CAPRICOR THERAPEUTICS, INC.
Form 10-K
March 31, 2014

UNITED STATES

SECURITIES AND EXCHANGE COMMISSION

WASHINGTON, D.C. 20549

FORM 10-K

þ Annual Report Pursuant to Section 13 or 15(d) of the Securities Exchange Act of 1934

for the fiscal year ended December 31, 2013

or

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

For the transition period from to

Commission File Number: 001-34058

CAPRICOR THERAPEUTICS, INC.

(Exact Name Of Registrant As Specified In Its Charter)

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

8840 Wilshire Blvd., 2nd Floor, Beverly Hills, California

(Address of principal executive offices)

90211

(Zip Code)

(310) 358-3200
(Registrant's telephone number, including area code)

Not applicable.

(Former name, former address and former fiscal year, if changed since last report)

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

None

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

Common Stock, par value $0.001 per share

Warrants (expiring April 21, 2015)

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

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

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

Indicate by check mark whether the registrant has submitted electronically and posted on its corporate Web site, if any, every Interactive Data File required to be submitted and posted pursuant to Rule 405 of Regulation S-T (§232.405 of this chapter) during the preceding 12 months (or for such shorter period that the registrant was required

to submit and post such files). Yes þ No o

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

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

Large accelerated filer	Accelerated filer ¨	Accelerated filer ¨
Non-accelerated filer ¨		Smaller reporting company þ

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

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

As of June 30, 2013: $1,698,139

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

As of March 26, 2014, there were 11,690,859 shares of the issuer's common stock, par value $0.001 per share, issued and outstanding.

TABLE OF CONTENTS

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

FORWARD-LOOKING STATEMENTS

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

We intend that all forward-looking statements be subject to the safe-harbor provisions of the Private Securities Litigation Reform Act of 1995. Forward-looking statements are subject to many risks and uncertainties that could cause our actual results to differ materially from any future results expressed or implied by the forward-looking statements. Pharmaceutical and biotechnology companies have suffered significant setbacks in advanced clinical trials, even after obtaining promising earlier trial results. Data obtained from such clinical trials are susceptible to varying interpretations, which could delay, limit or prevent regulatory approval. Readers are expressly advised to review and consider certain risk factors, which include risks associated with (1) our ability to successfully conduct clinical and pre-clinical trials for our product candidates, (2) our ability to obtain required regulatory approvals to develop and market our product candidates, (3) our ability to raise additional capital or to license our products on favorable terms, (4) our ability to execute our development plan on time and on budget, (5) our ability to identify and obtain additional product candidates, and (6) our ability to raise enough capital to fund our operations. Although we believe that the assumptions underlying the forward-looking statements contained in this Annual Report on Form 10-K are reasonable, any of the assumptions could be inaccurate, and therefore there can be no assurance that such statements will be accurate. In light of the significant uncertainties inherent in the forward-looking statements included herein, the inclusion of such information should not be regarded as a representation by us or any other person that the results or conditions described in such statements or our objectives and plans will be achieved. Furthermore, past performance in operations and share price is not necessarily indicative of future performance. Except to the extent required by applicable laws or rules, we do not undertake to update any forward-looking

statements or to announce publicly revisions to any of our forward-looking statements, whether resulting from new information, future events or otherwise.

The following discussion should be read together with our consolidated financial statements and related consolidated notes contained in this Annual Report on Form 10-K. Results for the year ended December 31, 2013 are not necessarily indicative of results that may be attained in the future.

Reverse Stock Split

On November 20, 2013, we effected a reverse split of our common stock, par value $0.001 per share, at a ratio of one-for-fifty. Unless otherwise indicated, all share amounts, per share data, share prices, exercise prices and conversion rates set forth in this Annual Report on Form 10-K have, where applicable, been adjusted retroactively to reflect this reverse stock split.

PART I

ITEM 1. BUSINESS

Company Overview

Overview of the Company

Capricor Therapeutics, Inc. is a development stage, biopharmaceutical company whose mission is to develop and commercialize regenerative medicine and large molecule products for the treatment of disease. Our initial pipeline products were developed to treat heart disease and its complications. We were originally incorporated in Delaware in August 2005 under the name Nile Pharmaceuticals, Inc. and we changed our name to Nile Therapeutics, Inc., or Nile Therapeutics, in January 2007. On September 17, 2007, we were acquired by SMI Products, Inc., or SMI, which was then a public shell company, in a reverse merger transaction whereby a wholly-owned subsidiary of SMI merged with and into Nile Therapeutics, with Nile Therapeutics remaining as the surviving corporation and a wholly-owned subsidiary of SMI in accordance with the terms of this transaction, the stockholders of Nile Therapeutics exchanged all of their shares of Nile Therapeutics common stock for shares of SMI common stock, which immediately following the transaction represented approximately 95 percent of the issued and outstanding common stock of SMI. Upon completion of the merger, the sole officer and director of SMI resigned and was replaced by the officers and directors of Nile Therapeutics. Additionally, following the merger, Nile Therapeutics, or Old Nile, was merged into SMI, and SMI changed its name to Nile Therapeutics, Inc., or Nile, and adopted the business plan of Old Nile. On November 20, 2013, pursuant to that certain Agreement and Plan of Merger and Reorganization, dated as of July 7, 2013, as amended by that certain First Amendment to Agreement and Plan of Merger and Reorganization, dated as of September 27, 2013 (as amended, the Merger Agreement), by and among Nile, Nile's wholly-owned subsidiary, Bovet Merger Corp., a Delaware corporation, or Merger Sub, and Capricor, Inc., or Capricor, a Delaware corporation, Merger Sub merged with and into Capricor and Capricor became a wholly-owned subsidiary of Nile (referred to herein as the Merger). Immediately prior to the effective time of the Merger and in connection therewith, Nile filed certain amendments to its certificate of incorporation which, among other things, (i) effected a 1-for-50 reverse split of its common stock (the Reverse Stock Split), (ii) changed its corporate name from "Nile Therapeutics, Inc." to "Capricor Therapeutics, Inc.," and (iii) effected a reduction in the total number of authorized shares of common stock from 100,000,000 to 50,000,000, and a reduction in the total number of authorized shares of preferred stock from 10,000,000 to 5,000,000.

Our wholly-owned subsidiary, Capricor, Inc., or Capricor, was founded in 2005 as a Delaware corporation based on the innovative work of its founder, Eduardo Marbán, M.D., Ph.D. First located in Baltimore, Maryland, adjacent to The Johns Hopkins University, or JHU, where Dr. Marbán was chief of cardiology, Capricor moved to Los Angeles, California in 2007 when Dr. Marbán was recruited to become Director of the Heart Institute at Cedars-Sinai Medical Center, or CSMC. Capricor's labs are located in space that Capricor leases from CSMC.

Our corporate headquarters are located at 8840 Wilshire Blvd., 2nd Floor, Beverly Hills, California 90211. Our telephone number is (310) 358-3200 and our internet address is *www.capricor.com*. The information on, or accessible through, our website is not part of this Annual Report on Form 10-K.

The initial discovery by Dr. Marbán and his colleagues was that a novel progenitor cell type called a CDC, or cardiosphere derived cell, can be isolated from heart tissue after passing through a cardiosphere phase and expanded into doses that can be delivered directly to the patient. These cells come from the heart and are potentially well-suited to treat the heart. Capricor believes that CDCs have anti-fibrotic, anti-apoptotic and angiogenic-functions that may reduce damage caused by myocardial ischemia and encourage blood vessel development in those areas of injury. This combination of properties may be able to treat other disease processes that cause the development of scar tissue. Capricor is evaluating the possibilities of applying these cells or similar cells into other therapeutic areas. Capricor has exclusively licensed intellectual property for CDCs and Capricor's other product candidate, cardiospheres, or CSps, from three academic institutions and also maintains its own intellectual property relating to these product candidates.

Capricor's proprietary methods center on producing therapeutic doses of cardiac-derived stem cells to boost the regenerative capacity of the heart and, with that, to perhaps improve cardiac function. A significant number of patients who suffer a heart attack eventually go on to develop heart failure. Heart attacks are one of the most common causes of heart failure. In patients with heart failure, the main pumping function of the heart is often diminished and results in symptoms and signs of poor cardiac function including shortness of breath, pulmonary congestion, diminished ability to perform activities of daily life (ADL) and, in some cases, death.

When a patient suffers a heart attack, also called a myocardial infarction (MI), blood cannot reach the area due to an artery being blocked, preventing blood from reaching the distal tissue. The tissue that is downstream of the blockage quickly dies. The dead tissue is now a scar, and the bigger the size of the scar, the greater the chance that a patient will have additional complications. CDCs have been shown in pre-clinical and clinical studies to reduce scar size following myocardial infarction. Further, it has been demonstrated that new tissue is generated in response to cell delivery. Capricor researchers believe that the reduced scar and new tissue may improve heart function so that it will work more efficiently. Should Capricor's CDCs prove to be effective at reducing the damage done to the heart by a heart attack, it is possible that fewer people may develop heart failure and suffer its devastating consequences.

The first trial using CDCs was CADUCEUS, sponsored by CSMC in collaboration with JHU. CADUCEUS was a twenty-five patient randomized open-label study using 25 million autologous CDCs (i.e. CDCs derived from the patient's own heart tissue) injected down the coronary artery thirty to ninety days after MI. Seventeen patients received CDCs and eight received standard of care for post heart attack patients. Sixteen of the seventeen patients treated with CDCs showed a reduction in infarct (scar) size and generation of new heart tissue. To the best of Capricor's knowledge, CADUCEUS is the first trial in the field of cardiac stem cell therapy that showed a significant reduction in scar size and new heart muscle as determined by blinded MRI analysis.

The precise mechanism of action of CDCs is not definitively understood. Capricor believes that CDCs work by harnessing and augmenting the natural healing powers that exist within the heart and that the cells act by recruiting the endogenous pool of stem cells to come to the site of injury and assist in repairing the damage that has been done. These natural healing effects may be enough for daily wear and tear on the heart but may not be strong enough for catastrophic injury like a heart attack. Capricor believes that the CDCs track to the area of injury and release growth factors and cytokines (molecules that stimulate specific cell responses) that signal the heart to repair itself. The CADUCEUS trial provides preliminary validation to the potential regenerative properties of CDCs.

Capricor's core technology is based in cardiospheres, or CSps, which are multi-cell clusters of cardiac derived cells that have been demonstrated to process regenerative properties in pre-clinical studies. The size of CSps is sufficiently large that injecting them directly into the infarct related artery is not feasible due to potential for impairment of blood flow. Capricor's lead product candidate, the CDC, is the single cell monolayer product of the CSps. CDCs are small enough that within acceptable dose limits, they can be injected down a coronary artery without damaging the heart muscle. Capricor has done studies to establish the range of doses that are safe to deliver to the heart. Capricor is not now actively developing CSps for clinical use although it has experimented with direct intra-myocardial injection. CSps appear to be no more effective than CDCs for the presently considered indications. It is possible that at some time in the future, the Company may evaluate the use of CSps for other indications.

Both CSps and CDCs are derived from either a deceased human donor (allogeneic source) or from heart tissue taken directly from recipient patients themselves (autologous source). The manufacturing method for both allogeneic and autologous CSps or CDCs is similar though the starting material comes from different sources. Capricor has data to demonstrate that CSps and CDCs can be readily grown from heart tissue of humans.

Our Product Candidates

We currently have five drug candidates in various stages of development:

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CAP-1002: Capricor's lead product candidate consists of allogeneic cardiosphere-derived cells, or CDCs. CAP-1002 is currently being tested in Capricor's ALLSTAR Phase I/II clinical trial which will determine if the cells can lead to reduction in scar size in patients who have had a heart attack. It is a dual cohort clinical trial that has two independently recruiting strata: the first are patients who have recently experienced a myocardial infarction, or MI (30-90 days post MI); the second are patients who have suffered an MI within one year (90 days to one-year post MI) to see if the cells can reduce the size of older, more established scar. In addition to measuring scar size, ALLSTAR will also look at a variety of clinical and quality of life endpoints. Phase I of the ALLSTAR trial was a 14 patient trial conducted at three sites to determine if allogeneic CDCs are safe for patients. Phase I of the trial was funded in large part by a grant received from the National Institutes of Health, or NIH. The primary endpoints focused on acute effects of cell delivery and potential immune consequences of allogeneic cell delivery. Patient enrollment was completed for the Phase I portion of the trial on October 11, 2013. On December 15, 2013, Capricor received notification from the National Heart Lung and Blood Institute (NHLBI) Gene and Cell Therapy (GST) Data Safety Monitoring Board (DSMB) that the 14-patient Phase I portion had met its safety endpoints and that Capricor was cleared to begin the Phase II portion of the trial. Capricor began enrollment of the Phase II portion of the ALLSTAR study in the first quarter of 2014. Phase II is an estimated 300 patient, double-blind, randomized, placebo-controlled trial which is powered to detect a reduction in infarct (scar) size as measured by MRI in both groups of patients, those with recent and chronic MI, at the one year follow-up. As infarct size was reduced significantly in the CADUCEUS patients at six months, Capricor intends to get a preliminary readout of ALLSTAR at six months post infusion. Phase II of ALLSTAR is being funded in large part through the support of the California Institute for Regenerative Medicine, or CIRM.

Capricor has been awarded a grant from the NIH to support further development of the CAP-1002 product. Dr. Eduardo Marbán of CSMC, and Capricor's founder, has received approval on a new IND for a trial named "DYNAMIC" (dilated cardiomyopathy intervention with allogeneic myocardially-regenerative cells). Presently, Capricor is in discussions with the NIH with respect to the possible use of the funds subject to the grant for other clinical purposes. It is possible that Capricor will deploy this grant to fund the Phase I portion of the DYNAMIC trial. The Phase I portion of the DYNAMIC trial would use CAP-1002 to treat patients with advanced heart failure and a recent hospitalization for such. Capricor's decision to become involved in the DYNAMIC trial will depend on multiple factors, including, but not limited to: approval by the NHLBI to utilize the grant monies to fund the DYNAMIC trial, the ability of Capricor to reach an agreement with CSMC regarding the clinical operations aspect of the trial, and the assessment by Capricor of the appropriateness of DYNAMIC with respect to the Company's pipeline development plan.

CAP-1001: CAP-1001 consists of autologous CDCs. This product was used in the Phase I CADUCEUS clinical trial, which was sponsored and conducted by CSMC in collaboration with JHU. In that study, 25 patients were enrolled, of which 17 patients received autologous CDCs. 16 of the 17 treated patients showed a mean reduction of approximately 45% in scar mass and an increase in viable heart muscle one-year post heart attack. The eight patients in the control group had no significant change in infarct (scar) size. At present there is no plan for another clinical trial for CAP-1001. The data from CADUCEUS, using autologous CDCs, suggests that the cells are effective in reducing scar within several months of a heart attack. The ALLSTAR trial is designed to validate the results of CADUCEUS using an allogeneic product while also looking for potential efficacy in patients between 90 days and one year post MI with a more chronic scar, a patient population that CADUCEUS was not designed to study.

- **CSps:** CSps are multicellular clusters called cardiospheres, a 3D micro-tissue from which CDCs are derived and have shown significant healing effects in pre-clinical models of heart failure. While Capricor considers the CSps an important product, at present there is no plan for a clinical trial for CSps.

- **Cenderitide *(CD-NP)*:** Cenderitide is a chimeric natriuretic peptide that is being considered for the treatment of heart failure. To date, we have explored the use of cenderitide in acute heart failure admissions as well as in the setting of patients in the vulnerable post-hospitalization phase. The current clinical plan is to consider cenderitide for the treatment of patients for up to 90 days at home following admission for acute 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., or Medtronic, 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. Any further development of cenderitide is subject to our ability to either raise additional capital or enter into a strategic transaction in which a 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. We are currently evaluating whether to proceed with further clinical development of this product.

