Nile Therapeutics, Inc.
Form PRE 14A
September 27, 2013

UNITED STATES

SECURITIES AND EXCHANGE COMMISSION

Washington, D.C. 20549

SCHEDULE 14A

Proxy Statement Pursuant to Section 14(a) of the Securities

Exchange Act of 1934

Filed by the Registrant x

Filed by a Party other than the Registrant ¨

Check the appropriate box:

x	Preliminary Proxy Statement
¨	**Confidential, for Use of the Commission Only (as permitted by Rule 14a-6(e)(2))**
¨	Definitive Proxy Statement
¨	Definitive Additional Materials
¨	Soliciting Material Pursuant to §240.14a-12

Nile Therapeutics, Inc.

(Name of Registrant as Specified In Its Charter)

(Name of Person(s) Filing Proxy Statement, if other than the Registrant)

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x	No fee required.

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4) Proposed maximum aggregate value of transaction:

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1) Amount Previously Paid:

2) Form, Schedule or Registration Statement No.:

3) Filing Party:

4) Date Filed:

NILE THERAPEUTICS, INC.

63 Bovet Rd., Suite 421

San Mateo, California 94402

Telephone: (650) 918-7489

NOTICE OF SPECIAL MEETING OF STOCKHOLDERS TO BE HELD ON , 2013

To Our Stockholders:

You are cordially invited to attend a Special Meeting of Stockholders of Nile Therapeutics, Inc., a Delaware corporation (the "Company"). The Special Meeting will be held at , on , 2013, at .m. (PDT), or at any adjournment or postponement thereof.

On July 8, 2013, the Company announced that it had entered into an Agreement and Plan of Merger and Reorganization with Capricor, Inc., a Delaware corporation ("Capricor"), pursuant to which a wholly-owned subsidiary of the Company will merge with and into Capricor and Capricor will remain as the surviving corporation and a wholly-owned subsidiary of the Company (the "Merger"). Capricor is a company whose mission is to improve the treatment of heart disease by commercializing cardiac stem cell therapies for patients.

In order to facilitate the Merger, there are four matters scheduled for a vote at the Special Meeting. Stockholders are being asked:

- to authorize the amendment of our certificate of incorporation to effect a combination (reverse split) of our common stock at a ratio not to exceed 1:100 (the "Reverse Stock Split"), and to reduce the total number of shares of common stock that we are authorized to issue from 100 million to 50 million and reduce the total number of shares of preferred stock that we are authorized to issue from 10 million to 5 million (the "Share Reduction");

- to authorize the amendment of our certificate of incorporation to change our name from "Nile Therapeutics, Inc." to "Capricor Therapeutics, Inc." (the "Name Change" and, together with the Reverse Stock Split and Share Reduction, the "Charter Amendment Proposals");

- to approve adjournments of the Special Meeting, if necessary, to solicit additional proxies if there are insufficient votes to approve the Charter Amendment Proposals; and

- to approve, on a nonbinding, advisory basis, the "golden parachute" compensation that may be paid or become payable to our named executive officers in connection with the consummation of the Merger.

Our Board of Directors has fixed the close of business on September , 2013, as the record date for the determination of stockholders entitled to notice of and to vote at the Special Meeting and at any adjournment or postponement thereof.

You may vote your shares at the Special Meeting only if you are present in person or represented by proxy. All stockholders are invited to attend the Special Meeting in person. Whether or not you plan to attend the meeting, please complete, date and sign the enclosed proxy and return it in the enclosed envelope, as promptly as possible. If you attend the meeting, you may withdraw the proxy and vote in person. If you have any questions regarding the completion of the enclosed proxy or would like directions to the Special Meeting, please call (650) 918-7489.

By Order of the Board of Directors,

NILE THERAPEUTICS, INC.

/s/ Darlene Horton, M.D.

Darlene Horton, M.D.
President & Chief Executive Officer

San Mateo, California

, 2013

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The enclosed proxy is solicited on behalf of the Board of Directors (the "Board") of Nile Therapeutics, Inc., a Delaware corporation (the "Company," "Nile," "we," "us," or "our"), for use at the Special Meeting of Stockholders to be held on 2013, at ..m. PDT (the "Special Meeting"), or at any adjournment or postponement thereof, for the purposes set forth herein and in the accompanying Notice of Special Meeting. The Special Meeting will be held at . We intend to first mail this proxy statement and the enclosed proxy card on or about , 2013, to all stockholders entitled to notice of, and to vote at, the Special Meeting.

Important Notice Regarding the Availability of Proxy Materials for the Special Meeting:

The proxy statement and the enclosed proxy card are available at

http://www.nilethera.com/inv_sec.html

QUESTIONS AND ANSWERS ABOUT THIS PROXY MATERIAL AND VOTING

Why am I receiving these materials?

We sent you this proxy statement, as well as the enclosed proxy card, because our Board is soliciting your proxy to vote at the Special Meeting. You are invited to attend the Special Meeting to vote on the proposals described in this proxy statement. The Special Meeting will be held on , 2013 at .m. (PDT) at . However, you do not need to attend the meeting to vote your shares. Instead, you may simply complete, sign and return the enclosed proxy card.

We intend to mail this proxy statement and accompanying proxy card on or about , 2013, to all stockholders entitled to notice of and to vote at the Special Meeting.

What am I voting on?

There are four matters scheduled for a vote at the Special Meeting. Stockholders are being asked:

1. to authorize the amendment of our certificate of incorporation to effect a combination (reverse split) of our common stock at a ratio not to exceed 1:100 (the "Reverse Stock Split"), and to reduce the total number of shares of common stock that we are authorized to issue from 100 million to 50 million and reduce the total number of shares of

preferred stock that we are authorized to issue from 10 million to 5 million (the "Share Reduction");

2. to authorize the amendment of our certificate of incorporation to change our name from "Nile Therapeutics, Inc." to "Capricor Therapeutics, Inc." (the "Name Change" and, together with the Reverse Stock Split and Share Reduction, the "Charter Amendment Proposals");

3. to approve adjournments of the Special Meeting, if necessary, to solicit additional proxies if there are insufficient votes to approve the Charter Amendment Proposals; and

4. to approve, on a nonbinding, advisory basis, the "golden parachute" compensation that may be paid or become payable to our named executive officers in connection with the consummation of the Merger.

Why am I being asked to approve these proposals?

On July 7, 2013, we entered into an Agreement and Plan of Merger and Reorganization (the "Merger Agreement") with Capricor, Inc., a Delaware corporation ("Capricor"), pursuant to which our wholly-owned subsidiary, Bovet Merger Corp. ("Merger Sub"), will merge with and into Capricor and Capricor will remain as the surviving corporation and our wholly-owned subsidiary (the "Merger"). As consideration for their shares of Capricor capital stock, we will issue to Capricor's stockholders aggregate consideration consisting of a number of shares of our common stock (the "Merger Shares") such that, immediately following the completion of the Merger, the Capricor stockholders will hold 90 percent of our issued and outstanding shares of common stock on a fully-diluted basis.

While our stockholders are not required to approve the Merger itself, stockholder approval of the Charter Amendment Proposals is required in order for us to consummate the Merger. In particular, the Reverse Stock Split is necessary because, under our certificate of incorporation, we do not currently have a sufficient number of authorized but unissued shares of common stock to allow us to issue the Merger Shares to Capricor's stockholders upon consummation of the Merger. Our certificate of incorporation currently authorizes the issuance of 100 million shares of common stock. On July 5, 2013, the last business day immediately prior to the execution of the Merger Agreement, there were 43,062,231 shares of our common stock issued and outstanding, not including shares issuable upon exercise of outstanding options and warrants or upon conversion of outstanding convertible promissory notes. By combining our common stock at a ratio of up to 1:100, we will sufficiently reduce the number of outstanding shares of common stock, as well as the number of shares issuable upon exercise or conversion of derivative instruments, so as to allow us to issue the Merger Shares to Capricor's stockholders in connection with the Merger.

Because we will be unable to consummate the Merger without stockholder approval of the Charter Amendment Proposals, stockholders are also being asked to approve a proposal granting us the flexibility to adjourn the Special Meeting, if necessary, to solicit additional proxies if there are insufficient votes to approve the Charter Amendment Proposals.

Pursuant to the Dodd-Frank Wall Street Reform and Consumer Protection Act and Section 14A of the Securities Exchange Act of 1934, as amended (the "Exchange Act"), we are required to hold a nonbinding, advisory vote on the "golden parachute" compensation that may be paid or become payable to our named executive officers in connection with the consummation of the Merger. The results of this vote will not be binding on us.

Who can vote at the Special Meeting?

Only stockholders of record at the close of business on September , 2013, will be entitled to vote at the Special Meeting. On this record date, there were 43,520,563 shares of our common stock outstanding and entitled to vote.

Stockholder of Record: Shares Registered in Your Name

If on September , 2013, your shares were registered directly in your name with our transfer agent, American Stock Transfer and Trust Company, then you are a stockholder of record. As a stockholder of record, you may vote in person at the meeting or vote by proxy. Whether or not you plan to attend the meeting, we urge you to fill out and return the enclosed proxy card to ensure your vote is counted.

Beneficial Owner: Shares Registered in the Name of a Broker or Bank

If on September , 2013, your shares were held, not in your name, but rather in an account at a brokerage firm, bank, dealer, or other similar organization, then you are the beneficial owner of shares held in "street name" and these proxy materials are being forwarded to you by that organization. The organization holding your account is considered to be the stockholder of record for purposes of voting at the Special Meeting. As a beneficial owner, you have the right to direct your broker or other agent on how to vote the shares in your account. You are also invited to attend the Special Meeting. However, since you are not the stockholder of record, you may not vote your shares in person at the meeting unless you request and obtain a valid proxy from your broker or other agent.

How do I vote?

You may vote "For" or "Against" or "Abstain" from voting on each of the four proposals. The procedures for voting are as follows:

Stockholder of Record: Shares Registered in Your Name

If you are a stockholder of record, you may vote in person at the Special Meeting, or vote by proxy using the enclosed proxy card. Whether or not you plan to attend the meeting, we urge you to vote by proxy to ensure your vote is counted. You may still attend the meeting and vote in person if you have already voted by proxy.

- To vote in person, come to the Special Meeting, where a ballot will be made available to you.

- To vote using the proxy card, simply complete, sign and date the enclosed proxy card and return it promptly in the envelope provided. If you return your signed proxy card to us before the Special Meeting, we will vote your shares as you direct.

Beneficial Owner: Shares Registered in the Name of Broker or Bank

If you are a beneficial owner of shares registered in the name of your broker, bank or other agent, you should have received a proxy card and voting instructions with these proxy materials from that organization rather than from us. Simply complete and mail the proxy card to ensure that your vote is counted. Alternatively, you may vote by telephone or over the Internet as instructed by your broker or bank, if your broker or bank makes telephone or Internet voting available. To vote in person at the Special Meeting, you must obtain a valid proxy from your broker, bank or other agent. Follow the instructions from your broker or bank included with these proxy materials, or contact your broker or bank to request a proxy form.

How many votes do I have?

You have one vote for each share of common stock you own as of the close of business on September , 2013.

What is a broker non-vote?

Under the rules that govern brokers and banks who have record ownership of our shares of common stock that are held in street name for their clients who are the beneficial owners of the shares, brokers and banks have the discretion to vote such shares on routine matters. For non-routine matters, brokers and banks do not have such discretion, resulting in a broker non-vote.

What are the Board's recommendations?

The Board's recommendations are set forth after the description of each proposal in this proxy statement. In summary, the Board recommends a vote:

- **FOR** the Reverse Stock Split and Share Reduction (see Proposal No. 1 on page 44).

- **FOR** the Name Change (see Proposal No. 2 on page 49).

- **FOR** the approval of adjournments of the Special Meeting, if necessary, to solicit additional proxies if there are insufficient votes to approve the Charter Amendment Proposals (see Proposal No. 3 on page 50).

- **FOR** the approval, on a nonbinding, advisory basis, of the "golden parachute" compensation that may be paid or become payable to our named executive officers in connection with the consummation of the Merger (see Proposal No. 4 on page 51).

If you return a signed and dated proxy card without marking any voting selections, your shares will be voted in accordance with the recommendations of the Board.

In considering the Board's recommendations, you should be aware that some of our directors and officers have interests in the Merger that are different from, or in addition to, those of our stockholders generally. See the section of this proxy statement entitled "Summary Term Sheet—Interests of our Executive Officers and Directors in the Merger" beginning on page 11.

What vote is required to approve each proposal?

- **Proposal No. 1.** Stockholder approval of the proposal to authorize the amendment of our certificate of incorporation to effect the Reverse Stock Split and Share Reduction requires the affirmative vote of a majority of our outstanding shares of common stock as of the record date. You may vote either "FOR" or "AGAINST" the proposed amendment, or you may "ABSTAIN." Abstentions and broker non-votes will have the same effect as "AGAINST" votes.

- **Proposal No. 2** Stockholder approval of the proposal to authorize the amendment of our certificate of incorporation to effect the Name Change requires the affirmative vote of a majority of our outstanding shares of common stock as of the record date. You may vote either "FOR" or "AGAINST" the proposed amendment, or you may "ABSTAIN." Abstentions and broker non-votes will have the same effect as "AGAINST" votes.

- **Proposal No. 3.** Stockholder approval of the proposal to authorize adjournments of the Special Meeting, if necessary, to solicit additional proxies if there are insufficient votes to approve the Charter Amendment Proposals requires the number of votes cast in favor of the proposal to exceed the number of votes cast against the proposal. You may vote either "FOR" or "AGAINST" the proposal, or you may "ABSTAIN." Abstentions and broker non-votes will have no effect on the outcome of the vote.

- **Proposal No. 4.** Stockholder approval of the proposal to approve, on a nonbinding, advisory basis, the "golden parachute" compensation that may be paid or become payable to our named executive officers in connection with the consummation of the Merger requires the number of votes cast in favor of the proposal to exceed the number of votes cast against the proposal. You may vote either "FOR" or "AGAINST" the proposal, or you may "ABSTAIN." Abstentions and broker non-votes will have no effect on the outcome of the vote.

Who is paying for this proxy solicitation?

We will pay for the entire cost of soliciting proxies. In addition to these mailed proxy materials, our directors and employees may also solicit proxies in person, by telephone, or by other means of communication. Directors and employees will not be paid any additional compensation for soliciting proxies. We may also reimburse brokerage firms, banks and other agents for the cost of forwarding proxy materials to beneficial owners.

What does it mean if I receive more than one proxy card?

If you receive more than one proxy card, your shares are registered in more than one name or are registered in different accounts. Please complete, sign and return each proxy card to ensure that all of your shares are voted.

Can I change my vote after submitting my proxy?

Yes. You can revoke your proxy at any time before the final vote at the meeting. If you are the record holder of your shares, you may revoke your proxy in any one of three ways:

- You may submit another properly completed proxy card with a later date.

- You may send a written notice that you are revoking your proxy to the following address: Corporate Secretary, Nile Therapeutics, Inc., c/o Fredrikson & Byron, P.A. at 200 South Sixth Street, Suite 4000, Minneapolis, MN 55402.

. You may attend the meeting and vote in person. Simply attending the Special Meeting will not, by itself, revoke your proxy.

If your shares are held by your broker or bank as a nominee or agent, you should follow the instructions provided by your broker or bank.

What is the quorum requirement?

A quorum of stockholders is necessary to hold a valid meeting. A quorum will be present if the holders of at least a majority of the outstanding shares of common stock are present at the meeting in person or by proxy. On the record date, there were 43,520,563 shares of common stock outstanding and entitled to vote. Your shares will be counted towards the quorum only if you submit a valid proxy (or one is submitted on your behalf by your broker, bank or other nominee) or if you vote in person at the meeting. Abstentions and broker non-votes will be counted towards the quorum requirement. If there is no quorum, either the chairman of the meeting or a majority of the votes present may adjourn the meeting to another date.

How can I find out the results of the voting at the Special Meeting?

Preliminary voting results will be announced at the Special Meeting. Final voting results will be disclosed in a Current Report on Form 8-K within four business days of the Special Meeting.

SUMMARY TERM SHEET

This summary term sheet highlights the most material terms of the proposed merger, or the Merger. While this summary term sheet describes the principal terms of the Merger, this summary term sheet may not contain all of the information that is important to you. To understand the Merger fully and for a more complete description of the legal terms of the Merger, you should carefully read this entire proxy statement and the documents to which we have referred you. In particular, you should read the appendices to this proxy statement, including the Agreement and Plan of Merger and Reorganization, dated as of July 7, 2013,as amended, by and among Nile, Merger Sub, and Capricor, or the Merger Agreement, which is attached as Appendix A to this proxy statement. We have included page references in parentheses to direct you to a more complete description of the topics presented in this summary term sheet. See the section of this proxy statement entitled "Where You Can Find More Information" beginning on page 123.

The Parties to the Merger

Nile Therapeutics, Inc.

63 Bovet Rd., Suite 421

San Mateo, California 94402

Telephone: (650) 918-7489

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, Inc., with Nile Therapeutics, Inc. 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, Inc. exchanged all of their shares of Nile Therapeutics, Inc. 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, Inc.. Additionally, following the merger, Nile Therapeutics, Inc., 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 develop innovative products for the treatment of cardiovascular diseases. Our common stock trades on the OTC Markets under the symbol "NLTX." Additional information regarding Nile is contained in our filings with the Securities and Exchange Commission, or the SEC. See the section of this proxy statement entitled "Where You Can Find More Information" beginning on page 123.

Bovet Merger Corp.

c/o Nile Therapeutics, Inc.

63 Bovet Rd., Suite 421

San Mateo, California 94402

Telephone: (650) 918-7489

Bovet Merger Corp., or Merger Sub, is a Delaware corporation and a wholly-owned subsidiary of Nile. Merger Sub exists solely to facilitate the Merger and has not engaged in any operations other than in connection with its formation and the negotiation and execution of the Merger Agreement.

Capricor, Inc.

8840 Wilshire Boulevard, 2nd Floor

Beverly Hills, California 90211

Telephone: (310) 358-3200

Capricor, Inc., or Capricor, is a company whose mission is to improve the treatment of heart disease by commercializing cardiac stem cell therapies for patients.

The Merger (See Page 29)

This proxy statement relates to the transactions contemplated by an Agreement and Plan of Merger and Reorganization, dated as of July 7, 2013, among Nile, Merger Sub, and Capricor, as amended on September 27, 2013. **We have attached a copy of this agreement (as amended), which we refer to as the Merger Agreement, as Appendix A to this proxy statement. We encourage you to read the Merger Agreement in its entirety.** Upon the terms and subject to the conditions of the Merger Agreement, Merger Sub will merge with and into Capricor and Capricor will remain as the surviving corporation and our wholly-owned subsidiary.

Effect on Capital Stock (See Page 36)

The Merger will have no effect on the shares of our common stock that are currently issued and outstanding. If the Merger is completed, as consideration for their shares of Capricor capital stock, we will issue to Capricor's stockholders aggregate consideration consisting of a number of shares of our common stock, which we refer to as the Merger Shares, such that, immediately following the completion of the merger, the Capricor stockholders will hold 90 percent of our issued and outstanding shares of common stock on a fully-diluted basis.

Effect on Equity Awards (See Page 37)

The Merger will have no effect on the options and warrants to purchase shares of our common stock that are currently outstanding. If the Merger is completed, we will assume all outstanding options to purchase shares of Capricor's common stock, which options will be converted into options to purchase shares of our common stock. All outstanding warrants to purchase shares of Capricor's common stock will automatically be terminated upon completion of the Merger in accordance with their terms.

Directors and Officers (See Page 36)

As of the effective time of the Merger, Nile's current directors and officers will resign from their respective positions. At the effective time of the Merger, Nile's board of directors, or the Board, will be reconstituted to consist of nine directors, seven of whom shall be designated by Capricor and two of whom shall be designated by Nile and Capricor by mutual consent. It is expected that the reconstituted board of directors will appoint Capricor's current executive officers to serve as executive officers of Nile.

The Merger Agreement (See Page 36)

Conditions to the Merger

The obligations of each of Nile and Merger Sub, on the one hand, and Capricor, on the other hand, to complete the Merger depend on the satisfaction or waiver, on or prior to the effective time of the Merger, of a number of conditions, including:

- our receipt of the required stockholder votes to amend our certificate of incorporation to: (i) effect a combination (reverse split) of our common stock at a ratio not to exceed 1:100, or the Reverse Split, and reduce the total number of authorized shares of common stock and preferred stock of the Company, or the Share Reduction, and (ii) change our name from "Nile Therapeutics, Inc." to "Capricor Therapeutics, Inc.", or the Name Change;

- Capricor's receipt of the required stockholder votes to adopt the Merger Agreement and approve the Merger;

- there being no restraining orders, injunctions or other orders preventing completion of the Merger, and there being no law enacted or deemed applicable to the Merger that makes consummation of the Merger illegal;

- for each party, specified levels of compliance by the other with its representations, warranties and obligations under the Merger Agreement; and

- for each party, the other party shall not have suffered a material adverse effect (as defined in the Merger Agreement), and no event shall have occurred or circumstance exist that, in combination with any other events or circumstances, could reasonably be expected to have such a material adverse effect.

The obligation of Capricor to complete the Merger is subject to the following additional conditions:

- our delivery to Capricor of a written strategic plan, in form and substance satisfactory to Capricor, regarding the movement of cenderitide forward for a Phase IB and Phase II program that includes, among other things, clinical and scientific development plans and budgets, all with appropriate timelines;

- our entry into amendments to our license agreements for cenderitide and CU-NP with the Mayo Foundation for Medical Education and Research, or the Mayo Foundation, in form and substance satisfactory to Capricor, and our terminating certain agreements and receiving full releases from certain parties; and

- our outstanding payables to employees and third parties shall not exceed $100,000.

Termination

Regardless of whether our stockholders have voted to amend our certificate of incorporation to effect the Reverse Stock Split, Share Reduction and Name Change, which we refer to as the Charter Amendment Proposals, the Merger Agreement may be terminated and the Merger may be abandoned at any time prior to the effective time of the Merger:

- by mutual written consent of Capricor and us;

- by either Capricor or us, if the Merger has not occurred on or before November 15, 2013, for any reason other than delay, nonperformance or breach of the Merger Agreement, or any other agreement contemplated by the Merger Agreement, by the party seeking such termination;

- by Capricor, under circumstances that involve any of the following:

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our uncured, or an incurable, breach of any of our representations, warranties, covenants or agreements contained in the Merger Agreement, or any representation or warranty becoming untrue after the date of the signing of the Merger Agreement, which would result in the conditions to Capricor's obligation to complete the Merger not being satisfied; or

- our violation or breach of our obligations under the nonsolicitation provisions of the Merger Agreement;

- by us, under circumstances that involve any of the following:

- Capricor's uncured, or an incurable, breach of any of its representations, warranties, covenants or agreements in the Merger Agreement, or any representation or warranty becoming untrue after the date of the signing of the Merger Agreement, which would result in the conditions to our obligation to complete the Merger not being satisfied; or

- our Board's determination to enter into a definitive acquisition agreement providing for a superior proposal in compliance with our nonsolicitation obligations, and we concurrently enter into a definitive agreement for such superior proposal and pay to Capricor of the $350,000 termination fee.

Termination Fee

The Merger Agreement provides that we will be required to pay Capricor a termination fee of $350,000 under circumstances that involve any of the following:

- Capricor terminates the Merger Agreement for either of the following reasons, and we enter into an agreement with respect to, or consummate within 18 months after termination, any competing "acquisition transaction" (as defined in the Merger Agreement) in connection with an "acquisition proposal" (as defined in the Merger Agreement) received by our Board prior to such termination: (i) because of our uncured, or an incurable, breach of any of our representations, warranties, covenants or agreements in the Merger Agreement, which would result in the conditions to Capricor's obligation to complete the Merger not being satisfied; or (ii) because the Merger has not occurred on or before November 15, 2013, for any reason other than the delay, nonperformance or breach of the Merger Agreement, or any other agreement contemplated by the Merger Agreement, by Capricor;

- Capricor terminates the Merger Agreement as a result of our violation or breach of our obligations under the nonsolicitation provisions of the Merger Agreement; or

- we terminate the Merger Agreement in connection with accepting a superior proposal (as defined in the Merger Agreement).

No Solicitation of Alternative Transactions

The Merger Agreement contains restrictions on our ability to solicit or engage in discussions or negotiations with a third party with respect to a competing acquisition transaction. Notwithstanding these restrictions, the Merger Agreement provides that if, under specified circumstances and if prior to the consummation of the Merger, we receive an unsolicited acquisition proposal from a third party that is or is reasonably likely to result in a superior proposal (as defined in the Merger Agreement), we may, if our Board determines in good faith (after taking into account the advice of outside legal counsel) that the failure to take such action would constitute a breach of the Board's fiduciary duties to our stockholders, and if we provide Capricor with at least two business days' advance notice, furnish nonpublic information to that third party and engage in negotiations with that third party.

Recommendation of our Board of Directors (See Page 34)

After careful consideration of the factors described in the section of this proxy statement entitled "The Merger—Recommendation of our Board of Directors" beginning on page 34, our Board unanimously:

- determined that the Merger is advisable and fair to, and in the best interests of, Nile and its stockholders;

- authorized and approved the Merger Agreement and the other transactions contemplated by the Merger Agreement; and

- recommends that our stockholders approve the Charter Amendment Proposals in order to facilitate the Merger.

Our Board also recommends that our stockholders: (i) vote "FOR" the approval of adjournments of the Special Meeting, if necessary, to solicit additional proxies if there are insufficient votes to approve the Charter Amendment Proposals; and (ii) vote "FOR" the approval, on a nonbinding, advisory basis, of the "golden parachute" compensation that may be paid or become payable to our named executive officers in connection with the consummation of the Merger.

