter agreement with Dr. Horton, pursuant to which Dr. Horton agreed to reduce her monthly salary to $100 effective November 1, 2012, and defer the balance of her $28,314 monthly base salary (the "Deferred Salary") until such time as the Company completes an Interim Financing Event (defined below). The term "Interim Financing Event" means the consummation on or before December 31, 2013, of one or more transactions pursuant to which the Company shall have received, whether by a financing, strategic transaction or another means (or any combination thereof), an aggregate of at least $1,000,000 in gross proceeds. As of December 31, 2012, the Company has an accrual of $56,428, representing approximately 2 months of Deferred Salary.

On March 21, 2013, the Company entered into agreements with Dr. Horton and Daron Evans, the Company's Chief Financial Officer, pursuant to which Dr. Horton and Mr. Evans will be entitled to certain payments upon a "Change of

Control Transaction" (Note 16).

16. SUBSEQUENT EVENTS

March 2013 Financing.

On March 15, 2013, the Company entered into a convertible note purchase agreement with certain accredited investors pursuant to which the Company agreed to sell an aggregate principal amount of up to $500,000 of secured convertible promissory notes (the "Notes") for an aggregate original issue price of $425,000, representing a 15% original issue discount. The closing of the private placement also occurred on March 15, 2013, and resulted in the sale of Notes in the aggregate principal amount of $450,000 for an aggregate original issue price of $382,500.

The Notes, which have a maturity date of March 15, 2014, do not bear interest and may be prepaid without penalty upon 30 days' written notice, on the terms set forth in the Notes. The Notes are secured by a blanket lien on the Company's assets pursuant to a security agreement dated March 15, 2013.

Upon a Change of Control (as defined in the Notes) in which either (i) the outstanding shares of the Company's common stock are exchanged for securities of another corporation, or (ii) the Company issues shares of common stock, with no securities or other consideration paid or payable to holders of our common stock (e.g., a merger transaction in which the Company acquires another corporation in exchange for shares of our common stock), then (A) the entire unpaid principal under the applicable Note shall automatically convert, as of immediately prior to the effective time of the Change of Control, into shares of the Company's common stock at a conversion price per share equal to the Closing Price (as defined in the Notes) on the effective date of the Change of Control, and (B) the Company shall also issue to each Note holder a five-year warrant entitling the holder to purchase, at an exercise price equal to the Closing Price on the effective date of the Change of Control, that number of shares of our common stock obtained by dividing (a) the sum of the outstanding principal under the applicable Note by (b) the Closing Price on the effective date of the Change of Control.

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Upon a Change of Control other than as described in the preceding paragraph, the Company shall pay to each Note holder an amount in cash equal to 175% of the principal amount then outstanding under the applicable Note. Upon payment of such amount to the Note holders, all of the obligations under the Notes shall be deemed paid and satisfied in full.

Amendment to Compensation of President and CEO.

On March 21, 2013, the Company entered into a letter agreement with Darlene Horton, M.D., its President and Chief Executive Officer, which letter agreement amends certain compensation terms under her existing letter agreement dated August 3, 2012, as previously amended on November 5, 2012.

Dr. Horton's existing letter agreement provided that if, prior to the date of a "compensation adjustment event," the Company completed a Change of Control Transaction (as defined in the agreement) and Dr. Horton's employment was terminated by the Company (or any successor entity) without cause during the period beginning on the effective date of the Change of Control Transaction and ending on the six-month anniversary of such effective date, then she would have been entitled to receive a cash payment equal to 5% of the applicable Change of Control Proceeds (as defined in the agreement). For purposes of the agreement, the term "compensation adjustment event" means the date on which the Company secures sufficient capital, whether by a financing or strategic transaction (or any combination thereof) or another means, in order to enable the Company to initiate and fund to completion a Phase 2 clinical trial of the Company's cenderitide product candidate.

The March 21, 2013 letter agreement amends the payment terms described in the preceding paragraph and provides that if, prior to December 31, 2013, the Company completes a Change of Control Transaction in which either (i) the outstanding shares of the Company's common stock are exchanged for securities of another corporation, or (ii) the Company issues shares of its common stock, with no securities or other consideration paid or payable to holders of the Company's common stock (e.g., a merger transaction in which the Company acquires another corporation in exchange for shares of the Company's common stock), then Dr. Horton will be entitled to receive, immediately prior to the effective time of the Change of Control Transaction, a number of shares of the Company's common stock equal to 5% of the shares of the Company's common stock then outstanding on a fully-diluted basis.