- **CU-NP**: 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. Any further development of CU-NP is subject to our ability to either raise additional capital or enter into a strategic transaction in which a strategic partner provides the capital necessary to continue development activities. We are currently evaluating whether to proceed with further clinical development of this product.

The following table summarizes our product development programs:

Product	Indications	Commercial Rights	Ongoing Studies / Status
CAP-1002	Cardiovascular	Capricor	ALLSTAR Phase II is currently open for enrollment. This study is an estimated 300 patient, double blind, placebo controlled, multi-center trial.
CAP-1001	Cardiovascular	Capricor	CSMC and JHU sponsored Phase I CADUCEUS trial has been completed. Funded by the NHLBI Specialized Centers for Cell-based Therapy.
CSps	Cardiovascular	Capricor	Preclinical.
Cenderitide	Cardiovascular	Capricor Therapeutics	Completed single -blind, placebo-controlled Phase I study of cenderitide in chronic heart failure patients in October 2011. Continued development and future clinical trials are being evaluated.

CU-NP	Cardiovascular	Capricor Therapeutics	Preclinical. Continued development and future clinical trials are being evaluated.

Intellectual Property and Proprietary Technology

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. To this end, we require all of our employees, consultants, advisors and other contractors to enter into confidentiality agreements that prohibit the disclosure and use of confidential information and, where applicable, require disclosure and assignment to us of the ideas, developments, discoveries and inventions important to our business.

The development of complex biotechnology products such as ours typically includes the early discovery of a technology platform – often in an academic institution – followed by increasingly focused development around a product opportunity, including identification and definition of a specific product candidate and development of scalable manufacturing processes, formulation, delivery and dosage regimens. As a result, biotechnology products are often protected by several families of patent filings that are made at different times of the development cycle and cover different aspects of the product. Earlier filed broad patent applications directed to the discovery of the platform technology thus usually expire ahead of patents covering later developments such as scalable manufacturing processes and dosing regimens. Patent expirations on products may therefore span several years and vary from country to country based on the scope of available coverage. There are also limited opportunities to obtain extensions of patent coverage in certain countries.

Capricor's Technology - CAP-1002, CAP-1001 and CSps

Capricor has entered into exclusive license agreements for intellectual property rights related to cardiac derived cells with Università Degli Studi Di Roma at la Sapienza (the University of Rome), JHU and CSMC. In addition, Capricor has filed patent applications related to enhancements or validation of the technology developed by its own scientists.

University of Rome License Agreement

Capricor and the University of Rome entered into a License Agreement, dated June 21, 2006 (the Rome License Agreement), which provides for the grant of an exclusive, world-wide, royalty-bearing license by the University of Rome to Capricor (with the right to sublicense) to develop and commercialize licensed products under the licensed patent rights in all fields. With respect to any new or future patent applications assigned to the University of Rome utilizing cardiac stem cells in cardiac care, Capricor has a first right of negotiation for a certain period of time to obtain a license thereto.

Pursuant to the Rome License Agreement, Capricor paid the University of Rome a license issue fee, as well as minimum annual royalties, and is obligated to pay a royalty received as a result of sublicenses granted. The minimum annual royalties are creditable against future royalty payments.

The Rome License Agreement will, unless extended or sooner terminated, remain in effect until the later of the last claim of any patent or until any patent application comprising licensed patent rights has expired or been abandoned. Under the terms of the Rome License Agreement, either party may terminate the agreement should the other party become insolvent or file a petition in bankruptcy. Either party shall have up to 90 days to cure its material breach.

The foregoing description of the Rome License Agreement is a summary of its material terms, does not purport to be complete, and is qualified in its entirety by reference to the Rome License Agreement, which, subject to any confidential treatment requested, is filed as an exhibit to this Annual Report on Form 10-K for the period ended December 31, 2013.

The Johns Hopkins University License Agreement

Capricor and JHU entered into an Exclusive License Agreement, effective June 22, 2006 (the JHU License Agreement), which provides for the grant of an exclusive, world-wide, royalty-bearing license by JHU to Capricor (with the right to sublicense) to develop and commercialize licensed products and licensed services under the licensed patent rights in all fields and a nonexclusive right to the know-how. In May 2009, the JHU License Agreement was amended to add additional patent rights to the License Agreement in consideration of a payment to JHU and reimbursement of patent costs. Capricor and JHU executed a Second Amendment to the JHU License Agreement, effective as of December 20, 2013, pursuant to which, among other things, certain definitions were added or amended, the timing of certain obligations was revised and other obligations of the parties were clarified.

Pursuant to the JHU License Agreement, JHU was paid an initial license fee and, thereafter, Capricor is required to pay minimum annual royalties on the anniversary dates of the JHU License Agreement. The minimum annual royalties are creditable against running royalties on net sales of products and net service revenues which Capricor is also required to pay under the JHU License Agreement. In addition, Capricor is required to pay a certain percentage of the consideration received by it from sublicenses granted, and is required to pay JHU certain defined development milestone payments upon the successful completion of certain phases of its clinical studies and upon receiving FDA approval.

The JHU License Agreement will, unless sooner terminated, continue in effect in each applicable country until the date of expiration of the last to expire patent within the patent rights, or, if no patents are issued, then for twenty years from the effective date. Under the terms of the JHU License Agreement, either party may terminate the agreement should the other party become insolvent or file a petition in bankruptcy, or fail to cure a material breach within 30 days after notice. In addition, Capricor may terminate for any reason upon 60 days' written notice.

The foregoing description of the JHU License Agreement, as amended, is a summary of its material terms, does not purport to be complete, and is qualified in its entirety by reference to the JHU License Agreement, and the amendments thereto, all of which, subject to any confidential treatment requested, are filed as an exhibit to this Annual Report on Form 10-K for the period ended December 31, 2013.

Cedars-Sinai Medical Center License Agreement

On January 4, 2010, Capricor entered into an Exclusive License Agreement with CSMC (the CSMC License Agreement), for certain intellectual property rights. In 2013, the CSMC License Agreement was amended twice resulting in, among other things, a reduction in the percentage of sublicense fees which would have been payable to CSMC. Effective December 30, 2013, Capricor entered into an Amended and Restated Exclusive License Agreement with CSMC (the Amended CSMC License Agreement) pursuant to which, among other things, certain definitions were added or amended, the timing of certain obligations was revised and other obligations of the parties were clarified.

The Amended CSMC License Agreement provides for the grant of an exclusive, world-wide, royalty-bearing license by CSMC to Capricor (with the right to sublicense) to conduct research using the patent rights and know-how and develop and commercialize products in the field using the patents rights and know-how. In addition, Capricor has the exclusive right to negotiate for an exclusive license to any future rights arising from related work conducted by or under the direction of Dr. Eduardo Marbán on behalf of CSMC. In the event the parties fail to agree upon the terms of an exclusive license, Capricor shall have a non-exclusive license to such future rights, subject to royalty obligations.

Pursuant to the CSMC License Agreement, CSMC was paid a license fee and Capricor was obligated to reimburse CSMC for certain fees and costs incurred in connection with the prosecution of certain patent rights. Additionally, Capricor was required to meet certain spending and development milestones. Pursuant to the Amended CSMC License Agreement, Capricor remains obligated to pay royalties on sales of royalty-bearing products as well as a percentage of the consideration received from any sublicenses or other grant of rights. In 2010, Capricor discontinued its research under some of the patents.

The Amended CSMC License Agreement will, unless sooner terminated, continue in effect on a country by country basis until the last to expire of the patents covering the patent rights or future patent rights. Under the terms of the Amended CSMC License Agreement, unless waived by CSMC, the agreement shall automatically terminate: (i) if Capricor ceases, dissolves or winds up its business operations; (ii) in the event of the insolvency or bankruptcy of Capricor or if Capricor makes an assignment for the benefit of its creditors; (iii) if performance by either party jeopardizes the licensure, accreditation or tax exempt status of CSMC or the agreement is deemed illegal by a governmental body; (iv) within 30 days for non-payment of royalties; (v) within 90 days if Capricor fails to undertake commercially reasonable efforts to exploit the patent rights or future patent rights; (vi) if a material breach has not been cured within 90 days; or (vii) if Capricor challenges any of the CSMC patent rights. Capricor may terminate the agreement if CSMC fails to cure any material breach within 90 days after notice.

The foregoing description of the Amended CSMC License Agreement is a summary of its material terms, does not purport to be complete, and is qualified in its entirety by reference to the Amended CSMC License Agreement which, subject to any confidential treatment requested, is filed as an exhibit to this Annual Report on Form 10-K for the

period ended December 31, 2013.

Collaboration Agreement with Janssen Biotech, Inc.

On December 27, 2013, Capricor entered into a Collaboration Agreement and Exclusive License Option with Janssen Biotech, Inc., or Janssen, a wholly-owned subsidiary of Johnson & Johnson. Under the terms of the agreement, Capricor and Janssen agreed to collaborate on the development of Capricor's cell therapy program for cardiovascular applications, including its lead product, CAP-1002. Capricor and Janssen further agreed to collaborate on the development of cell manufacturing in preparation for future clinical trials. Under the agreement, Capricor was paid $12.5 million, and Capricor will contribute to the costs of development of a chemistry, manufacturing and controls (CMC) package. In addition, Janssen has the exclusive right to enter into an exclusive license agreement pursuant to which Janssen would receive a worldwide, exclusive license to exploit CAP-1002 as well as certain allogeneic cardiospheres and cardiosphere-derived cells in the field of cardiology. Janssen has the right to exercise the option at any time until 60 days after the delivery by Capricor of the six-month follow-up results from Phase II of Capricor's ALLSTAR clinical trial for CAP-1002. If Janssen exercises its option rights, Capricor would receive an upfront license fee and additional milestone payments which may total up to $325 million. In addition, a double-digit royalty would be paid on sales of licensed products.

The foregoing description of the Collaboration Agreement and Exclusive License Option is a summary of its material terms, does not purport to be complete, and is qualified in its entirety by reference to the Collaboration Agreement and Exclusive License Option, which, subject to any confidential treatment requested, is filed as an exhibit to this Annual Report on Form 10-K for the period ended December 31, 2013.

Company's Technology – Cenderitide and CU-NP

The Company has entered into an exclusive license agreement for intellectual property rights related to natriuretic peptides with the Mayo Foundation for Medical Education and Research and a Clinical Trial Funding Agreement with Medtronic, Inc., which also includes certain intellectual property licensing provisions.

Mayo License Agreement

The Company and the Mayo Foundation for Medical Education and Research, or Mayo, previously entered into a Technology License Agreement with respect to cenderitide on January 20, 2006, which was filed as Exhibit 10.6 to the Company's Current Report on Form 8-K filed with the Securities and Exchange Commission, or SEC, on September 21, 2007 and which was amended on June 2, 2008 (as so amended, the CD-NP Agreement). On June 13, 2008, the Company and Mayo entered into a Technology License Agreement with respect to CU-NP (the CU-NP Agreement), which was filed as Exhibit 10.1 to the Company's Quarterly Report on Form 10-Q filed with the SEC on

August 14, 2008. On November 14, 2013, the Company entered into an Amended and Restated License Agreement with Mayo (the Amended Mayo Agreement). The Amended Mayo Agreement amends and restates in its entirety each of the CD-NP Agreement and the CU-NP Agreement, and creates a single amended and restated license agreement between the Company and Mayo with respect to CD-NP and CU-NP.

The Amended Mayo Agreement provides for the grant of an exclusive, world-wide, royalty-bearing license by Mayo to the Company (with the right to sublicense) under the Mayo patents, patent applications and improvements, and a nonexclusive right under the know-how, for the development and commercialization of CD-NP and CU-NP in all therapeutic indications. With respect to any future patents and any improvements related to cenderitide and CU-NP owned by or assigned to Mayo, the Company has the exclusive right of first negotiation for the exclusive or non-exclusive rights (at the Company's option) thereto. Such exclusive right of negotiation shall be effective as of June 1, 2016, or such earlier date when the Company has satisfied certain payment obligations to Mayo.

Under each of the previous CD-NP Agreement and CU-NP Agreement, the Company paid Mayo up-front cash payments and the Company agreed to make certain performance-based cash payments to Mayo upon successful completion of certain milestones. Additionally, the Company issued certain amounts of common stock of the Company to Mayo under each agreement. The Amended Mayo Agreement restructured the economic arrangements of the CD-NP Agreement and CU-NP Agreement by, among other things, eliminating certain milestone payments and decreasing the royalty percentages payable upon the commercial sale of the products. Pursuant to the terms of the Amended Mayo Agreement, the Company agreed to pay to Mayo an annual license maintenance fee and to issue to Mayo an additional 18,000 shares of the Company's common stock as additional consideration for the grant of certain rights. Mayo also agreed to waive or defer the payment of certain fees owed to Mayo. All breaches and defaults by the Company under the terms of the CD-NP Agreement and CU-NP Agreement were waived by Mayo in the Amended Mayo Agreement.

The Amended Mayo Agreement will, unless sooner terminated, expire on the later of (i) the expiration of the last to expire valid claim contained in the Mayo patents, or (ii) the 20th anniversary of the Amended Mayo Agreement. Under the terms of the Amended Mayo Agreement, Mayo may terminate the agreement earlier (i) for the Company's material breach of the agreement that remains uncured after 90 days' written notice to the Company, (ii) for the Company's insolvency or bankruptcy, (iii) if the Company challenges the validity or enforceability of any of the patent rights in any manner, or (iv) if the Company has not initiated either the next clinical trial of cenderitide within two years of the effective date of the Amended Mayo Agreement or a clinical trial of CU-NP within two and one-half years of the effective date. The Company may terminate the Amended Mayo Agreement without cause upon 90 days' written notice.

The foregoing description of the Amended Mayo Agreement is a summary of its material terms, does not purport to be complete, and is qualified in its entirety by reference to the Amended Mayo Agreement, which, subject to any confidential treatment requested, is filed as an exhibit to this Annual Report on Form 10-K for the period ended December 31, 2013.

Medtronic Clinical Trial Funding Agreement

In February 2011, the Company entered into a Clinical Trial Funding Agreement with Medtronic, Inc. (Medtronic). Pursuant to the agreement, Medtronic provided 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 pump technology.

The agreement provided that intellectual property conceived in or otherwise resulting from the performance of the Phase I clinical trial will be jointly owned by the Company and Medtronic (the Joint Intellectual Property), and that the Company is to pay royalties to Medtronic based on the net sales of a product covered by the Joint Intellectual Property. The agreement further provided that, if the parties fail to enter into a definitive commercial license agreement with respect to cenderitide, each party will have a right of first negotiation to license exclusive rights to any Joint Intellectual Property.

Pursuant to its terms, the agreement expired in February 2012, following the completion of the Phase I clinical trial and the delivery of data and reports related to such study. Nile received the final reimbursement of $195,500 in February 2012 and a total of $1,550,000 over the life of the agreement. Although the Medtronic agreement expired, there are certain provisions that survive the expiration of the agreement, including the obligation to pay royalties on products that might be covered by the Joint Intellectual Property. Neither party has exercised its right to negotiate for exclusive rights to the Joint Intellectual Property.

Employees

Currently, we have 19 full-time employees, although several of them also perform part-time services for CSMC, including our Chief Executive Officer, Dr. Linda Marbán, who provides services on a part-time basis to CSMC. None of our employees are covered by a collective bargaining agreement. We believe that our relations with our employees are satisfactory. We have also retained several consultants to serve in various operational and administrative positions.