Interests of our Executive Officers and Directors in the Merger (See Page 35)

When considering the recommendation by our Board to vote in favor of the Charter Amendment Proposals in order to facilitate the Merger, you should be aware that our executive officers and directors have interests in the Merger that are different from yours, including, among others:

- Darlene Horton, M.D., our President and Chief Executive Officer and a member of our Board, will be entitled to receive, immediately prior to the effective time of the Merger, a number of shares of our common stock equal to 5% of the shares of common stock then outstanding on a fully-diluted basis; and

- Daron Evans, our Chief Financial Officer, will be entitled to receive, immediately prior to the effective time of the Merger, a number of shares of our common stock equal to 4.5% of the shares of common stock then outstanding on a fully-diluted basis.

Vote Required (See Page 48)

While our stockholders are not required to approve the Merger itself, stockholder approval of the Charter Amendment Proposals is required in order for us to consummate the Merger. In particular, the Reverse Stock Split is necessary because, under our certificate of incorporation, we do not currently have a sufficient number of authorized but unissued shares of common stock to allow us to issue the Merger Shares to Capricor's stockholders. The affirmative vote of holders of a majority of our outstanding common stock is required to approve the Charter Amendment Proposals.

Market Price and Dividend Data (See Page 62)

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." On July 5, 2013, the last full trading day prior to the public announcement of the proposed Merger, our common stock closed at a price of $0.06. On , 2013 the last practicable trading day prior to the printing of this proxy statement, our common stock closed at a price of $. To date, we have not paid any dividends on our common stock.

Regulatory Matters (See Page 35)

We are not aware of any federal, state or local regulatory requirements that must be complied with or approvals that must be obtained prior to consummation of the Merger pursuant to the Merger Agreement, other than compliance with applicable federal and state securities laws and the filing of a certificate of merger with the Secretary of State of the State of Delaware in accordance with the General Corporation Law of the State of Delaware after all conditions to the completion of the Merger have been satisfied.

Appraisal Rights (See Page 35)

Under the General Corporation Law of the State of Delaware, because the approval of our stockholders is not required in order for us to consummate the Merger, our stockholders are not entitled to appraisal rights in connection with the

Merger.

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CAUTIONARY STATEMENT REGARDING FORWARD-LOOKING STATEMENTS

This proxy statement and the documents to which we refer you in this proxy statement contain forward-looking statements within the meaning of the "safe harbor" provisions of the Private Securities Litigation Reform Act of 1995. Forward-looking statements also include the assumptions underlying or relating to any of the foregoing statements. Such forward-looking statements are based upon current expectations and beliefs and are subject to a number of factors and uncertainties that could cause actual results to differ materially from those described in the forward-looking statements. The forward-looking statements contained in this proxy statement include statements concerning the proposed Merger. These statements are not guarantees of future performance, involve certain risks, uncertainties and assumptions that are difficult to predict, and are based upon assumptions as to future events that may not prove accurate. Therefore, actual outcomes and results may differ materially from what is expressed herein. For example, if we do not receive the required stockholder approvals or fail to satisfy other conditions to closing, the Merger will not be consummated. All forward-looking statements included in this proxy statement are based on information available to us on the date hereof. We undertake no obligation (and expressly disclaim any such obligation) to update forward-looking statements made in this proxy statement to reflect events or circumstances after the date of this proxy statement or to update reasons why actual results could differ from those anticipated in such forward-looking statements.

RISK FACTORS

You should carefully consider the following risk factors and the other information contained elsewhere in this proxy statement before making a decision regarding approval of the four matters scheduled for a vote at the Special Meeting.

Risks Relating to the Merger

The ratio by which the shares of Capricor capital stock are exchanged for shares of Nile common stock is not adjustable based on the market price of Nile common stock and if the market price of Nile common stock fluctuates, the market value of the shares of Nile common stock to be received by the Capricor stockholders in connection with the Merger is subject to change prior to the completion of the Merger.

The aggregate percentage of shares of Nile common stock to be issued to Capricor stockholders will represent 90% of the outstanding shares of common stock of Nile calculated on a fully diluted basis as of immediately following the completion of the Merger. The Exchange Ratio, as such ratio is calculated pursuant to the formula set forth in the Merger Agreement, is based on the number of shares of Nile common stock and Capricor capital stock outstanding, in each case calculated on a fully diluted basis as of immediately prior to the completion of the Merger, and as a result

will not be determined until that time.

No adjustments to the exchange ratio will be made based on changes in the trading price of Nile common stock or the value of Capricor capital stock prior to the completion of the Merger. Changes in the trading price of Nile common stock or the value of Capricor capital stock may result from a variety of factors, including, among others, general market and economic conditions, changes in Nile's or Capricor's respective businesses, operations, and prospects, market assessment of the likelihood that the Merger will be completed as anticipated or at all, and regulatory considerations. Many of these factors are beyond Nile's or Capricor's control. As a result, the value of the shares of Nile common stock issued to Capricor stockholders in connection with the Merger could be substantially less or substantially more than the current market value of Nile's common stock.

The announcement and pendency of the Merger could have an adverse effect on Nile's stock price and/or the business, financial condition, results of operations, or business prospects for Nile and/or Capricor.

The announcement and pendency of the Merger could disrupt Nile's and/or Capricor's businesses. For example, Nile and Capricor management may need to focus additional attention on the completion of the Merger and related matters, thereby diverting their attention from the day-to-day business operations of their respective companies. Should these disruptions occur, any of these matters could adversely affect the stock price of Nile or harm the financial condition, results of operations, or business prospects of Nile, Capricor, and/or Capricor Therapeutics.

Some of the directors and executive officers of Nile and Capricor have interests in the Merger that are different from, or in addition to, those of the other Nile and Capricor stockholders.

When considering the recommendation by the Nile Board that the Nile stockholders approve the proposed amendments to the Company's certificate of incorporation, which is a condition to the completion of the Merger, the Nile stockholders should be aware that certain of the directors and executive officers of Nile and Capricor have arrangements that provide them with interests in the Merger that are different from, or in addition to, those of the stockholders of Nile and Capricor.

In accordance with the terms of their respective employment agreements, the employment of Darlene Horton, M.D., our current President and Chief Executive Officer, and Daron Evans, our current Chief Financial Officer, will terminate immediately prior to the consummation of the Merger and they will each be entitled to stock issuances of 5% and 4.5%, respectively, of the common stock of Nile on a fully diluted basis prior to the Merger.

During the period from September 2009 until October 2012, Frank Litvack, M.D., Capricor's Executive Chairman, served as a director of Nile and received grants of stock options, all of which have since expired. Additionally, Dr. Litvack is a non-managing member of Calmedica LLC, the general partner of Calmedica L.P., which owns 200,000 shares of Nile common stock and 200,000 Nile warrants, and Dr. Litvack is also a limited partner of Calmedica L.P.

Capricor's director, David Musket, has a financial interest in ProMed Partners LP. ProMed owns 19,500 publicly traded Nile warrants that were acquired as part of a unit offering of Nile in April 2010.

The following current directors of Capricor will serve as directors on the Board of Capricor Therapeutics, Inc. ("Capricor Therapeutics") following the completion of the Merger: Dr. Frank Litvack, Louis Manzo, Louis Grasmick, David Musket, George Dunbar, Earl Collier, Jr., and Linda Marbán, Ph.D. Joshua Kazam and Gregory Schafer, who are both current directors of Nile, will also serve as directors on the Board of Capricor Therapeutics following completion of the Merger. Likewise, certain officers of Capricor will continue to serve as executive officers of Capricor Therapeutics following the completion of the Merger.

The directors and executive officers of Nile and Capricor also have certain rights to indemnification and to directors' and officers' liability insurance that will be provided by Capricor Therapeutics following the completion of the Merger.

Our Board was aware of these potential interests and considered them in making their respective recommendations to approve the Charter Amendment Proposals.

During the pendency of the Merger, we may not be able to enter into a business combination with a third party, even if on better terms than the proposed Merger with Capricor, because of restrictions in the Merger Agreement.

The Merger Agreement restricts our ability to make acquisitions of or be acquired by another company. While the Merger Agreement is in effect, subject to limited exceptions, we are prohibited from soliciting, initiating, encouraging or taking actions designed to facilitate any inquiries or the making of any proposal or offer that could lead to us entering into certain extraordinary transactions with a third party, such as a sale of our company or other business combination transaction, even if such transactions would be beneficial to our stockholders.

We do not have the necessary resources to develop our product candidates. Our ability to increase stockholder value is dependent on our ability to successfully complete a strategic transaction or transactions for the sale of our company or the sale of the rights to our product candidates, which we may be unable to complete.

We have been developing cenderitide, our lead product candidate, for the treatment of patients for up to 90 days following hospital admission for acutely decompensated heart failure, or ADHF. In October 2011, we completed a Phase I clinical trial in collaboration with Medtronic, Inc. We believe the next step in the development of cenderitide is a Phase II clinical trial to test the safety and tolerability of cenderitide when administered to patients for up to 90 days following admission for ADHF. However, we do not have the capital resources necessary to initiate or complete this clinical trial and have been unsuccessful in raising such capital in either a financing or collaboration or other strategic transaction. We believe the proposed Merger with Capricor represents our only alternative to continue the development of cenderitide and to otherwise preserve our ability to increase stockholder value. If we are unable to complete the Merger, we would likely lose our rights to our product candidates and be forced to liquidate our business, in which case our common stockholders will lose their entire investment.

Risks Relating to Capricor Therapeutics if the Merger Is Completed

The failure to integrate successfully the businesses of Nile and Capricor in the expected timeframe could adversely affect Capricor Therapeutics' future results following the completion of the Merger.

The success of the Merger will depend, in large part, on the ability of Capricor Therapeutics following the completion of the Merger to realize the anticipated benefits from combining the businesses of Nile and Capricor. The continued operation of the two companies will be complex.

The failure to integrate successfully and to manage successfully the challenges presented by the integration process may result in the combined company's failure to achieve some or all of the anticipated benefits of the Merger.

Potential difficulties that may be encountered in the integration process include the following:

- using the combined company's cash and other assets efficiently to develop the business of Capricor Therapeutics;
- appropriately managing the liabilities of Capricor Therapeutics;
- potential unknown or currently unquantifiable liabilities associated with the Merger and the operations of the combined company;
- potential unknown and unforeseen expenses, delays or regulatory conditions associated with the Merger; and
- performance shortfalls at one or both of the companies as a result of the diversion of management's attention caused by completing the Merger and integrating the companies' operations.

The Merger will result in changes to the Nile Board of Directors that may affect the combined company's operations.

If the parties complete the Merger, the composition of the Nile Board will change in accordance with the Merger Agreement. Following the completion of the Merger, Nile's Board will consist of nine members, including two of the current directors of Nile and seven of the current directors of Capricor. This new composition of the Board may affect the business strategy and operating decisions of the combined company upon completion of the Merger.

Ownership of Nile's common stock may be highly concentrated, and it may prevent you and other stockholders from influencing significant corporate decisions and may result in conflicts of interest that could cause Capricor Therapeutics' stock price to decline.

Upon completion of the Merger, Capricor's executive officers and directors continuing with Capricor Therapeutics, together with their respective affiliates, are expected to beneficially own or control a significant portion of Nile. Accordingly, these executive officers, directors and their affiliates, acting individually or as a group, will have substantial influence over the outcome of a corporate action of Capricor Therapeutics requiring stockholder approval, including the election of directors, any merger, consolidation or sale of all or substantially all of Capricor Therapeutics' assets or any other significant corporate transaction. These stockholders may also exert influence in delaying or preventing a change in control of Capricor Therapeutics, even if such change in control would benefit the other stockholders of Capricor Therapeutics. In addition, the significant concentration of stock ownership may adversely affect the market value of Capricor Therapeutics' common stock due to investors' perception that conflicts of interest may exist or arise.

If Capricor Therapeutics is unable to retain and recruit qualified scientists and advisors, or if any of its key executives, key employees or key consultants discontinues his or her employment or consulting relationship with Capricor Therapeutics, it may delay Capricor Therapeutics' development efforts or otherwise harm its business.

The loss of any of Capricor's key employees or key consultants could impede the achievement of Capricor Therapeutics' research and development objectives. Furthermore, recruiting and retaining qualified scientific personnel to perform research and development work in the future is critical to Capricor Therapeutics' success. Capricor Therapeutics may be unable to attract and retain personnel on acceptable terms given the competition among biotechnology, biopharmaceutical, and health care companies, universities, and non-profit research institutions for experienced scientists. Certain of Capricor Therapeutics' officers, directors, scientific advisors, and/or consultants or certain of the officers, directors, scientific advisors, and/or consultants hereafter appointed may from time to time serve as officers, directors, scientific advisors, and/or consultants of other biopharmaceutical or biotechnology companies. Capricor Therapeutics may not maintain "key man" insurance policies on any of its officers or employees. All of Capricor Therapeutics' employees will be employed "at will" and, therefore, each employee may leave the employment of Capricor Therapeutics at any time. If Capricor Therapeutics is unable to retain Capricor's existing employees, including qualified scientific personnel, and attract additional qualified candidates, Capricor Therapeutics' business and results of operations could be adversely affected.

The success of Capricor Therapeutics will depend in part on relationships with third parties, which relationships may be affected by third-party preferences or public attitudes about the Merger. Any adverse changes in these relationships could adversely affect Capricor Therapeutics' business, financial condition, or results of operations.

Capricor Therapeutics' success will be dependent on its ability to maintain and renew the business relationships of both Nile and Capricor and to establish new business relationships. There can be no assurance that the management of Capricor Therapeutics will be able to maintain such business relationships, or enter into or maintain new business contracts and other business relationships, on acceptable terms, if at all. The failure to maintain important business relationships could have a material adverse effect on the business, financial condition, or results of operations of Capricor Therapeutics.

Capricor Therapeutics' ability to utilize Nile's net operating loss and tax credit carryforwards in the future is subject to substantial limitations and may be further limited as a result of the Merger.

Federal and state income tax laws impose restrictions on the utilization of net operating loss, or NOL, and tax credit carryforwards in the event that an "ownership change" occurs for tax purposes, as defined by Section 382 of the Code. In general, an ownership change occurs when shareholders owning 5% or more of a "loss corporation" (a corporation entitled to use NOL or other loss carryforwards) have increased their aggregate ownership of stock in such corporation by more than 50 percentage points during any three-year period. If an "ownership change" occurs, Section 382 of the Code imposes an annual limitation on the amount of post-ownership change taxable income that may be offset with

pre-ownership change NOLs of the loss corporation experiencing the ownership change. The annual limitation is calculated by multiplying the loss corporation's value immediately before the ownership change by the greater of the long-term tax-exempt rate determined by the IRS in the month of the ownership change or the two preceding months. This annual limitation may be adjusted to reflect any unused annual limitation for prior years and certain recognized built-in gains and losses for the year. Section 383 of the Code also imposes a limitation on the amount of tax liability in any post-ownership change year that can be reduced by the loss corporation's pre-ownership change tax credit carryforwards.

It is expected that the Merger will result in another "ownership change" of Nile. Accordingly, Capricor Therapeutics' ability to utilize Nile's NOL and tax credit carryforwards may be substantially limited. These limitations could, in turn, result in increased future tax payments for Capricor Therapeutics, which could have a material adverse effect on the business, financial condition, or results of operations of Capricor Therapeutics.

The price of Nile common stock after the Merger is completed may be affected by factors different from those currently affecting the shares of Nile.

Upon completion of the Merger, holders of Capricor capital stock will become holders of Nile common stock. The business of Nile differs significantly from the business of Capricor and, accordingly, the results of operations of the combined company and the trading price of Nile common stock following the completion of the Merger may be significantly affected by factors different from those currently affecting the independent results of operations of Nile because the combined company will be conducting costly drug development activities not undertaken by Nile prior to the completion of the Merger.

Because Capricor Therapeutics' common stock will be 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 its common stock was traded on a national securities exchange.

Trading of Nile's common stock on the NASDAQ Capital Market was suspended in May 2011 and trading in Nile's common stock has since been conducted on the OTC Markets, an automated quotation system. Trading in Nile's common stock was moved to the lower OTC Pink tier of the OTC markets. Capricor Therapeutics' shares after the Merger will similarly be traded on the OTC Pink tier of the OTC Markets. Stock traded on the OTC Pink tier of the OTC Markets is often less liquid than stock 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 Capricor Therapeutics by security analysts and media. This may result in lower prices for Capricor Therapeutics' common stock than might otherwise be obtained if the common stock were traded on a national securities exchange, and could also result in a larger spread between the bid and asked prices for Capricor Therapeutics' common stock. There is no guarantee that Capricor Therapeutics will be able to re-list its common stock on the NASDAQ Capital Market or any other market after the Merger, if at all.

Capricor Therapeutics' management will be required to devote substantial time to comply with public company regulations.

As a public company, Capricor Therapeutics will incur significant legal, accounting and other expenses that Capricor did not incur as a private company. The Sarbanes-Oxley Act of 2002, or Sarbanes-Oxley, as well as rules implemented by the SEC and any market on which Capricor Therapeutics' shares may be listed in the future, impose various requirements on public companies, including those related to corporate governance practices. Capricor Therapeutics' management and other personnel will need to devote a substantial amount of time to these requirements. Most members of Capricor's management, which will substantially continue as the management of Capricor Therapeutics, do not have experience in addressing these requirements. Moreover, these rules and regulations will increase Capricor Therapeutics' legal and financial compliance costs relative to those of Capricor and will make some activities more time consuming and costly.

Material weaknesses may exist when Capricor Therapeutics reports on the effectiveness of its internal control over financial reporting for purposes of its reporting requirements.

Capricor has not been subject to Sarbanes-Oxley. Therefore, Capricor's management and independent registered public accounting firm did not perform an evaluation of Capricor's internal control over financial reporting as of December 31, 2012 in accordance with the provisions of Sarbanes-Oxley. Material weaknesses may exist when Capricor Therapeutics reports on the effectiveness of its internal control over financial reporting for purposes of its reporting requirements under the Exchange Act. The existence of one or more material weaknesses would preclude a conclusion that Capricor Therapeutics maintains effective internal control over financial reporting. Such a conclusion would be required to be disclosed in Capricor Therapeutics' future Annual Reports on Form 10-K and could impact the accuracy and timing of its financial reporting and the reliability of its internal control over financial reporting, which could harm Capricor Therapeutics' reputation and cause the market price of its common stock to drop.

Nile and Capricor do not expect Capricor Therapeutics to pay cash dividends.

Nile and Capricor anticipate that Capricor Therapeutics will retain its earnings, if any, for future growth and therefore does not anticipate paying cash dividends in the future. Investors seeking cash dividends should not invest in Capricor Therapeutics' common stock for that purpose.

Because the lack of a public market for Capricor's capital stock makes it difficult to evaluate the fairness of the Merger, Capricor's stockholders may receive consideration in the Merger that is greater than or less than the fair market value of Capricor's capital stock.

The outstanding capital stock of Capricor is privately held and is not traded in any public market. The lack of a public market makes it difficult to determine the fair market value of Capricor. Since the percentage of Nile common stock to be issued to Capricor's stockholders was determined based on negotiations between the parties, it is possible that the value of the Nile common stock to be issued in connection with the Merger will be greater than the fair market value of Capricor. Alternatively, it is possible that the value of the shares of Nile common stock to be issued in connection with the Merger will be less than the fair market value of Capricor.

Risks Relating to Capricor and its Business

Capricor's technology is not yet proven, and Capricor is still in an early stage of its product development.

Each of Capricor's product candidates, CAP-1001, CAP-1002 and cardiospheres, is in an early stage of development and requires extensive clinical testing before it will be approved by the U.S. Food and Drug Administration, or FDA, or another regulatory authority in a jurisdiction outside the United States. The effectiveness of Capricor's technology has not been definitively proven in completed human clinical trials or preclinical studies. Capricor's failure to establish the efficacy of its technology would have a material adverse effect on Capricor. Capricor cannot predict with any certainty the results of such clinical testing, including the results of its planned Phase I/II ALLSTAR clinical trial. Capricor cannot predict with any certainty if, or when, it might commence Phase II of such clinical trial or whether such trials will yield sufficient data to permit Capricor to proceed with additional clinical development and ultimately submit an application for regulatory approval of its product candidates in the United States or abroad, or whether such applications will be accepted by the appropriate regulatory agencies.

Capricor's products will require substantial time and resources in order to be developed, and there is no guarantee that Capricor will develop them successfully.

Capricor has not completed the development of any products and may not have products to sell commercially for many years, if at all. Its potential products will require substantial additional research and development time and expense, as well as extensive clinical trials and perhaps additional preclinical testing, prior to commercialization, which may never occur. There can be no assurance that products will be developed successfully, perform in the manner anticipated, or be commercially viable.

Capricor has a limited operating history, and has experienced losses.

Capricor has a limited operating history and it expects a number of factors to cause its operating results to fluctuate on a quarterly and annual basis, which may make it difficult to predict its future performance. Capricor's operations to date have been primarily limited to organizing and staffing its company, developing its technology, and undertaking preclinical studies and clinical trials of its product candidates. Capricor has not yet obtained regulatory approvals for any of its product candidates. Consequently, any predictions made about Capricor's future success or viability may not be as accurate as they could be if it had a longer operating history. Specifically, Capricor's 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 its control. Capricor has a history of net losses, expects to continue to incur substantial and increasing net losses for the foreseeable future, and may never achieve or maintain profitability.

Capricor's performance will likely fluctuate significantly in the future.

Factors relating to Capricor's business that may contribute to these fluctuations include the following factors, as well as other factors described elsewhere in these Risk Factors:

- the need for substantial additional capital to fund Capricor's development programs;
- delays in the commencement, enrollment and timing of clinical testing;
- the success of Capricor's clinical trials through all phases of clinical development;
- the success of Capricor's ALLSTAR clinical trial and other trials for other product candidates or future product candidates;
- any delays in regulatory review and approval of Capricor's product candidates in clinical development;
- Capricor's ability to receive regulatory approval or commercialize its product candidates within and outside the United States;
- potential side effects of Capricor's current or future products and product candidates that could delay or prevent commercialization;
- Capricor's ability to establish an effective sales and marketing infrastructure once its products are commercialized;
- competition from existing products or new products that may emerge;
- the impact of competition in the market in which Capricor competes on the commercialization of its product candidates;
- guidelines and recommendations of therapies published by various organizations;
- the ability of patients to obtain coverage of or sufficient reimbursement for Capricor products;
- Capricor's ability to maintain adequate insurance policies;
- Capricor's ability to maintain its current manufacturing facility and secure other facilities as determined to be necessary;
- Capricor's dependency on third parties to formulate and manufacture its product candidates;
- Capricor's ability to establish or maintain collaborations, licensing or other arrangements;
- Capricor's ability and the ability of third parties to protect intellectual property rights;
- costs related to and outcomes of potential intellectual property litigation;
- compliance with obligations under intellectual property licenses with third parties;
- Capricor's ability to adequately support future growth;
- Capricor's ability to attract and retain key personnel to manage its business effectively;
- Capricor's ability to continue to undertake pre-clinical development and clinical trials for its product candidates;
- Capricor's ability to seek regulatory approvals for its product candidates;
- Capricor's ability to in-license or otherwise acquire additional products or product candidates; and
- Capricor's ability to implement additional internal systems and infrastructure.

Capricor has received government grants and a loan award which impose certain conditions on Capricor's operations.

Commencing in 2009, Capricor received several grants from the NIH to fund various projects, including Phase I of Capricor's ALLSTAR trial. These awards are subject to annual and quarterly reporting requirements. If Capricor fails

to meet these requirements, the NIH could cease further funding.

On February 5, 2013, Capricor entered into a Loan Agreement with the California Institute for Regenerative Medicine, or CIRM, pursuant to which CIRM has agreed to disburse $19,782,136 to Capricor over a period of three and one-half years to support Phase II of Capricor's ALLSTAR clinical trial. Under the Loan Agreement, Capricor is required to repay the CIRM loan with interest at maturity. The loan also provides for the payment of a risk premium whereby Capricor is required to pay CIRM a premium up to 500% of the loan amount upon the achievement of achieving certain revenue thresholds. The loan has a term of five years and is extendable annually up to ten years from the original issuance at Capricor's option if certain conditions are met. CIRM has the right to cease disbursements if a no-go milestone occurs. The timing of the distribution of funds pursuant to the Loan Agreement is contingent upon the availability of funds in the California Stem Cell Research and Cures Fund in the State Treasury, as determined by CIRM in its sole discretion. So long as Capricor is not in default, the loan may be forgiven during the term of the project period if Capricor abandons the trial due to the occurrence of a no-go milestone. After the end of the project period, the loan may be forgiven if Capricor elects to abandon the project. Under the Loan Agreement, Capricor is also required to meet certain financial milestones by demonstrating to CIRM prior to each disbursement of loan proceeds that it has funds available sufficient to fund all costs and expenses anticipated to be required to continue Phase II of the ALLSTAR trial for at least the following 12-month period, less the costs budgeted to be covered by planned loan disbursements. There is no assurance that Capricor will meet its milestones under the Loan Agreement or that CIRM will not discontinue the disbursement of funds.