The agreement further provides that if, prior to December 31, 2013, the Company completes a Change of Control Transaction other than as described in the preceding paragraph, then Dr. Horton will be entitled to receive a cash payment, on the date of such Change of Control Transaction, equal to 5% of the applicable Change of Control Proceeds (as defined in the agreement).

Amendment to Compensation of Chief Financial Officer.

On March 21, 2013, the Company entered into a letter agreement with Daron Evans, its Chief Financial Officer, pursuant to which Mr. Evans agreed to reduce his monthly salary to $100 effective February 1, 2013, and defer the balance of his $22,917 monthly base salary until such time as the Company completes an Interim Financing Event. The term “Interim Financing Event” means the consummation on or before December 31, 2013, of one or more transactions pursuant to which the Company shall have received, whether by a financing, strategic transaction or another means (or any combination thereof), an aggregate of at least $1,000,000 in gross cash proceeds.

In addition, the agreement provides that if, prior to December 31, 2013, the Company completes a Change of Control Transaction (as defined in the agreement) in which either (i) the outstanding shares of the Company’s common stock are exchanged for securities of another corporation, or (ii) the Company issues shares of its common stock, with no securities or other consideration paid or payable to holders of the Company’s common stock (e.g., a merger transaction in which the Company acquires another corporation in exchange for shares of the Company’s common stock), then Mr. Evans will be entitled to receive, immediately prior to the effective time of the Change of Control Transaction, a number of shares of the Company’s common stock equal to 4.5% of the shares of the Company’s common stock then outstanding on a fully-diluted basis.

The agreement further provides that if, prior to December 31, 2013, the Company completes a Change of Control Transaction other than as described in the preceding paragraph, then Mr. Evans will be entitled to receive a cash payment, on the date of such Change of Control Transaction, equal to 4.5% of the applicable Change of Control Proceeds (as defined in the agreement).

In consideration of the foregoing, the agreement provides that the Company shall have no further obligations pursuant to the Severance Benefits Agreement between the Company and Mr. Evans, dated July 24, 2010.

Termination of Lease Agreement.

On February 28, 2013, the Company terminated its office lease at 4 West 4th, Suite 400, San Mateo, CA.

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

Not applicable.

ITEM 9A. CONTROLS AND PROCEDURES

Evaluation of Disclosure Controls and Procedures

We conducted an evaluation as of December 31, 2012, under the supervision and with the participation of our management, including our Chief Executive Officer and Chief Financial Officer, of the effectiveness of the design and operation of our disclosure controls and procedures, which are defined under SEC rules as controls and other procedures of a company that are designed to ensure that information required to be disclosed by a company in the reports that it files under the Securities Exchange Act of 1934, as amended, is recorded, processed, summarized and reported within required time periods. Based upon that evaluation, our Chief Executive Officer and Chief Financial Officer concluded that, as of such date, our disclosure controls and procedures were effective.

Management's Report on Internal Control over Financial Reporting

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

Under the supervision and with the participation of our management, including our Chief Executive Officer and Chief Financial Officer, we conducted an evaluation of the effectiveness of our internal control over financial reporting based on criteria established in the Internal Control—Integrated Framework issued by the Committee of Sponsoring Organizations of the Treadway Commission. Management's assessment included evaluation of such elements as the design and operating effectiveness of key financial reporting controls, process documentation, accounting policies, and our overall control environment. Based on this evaluation, our management concluded that our internal control over financial reporting was effective as of December 31, 2012.

Limitations on the Effectiveness of Controls

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

Changes in Internal Controls over Financial Reporting

There was no change in our internal control over financial reporting (as defined in Rule 13a-15(f) of the Exchange Act) that occurred during the fourth quarter of the year ended December 31, 2012 that has materially affected, or is reasonably likely to materially affect, our internal control over financial reporting.

ITEM 9B. OTHER INFORMATION

None.

Part III

ITEM 10. Directors, Executive Officers and Corporate Governance

Directors and Executive Officers

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

Name	Age	Positions Held
Darlene Horton, M.D.	51	President, Chief Executive Officer and Director
Daron Evans	39	Chief Financial Officer
Arie S. Belldegrun, M.D.	63	Director
Pedro Granadillo	66	Director
Peter M. Kash, Ed.D.	51	Director
Joshua A. Kazam	36	Director
Paul A. Mieyal, Ph.D.	43	Director
Gregory W. Schafer	48	Director