All former employees of Nile were terminated upon consummation of the merger between Nile and Capricor, a wholly-owned subsidiary of Nile. The employees of Capricor are continuing their employment relationship with Capricor. Certain officers of Capricor are also serving as officers of the Company.

Manufacturing

Capricor presently maintains its laboratory 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 30 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 its Phase II trial of CAP-1002. If the lab 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 Capricor's clinical trials and regulatory approvals. In addition, Capricor would have to build out its own manufacturing facility for any Phase III trial or establish a collaboration agreement with a third party.

CAP-1001:

The manufacturing process begins with a biopsy of cardiac tissue from the patient taken during a simple outpatient procedure. This tissue is taken to the lab where the cells are isolated, expanded, and processed through a series of proprietary unit operations. After release testing and quality review of the manufacturing data, this drug product is then administered into the same patient. The time frame for autologous manufacturing is 6-8 weeks post-biopsy until the product can be administered to the patient.

CAP-1002:

The process for manufacturing CAP-1002 differs very little from the CAP-1001 process, except that it can be executed at a significantly larger scale. This is because the starting material is from an entire heart taken from a donor, and collected from an organ procurement organization (OPO), rather than a small biopsy taken from the patient. After expanding, processing, release testing and quality review, the CAP-1002 product becomes available for administration to patients. CAP-1002 is cryo-preserved, enabling us to produce large lots that can be frozen and then administered to patients as needed. The shelf life of the product is currently one year after freezing. We believe that the allogeneic nature of CAP- 1002 enables us to create a commercially scalable stem cell product.

Cenderitide and CU-NP:

We do not currently manufacture cenderitide or CU-NP in-house, nor do we have the capacity to do so. Accordingly, we will need to establish relationships with third-party manufacturers and other service providers to perform these

services for us.

Research and Development

Capricor's research and development program has been funded in large part through Federal grants totaling approximately $7.0 million. In addition, Capricor has been granted a loan award in the approximate amount of $19.8 million from the California Institute for Regenerative Medicine, or CIRM, to fund Phase II of the ALLSTAR trial. The Company's research and development efforts to date have led to the development of three product candidates which have reached various stages of clinical development, autologous CDCs, allogeneic CDCs and cenderitide. We are currently evaluating whether the third candidate, cenderitide, will continue to be pursued. Ongoing research focuses on in-depth product characterization, expanded use of current products, development of next generation products and identification of new technologies. Capricor aims to create a pipeline of regenerative medicine products potentially capable of improving the healing capacity of injured tissue. Capricor's research continues to explore the growth factors and cytokines that have been shown to reduce both infarct (scar) size and promote regeneration of heart muscle or other tissues injured by ischemia. Our research and development program for cenderitide and CU-NP is currently under review. Our Board of Directors will determine whether we will proceed with any future development of these products. Capricor spent approximately $5.2 million and $2.6 million on research and development activities for the years ended December 31, 2013 and 2012, respectively.

Competition

We are 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. The pharmaceutical industry is highly competitive, with a number of established, large pharmaceutical companies, as well as many smaller companies. Many of the organizations competing with us 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 we do. There are many pharmaceutical companies, biotechnology companies, public and private universities, government agencies, and research organizations actively engaged in research and development of products which may target the same indications as our product candidates. We expect any future products and product candidates we develop to compete on the basis of, among other things, product efficacy and safety, time to market, price, extent of adverse side effects, and convenience of treatment procedures. The biotechnology and pharmaceutical industries are subject to rapid and significant technological change. The drugs that we are attempting to develop will have to compete with existing therapies. Our future success will depend in part on our 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 our potential products obsolete or noncompetitive. In addition, companies pursuing different but related fields represent substantial competition. These organizations also compete with us to attract qualified personnel and parties for acquisitions, joint ventures, or other collaborations.

Government Regulation

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

Drug Approval Process

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

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

Regulation by United States and foreign governmental authorities is a significant factor affecting our ability to commercialize any of our products, as well as the timing of such commercialization and our ongoing research and development activities. The commercialization of drug products requires regulatory approval by governmental agencies prior to commercialization. Various laws and regulations govern or influence the research and development, non-clinical and clinical testing, manufacturing, processing, packing, validation, safety, labeling, storage, record keeping, registration, listing, distribution, advertising, sale, marketing and post-marketing commitments of our products. The lengthy process of seeking these approvals, and the subsequent compliance with applicable laws and regulations, require expending substantial resources.

Pharmaceutical products such as ours may not be commercially marketed without prior approval from the FDA and comparable regulatory agencies in other countries. In the United States, the process for obtaining FDA approval typically includes pre-clinical studies, the filing of an IND, human clinical trials and filing and approval of either an NDA, for chemical pharmaceutical products, or a BLA for biological pharmaceutical products. The results of

pre-clinical testing, which include laboratory evaluation of product chemistry and formulation, animal studies to assess the potential safety and efficacy of the product and its formulations, details concerning the drug manufacturing process and its controls, and a proposed clinical trial protocol and other information must be submitted to the FDA as part of an IND that must be reviewed and become effective before clinical testing can begin. The study protocol and informed consent information for patients in clinical trials must also be submitted to an independent Institutional Review Board, or IRB, for approval covering each institution at which the clinical trial will be conducted. Once a sponsor submits an IND, the sponsor must wait 30 calendar days before initiating any clinical trials. If the FDA has comments or questions within this 30-day period, the issue(s) must be resolved to the satisfaction of the FDA before clinical trials can begin. In addition, the FDA, an IRB or Capricor may impose a clinical hold on ongoing clinical trials due to safety concerns. If the FDA imposes a clinical hold, clinical trials can only proceed under terms authorized by the FDA. Our non-clinical and clinical studies must conform to the FDA's Good Laboratory Practice, or GLP, and Good Clinical Practice, or GCP, requirements, respectively, which are designed to ensure the quality and integrity of submitted data and protect the rights and well-being of study patients. Information for certain clinical trials also must be publicly disclosed within certain time limits on the clinical trial registry and results databank maintained by the NIH.

Typically, clinical testing involves a three-phase process; however, the phases may overlap or be combined:

- Phase I clinical trials typically are conducted in a small number of volunteers or patients to assess the early tolerability and safety profile, and the pattern of drug absorption, distribution and metabolism;

- Phase II clinical trials typically are conducted in a limited patient population with a specific disease in order to assess appropriate dosages and dose regimens, expand evidence of the safety profile and evaluate preliminary efficacy; and

- Phase III clinical trials typically are larger scale, multicenter, well-controlled trials conducted on patients with a specific disease to generate enough data to statistically evaluate the efficacy and safety of the product, to establish the overall benefit-risk relationship of the drug and to provide adequate information for the registration of the drug.

The results of the pre-clinical and clinical testing, chemistry, manufacturing and control information proposed labeling and other information are then submitted to the FDA in the form of either an NDA or BLA for review and potential approval to begin commercial sales. In responding to an NDA or BLA, the FDA may grant marketing approval, request additional information in a Complete Response Letter, or CRL, or deny the approval if it determines that the NDA or BLA does not provide an adequate basis for approval. A CRL generally contains a statement of specific conditions that must be met in order to secure final approval of an NDA or BLA and may require additional testing. If and when those conditions have been met to the FDA's satisfaction, the FDA will typically issue an approval letter, which authorizes commercial marketing of the product with specific prescribing information for specific indications, and sometimes with specified post-marketing commitments and/or distribution and use restrictions imposed under a REMS program. Any approval required from the FDA might not be obtained on a timely basis, if at all.

Among the conditions for an NDA or BLA approval is the requirement that the manufacturing operations conform on an ongoing basis with current cGMP. In complying with cGMP, we must expend time, money and effort in the areas of training, production and quality control within our own organization and at our contract manufacturing facilities. A successful inspection of the manufacturing facility by the FDA is usually a prerequisite for final approval of a pharmaceutical product. Following approval of the NDA or BLA, we and our manufacturers will remain subject to periodic inspections by the FDA to assess compliance with cGMP requirements and the conditions of approval. We will also face similar inspections coordinated by foreign regulatory authorities.

Post -Approval Requirements

Often times, even after a drug has been approved by the FDA for sale, the FDA may require that certain post-approval requirements be satisfied, including the conduct of additional clinical studies. If such post-approval requirements are not satisfied, the FDA may withdraw its approval of the drug. In addition, holders of an approved NDA or BLA 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 current Good Manufacturing Practices, or 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.

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 its Phase II trial. If CSMC were to revoke 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 Capricor's clinical trials and regulatory approvals. In addition, Capricor would have to build out its own manufacturing facility for the Phase III trial or establish a collaboration agreement with a third party.

If we proceed with the development of cenderitide or CU-NP, 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 or BLA, including withdrawal of the product from the market.

ITEM 1A. RISK FACTORS

RISK FACTORS

Investment in our common stock involves significant risk. You should carefully consider the information described in the following risk factors, together with the other information appearing elsewhere in this annual report, before making an investment decision regarding our common stock. If any of the events or circumstances described in these risks actually occur, our business, financial conditions, results of operations and future growth prospects would likely be materially and adversely affected. In these circumstances, the market price of our common stock could decline, and you may lose all or a part of your investment in our common stock. Moreover, the risks described below are not the only ones that we face.

Risks Relating to Our Business

We need substantial additional funding before we can complete the development of our product candidates. If we are unable to obtain such additional capital, we will be forced to delay, reduce or eliminate our product development programs and may not have the capital required to otherwise operate our business.

Developing biopharmaceutical products, including conducting pre-clinical studies and clinical trials and establishing manufacturing capabilities, is expensive. As of December 31, 2013, we had cash, cash resources, and marketable securities totaling approximately $2.1 million plus approximately $1.4 million restricted cash in loans for our ALLSTAR clinical trial. We have not generated any product revenues, and will not generate any product revenues until, and only if, we receive approval to sell our drug candidates from the FDA and other regulatory authorities for our product candidates.

From inception, we have financed our operations through public and private sales of our equity and debt securities, NIH grants, and a CIRM loan award. We also recently entered into a collaboration agreement with Janssen Biotech, Inc., or Janssen, which provides for funding for the collaboration of our cell therapy program for cardiovascular applications, including CAP-1002. 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 expect our research and development expenses to increase in connection with our ongoing activities, particularly if we continue to develop cenderitide and initiate clinical development of CU-NP. In addition, our expenses could

increase beyond expectations if the FDA requires that we perform additional studies to those that we currently anticipate, and the timing of any potential product approval may be delayed. Other than our cash on hand, we currently have no commitments or arrangements for any additional financing to fund the research and development of cenderitide and CU-NP. All further clinical and other development activities for our cenderitide and CU-NP programs are being evaluated by our Board of Directors before further development will be commenced.

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.

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

- the scope, rate of progress, cost and results of our research and development activities, especially our Phase II clinical trial of CAP-1002;
- the continued availability of funding from NIH and CIRM;
- the costs and timing of regulatory approval;
- the costs of filing, prosecuting, defending and enforcing any patent claims and other intellectual property rights;
- the effect of competing technological and market developments;
- the terms and timing of any collaboration, licensing or other arrangements that we may establish;
- the cost and timing of completion of clinical and commercial-scale outsourced manufacturing activities; and
- the costs of establishing sales, marketing and distribution capabilities for any product candidates for which we may receive regulatory approval.

We have a history of net losses, and we expect losses to continue for the foreseeable future. In addition, a number of factors may cause our operating results to fluctuate on a quarterly and annual basis, which may make it difficult to predict our future performance.

We have a history of net losses, expect to continue to incur substantial and increasing net losses for the foreseeable future, and may never achieve or maintain profitability. Our operations to date have been primarily limited to organizing and staffing our company, developing our technology, and undertaking pre-clinical studies and clinical trials of our product candidates. We have not yet obtained regulatory approvals for any of our product candidates. Consequently, any predictions made about our future success or viability may not be as accurate as they could be if we had a longer operating history. Specifically, our financial condition and operating results have varied significantly in the past and will continue to fluctuate from quarter-to -quarter and year-to -year in the future due to a variety of factors, many of which are beyond our control. Factors relating to our business that may contribute to these fluctuations include the following factors, as well as other factors described elsewhere in this annual report:

- our need for substantial additional capital to fund our development programs;
- delays in the commencement, enrollment, and timing of clinical testing;
- the success of the ALLSTAR clinical trial through all stages of clinical development;
- if further clinical trials are conducted, the success of clinical trials of cenderitide and CU -NP product candidates or future product candidates;
- any delays in regulatory review and approval of our product candidates in clinical development;
- our ability to receive regulatory approval or commercialize our product candidates, within and outside the United States;
- potential side effects of our current or future products and product candidates that could delay or prevent commercialization or cause an approved treatment drug to be taken off the market;
- regulatory difficulties relating to products that have already received regulatory approval;
- market acceptance of our product candidates;
- our ability to establish an effective sales and marketing infrastructure once our products are commercialized;
- our ability to establish or maintain collaborations, licensing or other arrangements;
- our ability and third parties' abilities to protect intellectual property rights;
- competition from existing products or new products that may emerge;
- guidelines and recommendations of therapies published by various organizations;
- the ability of patients to obtain coverage of or sufficient reimbursement for our products;
- our ability to maintain adequate insurance policies;
- our dependency on third parties to formulate and manufacture our product candidates;
- our ability to maintain our current manufacturing facility and secure other facilities as determined to be necessary;
- costs related to and outcomes of potential intellectual property litigation;
- compliance with obligations under intellectual property licenses with third parties;
- our ability to seek regulatory approvals for our product candidates;
- our ability to implement additional internal systems and infrastructure;
- our ability to adequately support future growth;
- our ability to attract and retain key personnel to manage our business effectively; and
- the ability of our senior management who have limited experience in managing a public company to manage our business and operations.

The Company's technology is not yet proven and each of our product candidates is in an early stage of development.

Each of the Company's five product candidates, CAP-1002, CAP-1001, CSps, cenderitide and CU –NP, is in an early stage of development and requires extensive clinical testing before it may be approved by the U.S. Food and Drug Administration, or FDA, or another regulatory authority in a jurisdiction outside the United States, which could take several years to complete, if ever. The effectiveness of the Company's technology has not been definitively proven in completed human clinical trials or preclinical studies. The Company's failure to establish the efficacy of its technology would have a material adverse effect on the Company. We cannot predict with any certainty the results of such clinical testing, including the results of our planned ALLSTAR trial. We cannot predict with any certainty if, or when, we might commence any clinical trials of our product candidates other than the ALLSTAR trial or whether such trials will yield sufficient data to permit us to proceed with additional clinical development and ultimately submit an application for regulatory approval of our product candidates in the United States or abroad, or whether such applications will be accepted by the appropriate regulatory agency.

We may not be able to manage our growth.

Should we achieve our near-term milestones, of which no assurance can be given, our long -term viability will depend upon the expansion of our operations and the effective management of our growth, which will place a significant strain on our management and on our administrative, operational and financial resources. To manage this growth, we may need to expand our facilities, augment our operational, financial and management systems and hire and train additional qualified personnel. If we are unable to manage our growth effectively, our business would be harmed.

Risks Relating to Clinical and Commercialization Activities

Our product candidates will require substantial time and resources in order to be developed, and there is no guarantee that we will develop them successfully.

We have not completed the development of any products and may not have products to sell commercially for many years, if at all. Our 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.

Our success depends upon the viability of our product candidates and we cannot be certain any of them will receive regulatory approval to be commercialized.

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

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

The Company has limited experience in conducting clinical trials.

The Company 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, time-consuming, and uncertain as to outcome (and pharmaceutical products and products used in the regeneration of tissue may invite particularly close scrutiny and requirements from the FDA and other regulatory bodies). Our failure or the failure of our collaborators to conduct human clinical trials successfully or our failure to capitalize on the results of human clinical trials for our product candidates would have a material adverse effect on the Company. If our clinical trials of our product candidates or future product candidates do not produce results necessary to support regulatory approval in the United States or elsewhere, or if they show undesirable side effects, we will be unable to commercialize these product candidates.