***Capricor will need substantial additional funds for its programs*.**

As of June 30, 2013, Capricor only had approximately $3.3 million in cash and cash resources. Capricor believes that its currently available cash resources are only sufficient to fund its operations into the middle of 2014. As a result, Capricor's financial statements reflect an uncertainty about its ability to continue as a going concern, which is also reflected in the report from Capricor's auditors on the audit of its financial statements as of and for the year ended December 31, 2012 included elsewhere in this proxy statement. The development and operation of Capricor's business and especially company-sponsored clinical trials, such as its late stage Phase II and III trials, will require substantial additional capital resources. Accordingly, Capricor will need to raise additional capital to fund its activities. While it may be able to obtain additional funds through corporate partnering arrangements, strategic alliances, additional equity offerings, or other sources of future equity or debt financing, there can be no assurance that such funds will be available to Capricor when required or on terms acceptable to it, if at all. The current global economy and capital markets have been challenging for any issuer to raise capital through public offerings or private placements of securities, and especially so with respect to the biotechnology sector in which Capricor operates. This situation makes the timing and potential for future equity financings uncertain. Future equity or debt financings may result in significant dilution to then-existing stockholders. In the event Capricor is unable to raise additional funds, it may be required to delay, scale back, or eliminate certain research and development programs or relinquish marketing, distribution, development, manufacturing, or other rights to its products under development. Any of these actions could have a material adverse effect on Capricor's current operations and future viability.

Capricor's forecasts regarding the sufficiency of its financial resources to support its 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. Capricor has based these estimates on assumptions that may prove to be wrong, and Capricor could utilize its available capital resources sooner than currently expected.

Capricor's future funding requirements will depend on many factors, including, but not limited to:

- the scope, rate of progress, cost and results of Capricor's research and development activities, especially its planned Phase I/II ALLSTAR clinical trial;
- 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 Capricor 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 Capricor may receive regulatory approval.

Capricor has limited experience in conducting clinical trials.

Capricor has limited human clinical trial experience with respect to its product candidates. The clinical testing process is governed by stringent regulation and is highly complex, costly, and time-consuming (and products in the regeneration of tissue may invite particularly close scrutiny and requirements from the FDA and other regulatory bodies). Capricor's failure or the failure of its collaborators to conduct human clinical trials successfully or its failure to capitalize on the results of human clinical trials for its product candidates would have a material adverse effect on Capricor. If its clinical trials of its 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, Capricor will be unable to commercialize these product candidates.

To receive regulatory approval for the commercial sale of its product candidates, Capricor 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. Capricor's clinical trials may produce negative or inconclusive results, and it may decide, or regulators may require it, to conduct additional clinical and/or non-clinical testing. In addition, the results of Capricor's clinical trials may show that its 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 addition, negative or inconclusive results may result in:

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

If there are delays in clinical testing, Capricor's future financial performance may suffer.

Delays in the commencement or completion of clinical testing could significantly affect Capricor's product development costs. A clinical trial may be suspended or terminated by Capricor, the FDA, or other regulatory authorities due to a number of factors. Capricor does not know whether planned clinical trials will begin on time or be completed on schedule, if at all. The commencement and completion of clinical trials can be delayed for a number of reasons, including, but not limited to, delays related to:

- findings in preclinical studies;
- obtaining regulatory approval to commence a clinical trial, complying with conditions imposed by a regulatory authority regarding the scope or term of a clinical trial, or being required to conduct additional trials before moving on to the next phase of trials;
- reaching agreement on acceptable terms with prospective contract 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;

- manufacturing sufficient quantities of a product candidate for use in clinical trials;

- breaches in quality of manufacturing runs that compromise all or some of the doses made, or positive results in FDA-required viral testing; karyotypic abnormalities in the cells; either event which would necessitate disposal of all cells made from that source;

- availability of adequate amounts of tissue for preparation of master cell banks;

- obtaining institutional review board or ethics committee approval to conduct a clinical trial at a prospective site;

- recruiting and enrolling patients to participate in clinical trials for a variety of reasons, including size of patient population, nature of trial protocol, screening failures, the availability of approved effective treatments for the relevant disease and competition from other clinical trial programs for similar indications;

- severe or unexpected drug-related side effects experienced by patients in a clinical trial;

- retaining patients who have enrolled in a clinical trial but may be prone to withdraw due to rigors of the trial, lack of efficacy, side effects, or personal issues, 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 received from the FDA;

- inability to find a tissue source with an HLA haplotype that is compatible with the recipient may lead to limited utility of the product in a broad population;

- collecting, analyzing and reporting final data from the clinical trials;
- failure to conduct the clinical trial in accordance with regulatory requirements or Capricor's 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 Capricor's CROs and other third parties.

In addition, if Capricor is required to conduct additional clinical trials or other testing of its product candidates beyond those that are currently contemplated, Capricor or its development partners, if any, may be delayed in obtaining, or may not be able to obtain, marketing approval for these product candidates. Capricor 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 it sought approval.

Capricor's products face a risk of failure due to adverse immunological reactions.

A potential risk of an allogeneic therapy is that patients might develop an immune response to the cells being infused. Such an immune response may induce adverse clinical effects which would impact the safety of Capricor's product and the success of Capricor's trials. Additionally, if patients have pre-existing antibodies or other immune sensitization to Capricor's cells, there is a potentiality that Capricor's cells and the therapy would be rendered ineffective.

Capricor has limited manufacturing capability, and may not be able to maintain its manufacturing licenses.

Capricor presently maintains its lab and research facilities in leased premises located at CSMC. Such premises are being leased on a month-to month basis and may be terminated upon thirty days' notice to Capricor. Capricor presently manufactures its cells in an accredited GMP facility which is owned by and located within CSMC. Capricor's intention is to manufacture cells at this facility for the Phase I/II trials. If the lease is terminated or if CSMC revokes its permission to allow Capricor to utilize the GMP facility, Capricor would have to secure alternative facilities in which to operate its research and development activities and/or manufacture its products which would involve a significant monetary investment and would negatively impact the progress of its clinical trials and regulatory approvals. In

addition, Capricor will have to build out its own manufacturing facility for the Phase III trial or establish a collaboration agreement with a third party.

Capricor is required to obtain and maintain certain licenses in connection with its manufacturing facilities and activities. Capricor has been issued a Manufacturing License and a Tissue Bank License from the State of California. There is no guarantee that any licenses issued to Capricor will not be revoked or forfeited by operation of law. If Capricor were denied any required license or if any of its licenses were to be revoked or forfeited, Capricor could suffer significant harm. Additionally, in the event a serious adverse event in Capricor's clinical trial were to occur during the period in which any required license was not in place, Capricor could be exposed to additional liability if it were determined that the event was due to the fault of Capricor and Capricor had not secured the required license.

Capricor's business faces significant government regulation, and there is no guarantee that Capricor's products will receive regulatory approval.

Capricor's research and development activities, preclinical studies, anticipated human clinical trials, and anticipated manufacturing and marketing of its potential products are subject to extensive regulation by the FDA and other regulatory authorities in the United States, as well as by regulatory authorities in other countries. In the United States, Capricor's product candidates are subject to regulation as biological products under the Public Health Service Act or as combination biological products/medical devices. Different regulatory requirements may apply to its products depending on how they are categorized by the FDA under these laws. These regulations can be subject to substantial and significant interpretation, addition, amendment or revision by the FDA and by the legislative process. The FDA may determine that Capricor will need to undertake clinical trials beyond those currently planned. Furthermore, the FDA may determine that results of clinical trials do not support approval for the product. Similar determinations may be encountered in foreign countries. The FDA will continue to monitor products in the market after approval, if any, and may determine to withdraw its approval or otherwise seriously affect the marketing efforts for any such product. The same possibilities exist for trials to be conducted outside of the United States that are subject to regulations established by local authorities and local law. Any such determinations would delay or deny the introduction of Capricor's product candidates to the market and have a material adverse effect on its business, financial condition, and results of operations.

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. Capricor does not have control over third-party manufacturers' compliance with these regulations and standards. Other risks include:

- 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;
- Capricor may be required to change the way the product is administered, conduct additional clinical trials or change the labeling of the product;
- Capricor may have limitations on how it promotes its products;
- regulatory authorities may require Capricor to take its approved product off the market;
- sales of products may decrease significantly;
- Capricor may be subject to litigation or product liability claims; and
- Capricor's reputation may suffer.

Even if Capricor's product candidates receive regulatory approval in the United States, it may never receive approval or commercialize its product candidates outside of the United States. In order to market and commercialize any product candidate outside of the United States, Capricor 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 Capricor's product candidates may not be approved for all indications requested, which could limit the uses of its 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.

Even if Capricor can commercialize its products, it will face uncertainty in health care reimbursement policies.

Capricor's ability to commercialize its products successfully will depend in large part on the extent to which the cost of such products and related treatments will be reimbursed by government health administrative authorities, private health insurers, and other organizations in both the United States and other countries (particularly the willingness to fund the banking of cells for individuals at risk). Since significant uncertainty exists as to the reimbursement of newly approved health care products, there can be no assurance that adequate third-party insurance coverage will be available for Capricor to establish and maintain price levels sufficient for realization of an appropriate return on its investment in developing new therapies. Failure by payers to cover adequately and reimburse usage of Capricor's products would have a material adverse effect on its ability to generate revenues.

Capricor's growth depends in part upon strategic relationships and these relationships face their own uncertainties, which Capricor will not be able to control.

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

If Capricor enters into strategic partnerships, it may be required to relinquish important rights to and control over the development of its product candidates or otherwise be subject to unfavorable terms.

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

· delays in the commercialization of, and Capricor's ability to derive product revenues from, its product candidates;

· the imposition of costly procedures on Capricor;

· diminishing any competitive advantages that Capricor may otherwise enjoy;

· Capricor may not be able to control the amount and timing of resources that its 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 Capricor's potential revenues from these products;

· disputes may arise between Capricor and its strategic partners that result in the delay or termination of the research, development or commercialization of its 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 Capricor's intellectual property rights or may use Capricor's proprietary information in a manner that could jeopardize or invalidate its proprietary information or expose it 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 Capricor's competitors.

Capricor's products will likely face intense competition.

Capricor is engaged in fields that are characterized by extensive worldwide research and competition by pharmaceutical companies, medical device companies, specialized biotechnology companies, hospitals, physicians and academic institutions, both in the United States and abroad. Capricor will experience intense competition with respect to its 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 organizations competing with Capricor have substantially greater financial resources, larger research and development staffs and facilities, longer drug development history in obtaining regulatory approvals, and greater manufacturing and marketing capabilities than Capricor does. 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 Capricor's product candidates. Capricor expects any future products and product candidates it develops 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 Capricor's competitors may develop products based upon the principles underlying its proprietary technologies earlier than Capricor, obtain approvals for such products from the FDA more rapidly than Capricor, or develop alternative products or therapies that are safer, more effective and/or more cost effective than any products developed by Capricor. Competitors may seek to develop alternative formulations of Capricor's product candidates that address its targeted indications. The commercial opportunity for Capricor's product candidates could be significantly harmed if competitors are able to develop alternative formulations outside the scope of Capricor's product candidates. Capricor's competitors may obtain regulatory approval of their products more rapidly than Capricor is able to or may obtain patent protection or other intellectual property rights that limit Capricor's ability to develop or commercialize its product candidates. Capricor competitors may also develop drugs that are more effective, useful, and less costly than those of Capricor, and may also be more successful than Capricor in manufacturing and marketing their products.

Capricor possesses intellectual property related to the nature of its cells and their processing for clinical use. Other companies as well as individual investigators have deployed human cells for identical or similar indications. It is possible that one or more of these individuals or groups may commercialize human cells in competition with Capricor's products.

Capricor's future success will depend in part on its ability to maintain a competitive position with respect to evolving cell therapies as well as other novel technologies. There can be no assurance that existing or future therapies developed by others will not render Capricor's potential products obsolete or noncompetitive. The biotechnology and pharmaceutical industries are subject to rapid and significant technological change. The drugs that Capricor is attempting to develop will have to compete with existing therapies. In addition, companies pursuing different but related fields represent substantial competition. These organizations also compete with Capricor to attract qualified personnel and parties for acquisitions, joint ventures, or other collaborations.

If any of Capricor's product candidates for which it receives regulatory approval do not achieve broad market acceptance, the revenues that Capricor generates from their sales will be limited. The commercial viability of Capricor's product candidates for which it obtains 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 Capricor's approved products will depend on a number of factors, including:

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

· potential product liability claims.

Capricor's business faces great uncertainty produced by the rapid technology changes that occur in the biotechnology industry generally, and the cardiac therapeutic industry specifically.

Capricor conducts its research and development activities in an environment of rapidly evolving biotechnology. Its cardiac stem cell technology is still being developed and refined. The physiology of cardiac tissue repair is complex and the biological processes involved are not fully understood. Capricor's competitors and other entities are pursuing related avenues of research and development that are likely to affect the commercial viability of Capricor's cardiac stem cell technology (whether in cardiac stem cell or other stem cell approaches) and the course of its future research and development activities. There can be no assurance that Capricor will be able to remain abreast of the evolving knowledge, research, and technologies having significant implications for its own research and development activities, and failure to do so would adversely affect its ability to develop and market commercially useful products.

Capricor may face uncertainty and difficulty in obtaining and enforcing its patents and other proprietary rights.

Capricor's success will depend in large part on its ability to obtain, maintain, and defend patents on its products, obtain licenses to use third party technologies, protect its trade secrets and operate without infringing the proprietary rights of others. Legal standards regarding the scope of claims and validity of biotechnology patents are uncertain and evolving. There can be no assurance that Capricor's pending, licensed-in patent applications will be approved, or that challenges will not be instituted against the validity or enforceability of any patent licensed-in or owned by Capricor. Additionally, Capricor has entered into various confidentiality agreements with employees and third parties. There is no assurance that such agreements will be honored by such parties or enforced in whole or part by the courts. The cost of litigation to uphold the validity and prevent infringement of a patent is substantial. Furthermore, there can be no assurance that others will not independently develop substantially equivalent technologies not covered by patents to which Capricor owns rights or obtain access to Capricor's know-how. In addition, the laws of certain countries may not adequately protect Capricor's intellectual property. Capricor's competitors may possess or obtain patents on products or processes that are necessary or useful to the development, use, or manufacture of its products. There can also be no assurance that Capricor's proposed technology will not infringe patents or proprietary rights owned by others, with the result that others may bring infringement claims against Capricor and require it to license such proprietary rights, which may not be available on commercially reasonable terms, if at all. Any such litigation, if instituted, will have a material adverse effect, including monetary penalties, diversion of management resources, and injunction against continued manufacture, use, or sale of certain products or processes. Certain of Capricor's technology has resulted and will result from research funded by agencies of the United States government and the State of California. As a result of such funding, the United States government and the State of California have certain rights in the technology developed with the funding. These rights include a non-exclusive, paid-up, worldwide license under such inventions for any governmental purpose. In addition, under certain conditions, the government has the right to require Capricor to grant third parties licenses to such technology. Capricor also relies upon non-patented proprietary know-how. There can be no assurance that Capricor can adequately protect its rights in such non-patented proprietary know-how, or that others will not independently develop substantially equivalent proprietary information or techniques or gain access to Capricor's proprietary know-how. Any of the foregoing events could have a material adverse effect on Capricor. In addition, if any of Capricor's trade secrets, know-how or other proprietary information is disclosed, the value of its trade secrets, know-how and other proprietary rights would be significantly impaired and Capricor's business and competitive position would suffer.

Capricor's products may expose it to potential product liability, and there is no guarantee that Capricor will be able to obtain and maintain adequate insurance to cover these liabilities.

The testing, marketing, and sale of human cell therapeutics, pharmaceuticals, and services entail an inherent risk of adverse effects or medical complications to patients and, as a result, product liability claims may be asserted against Capricor. A future product liability claim or product recall could have a material adverse effect on Capricor. There can be no assurance that product liability insurance will be available to Capricor in the future on acceptable terms, if at all, or that coverage will be adequate to protect Capricor against product liability claims. In the event of a successful claim against Capricor, insufficient or lack of insurance or indemnification rights could result in liability to it, which could have a material adverse effect on Capricor and its future viability. The use of Capricor's product candidates in clinical trials and the sale of any products for which it obtains marketing approval, if at all, expose Capricor to the risk of

product liability claims. Product liability claims might be brought against it by consumers, health care providers or others using, administering or selling Capricor's products. If Capricor cannot successfully defend itself against these claims, it will incur substantial liabilities. Capricor has obtained clinical trial insurance coverage for its clinical trials. However, such insurance coverage may not reimburse Capricor or may not be sufficient to reimburse it for any expenses or losses it may suffer. Moreover, insurance coverage is becoming increasingly expensive, and, in the future, Capricor may not be able to maintain insurance coverage at a reasonable cost or in sufficient amounts to protect it against losses due to liability. Capricor intends to expand its insurance coverage to include the sale of commercial products if it obtains marketing approval for its product candidates in development, but Capricor 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 Capricor could have a material adverse effect on it and, if judgments exceed Capricor's insurance coverage, could decrease its cash and adversely affect its business.

Capricor is dependent on its relationships with its licensors and collaborators and there is no guarantee that such relationships will be maintained or continued.

Capricor has entered into certain license agreements for certain intellectual property rights which are essential to enable Capricor to develop and commercialize its products. Agreements have been entered into with the University of Rome, JHU and CSMC, which is a shareholder of Capricor. Each of those agreements provides for an exclusive license to certain patents and other intellectual property and requires the payment of fees, milestone payments and/or royalties to the institutions that will reduce the net revenues of Capricor, if and to the extent that Capricor has future revenues. Each of those agreements also contains additional obligations that Capricor is required to satisfy. There is no guarantee that Capricor will be able to satisfy all of its obligations under its license agreements to each of the institutions and that such license agreements will not be terminated. Each of the institutions receives funding from independent sources such as the NIH and other private non-for-profit sources and are investigating scientific and clinical questions of interest to their own principal investigators as well as the scientific and clinical communities at large. These investigators (including Capricor's founder, Dr. Eduardo Marbán, who is the Director of the Heart Institute at CSMC) are under no obligation to conduct, continue, or conclude either current or future studies utilizing Capricor's stem cell technology, and they are not compelled to license any further technologies or intellectual property rights to Capricor except as may be stated in the applicable licensing agreements between those institutions and Capricor. Changes in these collaborators' research interests or their funding sources away from Capricor's technology would have a material adverse effect on Capricor. Capricor is substantially dependent on its relationships with these institutions from which it licenses the rights to its technologies and know-how. If requirements under its license agreements are not met, Capricor could suffer significant harm, including losing rights to its product candidates.

In addition to Dr. Eduardo Marbán, Capricor's Chief Executive Officer, Dr. Linda Marbán and several other Capricor employees render services on a part time basis to CSMC. In addition, the Chairman of the Board of Capricor is an emeritus member of the medical staff of CSMC. These employees may discover products and other patentable inventions to which CSMC could claim ownership instead of Capricor if such work were done on CSMC property outside of Capricor's leased premises. In those instances, Capricor would not have ownership or license rights to the products or other technologies unless otherwise provided under the License Agreement.

Capricor's future success depends on attracting and retaining top talent, and Capricor's business would suffer from the loss of key personnel.

Because of the specialized nature of Capricor's technology and its contribution to the development of future products and services, Capricor is dependent upon existing key personnel and on its ability to attract and retain qualified executive officers and scientific personnel for research, clinical studies, and development activities conducted or sponsored by Capricor. There is intense competition for qualified personnel in Capricor's fields of research and development, and there can be no assurance that Capricor will be able to continue to attract additional qualified personnel necessary for the development and commercialization of its product candidates or retain its current personnel. Capricor's Chief Executive Officer also provides services on a part-time basis to CSMC as do several other Capricor employees and Capricor's Chairman of the Board is only a part-time consultant to Capricor and provides

services to other non-competing enterprises. These individuals' multiple responsibilities on behalf of Capricor and other entities could cause Capricor harm in that such employees are unable to devote their full time and attention to Capricor.

Capricor's business involves risk associated with handling hazardous and other dangerous materials.

Capricor's research and development activities involve the controlled use of hazardous materials, chemicals, human blood and tissue, animal blood and blood products, and animal tissue, biological waste, and various radioactive compounds. The risk of accidental contamination or injury from these materials cannot be completely eliminated. The failure to comply with current or future regulations could result in the imposition of substantial fines against Capricor, suspension of production, alteration of its manufacturing processes, or cessation of operations.

Capricor's business depends on compliance with ever-changing environmental laws.

Capricor cannot accurately predict the outcome or timing of future expenditures that it may be required to expend to comply with comprehensive federal, state and local environmental laws and regulations. Capricor must comply with environmental laws that govern, among other things, all emissions, waste water discharge and solid and hazardous waste disposal, and the remediation of contamination associated with generation, handling and disposal activities. To date, it has not incurred significant costs and is not aware of any significant liabilities associated with its compliance with federal, state and local laws and regulations. However, environmental laws have changed in recent years and Capricor may become subject to stricter environmental standards in the future and may face large capital expenditures to comply with environmental laws. Capricor has limited capital and is uncertain whether it will be able to pay for significantly large capital expenditures. Also, future developments, administrative actions or liabilities relating to environmental matters may have a material adverse effect on Capricor's financial condition or results of operations.

***Capricor has no experience in selling, marketing or distributing products*.**

Capricor has no experience selling, marketing, or distributing products and no internal capability to do so. If it is unable to establish an effective and focused sales force and marketing infrastructure, Capricor will not be able to commercialize its product candidates successfully.

Capricor currently has no sales, marketing, or distribution capabilities. It does not anticipate having resources in the foreseeable future to allocate to the sales and marketing of its proposed products. Capricor's future success depends, in part, on its ability to enter into and maintain sales and marketing collaborative relationships, or on its ability to build sales and marketing capabilities internally. If Capricor enters into a sales and marketing collaborative relationship, then it 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. Capricor intends to pursue collaborative arrangements regarding the sales and marketing of its products, however, there can be no assurance that it 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 Capricor decides not to, or is unable to, enter into collaborative arrangements with respect to the sales and marketing of its 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 Capricor will be able to establish or maintain relationships with third-party collaborators or develop in-house sales and distribution capabilities. To the extent that Capricor depends on third parties for marketing and distribution, any revenues it receives 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 Capricor will be able to market and sell its products in the United States or overseas.

THE MERGER

The following discussion summarizes the material terms of the proposed Merger. Stockholders should read the Merger Agreement, which is attached as Appendix A to this proxy statement, carefully and in its entirety.

General Description of the Merger

Pursuant to the Merger Agreement, at the effective time of the Merger, Merger Sub will merge with and into Capricor and Capricor will remain as the surviving corporation and our wholly-owned subsidiary.

Merger Consideration

As consideration for their shares of Capricor capital stock, we will issue to Capricor's stockholders aggregate consideration consisting of a number of shares of our common stock such that, immediately following the completion of the Merger, the Capricor stockholders will hold 90 percent of our issued and outstanding shares of common stock on a fully-diluted basis.

Background to the Merger

Historical Background for Nile

Our historical operations have been focused on the development of cenderitide, our lead product candidate, for the treatment of heart failure. Cenderitide is a novel chimeric natriuretic peptide in clinical development for the treatment of heart failure. We hold exclusive, worldwide rights to develop and commercialize cenderitide pursuant to a January 2006 license agreement with Mayo Foundation for Medical Education and Research, or the Mayo Foundation.

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 Phase II clinical trials that we had previously conducted in 2009 and 2010, in which cenderitide was delivered through continuous i.v. infusion.

Our 2011 Phase II 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 our February 2011 collaboration agreement with Medtronic. In accordance with the terms of that agreement, Medtronic agreed to reimburse us for certain expenses of this Phase I study and provided the subcutaneous pumps used in the study. As a result of this Phase I study, we learned the following:

- 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 for 24 hours;

- Weight-based dosing reduced PK variability, as compared to a fixed dosing regimen.

We believe the next step in the clinical development of cenderitide is a Phase II 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 II study, up to 296 patients, will be approximately $15 million to $20 million and will take approximately 30 months to complete. However, since completing the 2011 Phase I clinical trial, we have lacked the necessary capital to conduct any additional development activities of cenderitide. In April 2012, we completed an offering of shares of our common stock and warrants to purchase additional shares of common stock pursuant to which we realized net proceeds of approximately $1.2 million. We used those proceeds to fund our basic ongoing organizational expenses, as well as to fund activities relating to planning and designing of the planned Phase II clinical trial of cenderitide.

Following completion of the 2011 Phase I clinical trial, we had ongoing discussions with Medtronic concerning its interest in further collaborating on a Phase II trial of cenderitide. However, on or about April 9, 2012, representatives of Medtronic informed us that they were no longer interested in pursuing a collaboration with us concerning further development of cenderitide. At a meeting of our board of directors on April 10, 2012, our board reviewed potential alternatives to consider for the further clinical development of cenderitide, which included securing strategic transactions, additional financing or a liquidation of the business. Our board of directors determined to first pursue seeking additional financing to fund the planned Phase II trial. Our board also established a special committee to consider and approve the engagement of a financial advisor to assist with such efforts. On April 13, 2012, the special committee approved the engagement of Ladenburg Thallman & Co., Inc. as our financial advisor for the purposes of raising additional financing to fund our planned Phase II trial of cenderitide.

From mid-April 2012 through August 2012, our management and financial advisor contacted potential investors concerning their interest in participating in a potential financing transaction with us. Many investors contacted were not interested in making an investment due to the early stage of the cenderitide program. Other investors indicated possible interest, but only to the extent we were able to secure a lead investor for the transaction or, in other cases, to the extent we were able to secure a strategic partner with which to co-develop cenderitide. During this same period, we also engaged in preliminary discussions with two strategic parties in the cardiovascular therapy space in order to gauge their interest in either collaborating on the development of cenderitide or otherwise entering into a strategic transaction with us.

In early September 2012, our management met with several additional potential financing parties in New York to discuss a potential financing transaction. Around this period, our management also made contact and engaged in preliminary discussions with several additional pharmaceutical and biotechnology companies concerning a potential collaboration or other strategic transaction. As a result of such discussions, several additional strategic parties began undertaking due diligence activities relating to cenderitide.