To receive regulatory approval for the commercial sale of its product candidates, we must conduct adequate and well-controlled clinical trials to demonstrate efficacy and safety in humans. Clinical failure can occur at any stage of the testing. Our clinical trials may produce negative or inconclusive results, and we may decide, or regulators may require us, to conduct additional clinical and/or non-clinical testing. In addition, the results of our clinical trials may show that our product candidates are ineffective or 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;

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

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

Delays in the commencement, enrollment or completion of clinical testing could significantly affect our product development costs. A clinical trial may be suspended or terminated by the Company, the FDA, or other regulatory authorities due to a number of factors. The commencement and completion of clinical trials requires us to identify and maintain a sufficient number of trial sites, many of which may already be engaged in other clinical trial programs for the same indication as our product candidates, may be required to withdraw from a clinical trial as a result of changing standards of care, or may become ineligible to participate in clinical studies. We do not know whether planned clinical trials will begin on time or be completed on schedule, if at all. The commencement, enrollment 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;
- reaching agreements on acceptable terms with prospective clinical research organizations, or CROs, and trial sites, the terms of which can be subject to extensive negotiation and may vary significantly among different CROs and trial sites; obtaining regulatory approval to commence a clinical trial;
- 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;
- obtaining institutional review board, or IRB, approval to conduct a clinical trial at numerous prospective sites;
- recruiting and enrolling patients to participate in clinical trials for a variety of reasons, including size of patient population, nature of trial protocol, meeting the enrollment criteria for our studies, screening failures, the availability of approved effective treatments for the relevant disease and competition from other clinical trial programs for similar indications;
- retaining patients who have initiated a clinical trial but may be prone to withdraw due to the treatment protocol, lack of efficacy, personal issues, or side effects from the therapy, or who are lost to further follow-up;
- manufacturing sufficient quantities of a product candidate for use in clinical trials;
- complying with design protocols of any applicable special protocol assessment we receive from the FDA;
- severe or unexpected drug-related side effects experienced by patients in a clinical trial;
- collecting, analyzing and reporting final data from the 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 our cell product; 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 for our products;
- our 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; and
- requirements to conduct additional trials and studies, and increased expenses associated with the services of the Company’s CROs and other third parties.

In addition, a clinical trial may be suspended or terminated by us, the FDA, or other regulatory authorities due to a number of factors. If we are required to conduct additional clinical trials or other testing of our product candidates beyond those that we currently contemplate, we or our development partners, if any, may be delayed in obtaining, or may not be able to obtain, marketing approval for these product candidates. We may not be able to obtain approval for indications that are as broad as intended, or we may be able to obtain approval only for indications that are entirely different than those indications for which we sought approval.

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

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

- impose costly procedures on us; or
- diminish any competitive advantages that we may otherwise enjoy.

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

Even if our clinical trials are completed as planned, including our ALLSTAR clinical trial of CAP-1002, we cannot be certain that their results will support the claims of our product candidates. Positive results in pre-clinical testing and early clinical trials does not ensure that results from later clinical trials will also be positive, and we cannot be sure that the results of later clinical trials will replicate the results of prior clinical trials and pre-clinical testing. A number of companies in the pharmaceutical industry, including those with greater resources and experience, have suffered significant setbacks in Phase III clinical trials, even after seeing promising results in earlier clinical trials.

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

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

Our products face a risk of failure due to adverse immunological reactions.

A potential risk of an allogeneic therapy such as that being tested by the Company 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 the Company’s products and the success of our trials. Additionally, if research subjects have pre-existing antibodies or other immune sensitization to our cells, there is a potentiality that our cells and the therapy would be rendered ineffective.

Our business faces significant government regulation, and there is no guarantee that our products will receive regulatory approval.

Our research and development activities, preclinical studies, anticipated human clinical trials, and anticipated manufacturing and marketing of our 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, our 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 our 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 we 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 our product candidates to the market and have a material adverse effect on our 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 Practices or GMPs and other government regulations and corresponding foreign standards. We do 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 or require us to take our approved products off the market;
- we may be required to change the way the product is administered, conduct additional clinical trials or change the labeling of our products;
- we may have limitations on how we promote our products; and
- we may be subject to litigation or product liability claims.

Even if our product candidates receive regulatory approval in the United States, we may never receive approval or commercialize our product candidates outside of the United States. In order to market and commercialize any product candidate outside of the United States, we must establish and comply with numerous and varying regulatory requirements of other countries regarding safety and efficacy. Approval procedures vary among countries and can involve additional product testing and additional administrative review periods. For example, European regulatory authorities generally require a trial comparing the efficacy of the new drug to an existing drug prior to granting approval. The time required to obtain approval in other countries might differ from that required to obtain FDA approval. The regulatory approval process in other countries may include all of the risks detailed above regarding FDA approval in the United States as well as other risks. Regulatory approval in one country does not ensure regulatory approval in another, but a failure or delay in obtaining regulatory approval in one country may have a negative effect on the regulatory approval process in others. Failure to obtain regulatory approval in other countries or any delay or setback in obtaining such approval could have the same adverse effects detailed above regarding FDA approval in the United States. Such effects include the risks that our product candidates may not be approved for all indications requested, which could limit the uses of our product candidates and have an adverse effect on product sales and potential royalties, and that such approval may be subject to limitations on the indicated uses for which the product may be marketed or require costly, post-marketing follow-up studies.

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

Even if United States regulatory approval is obtained, the FDA may still impose significant restrictions on a product's indicated uses or marketing, or impose ongoing requirements for potentially costly post-approval studies. Given the number of recent high -profile adverse safety events with certain drug products, the FDA may require, as a condition of approval, costly risk management programs which may include safety surveillance, restricted distribution and use, patient education, enhanced labeling, special packaging or labeling, expedited reporting of certain adverse events, pre-approval of promotional materials, and restrictions on direct-to -consumer advertising. Furthermore, heightened Congressional scrutiny on the adequacy of the FDA's drug approval process and the agency's efforts to assure the safety of marketed drugs has resulted in the proposal of new legislation addressing drug safety issues. If enacted, any new legislation could result in delays or increased costs during the period of product development, clinical trials, and regulatory review and approval, as well as increased costs to assure compliance with any new post-approval regulatory requirements. Any of these restrictions or requirements could force us to conduct costly studies or increase the time for us to become profitable. For example, any labeling approved for any of our product candidates may include a restriction on the term of its use, or it may not include one or more of our intended indications.

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

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

We have limited manufacturing capability, and may not be able to maintain our manufacturing licenses.

We presently maintain our lab and research facilities in leased premises at CSMC. These premises are being leased on a month-to month basis and may be terminated upon thirty days' notice to us. We presently manufacture our cells in an accredited GMP facility which is owned by and located within CSMC. Our intention is to manufacture cells at this facility for our Phase II trial. If the lease is terminated or if CSMC revokes its permission to allow us to utilize the GMP facility, we would have to secure alternative facilities in which to operate our research and development activities and/or manufacture our products, which would involve a significant monetary investment and would negatively impact the progress of our clinical trials and regulatory approvals. In addition, we will have to build out our own manufacturing facility for the Phase III trial or establish a collaboration agreement with a third party.

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

We obtain the donor hearts from which our CDCs are manufactured from an organ procurement organization, or OPO. There is no guarantee that the OPO which currently provides donor hearts to us will be able to continue to supply us with donor hearts in the future or that an alternative OPO will be available to us. If that OPO or an alternative OPO is not able or willing to supply us with donor hearts, we would be unable to produce our CDCs and the development of our lead product candidate would be significantly impaired and possibly terminated. Additionally, OPO's are subject to regulations of various government agencies. There is no guarantee that laws and regulations pursuant to which our OPO provides donor hearts will not change making it more difficult or even impossible for the OPO to continue to supply us with the hearts we need to produce our product.

We have no prior experience in manufacturing product for large clinical trials or commercial use.

Our manufacturing experience has been limited to manufacturing CAP-1002 for the current ALLSTAR trial. We have no prior history or experience in manufacturing our allogeneic product or any other product for any clinical use and no experience manufacturing any product for large clinical trials or commercial use. Our product has not previously been tested in any trials to show safety or efficacy. We face risks of manufacturing failures and risks of making products that are not proven to be safe or effective.

If we continue with the development of Cenderitide or CU-NP, we will rely exclusively on third parties to formulate and manufacture these product candidates.

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

- We may be unable to identify manufacturers needed to manufacture our product candidates on acceptable terms or at all, because the number of potential manufacturers is limited, and subsequent to approval of an NDA or BLA, the FDA must approve any replacement contractor. This approval would require new testing and compliance inspections. In addition, a new manufacturer may have to be educated in, or develop substantially equivalent processes for, production of our products after receipt of FDA approval, if any.
- Some of the raw materials needed to manufacture our product candidates are available from a very limited number of suppliers. Although we believe we have good relationships with these suppliers, we may have difficulty identifying alternative suppliers if our arrangements with our current suppliers are disrupted or terminated.
- Our third-party manufacturers might be unable to formulate and manufacture our drugs in the volume and of the quality required to meet our clinical and commercial needs, if any.
- Our future contract manufacturers may not perform as agreed or may not remain in the contract manufacturing business for the time required to supply our clinical trials or to successfully produce, store, and distribute our products.
- Drug manufacturers are subject to ongoing periodic unannounced inspection by the FDA, the Drug Enforcement Agency, and corresponding state agencies to ensure strict compliance with good manufacturing practice and other government regulations and corresponding foreign standards. We do not have control over third-party manufacturers' compliance with these regulations and standards.

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

Risks Related to Our Intellectual Property

We may face uncertainty and difficulty in obtaining and enforcing our patents and other proprietary rights.

Our success will depend in large part on our ability to obtain, maintain, and defend patents on our products, obtain licenses to use third party technologies, protect our 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 our pending, licensed-in or owned 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 us. Additionally, we have 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 we own rights or obtain access to our know-how. In addition, the laws of certain countries may not adequately protect our intellectual property. Our competitors may possess or obtain patents on products or processes that are necessary or useful to the development, use, or manufacture of our products. There can also be no assurance that our proposed technology will not infringe patents or proprietary rights owned by others, with the result that others may bring infringement claims against us and require us 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.

Some of our 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 us to grant third parties licenses to such technology. The licenses by which we have obtained some of our intellectual property are subject to the rights of the funding agencies. We also rely upon non-patented proprietary know-how. There can be no assurance that we can adequately protect our 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 our proprietary know-how. Any of the foregoing events could have a material adverse effect on us. In addition, if any of our trade secrets, know-how or other proprietary information is disclosed, the value of our trade secrets, know-how and other proprietary rights would be significantly impaired and our business and competitive position would suffer.

In September 2011, the Leahy-Smith America Invents Act, or the Leahy-Smith Act, was signed into law. The Leahy-Smith Act includes a number of significant changes to U.S. patent law. These include provisions that affect the way patent applications will be prosecuted and may also affect patent litigation. In particular, under the Leahy-Smith Act, the U.S. transitioned in March 2013 to a "first to file" system in which the first inventor to file a patent application will be entitled to the patent. Third parties are allowed to submit prior art before the issuance of a patent

by the USPTO and may become involved in opposition, derivation, reexamination, inter-parties review or interference proceedings challenging our patent rights or the patent rights of our licensors. An adverse determination in any such submission, proceeding or litigation could reduce the scope of, or invalidate, our or our licensors' patent rights, which could adversely affect our competitive position.

The USPTO is currently developing regulations and procedures to govern administration of the Leahy-Smith Act, and many of the substantive changes to patent law associated with the Leahy-Smith Act, and in particular, the first to file provisions, did not become effective until March 16, 2013. Accordingly, it is not clear what, if any, impact the Leahy-Smith Act will have on the operation of our business. However, the Leahy-Smith Act and its implementation could increase the uncertainties and costs surrounding the prosecution of our patent applications and the enforcement or defense of our issued patents and those licensed to us.

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

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

We have licensed certain patent and other intellectual property rights that cover our product candidates from University of Rome, JHU and CSMC. Under the license agreements with University of Rome and JHU, those institutions prosecute and maintain their patents and patent applications in collaboration with us. We rely on these institutions to file, prosecute, and maintain patent applications, and otherwise protect the intellectual property to which we have a license, and we have not had and do not have primary control over these activities for certain of these patents or patent applications and other intellectual property rights. We cannot be certain that such activities by these institutions have been or will be conducted in compliance with applicable laws and regulations, or will result in valid and enforceable patents and other intellectual property rights. Under the Amended CSMC License Agreement, we have assumed, in coordination with CSMC, responsibility for the prosecution and maintenance of all patents and patent applications. Our enforcement of certain of these licensed patents or defense of any claims asserting the invalidity of these patents would also be subject to the cooperation of the third parties.

We license certain patent and other intellectual property rights that cover our cenderitide and CU-NP product candidates from Mayo. In the past, we have relied on the Mayo to file, prosecute, and maintain patent applications, and otherwise protect the intellectual property to which we have a license, prior to the Amended Mayo License Agreement, we did not have primary control over these activities for certain of these patents or patent applications and other intellectual property rights. With the execution of the Amended Mayo License Agreement, we have the responsibility for the prosecution and maintenance of the Mayo patents and patent applications at our expense. We cannot be certain that that the activities conducted by Mayo have been or will be conducted in compliance with applicable laws and regulations, or will result in valid and enforceable patents and other intellectual property rights. Our enforcement of certain of these licensed patents or defense of any claims asserting the invalidity of these patents would also be subject to the cooperation of the third parties. We are also responsible for paying any prosecution and maintenance fees of all Mayo patents and Mayo patent applications now existing and included in the Amended Mayo License Agreement.

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

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

- others may be able to make compounds that are similar to our product candidates but that are not covered by the claims of any of our patents;
- we might not have been the first to make the inventions covered by any issued patents or patent applications we may have (or third parties from whom we license intellectual property may have);
- we might not have been the first to file patent applications for these inventions;
- it is possible that any pending patent applications we may have will not result in issued patents;
- any issued patents may not provide us with any competitive advantages, or may be held invalid or unenforceable as a result of legal challenges by third parties;
- we may not develop additional proprietary technologies that are patentable; or
- the patents of others may have an adverse effect on our business.

We also may rely on trade secrets to protect our technology, especially where we do not believe patent protection is appropriate or obtainable. However, trade secrets are difficult to protect. Although we use reasonable efforts to protect our trade secrets, our employees, consultants, contractors, outside scientific collaborators, and other advisors may unintentionally or willfully disclose our information to competitors. Enforcing a claim that a third party illegally

obtained and is using any of our trade secrets is expensive and time consuming, and the outcome is unpredictable. In addition, courts outside the United States are sometimes less willing to protect trade secrets. Moreover, our competitors may independently develop equivalent knowledge, methods, and know-how.

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

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

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

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

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

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

invention, resulting in a loss of our United States patent position with respect to such inventions.

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

Risks Related to Our Relationships with Third Parties

We are largely dependent on our relationships with our licensors and collaborators and there is no guarantee that such relationships will be maintained or continued.

We have entered into certain license agreements for certain intellectual property rights which are essential to enable us to develop and commercialize our products. Agreements have been entered into with the University of Rome, JHU and CSMC, which is also a shareholder of ours. 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 our net revenues, if and to the extent that we have future revenues. Each of those agreements also contains additional obligations that we are required to satisfy. There is no guarantee that we will be able to satisfy all of our obligations under our 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 not-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 our stem cell technology, and they are not compelled to license any further technologies or intellectual property rights to us except as may be stated in the applicable licensing agreements between those institutions and us. Changes in these collaborators' research interests or their funding sources away from our technology would have a material adverse effect on us. We are substantially dependent on our relationships with these institutions from which we license the rights to our technologies and know-how. If requirements under our license agreements are not met, we could suffer significant harm, including losing rights to our product candidates.