Between April 2012 and December 2012, our management and financial advisor contacted more than 110 potential investors to ascertain their interest and willingness to make an investment in Nile or to otherwise participate in a transaction that would provide the capital we needed to conduct the next phases of development of cenderitide. Of such total number of potential investors, our management had more detailed discussions with 8 institutional life

science investors. None of such parties was willing to move forward with a financing transaction that would enable us to continue the development of cenderitide.

Background of Transaction Between Nile and Capricor

In early Fall of 2012, Dr. Frank Litvack, a director of Nile and the Executive Chairman of Capricor, approached the Capricor board of directors and management about the possibility of a reverse merger with us. After speaking with certain members of Capricor's board of directors and Dr. Linda Marbán, Capricor's Chief Executive Officer, and following a meeting of our board of directors on September 28, 2012, Dr. Litvack informed our management that Capricor may have potential interest in a strategic transaction with us and that he intended to discuss such matters with the Capricor board of directors. As a result of such potential interest, Dr. Litvack declined to participate in two meetings of our board of directors held in October 2012 as he and Capricor considered a potential transaction. In late October 2012, Dr. Litvack informed our management that Capricor did wish to explore a potential business combination transaction with us. Because of that interest, and to avoid any potential conflict of interest, Dr. Litvack notified us of his resignation from our board on October 28, 2012.

In early November 2012, our management attended the American Heart Association, or AHA, Scientific Sessions conference in Los Angeles. During such conference, our management met with representatives of Capricor, including Dr. Litvack and Dr. Marbán, as well as two other interested strategic parties. In the weeks immediately following the AHA conference, both of such parties informed our management that they were not interested in pursuing a collaboration or other strategic transaction with us. However, shortly after the AHA conference, our management was contacted by a representative of another interested strategic party, referred to as Party A, concerning a potential strategic transaction with us.

On November 5, 2012, Capricor and Nile executed a Mutual Nondisclosure Agreement.

On November 13, 2012, the Capricor board of directors held a meeting at which Dr. Litvack presented the idea of Capricor entering into a reverse merger with us. The Capricor board of directors was updated on cenderitide and CU-NP. The Capricor board of directors was also made aware that Dr. Litvack had recently resigned from our board and had options and a financial interest in Calmedica, one of our shareholders and warrant holders. The Capricor board of directors also discussed the pros and cons of being a public company, and how the new combined company can possibly increase shareholder value, as it adds a new product to the pipeline and capitalizes on the cardiology expertise of both of the companies. Capricor's board of directors adopted a resolution to pursue additional due diligence review.

On or about November 26, 2012, Capricor submitted a due diligence request list to us. We began to submit documents to Capricor for their due diligence review. In November 2012, Capricor's management and members of Nile engaged in negotiations as to how the deal would be structured.

During November 2012, as Capricor continued its due diligence of our company, our cash resources were nearly exhausted. In order to preserve our remaining cash, our board of directors determined not to prepare and file our quarterly report on Form 10-Q for the quarter ended September 30, 2012, which was required to be filed with the SEC by November 14, 2012. In addition, we undertook additional measures to reduce all other operating expenses, including the reduction of our Chief Executive Officer's and Chief Financial Officer's salaries to $100 per month after October 31, 2012 and January 31, 2013, respectively.

In December, 2012, we sent Capricor our due diligence request list and documents were provided to us pursuant to that request. On December 20, 2012, Capricor sent to us an initial draft of a non-binding term sheet that outlined the terms of a potential business combination transaction whereby Capricor would merge into Nile, or a subsidiary of Nile, and the holders of Capricor's capital stock would receive a number of shares of our common stock, or options or warrants to purchase our common stock, such that the Capricor holders would own 92% of our total outstanding shares of common stock on a fully-diluted basis. Following receipt of the initial draft term sheet, our management and representatives of Capricor held discussions concerning various aspects of the proposed transaction. During such discussions, our management informed Capricor of the need to increase the ownership percentage of our stockholders

following the proposed transaction.

On January 7, 2013, our board of directors met to further discuss the proposed Capricor terms. At such meeting, the board authorized our management to submit to Capricor a counterproposal pursuant to which Nile stockholders would retain 15% of the fully-diluted ownership of the company after giving effect to the transaction and two of seven seats of the combined company's board of directors. Our management sent a revised draft of the term sheet with such provision to Capricor on the evening of January 7, 2013.

On January 9, 2013, Darlene Horton, M.D., our chief executive officer, and Daron Evans, our chief financial officer, met with representatives of Party A at the JPMorgan Global Healthcare Conference in San Francisco to further discuss cenderitide and the potential for a collaboration or other strategic transaction. In the course of such discussion, Party A informed Dr. Horton and Mr. Evans that Party A was interested in pursuing further discussions and that it intended to commence due diligence activities. On January 18, 2013, we entered into a confidentiality agreement with Party A in order to facilitate its due diligence review.

Following the transmission of the revised term sheet to Capricor on January 7, 2013, our management had additional discussions with representatives of Capricor concerning the terms of the proposed transaction. During a conversation on January 18, 2013, Capricor communicated to our management that it was willing to provide for two board seats to be held by designees of Nile, and that it would agree to increase the ownership by Nile's stockholders to 10% on a fully-diluted basis.

On January 21, 2013, our board of directors met again to consider the further revised offer from Capricor. Our board agreed to accept Capricor's revised offer for a merger transaction that would result in our stockholders retaining 10% of the fully-diluted common stock of the resulting company. In addition, we included a condition to the merger that our stockholders approve an amendment to our certificate of incorporation that provides us with a sufficient number of authorized shares of common stock with which to issue in the merger. Our management thereafter communicated such agreement to representatives of Capricor.

In January 2013, Capricor commenced internal discussions with our patent attorneys to assess the portfolio and license agreements in place. Over the next few months, we, with input from Capricor, pursued efforts to revise the License Agreements with the Mayo Foundation and the Clinical Trial Funding agreement with Medtronic. Several telephone conferences were had regarding the renegotiation of such agreements. In January 2013, we provided Capricor with copies of the proposed amendments to the Mayo Foundation and Medtronic agreements.

On February 4, 2013, Capricor's board of directors had a teleconference, whereby it was resolved that Dr. Marbán was authorized to execute a non-binding term sheet and to deliver the same to our management. On February 8, 2013, Capricor's board of directors had another teleconference, whereby the board of directors agreed that it would be in the best interests of Capricor to proceed with the proposed reverse merger with us but that, if possible, the board of directors would like the deal to be structured with an 8%/92% split. Dr. Marbán was again authorized to execute a non-binding term sheet on the most favorable terms possible and to deliver the same to our management. On February 11, 2013, Capricor informed us that its board of directors had reconsidered its most recent offer and determined to revert to its initial offer of a transaction whereby Nile stockholders would retain only 8% of the fully-diluted common stock of the resulting company. Following several additional discussions in late January and early February 2013, Capricor agreed to the 90%-10% fully-diluted equity split between the two companies' stockholder groups. On February 13, 2013, we and Capricor signed a non-binding term sheet providing for the terms of such a merger transaction between the companies.

During late January 2013 and through February 2013, Party A continued its due diligence activities and engaged in several discussions with members of our management concerning the cenderitide program and terms of a potential transaction. On February 26, 2013, Party A submitted to our management a written offer to acquire 100% of the outstanding equity of Nile for a total cash payment of $15 million. Party A's offer indicated that its proposal was subject to the satisfactory completion of its due diligence activities.

On February 22, 2013, the Capricor board of directors held a meeting at which the directors discussed, among other things, the progress of the reverse merger transaction with us. Also included in the discussion was a summary of the Mayo Foundation and Medtronic license agreements, as well as an update on the draft merger agreement, which was being prepared. Capricor continued to perform internal due diligence on us.

On February 28, 2013, Dr. Horton, Mr. Evans and representatives of Fredrikson & Byron, P.A., our legal counsel, held a telephone conference with representatives of Party A pursuant to which Party A further reviewed its proposal with us.

On February 28, 2013, our board of directors met to consider Party A's proposal. The board directed management to further discuss with Party A the basis for its valuation of our company and to seek certain other clarifications concerning the proposed transaction that were not addressed in Party A's written offer.

On March 1, 2013, Dr. Horton and Mr. Evans held a telephone discussion with a representative of Party A to obtain further clarification of Party A's transaction proposal and to determine the extent to which the aggregate consideration could be increased. The Party A representative agreed to consider such request and also informed our management that Party A was nearing completion of its scientific due diligence review of the cenderitide program.

On March 7, 2013, we received from Capricor the initial draft of a definitive merger agreement. Our board of directors held a meeting on March 15, 2013 in order to review and discuss the draft agreement. At such meeting, our legal counsel reviewed the proposed terms and answered questions from the board concerning the draft agreement.

On March 15, 2013, we entered into a convertible note purchase agreement with certain accredited investors pursuant to which we sold an aggregate principal amount of $450,000 of secured convertible promissory notes for an aggregate original issue price of $382,500, representing a 15% original issue discount. The purpose of the issuance and sale of these notes was to provide us with capital to fund the expenses we expected to incur in order to consummate a transaction with either Party A or Capricor.

On March 20, 2013, representatives of Capricor and its counsel, Paul Hastings LLP, met by telephone conference with Dr. Horton, Mr. Evans and Fredrikson & Byron to discuss the draft merger agreement.

On March 22, 2013, a representative of Party A telephoned Mr. Evans and informed him that Party A had completed its scientific due diligence review and concluded that it was no longer interested in pursuing the proposed transaction with us.

Between March 2013 and late June 2013,we and Capricor exchanged several drafts of the merger agreement, related disclosure schedules and other ancillary documents. During this period, each party also continued its due diligence review of the other. Several telephonic meetings were held with respect to the Medtronic Clinical Trial Funding Agreement and the Mayo Foundation Licenses Agreements. Negotiations with Medtronic did not result in any revisions to its agreement. Negotiations with the Mayo Foundation were productive and are continuing to date. In addition, Capricor informed us that it would require us to become current in our period reporting with the SEC. In particular, prior to signing the merger agreement, Capricor informed us that it would require all delinquent reports to be filed, which would include the 2012 third quarter Form 10-Q, our annual report on Form 10-K for the year ended December 31, 2012, as well as any subsequent reports that would become due prior to signing the merger agreement. As a result, from between late March to late June 2013, our management focused significant attention on preparing all such periodic reports for filing with the SEC.

On May 14, 2013, the Capricor board of directors held a teleconference whereby the board of directors was presented with a summary of the merger agreement, as well as a draft of the merger agreement, and an update on the license agreement amendments for Nile. Capricor’s management also reported that the audit of its financial statements as of and for the years ended December 31, 2012 and 2011 had been completed.

On June 10, 2013, we filed a Certificate of Incorporation for Bovet Merger Corp. with the Secretary of State of the State of Delaware.

On June 12, 2013, the Capricor board of directors held a teleconference discussing various issues surrounding the proposed merger, including the merger agreement, timing of the close, stock split and various other issues.

On or about June 20, 2013, we and Capricor had completed our substantive negotiations of the merger agreement and ancillary documents.

On June 20, 2013, our board of directors held a telephone conference meeting to discuss the final terms of the proposed merger with Capricor. Prior to the meeting, our board received the most recent draft of the merger agreement and related documents. Our management and legal counsel reviewed the terms of the proposed transaction and answered all questions of directors. After a discussion, our board of directors unanimously approved the merger.

On June 26, 2013, the Capricor board of directors had a call to finalize the merger agreement and obtain final approval to execute the document. It was voted unanimously to enter into a definitive agreement subject to certain conditions and terms.

On July 7, 2013, we entered into an Agreement and Plan of Merger and Reorganization with Capricor and Bovet Merger Corporation. On July 8, 2013, we issued a press release announcing the execution of the Agreement and Plan of Merger and Reorganization with Capricor.

Recommendation of Our Board of Directors

Reasons for the Merger. In the course of reaching its decision to approve the Merger and enter into the Merger Agreement, our Board consulted with our management and outside legal counsel, and reviewed a significant amount of information and considered a number of factors, including, among others, the following factors:

- Since April 2012, our management and advisors contacted more than 110 potential investors in order to secure additional capital to fund the next clinical study of cenderitide, a Phase II trial. None of the investors contacted were willing to participate in a financing transaction that would enable us to continue the development of cenderitide and to otherwise remain an independent company.

- In addition, since April 2012, our management contacted more than 20 biotechnology and pharmaceutical companies in order to discuss with them the possibility of either collaborating on the further development of cenderitide or acquiring Nile. Other than Capricor, no party has indicated an interest in completing an acquisition or other strategic transaction.

- As a result of the financial condition of Nile, including the fact that the amount of our liabilities exceeds the amount of our assets, a liquidation of Nile would be unlikely to return any value to our stockholders. The proposed Merger with Capricor has emerged as our only viable alternative to continue the development of cenderitide and to preserve any potential for future value to our stockholders.

- Our Board considered the status of the development of Capricor's lead product candidate, cardiosphere-derived stem cell, or CDC, technology, which is currently enrolling in a Phase 1/II clinical trial. Our Board also considered the status of Capricor's Phase I clinical trial of its CDC technology, and the fact that Capricor's Phase II clinical trial is being funded in large part with an approximately $19.8 million loan award from the California Institute for Regenerative Medicine ("CIRM").

- Our Board believes that the combined company will provide stockholders with two product candidates that have the potential to allow Nile stockholders to realize future value.

In the course of its deliberations, our Board also identified and considered a variety of risks and other countervailing factors, including:

- Capricor's technology is novel and unproven and Capricor will face significant competition in developing its CDC technology.

- Capricor faces significant risks associated with protecting its intellectual property and creating a validated manufacturing process for its CDC technology.

- Capricor faces risks relating to potential safety issues that it may encounter in developing its CDC technology. In addition, Capricor may be adversely affected by safety issues experienced by its competitors developing CDC technologies.

- Our stockholders may not approve the Charter Amendment Proposals and other items to be considered at the Special Meeting, which are necessary to satisfy conditions to the parties' obligations to consummate the Merger.

While our Board considered potentially negative and potentially positive factors, the Board concluded that, overall, the potentially positive factors outweighed the potentially negative factors.

The preceding discussion is not meant to be an exhaustive description of the information and factors considered by our Board, but is believed to address the material information and factors considered. Our Board collectively reached the unanimous decision to approve the Merger Agreement in light of the factors described above and other factors that each member of the Board felt were appropriate. In view of the wide variety of factors considered in connection with its evaluation of the Merger and the complexity of these matters, many of which are qualitative or difficult to quantify, and the quality and amount of information considered, our Board did not find it practicable to and did not make specific assessments of, quantify or otherwise assign relative weights to the specific factors considered in reaching its determination. In considering the factors described above, individual members of the Board may have given different weight to different factors.

Board of Directors' Recommendation. After careful consideration, and taking into account all of the factors outlined above, our Board unanimously determined that the Merger is advisable and fair to, and in the best interests of, Nile and its stockholders, and authorized and approved the Merger Agreement and the other transactions contemplated by the Merger Agreement, and our Board unanimously recommends that our stockholders approve the Charter Amendment Proposals in order to facilitate the Merger. Our Board also recommends that our stockholders: (i) vote "FOR" the approval of adjournments of the Special Meeting, if necessary, to solicit additional proxies if there are insufficient votes to approve the Charter Amendment Proposals; and (ii) vote "FOR" the approval, on a nonbinding, advisory basis, of the "golden parachute" compensation that may be paid or become payable to our named executive officers in connection with the consummation of the Merger.

Interests of our Executive Officers and Directors in the Merger

In considering the recommendation of our Board in favor of the adoption of the Merger Agreement and approval of the Merger, you should be aware that our executive officers and members of our Board have interests in the Merger that are different from, or in addition to, yours.

Apart from the interests described below, such persons have, to our knowledge, no material interest in the Merger apart from those of stockholders generally. Our Board was aware of, and considered the interests of, our executive officers and directors in adopting the Merger Agreement and approving the Merger.

Darlene Horton, M.D., our President and Chief Executive Officer and a member of our Board, will be entitled to receive, immediately prior to the effective time of the Merger, a number of shares of our common stock equal to 5% of the shares of common stock then outstanding on a fully-diluted basis, and Daron Evans, our Chief Financial Officer, will be entitled to receive, immediately prior to the effective time of the Merger, a number of shares of our common stock equal to4.5% of the shares of common stock then outstanding on a fully-diluted basis.

On , 2013, the last practicable trading day prior to the printing of this proxy statement, there were 52,671,963 shares of our common stock issued and outstanding on a fully-diluted basis. In addition, assuming a conversion price relating to our 2013 bridge notes in the principal amount of $450,000 $0.05 per share, which is the approximately trailing volume weighted average price of our common stock from July 8, 2013 to September 30, 2013, we will issue an additional 9,000,000 shares of common stock and warrants to purchase 9,000,000 shares of common stock, which will bring our total fully-diluted number of outstanding shares of common stock to 70,671,963. Accordingly, if the Merger had been completed on , 2013, Dr. Horton would have been entitled to receive approximately [3,533,598] shares of our common stock, having a value of approximately $176,680, and Mr. Evans would have been entitled to receive approximately [3,180,238] shares of our common stock, having a value of approximately $159,012.

For additional information regarding our agreements with Dr. Horton and Mr. Evans, please the section of this proxy statement entitled “Certain Information Regarding the Company—Executive Compensation— Employment—Employment Agreements and Post-Termination Benefits” beginning on page 89.

Regulatory Matters

We are not aware of any federal, state or local regulatory requirements that must be complied with or approvals that must be obtained prior to consummation of the Merger pursuant to the Merger Agreement, other than compliance with applicable federal and state securities laws and the filing of a certificate of merger with the Secretary of State of the State of Delaware in accordance with the General Corporation Law of the State of Delaware after all conditions to the completion of the Merger have been satisfied.

Appraisal Rights

Under the General Corporation Law of the State of Delaware, because the approval of our stockholders is not required in order for us to consummate the Merger, our stockholders are not entitled to appraisal rights in connection with the Merger and we will not independently provide our stockholders with any such right.

THE MERGER AGREEMENT

The following is a description of the material aspects of the Merger Agreement, but does not purport to describe all of the terms of the Merger Agreement. While we believe that the following description covers the material terms of the Merger Agreement, the description may not contain all of the information that is important to you. We encourage you to read carefully this entire document, including the Merger Agreement attached to this proxy statement as Appendix A, for a more complete understanding of the Merger. The following description is subject to, and is qualified in its entirety by reference to, the Merger Agreement.

The Merger Agreement has been included to provide you with information regarding its terms. It is not intended to provide any other factual information about Nile or its business. Such information can be found elsewhere in this proxy statement and in the other public filings we make with the SEC, which are available without charge at www.sec.gov.

The Merger

Pursuant to the Merger Agreement, Merger Sub will merge with and into Capricor, with Capricor surviving as a wholly-owned subsidiary of Nile. At the effective time of the Merger, all of Capricor's property, rights, privileges, powers and franchises before the Merger will vest in the surviving corporation and all of Capricor's debt, liabilities and duties before the Merger will become the debts, liabilities and duties of the surviving corporation.

Closing; Effective Time

The consummation of the Merger will take place on the second business day following the satisfaction or waiver of the conditions to the closing of the Merger set forth in the Merger Agreement and described in this proxy statement, or on such other day as Nile and Capricor may mutually agree. The Merger will become effective upon the filing of the certificate of merger with the Secretary of State of the State of Delaware, or at such later time as is agreed by Nile and Capricor and specified in the certificate of merger.

Certificate of Incorporation and Bylaws

The Merger Agreement provides that at the effective time of the Merger, the certificate of incorporation of Capricor in effect immediately prior to the effective time will be amended as a result of the Merger and, as so amended, will be the certificate of incorporation of the surviving corporation, and the bylaws of Capricor as in effect immediately prior to the effective time of the Merger will be amended and, as so amended, will be the bylaws of the surviving corporation.

Directors and Officers

The directors and officers of Capricor immediately prior to the effective time of the Merger will be the initial directors and officers, respectively, of Capricor Therapeutics.

As of the effective time of the Merger, Nile's current directors and officers will resign from their respective positions. At the effective time of the Merger, Nile's Board will be reconstituted to consist of nine directors, seven of whom shall be designated by Capricor and two of whom shall be designated by Nile and Capricor by mutual consent. It is expected that the reconstituted Board will appoint Capricor's current executive officers to serve as executive officers of Capricor Therapeutics.

Effect on Capital Stock

The Merger will have no effect on the shares of our common stock that are currently issued and outstanding. If the Merger is completed, as consideration for their shares of Capricor capital stock, we will issue to Capricor's stockholders aggregate consideration consisting of a number of shares of our common stock, which we refer to as the Merger Shares, such that, immediately following the completion of the Merger, the Capricor stockholders will hold 90 percent of our issued and outstanding shares of common stock on a fully-diluted basis.

Effect on Equity Awards

The Merger will have no effect on the options and warrants to purchase shares of our common stock that are currently outstanding. If the Merger is completed, we will assume all outstanding options to purchase shares of Capricor's common stock, which options will be converted into options to purchase shares of our common stock. All outstanding warrants to purchase shares of Capricor's common stock will automatically be terminated upon completion of the Merger in accordance with their terms.

Representations and Warranties

The Merger Agreement contains representations and warranties made by us to Capricor and by Capricor to us, and may be subject to important limitations and qualifications agreed to by the parties in connection with negotiating the terms of the Merger Agreement. The statements embodied in those representations and warranties are qualified by information in a confidential disclosure schedule that we have exchanged in connection with signing the Merger Agreement, or as otherwise provided in the Merger Agreement. While we do not believe that the confidential disclosure schedule contains information that securities laws require us to publicly disclose other than information that has already been so disclosed, the confidential disclosure schedule does contain information that modifies, qualifies and creates exceptions to the representations and warranties set forth in the attached Merger Agreement. In addition, the representations and warranties may have been included in the Merger Agreement for the purpose of allocating risk between Nile and Capricor, rather than to establish matters as facts. The confidential disclosure schedule contains information that has been included in our general prior public disclosures, as well as potential additional nonpublic information. Moreover, information concerning the subject matter of the representations and warranties may have changed since the date of the Merger Agreement, which subsequent information may or may not be fully reflected in our public disclosures. For the foregoing reasons, you should not rely on the representations and warranties contained in the Merger Agreement as statements of factual information.

At the effective time of the Merger, the representations and warranties contained in the Merger Agreement are only required to be true and correct subject to the materiality standards contained in the Merger Agreement, which may differ from what may be viewed as material by stockholders. The representations and warranties will not survive consummation of the Merger and cannot be the basis for any claim under the Merger Agreement by any party thereto after consummation of the Merger. The Merger Agreement should not be read alone, but should instead be read in conjunction with the other information regarding Nile and the Merger that is contained in this proxy statement as well as in the filings that Nile makes and has made with the SEC.

The representations and warranties contained in the Merger Agreement may or may not have been accurate as of the date they were made and we make no assertion herein that they are accurate as of the date of this proxy statement.

We made representations and warranties to Capricor regarding, among other things:

- corporate matters, including due organization and qualification to do business;
- authority relative to the execution and delivery of, and performance of obligations under, the Merger Agreement;
- consents, notices and filings required to consummate the Merger;
- our capitalization;
- title to our assets;
- real property matters, including leased properties;
- intellectual property matters, including our rights to use owned and licensed intellectual property;
- matters relating to material contracts;
- compliance with applicable laws and governmental authorizations;

- tax matters;
- environmental matters;
- reports filed with the SEC since January 1, 2010, and the financial statements included therein;
- the absence of undisclosed liabilities;
- internal controls over financial reporting, disclosure controls and procedures and required certifications;
- the valid issuance of the Merger Shares and our ownership of all outstanding shares of Merger Sub;
- the absence of pending or threatened litigation;
- the absence of any brokerage, finder's or other fee or commission in connection with the Merger; and
- the absence of bribes or other questionable payments.

Capricor made representations and warranties to us regarding, among other things:

- corporate matters, including due organization and qualification to do business;
- authority relative to the execution and delivery of, and performance of obligations under, the Merger Agreement;
- consents, notices and filings required to consummate the Merger;
- Capricor's capitalization;
- Capricor's title to its assets;
- real property matters, including leased properties;

- intellectual property matters;
- matters relating to material contracts;
- compliance with applicable laws and governmental authorizations;
- tax matters;
- environmental matters;
- Capricor's financial statements and the absence of undisclosed liabilities;
- pending or threatened litigation;
- the absence of any brokerage, finder's or other fee or commission in connection with the Merger; and
- the absence of bribes or other questionable payments.