Our rights to our cenderitide and CU -NP drug candidates were both derived from separate license agreements between us and Mayo. On November 14, 2013, we entered into an Amended and Restated Exclusive License Agreement, which we refer to as the Amended Mayo Agreement, with Mayo pursuant to which the rights to both cenderitide and CU-NP were included in the Amended Mayo Agreement and many of the terms of the former agreements were revised on terms more favorable to us. We are substantially dependent on our relationship with Mayo with respect to the rights to these two drug candidates. If requirements under our license agreement are not met, we could suffer significant harm. In order to develop these products, we will need to maintain the intellectual property rights to these product candidates. The Amended Mayo Agreement requires us to perform certain obligations that affect our rights under the Amended Mayo Agreement, including making cash payments if we were to enter into certain types of business transactions. If we fail to comply with our obligations required under the Amended Mayo Agreement, we could lose important patent and other intellectual property rights which may be critical to our business.

In addition, we are responsible for the cost of filing and prosecuting certain patent applications and maintaining certain issued patents licensed to us. If we do not meet our obligations under our license agreements in a timely manner, we could lose the rights to our proprietary technology.

Finally, we may be required to obtain licenses to patents or other proprietary rights of third parties in connection with the development and use of our product candidates and technologies. Licenses required under any such patents or proprietary rights might not be made available on terms acceptable to us, if at all.

We have received government grants and a loan award which impose certain conditions on our operations.

Commencing in 2009, we received several grants from the NIH to fund various projects, including Phase I of the ALLSTAR trial. These awards are subject to annual and quarterly reporting requirements. If we fail to meet these requirements, the NIH could cease further funding.

On February 5, 2013, we entered into a Loan Agreement with CIRM, pursuant to which CIRM has agreed to disburse $19,782,136 to us over a period of three and one-half years to support Phase II of our ALLSTAR clinical trial. Under the Loan Agreement, we are required to repay the CIRM loan with interest at maturity. The loan also provides for the payment of a risk premium whereby we are required to pay CIRM a premium up to 500% of the loan amount upon the achievement of certain revenue thresholds. The loan has a term of five years and is extendable annually up to ten years from the original issuance at our option if certain conditions are met. CIRM has the right to cease disbursements if a no-go milestone occurs or certain other conditions are not satisfied. 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 we are not in default, the loan may be forgiven during the term of the project period if we abandon the trial due to the occurrence of a no-go milestone. After the end of the project period, the loan may be forgiven if we elect to abandon the project under certain circumstances. Under the Loan Agreement, we are also required to meet certain financial milestones by demonstrating to CIRM prior

to each disbursement of loan proceeds that we have 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 we will meet our milestones under the Loan Agreement or that CIRM will not discontinue the disbursement of funds.

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

If we do not establish strategic partnerships, we will have to undertake development and commercialization efforts on our own, which would be costly and adversely impact our ability to commercialize any future products or product candidates. If we enter into any strategic partnerships with pharmaceutical, biotechnology or other life sciences companies, we will be subject to a number of risks, including:

- we may not be able to control the amount and timing of resources that our strategic partners devote to the development or commercialization of product candidates;
- strategic partners may delay clinical trials, provide insufficient funding, terminate a clinical trial or abandon a product candidate, repeat or conduct new clinical trials or require a new version of a product candidate for clinical testing;
- strategic partners may not pursue further development and commercialization of products resulting from the strategic partnering arrangement or may elect to discontinue research and development programs;
- strategic partners may not commit adequate resources to the marketing and distribution of any future products, limiting our potential revenues from these products;
- disputes may arise between us and our strategic partners that result in the delay or termination of the research, development or commercialization of our product candidates or that result in costly litigation or arbitration that diverts management's attention and consumes resources;
- strategic partners may experience financial difficulties;
- strategic partners may not properly maintain or defend our intellectual property rights or may use our proprietary information in a manner that could jeopardize or invalidate our proprietary information or expose us to potential litigation;
- business combinations or significant changes in a strategic partner's business strategy may also adversely affect a strategic partner's willingness or ability to complete its obligations under any arrangement; and
- strategic partners could independently move forward with a competing product candidate developed either independently or in collaboration with others, including our competitors.

Risks Related to Competitive Factors

Our products will likely face intense competition.

The Company 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. We will experience intense competition with respect to our existing and future product candidates. The pharmaceutical industry is highly competitive, with a number of established, large pharmaceutical companies, as well as many smaller companies. Many of these organizations competing with us have substantially greater financial resources, larger research and development staffs and facilities, greater clinical trial experience, longer drug development history in obtaining regulatory approvals, and greater manufacturing, distribution, sales and marketing capabilities than we do. There are many pharmaceutical companies, biotechnology companies, public and private universities, government agencies, and research organizations actively engaged in research and development of products which may target the same indications as our product candidates. We expect any future products and product candidates that we develop to compete on the basis of, among other things, product efficacy and safety, time to market, price, extent of adverse side effects, and convenience of treatment procedures. One or more of our competitors may develop products based upon the principles underlying our proprietary technologies earlier than we do, obtain approvals for such products from the FDA more rapidly than we do, or develop alternative products or therapies that are safer, more effective and/or more cost effective than any product developed by us. Our competitors may obtain regulatory approval of their products more rapidly than we are able to or may obtain patent protection or other intellectual property rights that limit our ability to develop or commercialize our product candidates. Our competitors may also develop drugs that are more effective, useful, and less costly than ours and may also be more successful than us in manufacturing and marketing their products.

Our future success will depend in part on our ability to maintain a competitive position with respect to evolving therapies as well as other novel technologies. There can be no assurance that existing or future therapies developed by others will not render our potential products obsolete or noncompetitive. The drugs that we are 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 us to attract qualified personnel and parties for acquisitions, joint ventures, or other collaborations.

If we are unable to retain and recruit qualified scientists and advisors, or if any of our key executives, key employees or key consultants discontinues his or her employment or consulting relationship with us, it may delay our development efforts or otherwise harm our business. In addition, several of our employees and consultants render services on a part-time basis to us or to other companies.

All former employees of Nile were terminated upon consummation of the merger between Nile and Capricor. The loss of any of our key employees or key consultants could impede the achievement of our research and development objectives. Furthermore, recruiting and retaining qualified scientific personnel to perform research and development work in the future is critical to the Company's success. The Company 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 the Company's 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. The Company may not maintain "key man" insurance policies on any of its officers or employees. All of the Company's employees will be employed "at will" and, therefore, each employee may leave the employment of the Company at any time. If we are unable to retain our existing employees, including qualified scientific personnel, and attract additional qualified candidates, the Company's business and results of operations could be adversely affected.

Because of the specialized nature of our technology, we are dependent upon existing key personnel and on our ability to attract and retain qualified executive officers and scientific personnel for research, clinical studies, and development activities conducted or sponsored by us. There is intense competition for qualified personnel in our fields of research and development, and there can be no assurance that we will be able to continue to attract additional qualified personnel necessary for the development and commercialization of our product candidates or retain our current personnel. Dr. Linda Marbán, our Chief Executive Officer and employee, also provides services on a part-time basis to CSMC as do several other of our employees and Dr. Frank Litvack is only a part-time consultant to the Company and provides services to other non-competing enterprises. These individuals' multiple responsibilities on behalf of the Company and other entities could cause the Company harm in that such employees are unable to devote their full time and attention to the Company.

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

An element of our business strategy includes potentially partnering with pharmaceutical, biotechnology and other companies to obtain assistance for the development and potential commercialization of our product candidates, including the cash and other resources we need for such development and potentially commercialization. We may not be able to negotiate strategic partnerships on acceptable terms, or at all. If we are unable to negotiate strategic partnerships for our product candidates we may be forced to curtail the development of a particular candidate, reduce or delay its development program, delay its potential commercialization, reduce the scope of our sales or marketing activities or undertake development or commercialization activities at our own expense. In addition, we will bear all the risk related to the development of that product candidate. If we elect to increase our expenditures to fund development or commercialization activities on our own, we will need to obtain substantial additional capital, which may not be available to us on acceptable terms, or at all. If we do not have sufficient funds, we will not be able to bring our product candidates to market and generate product revenue.

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

The Company currently has no sales, marketing, or distribution capabilities. We do not anticipate having resources in the foreseeable future to allocate to the sales and marketing of our proposed products. Our future success depends, in part, on our ability to enter into and maintain sales and marketing collaborative relationships, or on our ability to build sales and marketing capabilities internally. If we enter into a sales and marketing collaborative relationship, then we will be dependent upon the collaborator's strategic interest in the products under development, and such collaborator's ability to successfully market and sell any such products. We intend to pursue collaborative arrangements regarding the sales and marketing of our products, however, there can be no assurance that we will be able to establish or maintain such collaborative arrangements, or if able to do so, that they will have effective sales forces. To the extent that we decide not to, or are unable to, enter into collaborative arrangements with respect to the sales and marketing of our proposed products, significant capital expenditures, management resources, and time will be required to establish

and develop an in-house marketing and sales force with technical expertise. There can also be no assurance that we will be able to establish or maintain relationships with third-party collaborators or develop in-house sales and distribution capabilities. To the extent that we depend on third parties for marketing and distribution, any revenues we receive will depend upon the efforts of such third parties, and there can be no assurance that such efforts will be successful.

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

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

- limitations or warnings contained in a product's FDA -approved labeling;
- changes in the standard of care for the targeted indications for any of our product candidates, which could reduce the marketing impact of any claims that we could make following FDA approval;
- limitations inherent in the approved indication for any of our product candidates compared to more commonly understood or addressed conditions;

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

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

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

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

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

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

coverage of and reimbursement for medical products can differ significantly from payor to payor.

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

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

Risks Related to Product and Environmental Liability

Our products may expose us to potential product liability, and there is no guarantee that we 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 us. A future product liability claim or product recall could have a material adverse effect on the Company. There can be no assurance that product liability insurance will be available to us in the future on acceptable terms, if at all, or that coverage will be adequate to protect us against product liability claims. In the event of a successful claim against the Company, insufficient or lack of insurance or indemnification rights could result in liability to us, which could have a material adverse effect on the Company and its future viability. The use of our product candidates in clinical trials and the sale of any products for which we obtain marketing approval, if at all, expose the Company to the risk of product liability claims. Product liability claims might be brought against the Company by consumers, health care providers or others using, administering or selling our products. If we cannot successfully defend ourselves against these claims, we will incur substantial liabilities. Regardless of merit or eventual outcome, liability claims may result in:

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

The Company has obtained clinical trial insurance coverage for its clinical trials. However, such insurance coverage may not reimburse the Company 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, we may not be able to maintain insurance coverage at a reasonable cost or in sufficient amounts to protect the Company against losses due to liability. We intend to expand our insurance coverage to include the sale of commercial products if we obtain marketing approval for our product candidates in development, but we may be unable to obtain commercially reasonable product liability insurance for any products approved for marketing. On occasion, large judgments have been awarded in class action lawsuits based on drugs that had unanticipated side effects. A successful product liability claim or series of claims brought against the Company could have a material adverse effect on us and, if judgments exceed our insurance coverage, could decrease our cash position and adversely affect our business.

Our business involves risk associated with handling hazardous and other dangerous materials.

Our 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 the Company, suspension of production, alteration of our manufacturing processes, or cessation of operations.

Our business depends on compliance with ever-changing environmental laws.

We cannot accurately predict the outcome or timing of future expenditures that may be required to comply with comprehensive federal, state and local environmental laws and regulations. We 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, the Company 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 the Company may become subject to stricter environmental standards in the future and may face large capital expenditures to comply with environmental laws. We have limited capital and we are uncertain whether we will be able to pay for significantly large capital expenditures that may be required to comply with new laws. Also, future developments,

administrative actions or liabilities relating to environmental matters may have a material adverse effect on our financial condition or results of operations.

Risks Related to Our Common Stock

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

The stock market, particularly in recent years, has experienced significant volatility, particularly with respect to pharmaceutical, biotechnology and other life sciences company stocks. Our operating results may fluctuate from period to period for a number of reasons, and as a result our stock price may be subject to significant fluctuations. Factors that could cause volatility in the market price of our common stock include, but are not limited to:

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

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

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

Because the Company's common stock will be primarily traded on the OTCQB 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.

The Company's shares are traded on the OTCQB tier of the OTC Markets. Stock traded on the OTCQB 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 the Company by security analysts and media. This may result in lower prices for the Company's 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 the Company's common stock. There is no guarantee that the Company will be able to re-list its common stock on the NASDAQ Capital Market or any other market. The Company's management will be required to devote substantial time to comply with public company regulations.

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

We have never paid dividends on our capital stock and do not anticipate paying any dividends for the foreseeable future. We anticipate that the Company will retain its earnings, if any, for future growth. Investors seeking cash dividends should not invest in the Company's common stock for that purpose.

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

Our certificate of incorporation authorizes the issuance of up to 5,000,000 shares of preferred stock, none of which are issued or currently outstanding. Our Board of Directors will have the authority to fix and determine the relative rights and preferences of preferred shares, as well as the authority to issue such shares, without further stockholder approval. As a result, our Board of Directors could authorize the issuance of a series of preferred stock that is senior to our common stock that would grant to holders preferred rights to our assets upon liquidation, the right to receive dividends, additional registration rights, anti-dilution protection, the right to the redemption of such shares, together with other rights, none of which will be afforded holders of our common stock.

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

Recent global market and economic conditions have been unprecedented and challenging with tighter credit conditions leading to decreased spending by businesses and consumers alike. Continued turbulence in the U.S. and international markets and economies and prolonged declines in business and consumer spending may adversely affect our liquidity and financial condition, including our ability to access the capital markets to meet our liquidity needs.

We may not be able to attract the attention of major brokerage firms.

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

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

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

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

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

- authorizing the issuance of “blank check” preferred stock without any need for action by stockholders;
- eliminating the ability of stockholders to call special meetings of stockholders; and
- establishing advance notice requirements for nominations for election to the board of directors or for proposing matters that can be acted on by stockholders at stockholder meetings.

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

Ownership of the Company's common stock is highly concentrated, which may prevent you and other stockholders from influencing significant corporate decisions and may result in conflicts of interest that could cause the Company's stock price to decline.

Capricor's former stockholders, many of whom are executive officers and directors continuing with the Company, together with their respective affiliates beneficially own or control approximately 90% of the outstanding shares of the Company. Accordingly, stockholders, executive officers, directors and their affiliates, acting individually or as a group, will have substantial influence over the outcome of a corporate action of the Company requiring stockholder approval, including the election of directors, any merger, consolidation or sale of all or substantially all of the Company's assets or any other significant corporate transaction. These stockholders may also exert influence in delaying or preventing a change in control of the Company, even if such change in control would benefit the other stockholders of the Company. In addition, the significant concentration of stock ownership may adversely affect the market value of the Company's common stock due to investors' perception that conflicts of interest may exist or arise.

The Company's 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 recent merger with Capricor.

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 between Nile and Capricor resulted in another “ownership change” of Nile. Accordingly, the Company’s 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 the Company, which could have a material adverse effect on the business, financial condition, or results of operations of the Company.

Failure to achieve and maintain effective internal controls in accordance with Section 404 of the Sarbanes-Oxley Act of 2002 could have a material adverse effect on our business and stock price.

The Sarbanes-Oxley Act of 2002, or Sarbanes-Oxley, as well as rules implemented by the SEC and any market on which the Company’s shares may be listed in the future, impose various requirements on public companies, including those related to corporate governance practices. The Company’s management and other personnel will need to devote a substantial amount of time to these requirements. Moreover, these rules and regulations will increase the Company’s legal and financial compliance costs and will make some activities more time consuming and costly.

Section 404 of the Sarbanes-Oxley Act of 2002, or Section 404, requires that we establish and maintain an adequate internal control structure and procedures for financial reporting. Our annual reports on Form 10-K must contain an assessment by management of the effectiveness of our internal control over financial reporting and must include disclosure of any material weaknesses in internal control over financial reporting that we have identified. The requirements of Section 404 are ongoing and also apply to future years. We expect that our internal control over financial reporting will continue to evolve as our business develops. Although we are committed to continue to improve our internal control processes and we will continue to diligently and vigorously review our internal control over financial reporting in order to ensure compliance with Section 404 requirements, any control system, regardless of how well designed, operated and evaluated, can provide only reasonable, not absolute, assurance that its objectives will be met. Therefore, we cannot be certain that in the future material weaknesses or significant deficiencies will not exist or otherwise be discovered. If material weaknesses or other significant deficiencies occur, these weaknesses or deficiencies could result in misstatements of our results of operations, restatements of our consolidated financial statements, a decline in our stock price, or other material adverse effects on our business, reputation, results of operations, financial condition or liquidity.

ITEM 1B. UNRESOLVED STAFF COMMENTS

None.

ITEM 2. PROPERTIES

We do not own any real property. Our principal offices are located at 8840 Wilshire Blvd., 2nd Floor, Beverly Hills, California 90211. Under the terms of a two-year lease which expires on June 30, 2015, the base rent for the first 12-month period is $16,620 per month, and the base rent for the second 12-month period will be $17,285. Capricor currently leases our research laboratory from CSMC on a month to month basis for $4,554 per month. With permission from CSMC, Capricor presently manufactures its cells in an accredited GMP facility which is owned by and located within CSMC. Our laboratory and manufacturing facility are located at 8700 Beverly Blvd. Los Angeles, CA 90048. As our operations expand, we expect our space requirements and related expenses to increase.

ITEM 3. LEGAL PROCEEDINGS

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

ITEM 4. MINE SAFETY DISCLOSURES

Not applicable.

PART II

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

Market for Common Stock

Prior to May 12, 2011, our common stock traded on the NASDAQ Capital Market under the symbol "NLTX". On May 12, 2011, our common stock traded on the OTCQB tier of the OTC Markets under the symbol "NLTX.PK". On November 20, 2013, our symbol changed to "NLTXD". On December 20, 2013, we began trading under the symbol "CAPR". On November 20, 2013, we effected a 1:50 reverse stock split of all outstanding shares of common stock (the "Reverse Stock Split"). The following table lists the high and low closing prices of our common stock as quoted, in U.S. dollars, by the OTCQB during each quarter within the last two completed fiscal years. The quotations reflect inter-dealer prices, without retail markup, markdown or commission, and may not represent actual transactions. Consequently, the information provided below may not be indicative of our common stock price under different conditions. All share and per share information set forth in this report has been adjusted to reflect the Reverse Stock Split.

	High	Low
Year ended December 31, 2012		
First Quarter	$29.50	$22.00
Second Quarter	25.00	3.50
Third Quarter	7.50	4.50
Fourth Quarter	5.50	1.00
Year ended December 31, 2013		
First Quarter	$10.00	$2.00
Second Quarter	5.50	2.50
Third Quarter	3.50	1.50
Fourth Quarter	5.00	2.15

Holders

According to the records of our transfer agent, American Stock Transfer & Trust Company, as of March 26, 2014, we had 115 holders of record of common stock, not including those held in "street name."

Dividends

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

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

(1) On March 15, 2013, the Company 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. On September 27, 2013, the Company and the holders of the 2013 Notes entered into an amendment to the 2013 Notes, which provided, among other things, that upon a Change of Control (as defined in the 2013 Notes), the conversion price applicable to the 2013 Notes and the exercise price applicable to the warrants issuable upon a Change of Control would be equal to the average dollar volume weighted average price ("VWAP") of the Company's common stock for each trading day during the period from July 8, 2013 to September 30, 2013. The average VWAP during such period was approximately $0.045 per share.

On October 21, 2013, the Company and the holders of the 2013 Notes entered into an amendment to the Convertible Note Purchase Agreement pursuant to which the Company sold to such holders additional notes having an aggregate principal amount of $120,510 (the "Additional Notes"). The Additional Notes have identical terms and conditions as the 2013 Notes described above and were allocated among the holders on a pro rata basis based on their initial purchase of the 2013 Notes. In exchange for the issuance of the Additional Notes, the Company received aggregate gross proceeds of $102,433. The 2013 Notes and the Additional Notes are collectively referred to herein as the 2013 Notes.

The 2013 Notes and the Additional Notes converted at the close of the merger between Nile and Capricor on November 20, 2013 into 251,044 shares of our common stock on a post-Reverse Stock Split basis. Additionally, 251,044 warrants to purchase shares of our common stock at a strike price of $2.2725, on a post-Reverse Stock Split basis, were issued to the holders of the 2013 Notes and the Additional Notes. No additional proceeds were received by us as a result of the issuance of such shares. The offer and sale of the 2013 Notes and the Additional Notes described above constituted a private placement under Section 4(2) of the Securities Act in accordance with Regulation D promulgated thereunder.

(2) On November 13, 2013, the Company and certain holders of warrants that were originally issued on July 15, 2009 in connection with the Company's private placement of common stock and warrants, entered into warrant exchange agreements whereby the Company issued to such holders a total of 317 shares on a post-Reverse Stock Split basis. Upon such issuance, all rights of those holders who exchanged their warrants terminated. No proceeds were received by the Company from these issuances. The shares of common stock issued in consideration for the exchange of such warrants were not registered under the Securities Act at the time of sale. For these issuances, the Company relied upon the exemption from federal registration under Section 4(2) of the Securities Act and Rule 506 promulgated thereunder, based on the Company's belief that the offer and sale of such shares did not involve a public offering, as each purchaser of such securities was an "accredited investor" and no general solicitation was used.

(3) On August 1, 2013, the Company and the holders of warrants issued in connection with the Company's private placement in June 2011 entered into warrant exchange agreements whereby the Company issued a total of 9,166 shares of its common stock on a post-Reverse Stock Split basis. As a result, all of the warrants issued in connection with the June 2011 private placement were cancelled. No proceeds were received by the Company from these issuances. The shares of common stock issued in consideration for the exchange of such warrants were not registered under the Securities Act at the time of sale. For these issuances, the Company relied upon the exemption from federal registration under Section 4(2) of the Securities Act and/or Rule 506 promulgated thereunder, based on the Company's belief that the offer and sale of such shares did not involve a public offering, as each purchaser of such securities was an "accredited investor" and no general solicitation was used.

(4) In October and November 2013, the Company and certain holders of warrants to purchase 50,063 shares of common stock which were originally issued in April 2012, entered into agreements pursuant to which such holders agreed to receive, upon completion of the merger between Nile and Capricor, an equal number of shares of common stock in exchange for the surrender and cancellation of their warrants, including cancellation of their right to receive the cash payment of the Black-Scholes value of the warrants upon completion of the merger. On November 20, 2013, the effective date of the merger between Nile and Capricor, the Company issued to such holders an aggregate of 50,063 shares of the Company's common stock. No proceeds were received by the Company from these issuances. The shares of common stock to the former April 2012 warrant holders were issued in reliance upon exemptions from registration pursuant to Section 4(2) under the Securities Act and Rule 506 promulgated thereunder.

(5) Pursuant to the Amended and Restated Technology License Agreement between us and Mayo Foundation for Medical Education and Research, or Mayo, we issued Mayo 18,000 shares of our common stock, on a post-Reverse

Stock Split basis, immediately prior to the effective time of the merger between Nile and Capricor. No proceeds were received by the Company from this issuance. The shares of common stock issued to Mayo were offered and sold in reliance upon exemptions from registration pursuant to Section 4(2) under the Securities Act and Rule 506 promulgated thereunder.

(6) Immediately prior to the effective time of the merger, all shares of Capricor preferred stock were converted into shares of Capricor common stock pursuant to the terms of the merger agreement. On November 20, 2013, the shares of Capricor common stock which were exchanged for the shares of Capricor preferred stock, as a result of the merger and in accordance with the terms of the merger agreement, were exchanged according to the applicable multiplier for 6,591,494 shares of common stock of Capricor Therapeutics, and all rights and preferences attached to the shares of Capricor preferred stock were rendered void. Additionally, as a result of the merger between Nile and Capricor and in accordance with the terms of the merger agreement, each outstanding share of Capricor common stock was converted into the right to receive approximately 2.07 shares of Capricor Therapeutics common stock on November 20, 2013. No proceeds were received by the Company from the issuance of common stock to the former Capricor stockholders. For the issuance of shares of Capricor Therapeutics common stock to the former Capricor stockholders, the Company relied upon the exemption from federal registration under Section 4(2) of the Securities Act and Rule 506 promulgated thereunder.

Issuer Purchases of Equity Securities

None.

ITEM 6. SELECTED FINANCIAL DATA

Not Applicable.

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

The following discussion of our financial condition and results of operations should be read in conjunction with the consolidated financial statements and the consolidated notes to those statements included elsewhere in this Annual Report on Form 10-K. This discussion includes forward-looking statements that involve risks and uncertainties. As a result of many factors, our actual results may differ materially from those anticipated in these forward-looking statements.

Overview

The mission of Capricor Therapeutics, Inc. ("Capricor Therapeutics" or the "Company") is to improve the treatment of diseases by commercializing innovative therapies. Descriptions of the operations of Capricor prior to November 20, 2013 refer to Capricor, Inc., which became a wholly-owned subsidiary of Capricor Therapeutics, Inc. upon the merger of Capricor and Nile on November 20, 2013. Our executive offices are located at 8840 Wilshire Blvd., 2nd Floor, Beverly Hills, California 90211. Our telephone number is (310) 358-3200 and our Internet address is www.capricor.com.

Consummation of the Merger

On November 20, 2013, pursuant to that certain Agreement and Plan of Merger and Reorganization dated as of July 7, 2013, as amended by that certain First Amendment to Agreement and Plan of Merger and Reorganization dated as of September 27, 2013 (as amended, the "Merger Agreement"), by and among Nile Therapeutics, Inc., a Delaware corporation ("Nile"), Bovet Merger Corp., a Delaware corporation and a wholly-owned subsidiary of Nile ("Merger Sub"), and Capricor, Inc., a Delaware corporation ("Capricor"), Merger Sub merged with and into Capricor and Capricor became a wholly-owned subsidiary of Nile (the "Merger"). Immediately prior to the effective time of the Merger (the "Effective Time") and in connection therewith, Nile filed certain amendments to its certificate of incorporation which, among other things (i) effected a 1-for-50 reverse split of its common stock (the "Reverse Stock Split"), (ii) changed its corporate name from "Nile Therapeutics, Inc." to "Capricor Therapeutics, Inc.," and (iii) effected a reduction in the total number of authorized shares of common stock from 100,000,000 to 50,000,000, and a reduction in the total number of authorized shares of preferred stock from 10,000,000 to 5,000,000.

At the Effective Time and in connection with the Merger, each outstanding share of Capricor's Series A-1, Series A-2 and Series A-3 Preferred Stock was converted into one share of common stock, par value $0.001 per share, of Capricor (the "Capricor Common Stock").

As a result of the Merger and in accordance with the terms of the Merger Agreement, each outstanding share of Capricor Common Stock was converted into the right to receive approximately 2.07 shares of the common stock of Capricor Therapeutics, par value $0.001 per share (the "Capricor Therapeutics Common Stock"), on a post 1-for-50 Reverse Stock Split basis. Immediately after the Effective Time and in accordance with the terms of the Merger Agreement, the former Capricor stockholders owned approximately 90% of the outstanding common stock of Capricor Therapeutics, and the Nile stockholders owned approximately 10% of the outstanding common stock of Capricor Therapeutics, in each case on a fully-diluted basis. For accounting purposes, the Merger is accounted for as a reverse merger with Capricor as the accounting acquiror (legal acquiree) and Nile as the accounting acquiree (legal acquiror).

After the Effective Time, each then outstanding Capricor stock option, whether vested or unvested, was assumed by Capricor Therapeutics in accordance with the terms of (i) the Capricor, Inc. 2006 Stock Option Plan, (ii) the Capricor, Inc. 2012 Restated Equity Incentive Plan, or (iii) the Capricor, Inc. 2012 Non-Employee Director Stock Option Plan, as applicable, and the Stock Option Agreement under which each such option was issued. All rights with respect to Capricor Common Stock under outstanding Capricor options were converted into rights with respect to Capricor Therapeutics Common Stock.

Since Capricor was deemed to be the accounting acquiror in the merger, the historical financial information for periods prior to the merger reflect the financial information and activities solely of Capricor and not of Nile. The historical equity of Capricor has been retroactively adjusted to reflect the equity structure of Capricor Therapeutics using the respective exchange ratio established in the merger between Nile and Capricor, which reflects the number of shares Capricor Therapeutics issued to equity holders of Capricor as a result of the merger. The retroactive revision of Capricor's equity includes Capricor's preferred stock as if such shares of preferred stock had been converted into Capricor common stock at the respective dates of issuance, which is consistent with the terms of the merger. Accordingly, all common and preferred shares and per share amounts for all periods presented in the consolidated financial statements contained in this Annual Report on Form 10-K and notes thereto have been adjusted retrospectively, where applicable, to reflect the respective exchange ratio established in the merger.

Capricor, our wholly-owned subsidiary, was founded in 2005 as a Delaware corporation based on the innovative work of its founder, Eduardo Marbán, M.D., Ph.D., and his collaborators. First located in Baltimore, Maryland, adjacent to The Johns Hopkins University, or JHU, where Dr. Marbán was chief of cardiology, Capricor moved to Los Angeles, California in 2007 when Dr. Marbán become Director of the Heart Institute at Cedars-Sinai Medical Center, or CSMC. Capricor's labs are located in space that Capricor leases from CSMC.

We currently have five drug candidates in various stages of development:

- **CAP-1002:** Capricor's lead product candidate consists of allogeneic cardiosphere-derived cells, or CDCs. CAP-1002 is currently being tested in Capricor's ALLSTAR Phase I/II clinical trial which will determine if the cells can lead to reduction in scar size in patients who have had a heart attack. It is a dual cohort clinical trial that has two independently recruiting strata: the first are patients who have recently experienced a myocardial infarction, or MI (30-90 days post MI); the second are patients who have suffered an MI within one year (90 days to one-year post MI) to see if the cells can reduce the size of older, more established scar. In addition to measuring scar size, ALLSTAR will also look at a variety of clinical and quality of life endpoints. Phase I of the ALLSTAR trial was a 14 patient trial conducted at three sites to determine if allogeneic CDCs are safe for patients. Phase I of the trial was funded in large part by a grant received from the National Institutes of Health, or NIH. The primary endpoints focused on acute effects of cell delivery and potential immune consequences of allogeneic cell delivery. Patient enrollment was completed for the Phase I portion of the trial on October 11, 2013. On December 15, 2013, Capricor received notification from the National Heart Lung and Blood Institute (NHLBI) Gene and Cell Therapy (GST) Data Safety Monitoring Board (DSMB) that the 14-patient Phase I portion had met its safety endpoints and that Capricor was cleared to begin the Phase II portion of the trial. Capricor began enrollment of the Phase II portion of the ALLSTAR study in the first quarter of 2014. Phase II is an estimated 300 patient, double-blind, randomized, placebo-controlled trial which is powered to detect a reduction in infarct (scar) size as measured by MRI in both groups of patients, those with recent and chronic MI, at the one year follow-up. As infarct size was reduced significantly in the CADUCEUS patients at six months, Capricor intends to get a preliminary readout of ALLSTAR at six months post infusion. Phase II of ALLSTAR is being funded in large part through the support of the California Institute for Regenerative Medicine, or CIRM.