Covenants Relating to the Conduct of Our Business

From the date of the Merger Agreement through the effective time of the Merger, we have agreed to conduct our business and operations in the ordinary course and in accordance with past practice, and in compliance with the requirements of all contracts, governmental authorizations and applicable laws, and to use our best efforts to preserve intact our current business organization, keep available the services of our current officers and employees and maintain our relations and goodwill with all suppliers, customers, landlords, creditors, licensors, licensees, employees and other parties with whom we have business relationships. During the same period, we have also agreed that we will not, among other things, do any of the following without the prior written consent of Capricor, subject to certain exceptions:

- declare, accrue, set aside or pay any dividends on, or make any other distributions (whether in cash, stock or property) in respect of, our capital stock or other equity or voting interests;

- authorize for issuance or issue and deliver any additional shares of our capital stock;

- other than the Reverse Stock Split in a ratio not to exceed 1-for-100 that is contemplated by this proxy statement, split, combine or reclassify any shares of our capital stock or other equity or voting interests, or issue or authorize the issuance of any other equity or voting interests;

- purchase, redeem or otherwise acquire any shares of our capital stock or other securities, including shares of Merger Sub;

- take any action that would result in any change of any term (including any conversion price thereof) of any of our debt securities;

- other than the Charter Amendment Proposals contemplated by this proxy statement, amend or permit the adoption of any amendments of our certificate of incorporation or bylaws;

- become a party to or authorize any acquisition transaction, recapitalization, reclassification of shares, stock split, reverse stock split or similar transaction;

- except as required by applicable law, adopt or enter into any collective bargaining agreement or other labor union contract applicable to our employees;

- adopt a plan of complete or partial liquidation or dissolution or resolutions providing for or authorizing such a liquidation or dissolution;

- form any subsidiary or acquire any interest in any other entity;

- make any capital expenditure outside the ordinary course of business, make any single capital expenditure in excess of $1,000, or make capital expenditures in excess of $5,000 in the aggregate;

- except in the ordinary course of business and consistent with past practice, enter into or become bound by, or permit any of the assets owned or used by us to become bound by, any contract, or amend or terminate, or waive or exercise any material right or remedy under, any contract;

- acquire, lease or license any right or other asset from any third party or sell or otherwise dispose of, or lease, license or encumber, any right or other asset to any third party (except in each case for assets acquired, leased, licensed, encumbered or disposed of by us in the ordinary course of business and not having a value, or not requiring payments to be made or received, in excess of $1,000 individually, or $5,000 in the aggregate), or waive or relinquish any claim or right;

- repurchase, prepay or incur any indebtedness or guarantee any indebtedness of any third party, guarantee any debt securities of any third party, enter into any "keep well" or other agreement to maintain any financial statement condition of any third party or enter into any arrangement having the economic effect of any of the foregoing;

- grant, create, incur or suffer to exist any encumbrance on our assets that did not exist on the date of the Merger Agreement or write down the value of any asset or investment on our books or records, except for depreciation and amortization in the ordinary course of business and consistent with past practice;

- make any loans, advances or capital contributions to, or investments in, any third party;

- increase in any manner the compensation or benefits of, or pay any bonus to, any of our employees, officers, directors or independent contractors, except as required by applicable law;

- hire any new employee or engage any independent contractor whose relationship may not be terminated by us on 30 days' notice or less;

- except as required by generally accepted accounting principles or applicable laws, change our fiscal year, revalue any of our material assets or make any changes in financial or tax accounting methods, principles or practices;

- settle or compromise any litigation related to or in connection with our business;

- dispose of or permit to lapse any ownership and/or right to the use of, or fail to protect, defend and maintain the ownership, validity and registration of, our intellectual property;

- dispose of or disclose to any third party, any of our confidential information;

- take or omit to take any action that could, or is reasonably likely to, result in any of our representations and warranties set forth in the Merger Agreement or any certificate delivered in connection with the closing of the Merger being or becoming untrue in any material respect at any time at or prior to the effective time of the Merger, result in any of the conditions to the consummation of the Merger set forth in the Merger Agreement not being satisfied, or breach any provision of the Merger Agreement;

- cancel any insurance policy covering us or any of our current and future subsidiaries; or

- authorize, agree, commit or enter into any contract to take any of the actions described above.

No Solicitation of Alternative Transactions

The Merger Agreement provides that we will not, and will direct and use our reasonable best efforts to cause our officers, directors, employees, agents, attorneys, accountants, advisors and representatives not to, directly or indirectly:

- solicit, initiate, encourage, induce or facilitate the making, submission or announcement of any competing acquisition proposal;

- furnish any information to any third party in connection with or in response to any competing acquisition proposal or any inquiry or indication of interest that could reasonably be expected to lead to a competing acquisition proposal;

- engage in discussions or negotiations with any third party with respect to a competing acquisition proposal;

- approve, endorse or recommend any competing acquisition proposal; or

- enter into any letter of intent or similar document or any contract contemplating or otherwise relating to any competing acquisition proposal.

However, we may provide information to or enter into discussions with a third party that makes an unsolicited acquisition proposal that did not result from our breach of our nonsolicitation obligations, so long as the third party has executed a confidentiality agreement at least as restrictive in all material respects as the confidentiality agreement entered into by us and Capricor, if:

- our Board concludes in good faith, after having taken into account the advice of our outside legal counsel, that such action is required in order for our Board to comply with its fiduciary obligations to our stockholders under applicable law;

- at least two business days prior to furnishing any such nonpublic information to, or entering into discussions with, such third party, we give Capricor written notice of the identity of such third party and of our intention to furnish nonpublic information to, or enter into discussions with, such third party; and

- at least two business days prior to furnishing any nonpublic information to such third party, we furnish such nonpublic information to Capricor (to the extent such nonpublic information has not been previously furnished by us to Capricor).

We have also agreed to promptly (within 48 hours) advise Capricor of any competing acquisition proposal, any inquiry or indication of interest that could lead to an acquisition proposal or any request for nonpublic information (including the identity of the third party making or submitting such acquisition proposal, inquiry, indication of interest or request, and the terms thereof) that is made or submitted by any third party during the period between the signing of the Merger Agreement and completion of the Merger. We have agreed to keep Capricor fully informed with respect to the status of any such acquisition proposal, inquiry, indication of interest or request and any modification or proposed modification thereto.

Notwithstanding anything in the Merger Agreement to the contrary, at any time prior to the consummation of the Merger, we may terminate the Merger Agreement and enter into an agreement with a third party to effect a superior proposal (as defined in the Merger Agreement), if:

- an unsolicited, bona fide, written offer to effect a transaction of the type referred to below in the definition of the term superior proposal is made to us and is not withdrawn;

- such unsolicited, bona fide, written offer was not obtained or made as a direct or indirect result of a breach of (or any action inconsistent with) the Merger Agreement, the nondisclosure agreement between us and Capricor, or any "standstill" or similar agreement under which we have any rights or obligations;

- at least two business days prior to any meeting of our Board at which our directors will consider whether such offer is a superior proposal, we provide Capricor with a written notice specifying the date and time of such meeting, the reasons for holding such meeting, the terms and conditions of the offer that is the basis of the potential action by our Board (including a copy of any draft definitive agreement reflecting the offer), and the identity of the third party making the offer;

- our Board determines in good faith, after obtaining and taking into account the advice of an independent financial advisor of nationally recognized reputation and after consultation with outside legal counsel, that such offer constitutes a superior proposal;

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we do not terminate the Merger Agreement for at least five business days after we provide written notice to Capricor confirming that our Board has determined that such offer is a superior proposal;

- during such five business day period, if requested by Capricor, we engage in good faith negotiations with Capricor to amend the Merger Agreement in such a manner that the offer that was determined to constitute a superior proposal no longer constitutes a superior proposal;

- at the end of such five business day period, such offer has not been withdrawn and continues to constitute a superior proposal; and

- our Board determines in good faith, after consultation with outside legal counsel, that, in light of such superior proposal, terminating the Merger Agreement and entering into a definitive agreement with respect to such superior proposal is required in order for our Board to comply with its fiduciary obligations to our stockholders under applicable law.

A competing "acquisition proposal" is defined in the Merger Agreement as any proposal relating to a transaction or series of transactions involving (i) any merger, consolidation, share exchange, business combination, issuance of securities, direct or indirect acquisition of securities, recapitalization, tender offer, exchange offer or other similar transaction involving us; (ii) any direct or indirect sale, lease, exchange, transfer, license, acquisition or disposition of a material portion of our business or assets; or (iii) our liquidation or dissolution.

A “superior proposal” is defined in the Merger Agreement as any unsolicited, bona fide written offer made by a third party to acquire, directly or indirectly, by merger or otherwise, all of the outstanding shares of our common stock or all or substantially all of our assets, which our Board determines in its reasonable judgment, taking into account, among other things, all legal, financial, regulatory, and other aspects of the proposal and the third party making the proposal and an opinion of an independent financial advisor of nationally recognized reputation (a) is more favorable from a financial point of view to our stockholders than the terms of the Merger with Capricor, and (b) is reasonably capable of being consummated; provided, however, that any such offer shall not be deemed to be a “superior proposal” if any financing required to consummate the transaction contemplated by such offer is not committed and is not reasonably capable of being obtained by such third party.

Indemnification

We have agreed that all rights to indemnification, exculpation and advancement of expenses existing in favor of Capricor’s current or former directors, officers, and employees as provided in its certificate of incorporation and bylaws and in various agreements, as in effect on the date of the Merger Agreement with respect to matters occurring at or prior to the effective time of the Merger, will survive and continue in full force and effect after the effective time of the Merger.

Conditions to Completion of the Merger

The obligations of each of Nile and Merger Sub, on the one hand, and Capricor, on the other hand, to complete the Merger depend on the satisfaction or waiver, on or prior to the effective time of the Merger, of a number of conditions, including:

- our receipt of the required stockholder votes to amend our certificate of incorporation to effect (i) the Reverse Stock Split and Share Reduction, and (ii) the Name Change;
- Capricor’s receipt of the required stockholder votes to adopt the Merger Agreement and approve the Merger;
- there being no legal or regulatory restraints or prohibitions preventing completion of the Merger;
- for each party, specified levels of compliance by the other with its representations, warranties and obligations under the Merger Agreement; and

- for each party, the other shall not have suffered a material adverse effect (as defined in the Merger Agreement), and no event shall have occurred or circumstance exist that, in combination with any other events or circumstances, could reasonably be expected to have such a material adverse effect.

The obligation of Capricor to complete the Merger is subject to the following additional conditions:

- our delivery to Capricor of a written strategic plan, in form and substance satisfactory to Capricor, regarding the movement of cenderitide forward for a Phase IB and Phase II program that includes, among other things, clinical and scientific development plans and budgets, all with appropriate timelines; and

- our entry into amendments to our license agreements for cenderitide and CU-NP with the Mayo Foundation, in form and substance satisfactory to Capricor, and our terminating certain agreements and receiving full releases from certain third parties. For additional information regarding our license agreements for cenderitide and CU-NP, please refer to the section of this proxy statement entitled “Certain Information Regarding the Company—Management’s Discussion and Analysis of Financial Condition and Results of Operations—License Agreement Commitments” beginning on page 71; and

- our outstanding payables to employees and third parties shall not exceed $100,000.

Termination

Regardless of whether our stockholders have voted to amend our certificate of incorporation to effect the Reverse Stock Split, Share Reduction and Name Change, which we refer to as the Charter Amendment Proposals, the Merger Agreement may be terminated and the Merger may be abandoned at any time prior to the effective time of the Merger:

- by the mutual written consent of Capricor and us;

- by either Capricor or us, if the Merger has not occurred on or before November 15, 2013, for any reason other than delay, nonperformance or breach of the Merger Agreement by the party seeking such termination;

- by Capricor, under circumstances that involve any of the following:

  - our uncured, or an incurable breach, of any of our representations, warranties, covenants or agreements in the Merger Agreement, which would result in the conditions to Capricor's obligation to complete the Merger not being satisfied; or

  - our violation or breach of our obligations under the nonsolicitation provisions of the Merger Agreement;

- by us, under circumstances that involve any of the following:

  - Capricor's uncured, or an incurable breach, of any of its representations, warranties, covenants or agreements in the Merger Agreement, which would result in the conditions to our obligation to complete the Merger not being satisfied; or

  - our acceptance of a superior proposal in compliance with our nonsolicitation obligations, and payment to Capricor of the $350,000 termination fee.

Termination Fee

The Merger Agreement provides that we will be required to pay Capricor a termination fee of $350,000 under circumstances that involve any of the following:

- Capricor terminates the Merger Agreement for either of the following reasons, and we enter into an agreement with respect to, or consummate within 18 months after termination, any competing "acquisition transaction" (as defined in the Merger Agreement) with respect to an "acquisition proposal" (as defined in the Merger Agreement) received by our Board prior to such termination: (i) because of our uncured, or an incurable breach, of any of our representations, warranties, covenants or agreements in the Merger Agreement, which would result in the conditions to Capricor's obligation to complete the Merger not being satisfied; or (ii) because the Merger has not occurred on or before November 15, 2013, for any reason other than delay, nonperformance or breach of the Merger Agreement by Capricor;

- Capricor terminates the Merger Agreement as a result of our violation or breach of our obligations under the nonsolicitation provisions of the Merger Agreement; or

- we terminate the Merger Agreement in connection with accepting a superior proposal (as defined in the Merger Agreement).

For the purposes of the above termination fee discussion, "acquisition transaction" means any transaction of the type referred to in the definition of a competing "acquisition proposal" set forth above under "The Merger Agreement—No Solicitation of Alternative Transactions."

PROPOSAL NO. 1:

APPROVAL OF AMENDMENT OF CERTIFICATE OF INCORPORATION

TO EFFECT A REVERSE STOCK SPLIT AND SHARE REDUCTION

Overview

Stockholder approval of Proposal No.1 is a condition to our completion of the Merger. If Proposal No. 1 is approved and enacted, the reverse stock split will result in the combination of our common stock at a ratio not to exceed 1-for-100. This means that, at the greatest split ratio, every 100 shares of common stock outstanding prior to the effective time of the reverse stock split will represent only one share of common stock after the reverse stock split. The Share Reduction will decrease the number of shares of our common stock authorized for issuance from 100 million shares to 50 million shares, and will decrease the number of shares of our preferred stock authorized for issuance from 10 million shares to 5 million shares. Because the reduction in the authorized number of shares of our common stock and preferred stock will not be effected on a 1-for-100 basis, the reverse stock split will have the effect of creating additional unreserved shares of our authorized common stock. The par value of our common stock will remain unchanged at $0.001 per share following the reverse stock split. Except for any changes resulting from the treatment of fractional shares as discussed below, each stockholder will hold the same percentage of common stock outstanding immediately after the reverse stock split as such stockholder did immediately prior to the reverse stock split.

Reasons for the Reverse Stock Split and Share Reduction

In addition to the reasons discussed above with respect to the Merger, the Board believes that a reverse stock split and reduction in the number of authorized shares of our common stock and preferred stock is desirable and should be approved by our stockholders for a number of reasons, including:

- ***Increase in Shares Available for Issuance.*** Because the reduction in the number of authorized shares of our common stock and preferred stock is not being effected on a 1-for-100 basis, the reverse stock split will have the effect of providing us with an increased number of shares of common stock available for future issuance.

- ***Increase in Eligible Investors.*** A reverse stock split will allow a broader range of institutions to invest in our stock (namely, funds that are prohibited from buying stocks whose price is below a certain threshold), potentially increasing the trading volume and liquidity of our common stock.

Increased Analyst and Broker Interest. A reverse stock split will help increase analyst and broker interest in our stock as their policies can discourage them from following or recommending companies with low stock prices. Because of the trading volatility often associated with low-priced stocks, many brokerage houses and institutional investors have adopted internal policies and practices that either prohibit or discourage them from investing in such stocks or recommending such stocks to their customers. Some of those policies and practices may also function to make the processing of trades in low-priced stocks economically unattractive to brokers. Additionally, because brokers' commissions on transactions in low-priced stocks generally represent a higher percentage of the stock price than commissions on higher-priced stocks, the current average price per share of our common stock can result in individual stockholders paying transaction costs representing a higher percentage of their total share value than would be the case if the share price were substantially higher.

- ***Increased Possibility of Regaining NASDAQ Listing.*** We were delisted from the NASDAQ Capital Market in May 2011 and trading in our common stock has since been conducted on the OTC Markets. Stocks traded on 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. Among other things, one hurdle to our ability to regain listing on the NASDAQ Capital Market is the requirement that the bid price of our common stock, which was $ on the record date for the Special Meeting, must exceed $4.00 per share. By potentially increasing our stock price, the reverse stock split may increase the possibility that our stock could again be listed on the NASDAQ Capital Market.

Certain Risks Associated With the Reverse Stock Split

There can be no assurance that the total market capitalization of our common stock after the proposed reverse stock split will be equal to or greater than the total market capitalization before the proposed reverse stock split or that the per share market price of our common stock following the reverse stock split will either exceed or remain higher than the current per share market price.

There can be no assurance that the market price per share of our common stock after the reverse stock split will rise or remain constant in proportion to the reduction in the number of shares of our common stock outstanding before the reverse stock split. For example, based on the market price of our common stock on , 2013 of $ per share, following a 1-for-100 reverse stock split, there can be no assurance that the post-split market price of our common stock will be $ per share or greater. Accordingly, the total market capitalization of our common stock after the proposed reverse stock split may be lower than the total market capitalization before the proposed reverse stock split and, in the future, the market price of our common stock following the reverse stock split may not exceed or remain higher than the market price prior to the proposed reverse stock split. In many cases, the total market capitalization of a company following a reverse stock split is lower than the total market capitalization before the reverse stock split.

A decline in the market price for our common stock after the reverse stock split may result in a greater percentage decline than would occur in the absence of a reverse stock split, and the liquidity of our common stock could be adversely affected following a reverse stock split.

The market price of our common stock will also be based on our performance and other factors, some of which are unrelated to the number of shares outstanding. If a reverse stock split is effected and the market price of our common stock declines, the percentage decline as an absolute number and as a percentage of our overall market capitalization may be greater than would occur in the absence of a reverse stock split. In many cases, both the total market capitalization of a company and the market price of a share of such company's common stock following a reverse stock split are lower than they were before the reverse stock split. Furthermore, the liquidity of our common stock could be adversely affected by the reduced number of shares that would be outstanding after the reverse stock split. If approved and effected, the reverse stock split will result in some stockholders owning "odd lots" of less than 100 shares of our common stock. Brokerage commissions and other costs of transactions in odd lots are generally somewhat higher than the costs of transactions in "round lots" of even multiples of 100 shares.

The proposed reverse stock split may not increase our stock price, which would prevent us from realizing some of the anticipated benefits of the reverse stock split, including the possibility of regaining listing on the NASDAQ Capital Market.

The effect of a reverse stock split upon the market price of our common stock cannot be predicted with any certainty, and the history of similar stock splits for companies in like circumstances is varied. It is possible that the per share price of our common stock after the reverse stock split will not rise in proportion to the reduction in the number of shares of our common stock outstanding resulting from the reverse stock split. In particular, there can be no assurance that the market price per post-reverse split share will exceed the $4.00 minimum bid price that is required to regain listing on the NASDAQ Capital Market. Even if the market price per post-reverse split share does exceed $4.00, there can be no assurance that we will be able to satisfy the other listing standards of the NASDAQ Capital Market.

Principal Effects of the Reverse Stock Split

***Corporate Matters*.** If approved by our stockholders, the reverse stock split will have the following effects:

- the number of shares of our common stock issued and outstanding will be reduced proportionately based on the reverse split ratio;

- based on the reverse split ratio, proportionate adjustments will be made to the per share exercise price and the number of shares issuable upon the exercise of all outstanding options and warrants entitling the holders thereof to purchase shares of our common stock, which will result in approximately the same aggregate price being required to be paid for such options or warrants upon exercise of such options or warrants immediately preceding the reverse stock split; and

- the number of shares of common stock reserved for issuance under our existing stock option plans will be reduced proportionately based on the reverse split ratio.

The following table contains approximate pro forma information relating to our outstanding common stock, comparing (i) current information as of the record date and assuming the completion of the Merger, and (ii) the effectiveness of the reverse stock split at possible ratios of 1-for-25, 1-for-50, 1-for-75 and 1-for-100, a reduction in the number of authorized shares of common stock to 50,000,000 shares, and assuming the completion of the Merger.

	Current	1-for-25	1-for-50	1-for-75	1-for-100
Authorized shares	100,000,000	50,000,000	50,000,000	50,000,000	50,000,000
Issued and outstanding shares	43,520,563	1,740,823	870,411	580,274	435,206
Reserved for issuance pursuant to Nile common stock warrants	8,049,695	321,988	160,994	107,329	80,497
Reserved for options outstanding under 2005 Plan	1,101,705	44,068	22,034	14,689	11,017
Shares issuable to Nile management upon the Merger	6,713,836	268,553	134,277	89,518	67,138
Shares issuable upon conversion of Nile 2013 bridge notes, including shares underlying warrants issuable upon such conversion (1)	18,000,000	720,000	360,000	240,000	180,000
Shares to be issued in the Merger	428,741,131	17,149,645	8,574,823	5,716,548	4,287,411
Shares reserved for issuance pursuant to Capricor options and warrants	267,731,065	10,709,243	5,354,621	3,569,748	2,677,311
Authorized and unreserved shares	(673,857,995)	19,045,680	34,522,840	39,681,893	42,261,420

(1) For purposes of this table, numbers assume the bridge notes issued by us in March 2013 in the principal amount of $450,000 will convert into shares of our common stock at a price of $0.05 per share (which represents the approximate volume weighted average price of our common stock from July 8, 2013 through September 30, 2013), or 9,000,000 shares, plus an additional 9,000,000 shares that will be issuable upon the exercise of warrants to be issued to the holders of such notes.

When effected, the reverse stock split will be effected simultaneously for all of our common stock and the ratio will be the same for all of our common stock. The reverse stock split will affect all of our stockholders uniformly and will not affect any stockholder's percentage ownership interest in our company, except to the extent that the reverse stock split results in any of our stockholders owning a fractional share. As described below, stockholders holding fractional shares will be entitled to cash payments in lieu of such fractional shares. Such cash payments will reduce the number of post-split stockholders to the extent there are stockholders presently holding fewer shares than the size of the ratio of the reverse split. For example, if the reverse split is effected at a ratio of 1-for-100, any stockholder who currently holds fewer than 100 shares will no longer hold any shares of our common stock following the effective time of the reverse split. This, however, is not the purpose for which we are effecting the reverse stock split. Common stock

outstanding following the reverse stock split will remain fully paid and non-assessable. We will continue to be subject to the periodic reporting requirements of the Exchange Act.

Fractional Shares. No scrip or fractional certificates will be issued in connection with any reverse stock split. Stockholders who otherwise would be entitled to receive fractional shares because they hold, as of a date prior to the effective time of the reverse split, a number of shares of our common stock not evenly divisible by the reverse split ratio will be entitled, upon surrender of certificate(s) representing such shares, to a cash payment in lieu thereof. The cash payment will equal the product obtained by multiplying (a) the fraction to which the stockholder would otherwise be entitled by (b) the last quoted bid price of our common stock on the day immediately prior to the effective time of the reverse stock split, as reported on the OTC Markets. The ownership of a fractional interest will not give the holder thereof any voting, dividend or other rights except to receive payment therefor as described herein.

Stockholders should be aware that, under the escheat laws of the various jurisdictions where our stockholders reside, where we are domiciled and where the funds will be deposited, sums due for fractional interests that are not timely claimed after the effective time may be required to be paid to the designated agent for each such jurisdiction. Thereafter, stockholders otherwise entitled to receive such funds may have to seek to obtain them directly from the state to which they were paid.

Accounting Matters. Any reverse stock split will not affect the par value of our common stock, which is $0.001 per share. As a result, as of the effective time of any reverse stock split, the stated capital on our balance sheet attributable to our common stock will be reduced proportionately based on the reverse split ratio, and the additional paid-in capital account will be credited with the amount by which the stated capital is reduced. The per share net income or loss and net book value of our common stock will be restated because there will be fewer shares of common stock outstanding.

Procedure for Effecting Reverse Stock Split and Share Reduction and Exchange of Stock Certificates

In order to effect a reverse stock split and reduction in the total number of authorized shares, we will file an amendment to our certificate of incorporation with the Secretary of State of the State of Delaware to amend our existing certificate of incorporation in substantially the form attached hereto as Appendix B. The reverse stock split and reduction in the total number of authorized shares will become effective at the time specified in the amendment. Beginning at the effective time of the Merger, each certificate representing shares of common stock prior to the effective time of the reverse stock split will be deemed for all corporate purposes to evidence ownership of the resulting combined number of shares following such reverse stock split.

As soon as practicable after the effective time, stockholders will be notified that the reverse stock split has been effected. We expect that our transfer agent, American Stock Transfer & Trust Company, LLC, will act as exchange agent for purposes of implementing the exchange of stock certificates. Holders of pre-split common shares will be asked to surrender to the exchange agent certificates representing such shares in exchange for certificates representing post-split shares of common stock in accordance with the procedures to be set forth in the letter of transmittal that we send to our stockholders. No new certificates will be issued to a stockholder until such stockholder has surrendered such stockholder's outstanding certificate(s), together with the properly completed and executed letter of transmittal,

to the exchange agent. Any pre-split share certificates submitted for transfer, whether pursuant to a sale, other disposition or otherwise, will automatically be exchanged for certificates representing post-split shares. STOCKHOLDERS SHOULD NOT DESTROY ANY STOCK CERTIFICATE(S) AND SHOULD NOT SUBMIT ANY CERTIFICATE(S) UNTIL REQUESTED TO DO SO.

Federal Income Tax Consequences of the Reverse Stock Split

The following is a summary of certain material federal income tax consequences of the reverse stock split, does not purport to be a complete discussion of all of the possible federal income tax consequences of the reverse stock split and is included for general information only. Further, it does not address any state, local or foreign income or other tax consequences. Also, it does not address the tax consequences to holders that are subject to special tax rules, such as banks, insurance companies, regulated investment companies, personal holding companies, foreign entities, nonresident alien individuals, broker-dealers and tax-exempt entities. The discussion is based on the provisions of the United States federal income tax law as of the date hereof, which is subject to change retroactively as well as prospectively. This summary also assumes that the pre-split shares of common stock were, and the post-split shares of common stock will be, held as a “capital asset,” as defined in the Internal Revenue Code of 1986, as amended (i.e., generally, property held for investment). The tax treatment of a stockholder may vary depending upon the particular facts and circumstances of such stockholder. Each stockholder is urged to consult with such stockholder's own tax advisor with respect to the tax consequences of the reverse stock split.

Other than the cash payments for fractional shares discussed below, no gain or loss should be recognized by a stockholder upon such stockholder's exchange of certificates representing pre-split shares for post-split shares pursuant to the reverse stock split. The aggregate tax basis of the post-split shares received in the reverse stock split (including any fraction of a post-split share deemed to have been received) will be the same as the stockholder's aggregate tax basis in the pre-split shares exchanged therefore. In general, stockholders who receive cash in exchange for their fractional share interests in the post-split shares as a result of the reverse stock split will recognize gain or loss based on their adjusted basis in the fractional share interests redeemed. The stockholder’s holding period for the post-split shares will include the period during which the stockholder held the pre-split shares surrendered in the reverse stock split.