Capricor has been awarded a grant from the NIH to support further development of the CAP-1002 product. Dr. Eduardo Marbán of CSMC, and Capricor's founder, has received approval on a new IND for a trial named "DYNAMIC" (dilated cardiomyopathy intervention with allogeneic myocardially-regenerative cells). Presently, Capricor is in discussions with the NIH with respect to the possible use of the funds subject to the grant for other clinical purposes. It is possible that Capricor will deploy this grant to fund the Phase I portion of the DYNAMIC trial. The Phase I portion of the DYNAMIC trial would use CAP-1002 to treat patients with advanced heart failure and a recent hospitalization for such. Capricor's decision to become involved in the DYNAMIC trial will depend on multiple factors, including, but not limited to: approval by the NHLBI to utilize the grant monies to fund the DYNAMIC trial, the ability of Capricor to reach an agreement with CSMC regarding the clinical operations aspect of the trial, and the assessment by Capricor of the appropriateness of DYNAMIC with respect to the Company's pipeline development plan.

CAP-1001: CAP-1001 consists of autologous CDCs. This product was used in the Phase I CADUCEUS clinical trial, which was sponsored and conducted by CSMC in collaboration with JHU. In that study, 25 patients were enrolled, of which 17 patients received autologous CDCs. 16 of the 17 treated patients showed a mean reduction of approximately 45% in scar mass and an increase in viable heart muscle one-year post heart attack. The eight patients in the control group had no significant change in infarct (scar) size. At present there is no plan for another clinical trial for CAP-1001. The data from CADUCEUS, using autologous CDCs, suggests that the cells are effective in reducing scar within several months of a heart attack. The ALLSTAR trial is designed to validate the results of CADUCEUS using an allogeneic product while also looking for potential efficacy in patients between 90 days and one year post MI with a more chronic scar, a patient population that CADUCEUS was not designed to study.

CSps: CSps are multicellular clusters called cardiospheres, a 3D micro-tissue from which CDCs are derived and have shown significant healing effects in pre-clinical models of heart failure. While Capricor considers the CSps an important product, at present there is no plan for a clinical trial for CSps.

Cenderitide *(CD-NP)*: Cenderitide is a chimeric natriuretic peptide that is being considered for the treatment of heart failure. To date, we have explored the use of cenderitide in acute heart failure admissions as well as in the setting of patients in the vulnerable post-hospitalization phase. The current clinical plan is to consider cenderitide for the treatment of patients for up to 90 days at home following admission for acute 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., or Medtronic, 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. Any further development of cenderitide is subject to our ability to either raise additional capital or enter into a strategic transaction in which a 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. We are currently evaluating whether to proceed with further clinical development of this product.

- **CU-NP**: 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. Any further development of CU-NP is subject to our ability to either raise additional capital or enter into a strategic transaction in which a strategic partner provides the capital necessary to continue development activities. We are currently evaluating whether to proceed with further clinical development of this product.

We have no product sales to date and will not have the ability to generate any product revenue until after we have received approval from the U.S. Food and Drug Administration, or the FDA, or equivalent foreign regulatory bodies to begin selling our pharmaceutical product candidates. Developing pharmaceutical products is a lengthy and very expensive process. Even if we obtain the capital necessary 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 many years, if ever. To date, most of our development expenses have related to our product candidates, CAP-1002 and cenderitide. As we proceed with the clinical development of CAP-1002 and other potential indications for CAP-1002, or if we further develop cenderitide or other additional products, our expenses will further increase. To the extent that 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 equity sales, grants received from the NIH, and a loan award from CIRM.

Research and development, or R&D, expenses consist primarily of salaries and related personnel costs, clinical patient costs, consulting fees, costs of manufacturing personnel and supplies, and costs of service providers for pre-clinical, clinical and certain legal expenses resulting from intellectual property prosecution, and other expenses relating to the design, development, testing and enhancement of our product candidates. Except for certain capitalized patent expenses, R&D costs are expensed as incurred.

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

Our results have included non-cash compensation expense as a result of the issuance of stock options and warrants, as applicable. We expense the fair value of stock options and warrants over their vesting period as applicable. 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 statements of operations under G&A or R&D expenses, as applicable. We expect to record additional non-cash compensation expense in the future, which may be significant.

Results of Operations

General and Administrative Expenses. G&A expenses for the years ended December 31, 2013 and 2012 were approximately $2.2 million and $1.4 million, respectively. The increase of approximately $0.8 million compared to the same period of 2012 is primarily attributable to an increase of approximately $0.2 million in compensation costs, primarily related to increased headcount. Additionally, there was an increase in rent expense of approximately $0.1 million due to us amending our then current lease arrangement to provide for additional office space at our corporate offices. Additionally, there was an increase in professional fees related to legal, consulting and accounting work primarily related to the merger between Nile and Capricor of approximately $0.3 million compared to the same period of 2012.

Research and Development Expenses. R&D expenses for the years ended December 31, 2013 and 2012 were approximately $5.2 million and $2.6 million, respectively. The increase of approximately $2.6 million over the same period of 2012 is primarily due to the fact that Capricor was actively conducting clinical development activities of CAP-1002 in our Phase I/II trial throughout 2013. This resulted in an increase of approximately $2.1 million in clinical costs primarily related to contract research organizations for statistical programming and data management, as well as patient costs and expenses for the operational team that supports our clinical trial. Additionally, we had an increase of approximately $0.3 million in manufacturing costs, primarily related to the supplies and testing required to release our clinical product.

CAP-1002 - Although the development of CAP-1002 is in its early stages, we believe that it has the potential to treat heart disease. On December 15, 2013 the NHLBI Gene and Cell Therapy (GST) Data Safety Monitoring Board (DSMB) gave Capricor approval to move into the Phase II portion of the ALLSTAR trial. We expect to spend approximately $7.5 to $10.0 million during 2014 on the development of CAP-1002, which is primarily related to our Phase II ALLSTAR trial. The Phase I portion of the trial was funded in large part through a grant received from the NIH. We began enrollment of the Phase II portion of the ALLSTAR trial in the first quarter of 2014. Phase II is an estimated 300 patient, double blind, placebo controlled, multi-centered study in which CAP-1002 is administered to patients via intracoronary infusion within 30 days to one year following a heart attack. Phase II is substantially funded through the support of a loan award from CIRM for approximately $19.8 million. The trial will measure several endpoints, including infarct size. Additional endpoints include left ventricular end-systolic and diastolic volume and ejection fraction at six and twelve months. Our strategy for further development of CAP-1002 will depend to a large degree on the outcome of these planned studies.

CAP-1001 – In 2011, CSMC, in collaboration with JHU, completed a Phase I, 25 patient clinical trial called CADUCEUS. In this study, 25 patients were enrolled who had suffered a heart attack within a mean of 65 days. 17 of those patients received CAP-1001 and the remaining eight received standard of care. 12 months after the study was completed, no measurable safety effects occurred in the 17 patients who were treated with CAP-1001. 16 of the 17 treated patients showed a mean reduction of approximately 45% in scar mass and an increase in viable heart muscle one-year post heart attack. The eight patients in the control group had no significant change in infarct (scar) size. At present, there is no plan for another clinical trial for CAP-1001. Capricor's strategy for further development of CAP-1001 will depend to a large degree on the outcome of its trial involving its CAP-1002 product, and its ability to obtain significant capital to conduct further studies to further develop this product.

CSps – This product candidate is multicellular clusters called cardiospheres. This product is in pre-clinical development and has yet to be studied in humans. At present, there is no plan for a clinical trial of CSps.

Cenderitide. The Company acquired the rights to cenderitide in 2006, and incurred substantial losses surrounding the development of the product. Prior to the merger, Nile Therapeutics, Inc. had incurred approximately $19.9 million in expenses directly relating to the cenderitide development program through September 30, 2013. We are currently evaluating whether to proceed with further clinical development of this product.

CU-NP. The Company acquired the rights to CU-NP in September 2008. Prior to the merger, Nile Therapeutics, Inc. had incurred approximately $0.7 million directly relating to the CU-NP development program through September 30, 2013.We are currently evaluating whether to proceed with further clinical development of this product.

Our expenditures on current and future clinical development programs, particularly our CAP-1002 and cenderitide programs are expected to be substantial and to increase in relation to our available capital resources. 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, we cannot predict with any significant degree of certainty the amount of time which will be required to complete our clinical trials, the costs of completing 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 other factors, including:

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

Investment Income (Loss). Investment income (loss) for the years ended December 31, 2013 and 2012 was $(11,890) and $28,785, respectively. This decrease in investment income over the same period in 2012 is primarily due to realized losses on the marketable securities account as securities held were sold in 2013 due to additional operational cash needs.

Interest Expense. Interest expense for the years ended December 31, 2013 and 2012 was $58,134 and $0, respectively. This increase in interest expense over the same period in 2012 is due to the interest on the CIRM loan award, which was not disbursed until 2013.

Impairment of Goodwill. Goodwill impairment for the years ended December 31, 2013 and 2012 was approximately $1.9 million and $0, respectively. This impairment is a result of goodwill recorded at the consummation of the merger of approximately $1.9 million which the Company deemed fully impaired as of December 31, 2013.

Grant Income. Grant income for the years ended December 31, 2013 and 2012 was approximately $0.5 million and $1.9 million, respectively. This decrease in grant income in 2013 as compared to 2012 is primarily due to the timing of activities under certain research and development projects that are covered under grant awards. These activities are not necessarily consistent from project to project and period to period. Additionally, in 2013 Capricor's primary grants were approaching the ends of their respective project periods.

Liquidity and Capital Resources

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

Liquidity and capital resources	December 31, 2013	December 31, 2012
Cash and cash equivalents	$ 1,730	$ 170
Working Capital	$ 1,628	$ 4,664
Stockholders' equity	$ (535)	$ 4,894

	Years ending December 31,	
Cash flow data	2013	2012
Cash (used in) provided by:		
Operating activities	$(6,144)	$(2,063)
Investing activities	3,778	(4,317)
Financing activities	3,925	5,000
Net increase (decrease) in cash and cash equivalents	$1,559	$(1,380)

The Company's total cash resources as of December 31, 2013 were approximately $1.7 million compared to approximately $0.2 million as of December 31, 2012. Total marketable securities, consisting primarily of United States treasuries, were approximately $0.3 million as of December 31, 2013 and approximately $4.2 million as of December 31, 2012. As of December 31, 2013, the Company had approximately $6.1 million in liabilities, and approximately $1.6 million in net working capital. The Company incurred a net loss of approximately $8.9 million and had negative cash flow from operating activities of approximately $6.1 million for the year ended December 31, 2013. Since July 5, 2005 (inception) through December 31, 2013, the Company has incurred an aggregate net loss of approximately $16.1 million, while negative cash flow from operating activities has amounted to approximately $13.1 million. To the extent we obtain sufficient capital and/or long-term debt funding 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 flow 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.

The Company had negative cash flow from operating activities of approximately $6.1 million, $2.1 million and $13.1 million for the years ended December 31, 2013 and 2012, and for the period from July 5, 2005 (inception) through December 31, 2013, respectively. The difference of approximately $4.0 million in cash used in operating activities for the year ended December 31, 2013 as compared to the same period of 2012 is primarily due to the fact that Capricor's net loss was substantially higher in 2013 as compared to 2012. Capricor was actively involved in clinical activities relating to the ALLSTAR Phase I/II trial throughout 2013, which increased overall operational losses. To the extent the Company obtains sufficient capital and/or long-term debt funding and is able to continue developing its product candidates, it expects to continue incurring substantial and increasing losses, which will continue to generate negative net cash flows from operating activities as the Company expands its technology portfolio and engages in further research and development activities, particularly in conducting pre-clinical studies and clinical trials.

The Company had positive cash flow from investing activities of approximately $3.8 million for the year ended December 31, 2013, negative cash flow from investing activities of approximately $4.3 million for the year ended December 31, 2012, and negative cash flow from investing activities of approximately $0.8 million for the period from July 5, 2005 (inception) through December 31, 2013. The difference in cash used in investing activities for the year ended December 31, 2013 as compared to the same period of 2012 is primarily due to the proceeds and payments from purchases and sales of marketable securities.

The Company had positive cash flow from financing activities of approximately $3.9 million, $5.0 million and $15.6 million for the years ended December 31, 2013 and 2012, and for the period from July 5, 2005 (inception) through December 31, 2013, respectively. The cash flow of approximately $3.9 million in 2013 is a result of Capricor's CIRM loan financing, and the $5.0 million in 2012 is a result of a portion of the proceeds received from Capricor's A-3 financing.

Phase II of Capricor's ALLSTAR trial has been funded in large part through a loan award from CIRM. Following completion of the Phase II trial would be a Phase IIb and/or Phase III trial. If we continue with a Phase IIb or Phase III trial, we will need substantial additional capital in order to continue the development of CAP-1002. Pursuant to the Collaboration Agreement with Janssen, the CMC package will be developed by the joint efforts of Janssen and Capricor. Capricor will be required to reimburse Janssen for its costs of development up to an agreed-upon maximum amount. If Janssen exercises its exclusive option, Janssen will be responsible for any additional trials with respect to CAP-1002.

We need substantial additional capital in order to continue the development of cenderitide. We have not yet determined the exact nature of the next clinical trial or if there will be a clinical trial. Prior to the consummation of the Merger, the Company pursued alternative strategic transactions in an effort to obtain the means to continue development of cenderitide. Such alternatives included the possibility of collaborating with another biotechnology or pharmaceutical company to further develop cenderitide. Such efforts were unsuccessful and we were not able to raise the necessary funds that would allow us to proceed to the next clinical phase. All further clinical and other development activities for our cenderitide and CU-NP programs are being evaluated internally following the completion of the Merger.

From inception through December 31, 2013, Capricor has financed its operations through private sales of its equity securities, NIH grants, and a CIRM loan award. Prior to the Merger, Nile financed its operations through public sales of its equity. 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.

Our estimates regarding the sufficiency of our financial resources are based on assumptions that may prove to be wrong. We may need to obtain additional funds sooner than planned or in greater amounts than we currently anticipate. The actual amount of funds we will need to operate is subject to many factors, some of which are beyond

our control. These factors include the following:

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

Financing Activities by the Company

March 2013 Financing. On March 15, 2013, the Company 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.

On September 27, 2013, the Company and the holders of the 2013 Notes entered into an amendment to the 2013 Notes, which provided, among other things, that upon a Change of Control (as defined in the 2013 Notes), the conversion price applicable to the 2013 Notes and the exercise price applicable to the warrants issuable upon a Change of Control will be equal to the average dollar volume weighted average price ("VWAP") of the Company's common stock for each trading day during the period from July 8, 2013 to September 30, 2013. The average VWAP during such period was approximately $0.045 per share. Additionally, pursuant to the amendment, upon a conversion of the 2013 Notes in connection with a Change of Control, the holders confirmed that all obligations under the 2013 Notes would be deemed satisfied in full and released the Company from any claims relating to the 2013 Notes.

On October 21, 2013, the Company and the holders of the 2013 Notes entered into an amendment to the Convertible Note Purchase Agreement pursuant to which the Company sold to such holders additional notes having an aggregate principal amount of $120,510 (the "Additional Notes"). The Additional Notes have identical terms and conditions as the 2013 Notes described above and were allocated among the holders on a pro rata basis based on their initial purchase of the 2013 Notes. In exchange for the issuance of the Additional Notes, the Company received aggregate gross proceeds of $102,433. The 2013 Notes and the Additional Notes are collectively referred to herein as the 2013 Notes.