Our view regarding the tax consequences of the reverse stock split is not binding on the Internal Revenue Service or the courts. ACCORDINGLY, EACH STOCKHOLDER SHOULD CONSULT WITH HIS OR HER OWN TAX ADVISOR WITH RESPECT TO ALL OF THE POTENTIAL TAX CONSEQUENCES TO HIM OR HER OF THE REVERSE STOCK SPLIT.

Effective Date of Amendment to Certificate of Incorporation

As discussed above under “Procedure for Effecting Reverse Stock Split and Share Reduction and Exchange of Stock Certificates,” if approved by the stockholders, it is anticipated that the amendment to the certificate of incorporation contemplated by Proposal No. 1 will become effective upon the filing of a certificate of amendment, in substantially the form attached hereto as Appendix B, with the Secretary of State of the State of Delaware, which such filing is expected to occur as soon as practicable after the Special Meeting.

Reservation of Rights by the Board of Directors

If approved, the Board reserves the right to abandon the amendment contemplated by Proposal No. 1.

No Appraisal Rights

Under the General Corporation Law of the State of Delaware, our stockholders are not entitled to appraisal rights with respect to Proposal No. 1, and we will not independently provide stockholders with any such rights.

Vote Required and Recommendation of the Board

The amendment to our certificate of incorporation contemplated by Proposal No. 1 requires the affirmative vote of a majority of our outstanding shares of common stock as of the record date for the Special Meeting. You may vote either "FOR" or "AGAINST" Proposal No. 1, or you may "ABSTAIN." Abstentions and broker non-votes will have the same effect as "AGAINST" votes.

THE BOARD OF DIRECTORS UNANIMOUSLY RECOMMENDS THAT

YOU VOTE "FOR" PROPOSAL NO. 1.

PROPOSAL NO. 2:

APPROVAL OF AMENDMENT OF CERTIFICATE OF INCORPORATION

TO CHANGE THE COMPANY'S NAME

Overview; Reasons for the Name Change

Stockholder approval of Proposal No.2 is a condition to our completion of the Merger. If Proposal No. 2 is approved and enacted, and contingent upon consummation of the Merger, our corporate name will be changed from "Nile Therapeutics, Inc." to "Capricor Therapeutics, Inc." We, together with Capricor's management, believe that the corporate name change will better align our corporate name with our business and mission if the Merger is consummated.

Procedure for Effecting the Name Change

In order to effect the name change, we will file an amendment to our certificate of incorporation with the Secretary of State of the State of Delaware to amend our existing certificate of incorporation in substantially the form attached hereto as Appendix B. The name change will become effective at the time specified in the amendment.

Principal Effects of the Name Change

The change of our name to Capricor Therapeutics, Inc. will not affect in any way the validity of currently outstanding stock certificates or the trading of our securities. Our stockholders will not be required to surrender or exchange any of the Nile stock certificates that they currently hold. Stockholders with certificated shares may continue to hold their existing certificates or may elect to receive new certificates reflecting the name change by tendering the old certificates to our transfer agent, American Stock Transfer & Trust Company, LLC.

If the Merger is consummated and the name change is effected, we intend to change our OTC Markets trading symbol from "NLTX" to "CAPR."

Effective Date of Amendment to Certificate of Incorporation

As discussed above under "Procedure for Effecting the Name Change," if approved by the stockholders, it is anticipated that the amendment to the certificate of incorporation contemplated by Proposal No. 2 will become effective upon the filing of a certificate of amendment, in substantially the form attached hereto as Appendix B, with the Secretary of State of the State of Delaware, which such filing is expected to occur as soon as practicable after the Special Meeting.

Reservation of Rights by the Board of Directors

If approved, the Board reserves the right to abandon the amendment contemplated by Proposal No. 2.

No Appraisal Rights

Under the General Corporation Law of the State of Delaware, our stockholders are not entitled to appraisal rights with respect to Proposal No. 2, and we will not independently provide stockholders with any such rights.

Vote Required and Recommendation of the Board

The amendment to our certificate of incorporation contemplated by Proposal No. 2 requires the affirmative vote of a majority of our outstanding shares of common stock as of the record date for the Special Meeting. You may vote either "FOR" or "AGAINST" Proposal No. 2, or you may "ABSTAIN." Abstentions and broker non-votes will have the same effect as "AGAINST" votes.

THE BOARD OF DIRECTORS UNANIMOUSLY RECOMMENDS THAT

YOU VOTE "FOR" PROPOSAL NO. 2.

PROPOSAL NO. 3:

APPROVAL OF ADJOURNMENT OF SPECIAL MEETING

Overview

Because stockholder approval of Proposal No.1 and Proposal No. 2, which we refer to as the Charter Amendment Proposals, are conditions to our completion of the Merger, we are asking our stockholders to approve a proposal authorizing us to adjourn the Special Meeting, if necessary, to solicit additional proxies if there are insufficient votes to approve the Charter Amendment Proposals.

Vote Required and Recommendation of the Board

Stockholder approval of Proposal No. 3 requires the number of votes cast in favor of Proposal No. 3 to exceed the number of votes cast against Proposal No. 3. You may vote either “FOR” or “AGAINST” Proposal No. 3, or you may “ABSTAIN.” Abstentions and broker non-votes will have no effect on the outcome of the vote.

THE BOARD OF DIRECTORS UNANIMOUSLY RECOMMENDS THAT

YOU VOTE “FOR” PROPOSAL NO. 3.

PROPOSAL NO. 4:

ADVISORY VOTE ON "GOLDEN PARACHUTE" COMPENSATION

Overview

The Dodd-Frank Wall Street Reform and Consumer Protection Act and Section 14A of the Exchange Act require that we provide our stockholders the opportunity to vote on a nonbinding, advisory resolution regarding the compensation that may be paid or become payable to our named executive officers in connection with the consummation of the Merger. The description of the payments contained in the section of this proxy statement entitled "Summary Term Sheet—Interests of our Executive Officers and Directors in the Merger" is intended to comply with Item 402(t) of Regulation S-K, which requires disclosure regarding the compensation that may be paid or become payable to our named executive officers in connection with the consummation of the Merger.

Accordingly, our stockholders are being asked to approve the following resolution:

"**RESOLVED**, that the stockholders approve, on a nonbinding, advisory basis, the compensation that may be paid or become payable to our named executive officers in connection with the consummation of the Merger as disclosed pursuant to Item 402(t) of Regulation S-K and as further described in the section of this proxy statement entitled "Summary Term Sheet—Interests of our Directors and Executive Officers in the Merger."

Approval of this proposal is not a condition to completion of the Merger, and the vote with respect to this proposal is advisory only and will not be binding on us. If the Merger is completed, the "golden parachute" compensation may be paid to our named executive officers in accordance with the terms of their respective compensation arrangements even if our stockholders fail to approve this proposal.

Vote Required and Recommendation of the Board

Stockholder approval of Proposal No. 4 requires the number of votes cast in favor of Proposal No. 4 to exceed the number of votes cast against Proposal No. 4. You may vote either "FOR" or "AGAINST" Proposal No. 4, or you may "ABSTAIN." Abstentions and broker non-votes will have no effect on the outcome of the vote.

THE BOARD OF DIRECTORS UNANIMOUSLY RECOMMENDS THAT

YOU VOTE "FOR" PROPOSAL NO. 4.

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CERTAIN INFORMATION REGARDING THE COMPANY

OUR 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 I 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 I clinical trial, we had planned to initiate a Phase II 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 acquiror 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, Inc., with Nile Therapeutics, Inc. remaining as the surviving corporation and a wholly-owned subsidiary of SMI. In accordance with the terms of the transaction, the stockholders of Nile Therapeutics, Inc. exchanged all of their shares of Nile Therapeutics, Inc. 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, Inc.. Additionally, following the merger, Nile Therapeutics, Inc., or Old Nile, was merged with and into SMI, and SMI changed its name to Nile

Therapeutics, Inc., or Nile, and adopted the business plan of Old Nile. 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 proxy statement.

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 I 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 worsen 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 age 65, 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 I 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 I study in healthy volunteers was consistent with several pre-clinical findings, including that cenderitide was associated with increased levels of plasma current good manufacturing practices, or 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 I 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 I study indicated 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 II 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 II study indicated 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 II 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 II 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 II clinical trials, in which cenderitide was delivered through continuous i.v. infusion. The Phase II 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 I study and provided the subcutaneous pumps used in the study.

The top line results from the Phase I 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 I 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 II 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 II study, with 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. For more than 12 months, we have sought either additional financing to fund such activities or a collaboration or other strategic agreement with another company that would provide the capital needed to fund further development of our product candidates. Prior to our entry into the Merger Agreement with Capricor, we had been unsuccessful in securing such additional capital. The proposed Merger with Capricor is subject to several conditions, including the approval of our stockholders of a reverse split of our common stock at a ratio not to exceed 1-for-100. If such conditions are not satisfied, we may be unable to complete the proposed Merger and would be forced to liquidate the Company. See "Risk Factors – Risks Relating to the Merger – We do not have the necessary resources to develop our product candidates…."

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 Agreements

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

We 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 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 our 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 are 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, as long as Dr. Burnett continues to serve as chairman of our Scientific Advisory Board.

In addition to the potential milestone payments discussed above, the Cenderitide License Agreement requires us to issue shares of our 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, 2008, we received $482,235 in grant income for which we issued to the Mayo Foundation 63,478 shares (representing $182,236) of our 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. 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) for 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 Cenderitide License 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 the Mayo Foundation that allows us to maintain our rights to cenderitide.

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 certain 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 II clinical trial of the licensed product. The 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. Additionally, Dr. Burnett has applied for funding through the Mayo Foundation's Discovery-Translation Program. In the event Dr. Burnett is awarded funding through this program, and the funding is used for the development of the licensed product based on the patent applications, we agreed to grant to the Mayo Foundation an equivalent dollar value in warrants to purchase shares of our common stock. The number of shares purchasable under these warrants will be calculated using the Black-Scholes option-pricing model and the warrants will include a cashless exercise provision with language to be negotiated in good faith between the parties.

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

Pursuant to the CU-NP License Agreement, we have exclusive rights to one U.S. patent and three 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 CU-NP License Agreement, but we cannot guarantee that we will be able to reach an agreement with the Mayo Foundation that allows us to maintain our rights to CU-NP.

Medtronic Collaboration Agreement

In February 2011, we entered into a Clinical Trial Funding Agreement with Medtronic. Pursuant to the agreement, Medtronic provided the funding and equipment necessary for us to conduct our Phase I 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 with Medtronic, 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 I 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 1 clinical trial shall be jointly owned by us and Medtronic, 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 such jointly-owned 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 jointly-owned intellectual property.

Pursuant to its terms, the agreement expired in February 2012, following the completion of the Phase I clinical trial and the delivery of data and reports related to such study, but remains subject to certain provisions that are intended to survive expiration of the agreement.

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 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 investigational new drug application, or 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 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 and 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. However, we are aware that Zumbro Discovery, Inc., a privately-held start-up company based in Rochester, Minnesota and founded by researchers at Mayo Clinic, has rights to and is developing a pre-clinical compound in the same class as cenderitide for the treatment of hypertension. Daron Evans, our Chief Financial Officer, currently serves as interim chief executive officer of Zumbro Discovery on a consulting basis. Mr. Evans does not receive any cash compensation from Zumbro Discovery for his services, but was granted shares of common stock of Zumbro Discovery. In addition, prior to the formation of Zumbro Discovery, Mr. Evans provided consulting services to Mayo Clinic relating to the technology subsequently licensed to Zumbro Discovery, for which he was paid fees of approximately $17,000.

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 from 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.

Properties

As of December 31, 2012, our principal offices were located at 4 West 4th Ave., Suite 400, San Mateo, California 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.

Legal Proceedings

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

MARKET FOR OUR COMMON STOCK AND RELATED STOCKHOLDER MATTERS

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." On July 5, 2013, the last full trading day prior to the public announcement of the proposed Merger, our common stock closed at a price of $0.06. On , 2013 the last practicable trading day prior to the printing of this proxy statement, our common stock closed at a price of $. The following table lists the high and low sale prices 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 and the current fiscal year.

	High	Low
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
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, 2013		
First Quarter	$0.04	$0.20
Second Quarter	0.11	0.05
Third Quarter	0.03	0.07

Holders

According to the records of our transfer agent, American Stock Transfer & Trust Company, as of , 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.

Securities Authorized for Issuance Under Equity Compensation Plans

Our Amended and Restated 2005 Stock Option Plan (the "Plan"), which is currently our only equity compensation plan, has been approved by our stockholders. The following table sets forth certain information as of December 31, 2012 with respect to the Plan:

Plan Category	Number of Securities to be Issued Upon Exercise of Outstanding Options, Warrants and Rights (A)	Weighted-Average Exercise Price of Outstanding Options, Warrants and Rights (B)	Number of Securities Remaining Available for Future Issuance Under Equity Compensation Plans (Excluding Securities Reflected in Column (A))
Equity compensation plans approved by security holders:			
Amended and Restated 2005 Stock Option Plan	4,582,636	$ 1.24	4,525,932
Total	4,582,636	$ 1.24	4,525,932

Description of Our Capital Stock

General

Our certificate of incorporation authorizes us to issue 110,000,000 shares of capital stock, par value $0.001 per share, comprised of 100,000,000 shares of common stock, and 10,000,000 shares of preferred stock, none of which is currently outstanding.

Our board of directors has the authority to issue the authorized but unissued shares of our common stock without action by our stockholders. The issuance of such shares would reduce the percentage ownership held by current stockholders. Our board of directors also has the authority to fix and determine the relative rights and preferences of preferred shares, as well as the authority to issue such shares, without further stockholder approval. As a result, our board of directors could authorize the issuance of a series of preferred stock that is senior to the common stock and that would grant to holders preferred rights to our assets upon liquidation, the right to receive dividends, additional registration rights, anti-dilution protection, and the right to the redemption of such shares, together with other rights, none of which would be afforded holders of our common stock.

As of September , 2013, we have issued and outstanding approximately:

- 43,520,563 shares of our common stock;
- options to purchase 1,101,705 shares of our common stock at a weighted average exercise price of $1.01 per share; and
- warrants to purchase 8,049,695 shares of our common stock at a weighted average exercise price of $1.13 per share.

During July and August 2013, we issued an aggregate of 458,332 shares of our common stock in consideration of the cancellation of previously outstanding warrants to purchase an aggregate of 2,750,000 shares of our common stock.

Common Stock

The holders of our common stock are entitled to one vote for each share on all matters voted on by stockholders, including elections of directors, and, except as otherwise required by law or provided in any resolution adopted by our board with respect to any series of preferred stock, the holders of such shares possess all voting power. Our certificate of incorporation does not provide for cumulative voting in the election of directors. Subject to any preferential rights of any outstanding series of our preferred stock created by our board from time to time, the holders of common stock are entitled to such dividends as may be declared from time to time by our board from funds available therefore and upon liquidation are entitled to receive pro rata all assets available for distribution to such holders. Our common stock is not redeemable.

The holders of our common stock have no preemptive rights. The rights, preferences and privileges of holders of common stock are subject to, and may be adversely affected by, the rights of the holders of shares of any series of preferred stock which we may designate and issue in the future.

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 proxy statement. 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 our Annual Report on Form 10-K for the year ended December 31, 2012 and in Item 1A of Part II of our Quarterly Report on Form 10-Q for the quarter ended June 30, 2013, 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 I 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 I clinical trial, we had planned to initiate a Phase II 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 acquiror 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 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. As we proceed with the clinical development of cenderitide and as we further develop CU-NP, our second product candidate, our research and development expenses will further increase. To the extent we are successful in acquiring additional product candidates for our development pipeline, our need to finance further research and development activities will continue increasing. Accordingly, our success depends not only on the safety and efficacy of our product candidates, but also on our ability to finance the development of the products. Our major sources of working capital have been proceeds from private and public sales of our common stock, and debt financings.

On July 7, 2013, we entered into the Merger Agreement with Capricor, a privately held company based in Los Angeles, California, and Bovet Merger Corp., a Delaware corporation and our wholly-owned subsidiary ("Merger Sub"). Upon completion of the Merger, each outstanding share of Capricor capital stock, and each security convertible into Capricor common stock, will automatically convert into the right to receive a number of shares of our common stock or, as applicable, securities convertible into our common stock, such that, after giving effect to the Merger, the holders of Capricor capital stock immediately prior to the Merger will hold, in the aggregate, 90% of the total number of shares of our common stock on a fully-diluted basis. Capricor is a company whose mission is to improve the treatment of heart disease by commercializing cardiac stem cell therapies for patients.

The Merger Agreement contains customary representations and warranties by us and Capricor with respect to each company's business and the transactions contemplated by the Merger Agreement. Closing of the Merger is conditioned on, among other things, accuracy of such representations and warranties, approval of the Merger Agreement by the requisite number of Capricor's stockholders, conversion of each share of Capricor preferred stock into Capricor common stock, and stockholder approval of an amendment to our certificate of incorporation authorizing a reverse split of our common stock at a ratio not to exceed 1-for-100 and a reduction in the authorized capital of the company. In addition, the closing of the Merger is conditioned on us entering into an amendment to our technology license agreement with the Mayo Foundation and evidence of payment or other satisfaction in full (including releases) of our accrued liabilities and obligations (with the exception of obligations not to exceed the aggregate amount of $100,000, which may remain outstanding through the effective time of the Merger). The Merger Agreement may be terminated for certain reasons, including by either party if the closing thereof does not occur on or prior to November 15, 2013. The Merger Agreement also contains other customary terms and provisions as are common in similar agreements.

We do not have the capital resources available to continue the development of our product development programs or to otherwise remain in business. For more than 12 months, we have sought either additional financing to fund such activities or a collaboration or other strategic agreement with another company that would provide the capital needed to fund further development of our product candidates. Prior to our entry into the Capricor Merger Agreement, we had been unsuccessful in securing such additional capital. The proposed Merger with Capricor is subject to several conditions, including the approval of our stockholders of a reverse split of our common stock at a ratio not to exceed 1-for-100. If such conditions are not satisfied, we may be unable to complete the proposed Merger, in which case we would be forced to liquidate the Company.

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

Three and Six Months Ended June 30, 2013 Compared to Three and Six Months Ended June 30, 2012

General and Administrative Expenses. G&A expenses for the three months ended June 30, 2013 and 2012 were approximately $0.4 million and $0.4 million, respectively. There were no significant changes in G&A expenses for the three months ended June 30, 2013 as compared to the three months ended June 30, 2012.

G&A expenses for the six months ended June 30, 2013 and 2012 were approximately $0.6 million and $0.9 million, respectively. The decrease in G&A expenses compared to the same period in 2012 is primarily due to a decrease of approximately $0.1 million in stock compensation costs and a decrease of approximately $0.1 million in reduced professional fees due to the reduced use of outside management consultants during the first quarter of 2013 compared to the same period of 2012. Additionally, there was a decrease of approximately $0.1 million in general operating expenses during the six months ended June 30, 2013 as compared to the same period in 2012. This was primarily due to reduced operating activities in 2013 as we cut as many costs as possible to preserve remaining funds.

Research and Development Expenses. R&D expenses for the three months ended June 30, 2013 and 2012 were approximately $0.04 million and $0.3 million, respectively. This decrease of approximately $0.3 million over the same period of 2012 is primarily due to the fact that during the second quarter of 2012, we were still conducting some clinical development activities of cenderitide while during the second quarter of 2013, we had almost no development activities as we have wound down development of our products. This resulted in a decrease of approximately $0.2 million in development costs. Additionally, we had a reduction of approximately $0.1 million in compensation costs, including stock compensation, due to having no R&D employees during the three months ended June 30, 2013, compared to one employee during the same period in 2012.

R&D expenses for the six months ended June 30, 2013 and 2012 were approximately $0.1 million and $0.8 million, respectively. This decrease of approximately $0.7 million over the same period of 2012 is primarily due to the fact that during the six months ended June 30, 2012, we were still conducting some clinical development activities of cenderitide, while during the second quarter of 2013, we had almost no development activities as we have wound down development of our products. This resulted in a decrease of approximately $0.5 million in development costs. Additionally, we had a reduction of approximately $0.2 million in compensation costs, including stock compensation, due to having no R&D employees during the six months ended June 30, 2013, compared to one employee during the same period in 2012.

Cenderitide. Since acquiring our rights to cenderitide in 2006, we have incurred approximately $19.9 million in expenses directly relating to the program through June 30, 2013. All development of cenderitide is on hold pending

the results of our efforts to pursue strategic alternatives, including the proposed Merger with Capricor. After consummation of the proposed Merger with Capricor, the new management of Capricor Therapeutics will determine whether to continue the development of cenderitide.

CU-NP. Since acquiring our rights to CU-NP in June 2008, we have incurred a total of approximately $0.7 million in expenses directly relating to the program through June 30, 2013. All development of CU-NP is on hold pending the results of our efforts to pursue strategic alternatives, including the proposed Merger with Capricor. After consummation of the proposed Merger with Capricor, the new management of Capricor Therapeutics will determine whether to continue the development of CU-NP.

Our expenditures on current and future clinical development programs, particularly our cenderitide program, are expected to be substantial, and to increase particularly in relation to our available capital resources. In addition, assuming we complete the proposed Merger with Capricor, the research and development expenditures of the resulting company will increase substantially with the addition of Capricor's R&D programs. 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, among other things:

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

Interest Income. Interest income for the three and six months ended June 30, 2013 and 2012 was approximately $104, $144, $596 and $840, respectively. This decrease in interest income in 2013 over the same periods in 2012 is primarily due to lower average cash balances in 2013 than 2012 levels.

Collaboration Income. As a result of our February 2011 collaboration agreement with Medtronic pursuant to which Medtronic reimbursed us for R&D expenditures that we made in connection with our Phase I trial of cenderitide, we recognized income of $0, $0, $0 and $0.2 million for the three and six months ended June 30, 2013 and 2012, respectively. All amounts due under the agreement were paid as of February 2012, at which time the agreement expired.

Interest Expense. Interest expense for the three and six months ended June 30, 2013 and 2012 was approximately $0.1 million, $0.1 million, $0 and $0, respectively. The increase in interest expense in 2013 as compared to the same periods in 2012 of approximately $0.1 million is due to the convertible notes issued in March 2013. During 2012, there were no interest bearing notes outstanding.

Other Income (Expense). Other expense for the three months ended June 30, 2013 was approximately $0.1 million, as compared to other income of approximately $0.4 million for the three months ended June 30, 2012, due primarily to an approximately $0.2 million increase in the warrant liability in connection with the 2013 convertible notes during the three months ended June 30, 2013. This increase in the warrant liability valuation was driven primarily by the increased probability of issuance as a result of the announced merger with Capricor. There was no such warrant liability in connection with the convertible notes during the same period of 2012 as the notes were not issued until March 2013. Offsetting this increase in other expense for the three months ended June 30, 2013 was other income of approximately $0.1 million relating to a decrease in the April 2012 warrant liability, primarily as a result of the decrease in the Company’s stock price. During the second quarter of 2012, there was other income of approximately $0.4 million as a result of a decrease in the warrant liability relating to the April 2012 warrants. This decrease in the warrant liability during the three months ended June 30, 2012 was primarily driven by a decrease in the Company’s stock price.

Other expense for the six months ended June 30, 2013 was approximately $0.2 million, as compared to other income of approximately $0.4 million for the six months ended June 30, 2012, due primarily to an approximately $0.2 million increase in the warrant liability in connection with the 2013 convertible notes issued in March 2013. This increase in

the warrant liability valuation was driven primarily by the increased probability of issuance as a result of the announced merger with Capricor. There was no such warrant liability in connection with the convertible notes during the six months ended June 30, 2012 as the notes were not issued until March 2013. During the six months ended June 30, 2012, there was other income of approximately $0.4 million as a result of a decrease in the warrant liability relating to the April 2012 warrants. This decrease in the warrant liability during the six months ended June 30, 2012 was primarily driven by a decrease in the Company's stock price.

Year Ended December 31, 2012 Compared to Year Ended December 31, 2011

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 million for the year ended December 31, 2012 compared to the same period of 2011 due to requiring reduced services from outside consultants due to limited operations. There was also an approximately $0.1 million savings for the year ended December 31, 2012 compared to the same period in 2011 as a result of no longer being listed on the NASDAQ Capital Market 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, we were actively conducting clinical development activities of cenderitide and in 2012, we were 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.

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

Collaboration income. Collaboration income for the years ended December 31, 2012 and 2011 was 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 I 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 attributable 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 June 30, 2013 and December 31, 2012, and our net decrease in cash and cash equivalents for the six months ended June 30, 2013 and 2012 (the amounts stated are expressed in thousands):

Liquidity and capital resources	June 30, 2013	December 31, 2012
Cash and cash equivalents	$ 229	$ 47
Working capital deficiency	$ (726)	$ (159)
Stockholders' equity (deficit)	$ (1,223)	$ (167)

	Six Months Ended June 30,	
Cash flow data	2013	2012
Cash used in:		
Operating activities	$ (200)	$ (1,456)
Investing activities	-	-
Cash provided by:		
Financing activities	383	1,194
Net increase (decrease) in cash and cash equivalents	$ 183	$ (262)

Our total cash resources as of June 30, 2013 was $0.2 million compared to $0.05 million as of December 31, 2012. As of June 30, 2013, we had approximately $1.5 million in liabilities, of which approximately $0.5 million represented a noncash warrant liability, and $0.7 million in net working capital deficit. We incurred a net loss of approximately $1.1 million and had negative cash flow from operating activities of approximately $0.2 million for the six months ended June 30, 2013. Since August 1, 2005 (inception) through June 30, 2013, we have incurred an aggregate net loss of approximately $47.8 million, while negative cash flow from operating activities has amounted to $35.1 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 II trial. We estimate that this Phase II 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 II 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. As discussed above, in July 2013, we entered into the Merger Agreement with Capricor, a company whose mission is to improve the treatment of heart disease by commercializing cardiac stem cell therapies for patients. Although the resulting company will be primarily focused on the development of Capricor’s current technologies, we believe the resulting company will also be able to eventually continue the development of our cenderitide and CU-NP programs if the new management determines that it is in the best interests of the company to do so. Other than our Merger Agreement with Capricor, we have not been able to secure an agreement or other commitment from any collaboration partner with respect to the continued development of our cenderitide and CU-NP programs. All further clinical and other development activities for our cenderitide and CU-NP programs are on hold pending the completion of the proposed Merger with Capricor, and thereafter at such time as the resulting company has the additional capital needed to fund such activities and determines that such programs should be reinstated.

From inception through June 30, 2013, 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 with 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 middle of the third quarter of 2013. Further, beyond our general corporate activities, we need substantial additional capital to fund our planned Phase II 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 costs 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 "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 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 by us without penalty upon 30 days' written notice, on the terms set forth in the 2013 Notes. The 2013 Notes are secured by a blanket lien on our assets pursuant to a security agreement dated March 15, 2013.

The 2013 Notes contain an optional conversion feature that enables the holder to convert all outstanding shares into shares of our common stock at a conversion price per share equal to the average daily Closing Price (as defined in the 2013 Notes) over the ten consecutive trading days preceding the date of such prepayment notice. The optional conversion feature goes into effect only if the Company chooses to prepay the 2013 Notes in whole or in part without penalty upon 30 days' prior written notice to the holder (and conversion must occur within this 30 day period).

Upon a Change of Control (as defined in the 2013 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 2013 Note will automatically convert, as of immediately prior to the effective time of the Change of Control, into shares of our common stock at an automatic conversion price per share equal to the volume weighted average price of our common stock from July 8, 2013 through September 30, 2013, and (B) we will also issue to each 2013 Note holder a five-year warrant entitling the holder to purchase, at an exercise price equal to the automatic conversion price applicable to the 2013 Notes, that number of shares of our common stock obtained by dividing (1) the sum of the outstanding principal under the applicable 2013 Note by (2) the automatic conversion price applicable to the 2013 Notes.

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

April 2012 Financing. On April 4, 2012, we closed an offering with certain purchasers pursuant to which we sold 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 our 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 our common stock. The total gross proceeds from the offering were $1.34 million, before deducting selling commissions and other offering expenses of approximately $0.2 million. In connection with the offering, we engaged Roth Capital Partners, LLC, or Roth, to serve as the placement agent. Pursuant to the terms of the placement agent agreement, we paid Roth a cash fee equal to 7% of the gross proceeds received by us, or approximately $0.1 million, plus a non-accountable expense allowance of $35,000. Richard B. Brewer, our Executive Chairman, Joshua A. Kazam, our former President and Chief Executive Officer and a current 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 common stock and warrants to purchase 206,250 shares of common stock for an aggregate purchase price of $110,000.

The offer and sale of the shares of common stock and warrants was made pursuant to our shelf registration statement on Form S-3 (SEC File No. 333-165167), which became effective on March 12, 2010. Pursuant to the subscription agreements that we entered into with the purchasers in the April 2012 financing, we agreed to file, within 15 business days after the closing of the offering, a registration statement covering the issuance of the shares of our common stock upon exercise of the warrants and the subsequent resale of such shares (the "Additional Registration Statement"), and to cause such registration statement to be declared effective within 90 days following the closing of the offering. In the event the Additional Registration Statement was not declared effective by the SEC within such 90-day period, we agreed to pay liquidated damages to each purchaser in the amount of 1% of such purchaser's aggregate investment amount for each 30-day period until the Additional Registration Statement is declared effective, subject to an aggregate limit of 12% of such purchaser's aggregate investment amount. The Additional Registration Statement was filed on April 25, 2012 and was declared effective by the SEC on May 7, 2012.

License Agreement Commitments

Cenderitide License Agreement

Pursuant to our license agreement with the Mayo Foundation for Medical Education and Research (the "Mayo Foundation") for cenderitide, 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. Subsequent milestones achieved will require us to make additional milestone payments to the Mayo Foundation. We agreed to make contingent cash payments up to an aggregate amount 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 with the Mayo Foundation, 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. 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) for 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 license agreement without cause upon 90 days' written notice.

As of June 30, 2013, we were not in compliance with several terms of the cenderitide license agreement with the Mayo Foundation, 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 the Mayo Foundation that allows us to maintain our rights to cenderitide.

CU-NP License Agreement

On June 13, 2008, we entered into a second license agreement with the Mayo Foundation pursuant to which we acquired the rights to CU-NP. Under the terms of the agreement, the Mayo Foundation granted us a worldwide, exclusive license for the rights to commercially develop CU-NP for all therapeutic indications. We also were granted the rights to improvements to CU-NP and the 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, prior to 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 amount 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 CU-NP license agreement, we must also pay the Mayo Foundation an annual maintenance fee and a percentage of net sales of licensed products.

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) for our insolvency or bankruptcy, (iii) if we challenge the validity or enforceability of any of the patents in any manner, or (iv) upon receipt of notice from us that we have terminated all development efforts under the agreement. We may terminate the CU-NP license agreement without cause upon 90 days' written notice.

As of June 30, 2013, 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 the Mayo Foundation that allows us to maintain our rights to cenderitide.

Collaboration Agreement

In February 2011, we entered into a Clinical Trial Funding Agreement with Medtronic. Pursuant to the agreement, Medtronic provided the funding and equipment necessary for us to conduct a Phase I 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 with Medtronic, 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 Medtronic agreement until the earlier of: (i) three months following delivery to Medtronic of a final database with respect to the Phase I trial; and (ii) 15 months after the date of the agreement. The final database was delivered to Medtronic on November 19, 2011.

The agreement also provided that intellectual property conceived in or otherwise resulting from the performance of the Phase 1 clinical trial will be jointly owned by us and Medtronic, and that we will 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 jointly-owned intellectual property. The agreement further provided that, if the parties fail to enter into a definitive commercial license agreement with respect to cenderitide, then each party will have a right of first negotiation to license exclusive rights to any jointly-owned intellectual property. As of May 2012, three filed patent applications are considered jointly-owned intellectual property.

Pursuant to its terms, the agreement expired in February 2012, following the completion of the Phase I clinical trial and the delivery of data and reports related to such study, but remains subject to certain provisions that are intended to

survive expiration of the agreement. We received the final reimbursement of $195,500 in February 2012 and a total of $1,550,000 over the life of the Medtronic agreement. All amounts are recorded as collaboration income in our condensed statement of operations.

Merger Agreement with Capricor, Inc.

On July 7, 2013, we entered into the Merger Agreement with Capricor, which was amended on September 27, 2013. Upon completion of the Merger, each outstanding share of Capricor common stock, and each security convertible into Capricor common stock, will automatically convert into the right to receive a number of shares of our common stock or, as applicable, securities convertible into our common stock, such that, after giving effect to the Merger, the holders of Capricor capital stock immediately prior to the Merger will hold, in the aggregate, 90% of the total number of shares of the Company's common stock on a fully-diluted basis. See the discussions set forth in this proxy statement under the captions "The Merger" and "The Merger Agreement."

Off -Balance Sheet Arrangements

There were no off-balance sheet arrangements as of June 30, 2013.

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.

Collaboration Income

In February 2011, we entered into a collaboration agreement whereby we were reimbursed for work performed on behalf of the collaborator upon the achievement of certain milestones. We recorded all of these expenses as research and development expenses and the reimbursements upon the achievement of the milestones as income.

We recognize 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, we defer the milestone payment and recognize it as income over the remaining estimated period of performance under the contract as we complete our performance obligations.

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 contract research organizations, or 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 CROs 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 issued to non-employees (including consultants and all members of our Scientific Advisory Board) as consideration for goods or services received by us 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 service periods.

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

Warrant Liability

We account for the warrants issued in connection with the April 2012 financing and the embedded derivative warrant liability contained in the 2013 Notes 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 adjust 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 the April 2012 financing has been 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 our future expected stock prices, and their resulting probabilistic valuation. The fair value of the embedded derivative warrant liability contained in the 2013 Notes was estimated by management using the Black-Scholes option-pricing model.

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 proxy statement:

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	49	Director

Darlene Horton, M.D. has served as our President, Chief Executive Officer, and Director since August 2012, and previously served as our Chief Medical Officer from June 2012 until her appointment as President and Chief Executive Officer. Previously, she served as Chief Medical Officer of Itero Biopharmaceuticals, Inc., a venture-backed biosimilar company. As a co-founder of Itero, she helped raise $17 million in capital and lead the development team. The product was successfully out-licensed to Watson Pharmaceuticals. Previous to Itero, Dr. Horton served as Senior Vice President, Clinical Research at Scios, Inc., a Johnson & Johnson (J&J) company. During her 12 year tenure at Scios, she was the clinical lead for Natrecor®, a commercial product indicated for the treatment of acute heart failure. Dr. Horton led the Natrecor® program from late-stage development through FDA approval and commercialization, and was also part of the senior management team at the time of Scios's $2.4 billion acquisition by J&J. Dr. Horton also served as the Head of the Cardiovascular Therapeutic Area Center of Excellence for J&J pharmaceutical companies. Dr. Horton completed her fellowship in Pediatric Cardiology at the Cardiovascular Research Institute at the University of California San Francisco (UCSF), her residency in Pediatrics at UCSF, her M.D. at the University of Florida (UF) College of Medicine, and a B.S. in microbiology at UF. She is currently Assistant Clinical Professor in Pediatrics at UCSF.

Daron Evans has been our Chief Financial Officer since September 2007 and was our Chief Operating Officer from February 2007 to September 2007. Mr. Evans has over 15 years of professional experience in drug development, corporate strategy and financial management. From 2006 to 2007, Mr. Evans served as Director of Business Assessment at Vistakon, a Johnson & Johnson company, where he led efforts to improve R&D efficiency and speed to market. From 2004 to 2006, he was a Director of Portfolio & Business Analytics for Scios R&D, a Johnson & Johnson company, where he was responsible for financial controls and reporting for a portfolio of six clinical stage programs and five preclinical stage programs. While at Scios, Mr. Evans also served as Project Manager for the

European Registration Trial of NATRECOR® (nesiritide), a peptide indicated for the treatment of acute decompensated heart failure. Mr. Evans also has experience as co-founder of a biotechnology diagnostic company, and has worked as a Management Consultant in the pharmaceutical industry with Booz Allen Hamilton. Mr. Evans received his M.B.A. from The Fuqua School of Business at Duke University, his M.S. in Biomedical Engineering from Southwestern Medical School and University of Texas at Arlington and his B.S. in Chemical Engineering from Rice University.

Arie S. Belldegrun, M.D., FACS has been a director of Nile since September 2009. Dr. Belldegrun is Director of the Institute of Urologic Oncology at UCLA, Professor of Urology and Chief of the Division of Urologic Oncology. He holds the Roy and Carol Doumani Chair in Urologic Oncology at the David Geffen School of Medicine at the University of California, Los Angeles (UCLA). In 1997, Dr. Belldegrun founded Agensys, Inc., an early-stage privately-held biotechnology company based in Los Angeles, California, that is focused on the development of fully human monoclonal antibodies to treat solid tumor cancers in a variety of cancer targets. Dr. Belldegrun served as founding Chairman of Agensys from 1997 to 2002 and then as a director until December 2007, when the company was acquired by Astellas Pharma. Dr. Belldegrun served as Vice Chairman of the Board and Chairman of the Scientific Advisory Board of Cougar Biotechnology, Inc., a Los Angeles-based biopharmaceutical company, from December 2003 until its acquisition by Johnson & Johnson in July 2009. Since March 2008, Dr. Belldegrun has served as a director of Arno Therapeutics, Inc., a publicly-held, New Jersey-based biopharmaceutical company focused on the treatment of cancer patients. Since February 2013, Dr. Belldegrun has also served as a director of Teva Pharmaceutical Industries Ltd., a publicly-held, Israeli-based pharmaceutical company. Dr. Belldegrun has also served as Executive Chairman of the Board of Directors of Kite Pharma, Inc., a privately-held, California-based biotechnology company dedicated to the development of pioneering immune-based cancer therapies, since its inception in 2009. From February 2004 to December 2009, Dr. Belldegrun also served on the Board of Directors of Hana Biosciences, Inc., a publicly-held biopharmaceutical company. Dr. Belldegrun also serves as an officer of the managing member of Two River Consulting, LLC, an organization that provides management, consulting and operational services for development stage biotechnology companies, including Nile. Dr. Belldegrun's prior experience also includes serving as principal investigator of more than 50 clinical trials of anti-cancer drug candidates and therapies. Dr. Belldegrun completed his M.D. at the Hebrew University Hadassah Medical School in Jerusalem, his post graduate fellowship at the Weizmann Institute of Science and his residency in Urological Oncology at Harvard Medical School. Prior to UCLA, Dr. Belldegrun was at the National Cancer Institute/NIH as a research fellow in surgical oncology under Steven A. Rosenberg, M.D., Ph.D. He is certified by the American Board of Urology and is a Fellow of the American College of Surgeons and the American Association of Genitourinary Surgeons.

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

Peter M. Kash, Ed.D. has served as a director of Nile since its inception in August 2005, and also currently serves as the Chairman of the Nominating & Corporate Governance Committee and as a member of the Compensation Committee. Dr. Kash has also served as a director of Arno Therapeutics, Inc., a publicly-held, New Jersey-based biopharmaceutical company focused on the treatment of cancer patients, since its inception in August 2005. From December 2004 to December 2006, Dr. Kash served as a director of Javelin Pharmaceuticals, Inc., a publicly-held biopharmaceutical company focused on pain management. Dr. Kash is also the President and Chairman of Riverbank Capital Securities, Inc., a broker-dealer registered with the Financial Industry Regulatory Authority, or FINRA. From

1992 until 2004, Dr. Kash was a Senior Managing Director of Paramount BioCapital, Inc., a FINRA member broker-dealer, specializing in conducting private financings for public and private development stage biotechnology companies as well as Paramount BioCapital Investments, LLC, a venture capital company. Dr. Kash also served as Director of Paramount Capital Asset Management, Inc., the general partner of several biotechnology-related hedge funds and as member of the General Partner of the Orion Biomedical Fund, LP, a private equity fund. Dr. Kash received his B.S. in Management Science from SUNY Binghamton, his M.B.A. in Banking and International Finance from Pace University, and his doctorate in education at Yeshiva University.

Joshua A. Kazam has served as a director of Nile since its inception in August 2005, and previously served as our non-employee President and Chief Executive Officer from June 2009 until August 2012. Mr. Kazam also serves as an officer of the managing member of Two River Consulting, LLC, an organization that provides management, consulting and operational services for development stage biotechnology companies, including Nile. Mr. Kazam also serves as an officer and director of Riverbank Capital Securities, Inc. From 1999 to 2004, Mr. Kazam was a Managing Director of Paramount BioCapital, Inc. where he was responsible for ongoing operations of venture investments, and the Director of Investment for the Orion Biomedical Fund, LP., a private equity fund. Mr. Kazam also co-founded and served as a director of Arno Therapeutics, Inc., a publicly-held, New Jersey-based biopharmaceutical company focused on the treatment of cancer patients, from its inception in August 2005 until September 2010. Mr. Kazam currently serves as a director of Kirax Corporation (formerly Tigris Pharmaceuticals, Inc.) and Kite Pharma, Inc., both privately-held biotechnology companies, and Velcera, Inc., a privately-held specialty pharmaceutical company. Mr. Kazam is a graduate of the Wharton School of the University of Pennsylvania.

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

Gregory W. Schafer has served as a director of Nile since January 2008, and also serves as Chairman of the Audit Committee. Mr. Schafer has served as Chief Financial Officer of Jennerex, a biotherapeutics company focused in oncology, since June 2010. From April 2009 to June 2010, Mr. Schafer served as an independent consultant to private and public biotechnology companies. From April 2006 to January 2009, Mr. Schafer served as the Vice President and Chief Financial Officer of Onyx Pharmaceuticals, Inc., a publicly-held, California-based biopharmaceutical company dedicated to developing innovative therapies that target the molecular mechanisms that cause cancer. Prior to Onyx, from 2004 to 2006, Mr. Schafer served as a consultant to several private and public biotechnology companies. From 1997 to 2004, Mr. Schafer held various executive positions at Cerus Corporation, a public biotechnology company, including Vice President and Chief Financial Officer. Prior to joining Cerus, Mr. Schafer worked as a management consultant for Deloitte & Touche LLP. Mr. Schafer holds an M.B.A from the Anderson Graduate School of Management at UCLA and a BSE in Mechanical Engineering from the University of Pennsylvania.

Experience, Qualifications, Attributes and Skills of Directors

We look to our directors to lead us through our continued growth as an early-stage public biopharmaceutical company. Our directors bring their leadership experience from a variety of life science companies and professional backgrounds which we require to continue our growth and to bring value to our stockholders. Dr. Horton brings a wealth of clinical and operational expertise to us, including a deep knowledge of the heart failure space in particular, and her position as our President and Chief Executive Officer allows her to provide a unique insight into our development and growth. Dr. Kash, Mr. Kazam and Dr. Mieyal have venture capital or investment banking backgrounds and offer expertise in financing and growing small biopharmaceutical companies. Each of Dr. Belldegrun, Dr. Kash, Mr. Kazam, Dr. Mieyal and Mr. Schafer have significant experience with early stage private and public companies and bring depth of knowledge in building stockholder value, growing a company from inception and navigating significant corporate transactions and the public company process. Mr. Granadillo has extensive experience in the pharmaceutical industry, allowing him to contribute his significant operational experience. As a result of his experience in the role of chief financial officer of public companies, Mr. Schafer also brings extensive finance, accounting and risk management knowledge to us.

Independence of the Board of Directors

In determining whether the members of our board of directors and its committees are independent, we have elected to use the definition of "independence" set forth in the listing standards of the NASDAQ Stock Market. After considering all relevant relationships and transactions, our Board, in consultation with legal counsel, has determined that Messrs. Granadillo and Schafer and Drs. Kash and Mieyal are "independent" within the meaning of the applicable listing standards of the NASDAQ Stock Market. In making this determination with respect to Dr. Kash, the Board considered Dr. Kash's status as a principal of Riverbank Capital Securities, Inc., or Riverbank, which we engaged as our placement agent in connection with a private placement financing transaction in 2011. In connection with the 2011 private placement, we issued to Riverbank a five-year warrant to purchase 250,000 shares of our common stock, of which Dr. Kash was allocated a warrant relating to 19,500 shares, which had a value of approximately $16,000 based on a Black-Scholes analysis. Given the value of the warrant issued to Dr. Kash for his services on behalf of Riverbank in connection with the 2011 financing, the Board concluded that the warrant would not impair Dr. Kash's ability to exercise independent judgment.

Board Leadership Structure and Risk Management

Following the death of our former executive chairman of the Board in August 2012, we have not had a chairperson of the Board due to the changed focus of our management team. Since early 2012 we have not had sufficient capital with which to continue development activities relating to our cenderitide and CU-NP programs. Instead, our executive management was focused almost entirely on securing additional capital, whether through a financing or strategic transaction. During this period, our CEO has remained in close contact with the Board, both on an informal basis and through frequent telephone meetings in order to keep the Board apprised of developments in our pursuit of additional capital. As a result of the changed focus of our management team and the lack of clinical development activities, the Board did not believe it was necessary to appoint a successor to the role of Board chair. We believe this structure has allowed the Board to fulfill its oversight responsibility and fiduciary duties to our stockholders.

The Board of Directors believes that oversight of Nile's risk management efforts is a key responsibility that is shared by the entire Board. The Board regularly reviews risk management information regarding Nile's liquidity and operations. Board members regularly receive financial statements which are then discussed at the quarterly meetings of the Board. In addition, management frequently has informal discussions with Board members regarding risk management.

Board Committees and Meetings

The Board held 12 meetings (all by telephone conference) in 2012. All directors attended at least 75% of the aggregate meetings of the Board and of the committees on which they served. A director who is unable to attend a meeting is expected to notify the Chairman of the Board or the Chairman of the appropriate Committee in advance of such meeting, and, whenever possible, participate in such meeting via teleconference. In addition, directors are expected to make reasonable efforts to attend annual meetings of stockholders. One member of the Board attended our last annual meeting of stockholders, which was held on May 10, 2011.

The Board has established three standing committees: the Audit Committee, the Compensation Committee and the Nominating & Corporate Governance Committee. Each Committee of the Board has a charter that has been assessed and approved by the Board. The charters of these Committees are available on our website at www.nilethera.com. The following table provides membership for each of the Board committees:

Name of Committee	Membership
Audit	Mr. Granadillo, Dr. Mieyal and Mr. Schafer (Chair)
Compensation	Mr. Granadillo (Chair), Dr. Kash and Dr. Mieyal

Nominating & Corporate Governance Dr. Kash (Chair)

Audit Committee

The current members of our Audit Committee are Mr. Schafer (Chair), Mr. Granadillo and Dr. Mieyal. Our Board has determined that Mr. Schafer qualifies as an "audit committee financial expert," as defined by applicable rules of the SEC. The Board has further determined that Mr. Schafer is "independent" within the meaning of the applicable listing standard of the NASDAQ Stock Market. The Audit Committee held three meetings (all by telephone conference) in 2012.

Report of the Audit Committee

The following is the report of our Audit Committee with respect to our audited financial statements for the fiscal year ended December 31, 2012.

The purpose of the Audit Committee is to assist the Board in its general oversight of our financial reporting, internal controls and audit functions. The Audit Committee Charter describes in greater detail the full responsibilities of the Committee. The Audit Committee is comprised solely of independent directors as defined by the listing standards of the NASDAQ Stock Market.

Management is responsible for the preparation, presentation and integrity of our financial statements; accounting and financial reporting principles; establishing and maintaining disclosure controls and procedures (as defined in Exchange Act Rule 13a-15(e)); establishing and maintaining internal control over financial reporting (as defined in Exchange Act Rule 13a-15(f)); evaluating the effectiveness of disclosure controls and procedures; evaluating the effectiveness of internal control over financial reporting; and evaluating any change in internal control over financial reporting that has materially affected, or is reasonably likely to materially affect, internal control over financial reporting. Nile's independent registered public accounting firm, Crowe Horwath LLP, is responsible for performing an independent audit of the Company's financial statements in accordance with the standards of the Public Company Accounting Oversight Board. The primary function of the Audit Committee is to assist the Board of Directors in its oversight of Nile's financial reporting, internal controls, and audit functions.

The Audit Committee has reviewed and discussed our audited financial statements with management and Crowe Horwath LLP, our independent registered public accounting firm. The Audit Committee has also discussed with Crowe Horwath LLP the matters required to be discussed by Statement on Auditing Standards No. 61, as amended (AICPA, *Professional Standards*, Vol. 1. AU section 380), as adopted by the Public Company Accounting Oversight Board in Rule 3200T, which includes, among other items, matters related to the conduct of the audit of our financial statements. The Audit Committee has also received written disclosures and the letter from Crowe Horwath LLP required by Rule 3526 of the Public Company Accounting Oversight Board, which relates to the auditor's independence from us and our related entities, and has discussed with Crowe Horwath LLP their independence from us.

Based on the review and discussions referred to above, the Audit Committee recommended to our Board that our audited financial statements be included in our Annual Report on Form 10-K for the fiscal year ended December 31, 2012.

Gregory W. Schafer (Chair)
Pedro Granadillo
Paul A. Mieyal, Ph.D.

Compensation Committee

The current members of our Compensation Committee are Mr. Granadillo (Chair), Dr. Kash and Dr. Mieyal. The Compensation Committee oversees our compensation policies, plans and programs. The Compensation Committee reviews and approves corporate performance goals and objectives relevant to the compensation of our executive officers and other senior management; reviews and recommends to the Board the compensation and other terms of employment of our Chief Executive Officer and our other executive officers; and makes recommendations to the Board concerning the issuance of awards pursuant to our equity incentive plans. In making its compensation decisions and recommendations, the Compensation Committee may take into account the recommendations of our Chief Executive Officer. Other than giving such recommendations, however, the Chief Executive Officer has no formal role and no authority to determine the amount or form of executive compensation. The Compensation Committee is authorized to engage compensation consultants to provide advice or recommendations with respect to executive or director compensation. However, no compensation consultants were engaged during 2012. The Compensation Committee held three meetings (either in person or by telephone conference) in 2012.

Nominating & Corporate Governance Committee

Dr. Kash is currently the only member of our Nominating & Corporate Governance Committee. The Nominating & Corporate Governance Committee did not meet in 2012.

Process for Identifying and Evaluating Director Nominees

The Board is responsible for nominating directors for election at annual meetings of stockholders or to fill vacancies on the Board. The Board has delegated the selection and nomination process to the Nominating & Corporate Governance Committee, with the expectation that other members of the Board, and of management, will be requested to take part in the process as appropriate.

Procedures for Re-Nomination of a Current Director

The Nominating & Corporate Governance Committee reviews, at least annually, the performance of each current director and considers the results of such evaluation when determining whether or not to re-nominate such director for an additional term. In addition to reviewing the qualifications outlined in the "Director Qualifications" section below, in determining whether to recommend a director for re-election, the Nominating & Corporate Governance Committee also considers the director's past attendance at meetings and participation in and contributions to the activities of the Board. As part of this analysis, the Nominating & Corporate Governance Committee will also take into account the nature of and time involved in a director's service on other boards or committees. Following this review, the Nominating & Corporate Governance Committee nominated and recommended that all current members of the Board of Directors be elected to the Board of Directors.

New Candidates

Generally, the Nominating & Corporate Governance Committee identifies candidates for director nominees in consultation with management, through the use of search firms or other advisers, through recommendations submitted by stockholders or through such other methods as the Nominating & Corporate Governance Committee deems to be helpful to identify candidates. Once candidates have been identified, the Nominating & Corporate Governance Committee confirms that the candidates meet all of the minimum qualifications for director nominees established by the Nominating & Corporate Governance Committee. The Nominating & Corporate Governance Committee may gather information about the candidates through interviews, detailed questionnaires regarding experience, background and independence, comprehensive background checks from a qualified company of its choosing, or any other means that the Nominating & Corporate Governance Committee deems to be helpful in the evaluation process.

An initial reviewing member of the Nominating & Corporate Governance Committee will make a preliminary determination regarding whether a potential candidate is qualified to fill a vacancy or satisfy a particular need. If so, the full Nominating & Corporate Governance Committee will make an investigation and interview the potential candidate, as necessary, to make an informed final determination. The Nominating & Corporate Governance Committee will meet as a group to discuss and evaluate the qualities and skills of each candidate, both on an

individual basis and taking into account the overall composition and needs of the Board of Directors. The policy of the Nominating & Corporate Governance Committee is that there be no difference in the manner by which it evaluates director nominees, whether nominated by management, by a member of the Board or by a stockholder. Based on the results of the evaluation process, the Nominating & Corporate Governance Committee recommends candidates for the Board's approval as director nominees for election to the Board. The Nominating & Corporate Governance Committee also recommends candidates for the Board's appointment to the Committees of the Board.

Director Qualifications

The Nominating & Corporate Governance Committee is responsible for reviewing with the Board from time to time the appropriate qualities, skills and characteristics desired of members of the Board in the context of the needs of the business and current make-up of the Board. In evaluating the suitability of individual candidates (both new candidates and current members of the Board), the Nominating & Corporate Governance Committee, in nominating candidates for election, or the Board, in approving (and, in the case of vacancies, appointing) such candidates, takes into account many factors, including:

· personal and professional integrity, ethics and values;

- experience in corporate management, such as serving as an officer or former officer of a publicly-held company, and a general understanding of marketing, finance and other elements relevant to the success of a publicly-traded company in today's business environment;
- experience in our industry and with relevant social policy concerns;
- experience as a board member of another publicly-held company;
- academic expertise in an area of our operations; and
- practical and mature business judgment, including ability to make independent analytical inquiries.

Each candidate nominee must possess fundamental qualities of intelligence, honesty, good judgment, high ethics and standards of integrity, fairness and responsibility. A candidate must also have substantial or significant business or professional experience or an understanding of life sciences, finance, marketing, financial reporting, international business or other disciplines relevant to our business.

The Nominating & Corporate Governance Committee and the Board evaluate each individual in the context of the Board as a whole, with the objective of assembling a group that can best perpetuate the success of our business and represent stockholder interests through the exercise of sound judgment using its diversity of experience in these various areas. We do not have a diversity policy; however, as summarized above, the Nominating & Corporate Governance Committee seeks to nominate candidates with a diverse range of knowledge, experience, skills, expertise and other qualities that will contribute to the overall effectiveness of the Board.

Procedures for Recommendation of Director Nominees by Stockholders

The Nominating & Corporate Governance Committee will consider director candidates who are recommended by our stockholders. Stockholders, in submitting recommendations to the Nominating & Corporate Governance Committee for director candidates, must comply with our bylaws as well as the procedures established by the Nominating & Corporate Governance Committee, which provide that the person or group submitting the recommendation must provide the Nominating & Corporate Governance Committee with a notice that sets forth:

- all information relating to each nominee that is required to be disclosed in solicitations of proxies for election of directors in an election contest, or that is otherwise required, in each case, pursuant to Regulation 14A under the Exchange Act;

- information regarding the relationship between the recommending stockholder or recommending stockholder group and the nominee;

- whether the nominee or any immediate family member of the nominee has, during the year of the nomination or the preceding three fiscal years, accepted directly or indirectly certain consulting, advisory or other compensatory fees from the recommending stockholder or any member of the group of recommending stockholders or any affiliate of any such holder or member;

- such information as may be reasonably required to determine whether the nominee is qualified to serve on the Audit Committee of the Board;

- such information as may be reasonably required to determine whether the nominee complies with the standards of independence established by the NASDAQ Stock Market, if applicable;

- each nominee’s written consent to being named in a proxy statement as a nominee and to serving as a director if elected;

- the name and address of the recommending stockholder or recommending stockholder group giving the notice (and the beneficial owner, if any, on whose behalf the nomination is made);

- the class and number of shares of our capital stock that are owned beneficially and of record by such recommending stockholder or recommending stockholder group (and such beneficial owner, if applicable);

- a representation that the recommending stockholder or members of the recommending stockholder group are holders of record of our stock entitled to vote at such meeting and intend to appear in person or by proxy at the meeting to propose such nomination; and

- a representation whether the recommending stockholder or recommending stockholder group (or such beneficial owner, if any), intends to solicit proxies from stockholders in support of such nomination.

We may request from the recommending stockholder or recommending stockholder group such other information as may reasonably be required to determine whether each person recommended by a stockholder or stockholder group as a nominee meets the minimum director qualifications established by the Board and to enable us to make appropriate disclosures to stockholders entitled to vote in the next election of directors. Nominees are required to make themselves reasonably available to be interviewed by the Nominating & Corporate Governance Committee and members of management, as determined appropriate by the Nominating & Corporate Governance Committee. We will not accept a stockholder recommendation for a nominee if the recommended candidate's candidacy or, if elected, Board membership, would violate applicable state law, federal law or the rules of any exchange or market on which our securities are listed or traded.

Notices should be directed to the attention of the Corporate Secretary, Nile Therapeutics, Inc., 63 Bovet Rd., Suite 421, San Mateo, California 94402.

Section 16(a) Beneficial Ownership Reporting Compliance

Section 16(a) of the Exchange Act requires our directors, officers and persons who own more than ten percent of a registered class of our equity securities to file reports of ownership and reports of changes in ownership with the SEC. Such persons are required by SEC regulations to furnish us with copies of all Section 16(a) forms they file. Based solely on our review of the copies of the forms submitted to us during the last fiscal year, we believe that, during the last fiscal year, all such reports were timely filed.

Code of Business Conduct and Ethics

The Board has adopted a Code of Business Conduct and Ethics, or the Code, that applies to all directors, officers, employees, consultants, contractors and agents, wherever they are located and whether they work for us on a full- or part-time basis. The Code was designed to help such directors, employees and other agents resolve ethical issues encountered in the business environment. The Code covers topics such as conflicts of interest, compliance with laws,

confidentiality of Company information, encouraging the reporting of any illegal or unethical behavior, fair dealing and use of Company assets.

A copy of the Code, as adopted by the Board, is available at the Corporate Governance page of our website at www.nilethera.com. Please note that information contained on our website is not incorporated by reference in, or considered to be a part of, this proxy statement. We may post amendments to or waivers of the provisions of the Code, if any, made with respect to any directors and employees on that website.

Communications with the Board of Directors

We provide a process for stockholders to send communications to the Board, the non-management members as a group, or any of the directors individually. Stockholders may contact any of the directors, including the non-management directors, by writing to: c/o the Corporate Secretary, Nile Therapeutics, Inc., 63 Bovet Rd., Suite 421, San Mateo, California 94402. All communications will be compiled by our Corporate Secretary and submitted to the Board or the individual directors, as applicable, on a periodic basis.

Communications from our officers or directors and proposals submitted by stockholders to be included in our definitive proxy statement, pursuant to Rule 14a-8 of the Exchange Act (and related communications) will not be viewed as a stockholder communication. Communications from our employees or agents will be viewed as stockholder communications only if such communications are made solely in such employee’s or agent’s capacity as a stockholder.

EXECUTIVE COMPENSATION

The following summary compensation table reflects cash and non-cash compensation for the 2012 and 2011 fiscal years awarded to or earned by (i) each individual serving as a principal executive officer during the fiscal year ended December 31, 2012; (ii) each individual that served as an executive officer at the end of the fiscal year ended December 31, 2012 and whose total compensation during such fiscal year exceeded $100,000; and (iii) one additional individual whose total compensation during such fiscal year exceeded $100,000 but who was not serving as an executive officer at the end of such fiscal year. We refer to these individuals as our "named executive officers."

Summary Compensation Table

Name and Principal Position	Year	Salary ($)	Bonus ($)	Option Awards($)(1)	All Other Compensation ($)		Total ($)
Darlene Horton, M.D. (2) President & CEO	2012	$81,439	$ –	$ –	$ –		$81,439
Daron Evans	2012	$275,000	$ –	$ –	$ 30,805	(3)	$305,805
Chief Financial Officer	2011	$252,083	$ 87,500	$ 20,893	$ 530	(3)	$361,006
Richard B. Brewer (4)	2012	$–	$ –	$ –	$ –		$–
Former Executive Chairman	2011	$240,000	$ –	$ 82,626	$ –		$322,626
Joshua A. Kazam (5)	2012	$–	$ –	$ –	$ –		$–
Former President & CEO	2011	$–	$ –	$ 35,321	$ –		$35,321

(1) Amounts reflect the grant date fair value of awards granted under our Amended and Restated 2005 Stock Option Plan, computed pursuant to Financial Accounting Standards Board's Accounting Standards Codification 718 *"Compensation – Stock Compensation"*. Assumptions used in the calculation of these amounts are included in Note 10 of the Notes to Audited Financial Statements included elsewhere in this proxy statement. For awards that are subject to performance conditions, amounts reflect the assumption that the highest level of performance conditions will be achieved. See the *"Outstanding Equity Awards at Fiscal Year-End"* table, below, for information regarding all option awards outstanding as of December 31, 2012.

(2) Dr. Horton was appointed President and Chief Executive Officer on August 6, 2012. Prior to her appointment as President and Chief Executive Officer, Dr. Horton served as our Chief Medical Officer pursuant to the terms of a consulting agreement dated June 18, 2012. Dr. Horton does not receive additional compensation for her service as a director of the Company. Dr. Horton's 2012 salary excludes $56,428 in deferred compensation as the payment of this amount is not guaranteed and is contingent on the occurrence of certain events.

(3) In 2012, represents $30,275 in accrued vacation paid and $530 in premiums paid for life insurance. In 2011, the amount represents premiums paid for life insurance.

(4) Mr. Brewer served as our Executive Chairman from July 21, 2010 until his death on August 15, 2012. Mr. Brewer did not receive additional compensation for his service as a director of the Company.

(5) Pursuant to the terms of our services agreement with Two River Consulting, LLC, or TRC, Mr. Kazam served as our non-employee President and Chief Executive Officer from June 2009 until Dr. Horton's appointment as President and Chief Executive Officer on August 6, 2012. Mr. Kazam received no direct compensation for his services as President and Chief Executive Officer, though, as a principal owner of TRC, he indirectly received a portion of the monthly cash fees paid to TRC under the services agreement. See the section of this proxy statement entitled "Certain Relationships and Related Transactions" beginning on page 91. Mr. Kazam also serves as a director of Nile, and amounts reflected in the summary compensation table represent compensation received solely for his services as a director in accordance with the standard compensation applicable to our other non-employee directors.

Employment Agreements and Post-Termination Benefits

Darlene Horton, M.D. — President and Chief Financial Officer

Dr. Horton's employment with us is governed by a letter agreement dated August 3, 2012, as amended on November 5, 2012 and March 21, 2013, which provides for Dr. Horton's employment as our President and Chief Executive Officer for an indefinite term. The agreement provides for an initial monthly base salary of $28,314 and, if she remains employed as of the date of a "compensation adjustment event," then (i) her annualized base salary will be increased to $400,000, (ii) she will become eligible to receive an annual performance cash bonus in an amount up to 30% of her annualized base salary, and (iii) she will be granted a 10-year stock option to purchase a number of shares of our common stock equal to 5% of the then issued and outstanding shares of common stock at an exercise price equal to the current market price of the common stock on the date of grant. The stock option will vest ratably over a three-year period with respect to 50% of the underlying shares and over a three-year period upon the achievement of specified performance criteria with respect to the remaining 50% of the shares. For purposes of the agreement, the term "compensation adjustment event" means the date on which we secure sufficient capital, whether by a financing or strategic transaction (or any combination thereof) or another means, in order to enable us to initiate and fund to completion a Phase II clinical trial of cenderitide.

On November 5, 2012, 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 until such time as we complete 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 we receive, whether by a financing, strategic transaction or another means (or any combination thereof), an aggregate of at least $1,000,000 in gross proceeds.

The agreement provides that if we terminate Dr. Horton's employment without "cause" at any time after the date of a compensation adjustment event, then she will be entitled to continue receiving her then current annualized base salary and medical benefits (the "Severance Benefits") for a period of six months following such termination; provided, however, that if such termination occurs more than one year after the compensation adjustment event, then Dr. Horton will be entitled to receive the Severance Benefits for one year following such termination. For purposes of the agreement, the term "cause" means the following conduct or actions taken by Dr. Horton: (i) breach of any material term of the agreement or the confidentiality, non-competition and invention assignment agreement executed by Dr. Horton as a condition of her employment; (ii) conviction of any felony or other crime of moral turpitude; (iii) any act of fraud or dishonesty injurious to us or our reputation; (iv) continual failure or refusal to perform her employment duties; (v) any act or omission that, in our reasonable determination, indicates alcohol or drug abuse by Dr. Horton; or (vi) engagement in any form of harassment prohibited by law.

The agreement originally provided that if, prior to the date of a compensation adjustment event, we completed a Change of Control Transaction (as defined in the agreement) and Dr. Horton's employment was terminated by us (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 be entitled to receive a cash payment equal to 5% of the applicable Change of Control Proceeds (as defined in the agreement).

On March 21, 2013, the payment terms described in the preceding paragraph were amended to provide that if, prior to December 31, 2013, we complete a Change of Control Transaction in which either (i) the outstanding shares of our common stock are exchanged for securities of another corporation, or (ii) we issue shares of our 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 Dr. Horton will be entitled to receive, immediately prior to the effective time of the Change of Control Transaction, a number of shares of our common stock equal to 5% of the shares of common stock then outstanding on a fully-diluted basis. The proposed Merger with Capricor will trigger the issuance of such shares to Dr. Horton.

The March 21, 2013 amendment further provides that if, prior to December 31, 2013, we complete 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).

Prior to her appointment as President and Chief Executive Officer, Dr. Horton served as our Chief Medical Officer pursuant to the terms of a consulting agreement dated June 18, 2012, which agreement was terminated upon Dr. Horton's appointment as President and Chief Executive Officer.

On July 3, 2013, Dr. Horton signed a letter agreement acknowledging and confirming that, upon consummation of the Merger, the sole compensation that Dr. Horton is entitled to receive is the shares of our common stock described in the March 21, 2013 amendment, and further acknowledging and confirming that Dr. Horton is not entitled to any other compensation, including any deferred compensation or employee benefits.

Daron Evans — Chief Financial Officer

Mr. Evans' employment with us was initially governed by an employment agreement dated January 19, 2007, as amended on August 19, 2007 and March 4, 2008. The employment agreement, which initially provided for Mr. Evans' employment as Chief Operating Officer of our predecessor entity, a privately-held Delaware corporation(Old Nile), provided for a term that expired on February 13, 2010. Despite the expiration of the employment agreement, Mr. Evans' employment with us continues on an indefinite basis on substantially the same compensation terms. Under his former employment agreement, Mr. Evans was initially entitled to an annual base salary of $175,000. Mr. Evans' annual base salary was increased to $200,000 as of January 1, 2009, to $250,000 as of July 15, 2010, and to $275,000 as of December 1, 2011. In addition, Mr. Evans is eligible to receive an annual performance bonus of up to 30% of his annual base salary upon the successful completion of annual corporate and individual milestones.

Mr. Evans' former employment agreement also provided for the awarding of certain stock options, referred to as Employment Options, Performance Options and Technology Options. On September 17, 2007, Mr. Evans was granted Employment Options to purchase 239,896 shares of our common stock at an exercise price of $2.71, vesting in three equal installments on the day before each anniversary of his employment agreement. Mr. Evans was also granted Performance Options to purchase 288,458 shares of our common stock at an exercise price of $2.71, vesting up to one-third in each calendar year, or a pro-rata portion thereof for a period less than a full year, based on the successful completion of annual corporate and individual milestones as determined by our Board or its Compensation Committee. To the extent our Board or Compensation Committee declines to vest the maximum amount of Performance Options in any given calendar year, or a pro-rata portion thereof for a period less than a full year, such unvested amount is deemed forfeited by Mr. Evans. On March 4, 2008, the Compensation Committee determined that, for the pro-rated period ending December 31, 2007, Mr. Evans' Performance Options would vest in the amount of 76,528 shares out of a possible 84,562 shares, resulting in the forfeiture of Performance Options to purchase 8,034 shares. On January 16, 2009, the Compensation Committee determined that, for the calendar year ending December 31, 2008, Mr. Evans' Performance Options would vest in the amount of 43,269 shares out of a possible 96,153 shares, resulting in the forfeiture of Performance Options to purchase 52,884 shares. On January 19, 2010, the Compensation Committee determined that, for the calendar year ending December 31, 2009, Mr. Evans' Performance Options would vest in the amount of 50,000 shares out of a possible 96,153 shares, resulting in the forfeiture of Performance Options to purchase 46,153 shares. On July 8, 2010, Mr. Evans was granted a 10-year opt ion to purchase 200,000 shares of our common stock at an exercise price of $0.301 per share, which vests and becomes exercisable in 12 equal quarterly

installments commencing September 30, 2010. On July 26, 2010, Mr. Evans was granted a 10-year option to purchase 250,000 shares of our common stock at an exercise price of $0.37 per share, which vests and becomes exercisable in 12 equal quarterly installments commencing September 30, 2010. On April 18, 2011, Mr. Evans was granted a 10-year option to purchase 50,000 shares of our common stock at an exercise price of $0.69 per share, which option was fully-vested and immediately-exercisable upon the date of grant.

Pursuant to a Severance Benefits Agreement dated July 24, 2010, if Mr. Evans' employment had been terminated by us other than for cause, Mr. Evans would have been entitled, upon execution of a customary release, to continued payment of his then-current base salary for a period of six months. As discussed below, we have no further obligations to Mr. Evans pursuant to the Severance Benefits Agreement.

On March 21, 2013, we entered into a letter agreement with Mr. Evans, pursuant to which he 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 we complete an Interim Financing Event (as defined above).

The March 21, 2013 agreement further provides that if, prior to December 31, 2013, we complete a Change of Control Transaction in which either (i) the outstanding shares of our common stock are exchanged for securities of another corporation, or (ii) we issue shares of our 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 Mr. Evans will be entitled to receive, immediately prior to the effective time of the Change of Control Transaction, a number of shares of our common stock equal to 4.5% of the shares of common stock then outstanding on a fully-diluted basis.

The agreement further provides that if, prior to December 31, 2013, we complete 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). The proposed Merger with Capricor will trigger the issuance of such shares to Mr. Evans.

In consideration of the foregoing, the March 21, 2013 agreement provides that we shall have no further obligations pursuant to the Severance Benefits Agreement dated July 24, 2010.

On July 3, 2013, Mr. Evans signed a letter agreement acknowledging and confirming that, upon consummation of the Merger, the sole compensation that Mr. Evans is entitled to receive is the shares of our common stock described in the March 21, 2013 amendment, and further acknowledging and confirming that Mr. Evans is not entitled to any other compensation, including any deferred compensation or employee benefits.

Richard B. Brewer — Former Executive Chairman

Mr. Brewer served as our Executive Chairman until his death on August 15, 2012. Mr. Brewer's employment as our Executive Chairman was subject to the terms of a letter agreement dated July 15, 2010. In accordance with the agreement, Mr. Brewer was entitled to an annual salary of $240,000. In addition, upon Mr. Brewer's appointment, we issued to him a 10-year stock option to purchase 450,000 shares of our common stock at an exercise price of $0.32 per share and which was immediately exercisable. In addition, following the effective date of the amendment to our 2005 Stock Option Plan, we issued to Mr. Brewer a second 10-year option to purchase 900,000 shares of our common stock at an exercise price of $0.37 per share, vesting and becoming exercisable in eight equal quarterly installments commencing September 30, 2011, with such vesting accelerating in the event of a "change of control" (as defined under our 2005 Stock Option Plan). Both stock options were awarded pursuant to our 2005 Stock Option Plan and

terminated pursuant to their terms on November 13, 2012, ninety days after Mr. Brewer's death.

On May 14, 2012, we entered into a letter agreement with Mr. Brewer, terminating Mr. Brewer's status as a part-time employee, but providing that he would continue serving as our Executive Chairman as a non-employee. In addition, the letter agreement provided that Mr. Brewer's compensation would be reduced from $240,000 per year to $100,000 per year. The change in Mr. Brewer's status from employee to non-employee resulted from his acceptance of full-time employment as chief executive officer of Myrexis, Inc.

Outstanding Equity Awards at December 31, 2012

The following table sets forth information concerning stock options held by the named executive officers at December 31, 2012. Each of Mr. Evans and Mr. Kazam has agreed to the cancellation of the options listed below, effective immediately prior to the effective time of the proposed Merger with Capricor.

Name	Number of Securities Underlying Unexercised Options Exercisable	Number of Securities Underlying Unexercised Options Unexercisable	Equity Incentive Plan Awards: Number of Securities Underlying Unexercised Unearned Options	Option Exercise Price ($)	Option Expiration Date	
Darlene Horton, M.D.	—	—	—	—	—	
Daron G. Evans	421,283	—	—	2.71	09/17/2017	
	49,020	—	—	0.88	01/15/2019	
	85,628	—	—	0.89	06/24/2019	(1)
	166,667	33,333	—	0.30	07/08/2020	(2)
	208,333	41,667	—	0.37	07/26/2020	(2)
	50,000	—	—	0.69	04/18/2021	
Richard B. Brewer (3)	—	—	—	—	—	
Joshua A. Kazam (4)	50,000	—	—	4.50	01/25/2018	
	25,000	—	—	0.93	12/22/2018	
	65,000	—	—	1.77	07/21/2019	
	80,000	—	—	0.37	07/26/2020	
	80,000	—	—	0.73	05/10/2021	

(1) Option granted on June 24, 2009 to purchase up to a maximum of 100,000 shares, of which the right to purchase 25,000 vested immediately and the right to purchase remaining shares vested subject to the performance of specified clinical development milestones in two installments of up to 50,000 shares and up to 25,000 shares. On February 15, 2010, Mr. Evans' right to purchase 42,500 shares of such 50,000-share installment vested and the remaining 7,500 shares of such installment were forfeited. On January 3, 2011, Mr. Evans' right to purchase 18,128 shares of the final 25,000-share installment vested and the remaining 6,872 shares were forfeited.

(2) Option vests in 12 equal quarterly installments commencing September 30, 2010.

(3) All stock options previously held by Mr. Brewer terminated pursuant to their terms on November 13, 2012, 90 days after Mr. Brewer's death.

(4) All stock options held by Mr. Kazam were awarded as compensation for his services as a director.

Compensation of Directors

On July 8, 2010, the Compensation Committee of our Board amended the compensation plan applicable to our non-employee directors. As amended, our non-employee directors receive an annual stock option grant pursuant to our 2005 Stock Option Plan relating to 80,000 shares of common stock, and the chairs of the Board's Audit and Compensation Committees each receive an additional annual stock option grant relating to 20,000 shares. All of such stock options are awarded upon each director's re-election by our stockholders and vest in their entirety on the first anniversary of the grant date. Newly-appointed non-employee directors are entitled to receive a stock option to

purchase 130,000 shares of our common stock, which option vests in three equal annual installments commencing on the first anniversary of the grant date.

Prior to the adoption of this plan, our non-employee directors did not receive any cash fees for their service, but were periodically awarded stock options. No option awards were granted to our directors for their service in 2012. Further, all of the directors below have agreed to the cancellation of all of the stock options held by them, effective immediately prior to the completion of the proposed Merger with Capricor.

Name (1)	Fees Earned or Paid in Cash	Option Awards (2)	Total
Arie S. Belldegrun, M.D.	$ —	$ —	$ —
Pedro Granadillo	—	—	—
Peter M. Kash, Ed.D.	—	—	—
Joshua A. Kazam (3)	—	—	—
Frank Litvack, M.D. (4)	—	—	—
Paul A. Mieyal, Ph.D.	—	—	—
Gregory W. Schafer	—	—	—

(1) Darlene Horton, M.D., our President and Chief Executive Officer, has been omitted from this table since she receives no additional compensation for serving on our Board. Richard B. Brewer, our Executive Chairman until his death on August 15, 2012, has also been omitted from this table since he received no additional compensation for serving on our Board.

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

(3) Pursuant to the terms of our services agreement with Two River Consulting, LLC, or TRC, Mr. Kazam served as our non-employee President and Chief Executive Officer from June 2009 until Dr. Horton's appointment as President and Chief Executive Officer on August 6, 2012. Mr. Kazam received no direct compensation for his services as President and Chief Executive Officer, though, as a principal owner of TRC, he indirectly received a portion of the monthly cash fees paid to TRC under the services agreement. See the section of this proxy statement entitled "Certain Relationships and Related Transactions" beginning on page 90. Amounts reflected in the table above represent compensation received solely for Mr. Kazam's services as a director in accordance with the standard compensation applicable to our other non-employee directors.

(4) Dr. Litvack resigned from the Board effective as of October 28, 2012.

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