The 2013 Notes converted at the close of the merger between Nile and Capricor on November 20, 2013 into 251,044 shares of our common stock on a post-Reverse Stock Split basis. Additionally, 251,044 warrants to purchase our common stock at a strike price of $2.2725, on a post-Reverse Stock Split basis, were issued to the holders of the 2013 Notes. The shares of common stock underlying the 2013 Notes have not been registered. All obligations under the 2013 Notes are deemed satisfied, and the Company has been released from any claims relating to the 2013 Notes.

April 2012 Financing. On March 30, 2012, the Company entered into subscription agreements with certain purchasers pursuant to which we agreed to sell an aggregate of 67,000 shares of our common stock to such purchasers for a purchase price of $20.00 per share (calculated using the post-Reverse Stock Split factor of 1:50). In addition, for each share purchased, each purchaser also received three-fourths of a five-year warrant to purchase an additional share of common stock at an exercise price of $25.00 per share (calculated using the post-Reverse Stock Split factor of 1:50), resulting in the issuance of warrants to purchase an aggregate of 50,250 shares of our common stock. The total gross proceeds from the offering were $1.34 million, before deducting anticipated selling commissions and expenses of approximately $0.2 million. The closing of the offering occurred on April 4, 2012. In connection with the offering, we engaged Roth Capital Partners, LLC, or Roth, to serve as placement agent. Pursuant to the terms of the placement agent agreement, we agreed to pay Roth a cash fee equal to seven percent of the gross proceeds received by us, or approximately $93,800, plus a non-accountable expense allowance of $35,000. Richard B. Brewer, our former Executive Chairman, Joshua A. Kazam, our former President and Chief Executive Officer and a current director of the Company, Daron Evans, our former 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 5,500 shares of our common stock and warrants to purchase 4,125 shares of our common stock for an aggregate purchase price of $110,000.

The offer and sale of the shares and warrants were 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 was 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.

At the consummation of the merger between Nile and Capricor, warrants to purchase 50,063 shares of our common stock, which were issued in the April 2012 financing described above, were exchanged for 50,063 shares of our common stock, and certain April 2012 warrants were cancelled. After the exchange, warrants to purchase 187 shares of our common stock remain outstanding from the April 2012 issuance, which such warrants provide for a strike price of $2.2725.

Financing Activities by Capricor, Inc.

CIRM Loan Agreement. On February 5, 2013, Capricor entered into a Loan Agreement with CIRM (the "CIRM Loan Agreement"), pursuant to which CIRM agreed to disburse $19,782,136 to Capricor over a period of three and one-half years to support Phase II of the ALLSTAR clinical trial.

Under the CIRM Loan Agreement, Capricor is required to repay the CIRM loan with interest at the end of the loan period. The loan also provides for the payment of a risk premium whereby Capricor is required to pay CIRM a premium of up to 500% of the loan amount upon the achievement of certain revenue thresholds. The loan has a term of five years and is extendable annually up to ten years at Capricor's option if certain conditions are met. The interest rate for the initial term is set at the one-year LIBOR rate plus 2% ("base rate"), compounded annually, and becomes due at the end of the fifth year. After the fifth year, if the term of the loan is extended and if certain conditions are met, the interest rate will increase by 1% over the base rate each sequential year thereafter, with a maximum increase of 5% over the base rate in the tenth year. CIRM has the right to cease disbursements if a no-go milestone occurs or certain other conditions are not met. Under the terms of the CIRM Loan Agreement, CIRM deducted $36,667 from the initial disbursement to cover its costs in conducting financial due diligence on Capricor. CIRM will also deduct $16,667 from each disbursement made in the second and third year of the loan period to cover its costs of continuing due diligence. So long as Capricor is not in default under the terms of the CIRM Loan Agreement, 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 also be forgiven if Capricor elects to abandon the project under certain circumstances. Under the CIRM Loan Agreement, Capricor is required to meet certain financial milestones by demonstrating to CIRM prior to each disbursement of loan proceeds that it has funds available sufficient to cover 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. Capricor will not issue stock, warrants or other equity to CIRM in connection with this award.

The timing of the distribution of funds pursuant to the CIRM Loan Agreement shall be 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.

Convertible Preferred Stock. Prior to the Merger and without giving effect to the applicable multiplier, Capricor was authorized to issue 5,426,844 shares of convertible preferred stock, which was allocated as follows: Series A-1: 940,000 shares, all of which were issued; Series A-2: 736,844 shares, all of which were issued; and Series A-3: 3,750,000 shares, of which 1,500,000 shares were issued. During 2011 and 2012, the 1,500,000 shares of Series A-3 convertible preferred stock, par value of $0.001 per share, were issued by Capricor for cash proceeds of $6,000,000. Immediately prior to the effective time of the merger between Nile and Capricor, all shares of Capricor preferred stock were converted into shares of Capricor common stock pursuant to the terms of the merger agreement. The shares of Capricor preferred stock that were converted into Capricor common stock as a result of the merger and in accordance with the terms of the merger agreement, were exchanged according to the applicable multiplier for 6,591,494 shares of common stock of the Company, and all rights and preferences attached to the shares of Capricor preferred stock were rendered void.

Grant and Sub-grant Awards. In 2010, Capricor was awarded $2,993,268 in a federal grant from NIH to support the project entitled “Safety and Efficacy of Allogeneic Cardiosphere-derived Stem Cells After MI”. The award was issued under the American Recovery and Reinvestment Act of 2009. The award is subject to certain quarterly and annual reporting requirements as well as a final progress report. The award was used to fund a portion of the Phase I clinical trial for the CAP-1002 product, as well as various development activities associated with CAP-1002, and includes, among other permitted costs, certain allowable expenses such as personnel, supplies and certain patient costs. In the second quarter of 2013, the project period of the grant was extended until September 30, 2013 through an approved no-cost extension. As of December 31, 2013, the full amount of the award had been disbursed to Capricor.

In 2009, Capricor was awarded $124,791 in a federal grant through the NIH Small Business Innovation Research (“SBIR”) program for the project entitled, “Characterization and Potency of Optimized Cardiosphere-derived Stem Cell Method” (Phase I). The grant award is subject to quarterly and annual reporting requirements as stipulated in the Notice of Award, and is subject to certain terms and conditions. The award was complete as of December 31, 2013.

In 2011, Capricor was awarded an additional $397,217 (Phase II) in connection with the SBIR award from the NIH. In 2012, Capricor was awarded a third year under the award and was approved for an additional $425,410 (Phase III). In the third quarter of 2013, the project period of the grant was extended until August 30, 2013 through an approved no-cost extension. The award was complete as of December 31, 2013.

On August 21, 2013, Capricor was approved for a Phase IIB Bridge grant through the NIH SBIR program for continued development of its CAP-1002 product candidate. Under the terms of the grant, approximately $2,879,437 will be disbursed over three years subject to annual and quarterly reporting requirements. As of December 31, 2013,

no funds had been disbursed under the terms of this award. Capricor is currently in discussions with the NIH with respect to the possible use of the funds for other clinical purposes. It is possible that Capricor will deploy this grant to fund the Phase I portion of the DYNAMIC trial, the IND for which was submitted by Dr. Eduardo Marbán of CSMC. The Phase I portion of the DYNAMIC trial would be to use CAP-1002 to treat patients with advanced heart failure and a recent hospitalization for such. Capricor's decision to become involved in the DYNAMIC trial will depend on multiple factors, including, but not limited to: approval by the NHLBI to utilize the grant monies to fund the DYNAMIC trial, the ability of Capricor to reach an agreement with CSMC regarding the clinical operations aspect of the trial, and the assessment by Capricor of the appropriateness of DYNAMIC with respect to the Company's pipeline development plan.

Off -Balance Sheet Arrangements

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

Grant Income

The determination as to when income is earned is dependent on the language in each specific grant. Generally, the Company recognizes grant income in the period in which the expense is incurred for those expenses that are deemed reimbursable under the terms of the grant.

Research and Development Expenses and Accruals

Research and development, or R&D, expenses consist primarily of salaries and related personnel costs, clinical patient costs, consulting fees, costs of manufacturing personnel and supplies, and costs of service providers for pre-clinical, clinical and certain legal expenses resulting from intellectual property prosecution, and other expenses relating to the design, development, testing and enhancement of our product candidates. Except for certain capitalized patent expenses, R&D costs are expensed as incurred.

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 (“CROs”), clinical study sites, laboratories, consultants or other clinical trial vendors that perform activities in connection with a

trial. 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 fixed, variable and capped amounts. 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. These 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, 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 the accrual policy is to match the recording of expenses in the 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 estimates of the degree of completion of the event or events specified in the applicable 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, as applicable. We have issued stock options to employees, directors and consultants under our four stock option plans: (i) the Amended and Restated 2005 Stock Option Plan, (ii) the 2006 Stock Option Plan, (iii) the 2012 Restated Equity Incentive Plan (which superseded the 2006 Stock Option Plan), and (iv) the 2012 Non-Employee Director Stock Option Plan.

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

Stock options or other equity instruments to non-employees (including consultants) issued 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 general and administrative expense in the Statements of Operations. We expect to record additional non-cash compensation expense in the future, which may be significant.

Warrant Liability

The Company previously accounted 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. In connection with the merger between Nile and Capricor, 50,063 warrants issued in the April 2012 financing were eliminated and 50,063 shares of Company common stock were issued in exchange for cancellation of the warrants to purchase 50,063 shares of Company common stock. Furthermore, the 2013 Notes converted into shares of Company common stock and additional warrants for Company common stock were issued to the holders. Management has determined the warrant liability to be insignificant at December 31, 2013.

Long-Term Debt

Capricor accounts for the loan proceeds under its CIRM Loan Agreement as long-term liabilities. Capricor recognizes the CIRM loan disbursements as a loan payable as the principal is disbursed rather than recognizing the full amount of the award. Capricor recognizes the disbursements in this manner since the period in which the loan will be paid back will not be in the foreseeable future. The terms of the CIRM Loan Agreement contain certain forgiveness provisions that may allow for the principal and interest of the loan to be forgiven. The potential for forgiveness of the loan is contingent upon many conditions, some of which are outside of Capricor's control, and no such estimates are made to determine a value for this potential for forgiveness.

Restricted Cash

Capricor accounts for the disbursements received under the CIRM Loan Agreement which have not been attributed to a particular project's costs through the current period as restricted cash.

Recently Issued or Newly Adopted Accounting Pronouncements

In December 2011, the Financial Accounting Standards Board ("FASB") issued Accounting Standards Update ("ASU") No. 2011-11, *Disclosures about Offsetting Assets and Liabilities* ("ASU 2011-11"), and in January 2013, the FASB issued ASU No. 2013-01, *Clarifying the Scope of Disclosures about Offsetting Assets and Liabilities* ("ASU 2013-01"). The amendments in this update require enhanced disclosures around financial instruments and derivative instruments that are either (1) offset in accordance with either ASC 210, *Balance Sheet* ("ASC 210"), or ASC 815, *Derivatives and Hedging* ("ASC 815"), or (2) subject to an enforceable master netting arrangement or similar agreement, irrespective of whether they are offset in accordance with either ASC 210 or ASC 815. An entity should provide the disclosures required by those amendments retrospectively for all comparative periods presented. The Company adopted the disclosure requirements of ASU 2011-11. After considering the scope clarification in ASU 2013-01, the Company does not believe there will be a material effect on our consolidated financial statements or disclosures.

In February 2013, the FASB issued ASU 2013-02, *Reporting of Amounts Reclassified Out of Accumulated Other Comprehensive Income* ("ASU 2013-02"). ASU 2013-02 amends Accounting Standards Codification ("ASC") 220, *Comprehensive Income* ("ASC 220"), and requires entities to present the changes in the components of accumulated other comprehensive income for the current period. Entities are required to present separately the amount of the change that is due to reclassifications, and the amount that is due to current period other comprehensive income. These changes are permitted to be shown either before or net-of-tax and can be displayed either on the face of the financial statements or in the footnotes. ASU 2013-02 was effective for our interim and annual periods beginning January 1, 2013. The adoption of ASU 2013-02 did not have a material effect on our consolidated financial position or results of operations.

In July 2013, the FASB issued ASU 2013-11, *Income Taxes (Topic 740): Presentation of an Unrecognized Tax Benefit When a Net Operating Loss Carryforward, a Similar Tax Loss, or a Tax Credit Carryforward Exists* ("ASU 2013-11"), which eliminates diversity in practice for the presentation of an unrecognized tax benefit when a net operating loss carryforward, a similar tax loss or a tax credit carryforward is available to reduce the taxable income or tax payable that would result from disallowance of a tax position. ASU 2013-11 affects only the presentation of such amounts in an entity's balance sheet and is effective for fiscal years beginning after December 15, 2013 and interim periods within those years. Early adoption is permitted. We are evaluating the impact, if any, of the adoption of ASU 2013-11 on our consolidated balance sheet.

ITEM 7A. QUANTITATIVE AND QUALITATIVE DISCLOSURES ABOUT MARKET RISK

Interest Rate Sensitivity

The Company's exposure to market risk for changes in interest rates relates primarily to its marketable equity securities and cash and cash equivalents. As of December 31, 2013, the fair value of the Company's cash and cash equivalents and its marketable securities was approximately $2.1 million. Additionally, as of December 31, 2013, Capricor's portfolio consisted of marketable securities, including primarily United States treasuries and bank savings and checking accounts. Capricor did not have any investments with significant exposure to the subprime mortgage market issues.

The goal of the Company's investment policy is to place its investments with highly rated credit issuers and limit the amount of credit exposure. We seek to improve the safety and likelihood of preservation of our invested funds by limiting default risk and market risk. Our investments may be exposed to market risk due to fluctuation in interest rates, which may affect our interest income and the fair market value of our investments, if any. We will manage this exposure by performing ongoing evaluations of our investments. Due to the short-term maturities, if any, of our investments to date, their carrying value has always approximated their fair value. The Company's policy is to mitigate default risk by investing in high credit quality securities, and we currently do not hedge interest rate exposure. Due to our policy of only making investments in United States treasury securities with primarily short-term maturities, we believe that the fair value of our investment portfolio would not be significantly impacted by a hypothetical 100 basis

point increase or decrease in interest rates.

ITEM 8. Financial Statements and Supplementary Data

Financial Statements Index

REPORT OF INDEPENDENT REGISTERED PUBLIC ACCOUNTING FIRM

To the Board of Directors and Stockholders of Capricor Therapeutics, Inc.

We have audited the accompanying consolidated balance sheets of Capricor Therapeutics, Inc. and its Subsidiary as of December 31, 2013 and 2012, and the related consolidated statements of operations and comprehensive loss, shareholders' equity, and cash flows for the years then ended and for the period from July 5, 2005 (inception) through December 31, 2013. Capricor Therapeutics, Inc.'s management is responsible for these financial statements. Our responsibility is to express an opinion on these financial statements based on our audits.

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

In our opinion, the consolidated financial statements referred to above present fairly, in all material respects, the financial position of Capricor Therapeutics, Inc. and its Subsidiary as of December 31, 2013 and 2012, and the results of their operations and their cash flows for years then ended and for the period from July 5, 2005 (inception) through December 31, 2013 in conformity with accounting principles generally accepted in the United States of America.

/s/ Rose Snyder & Jacobs LLP

Rose, Snyder & Jacobs LLP

Encino, California

March 31, 2014

42

CAPRICOR THERAPEUTICS, INC.

(A DEVELOPMENT STAGE COMPANY)

CONSOLIDATED BALANCE SHEETS

DECEMBER 31, 2013 AND 2012

ASSETS

	2013	2012
CURRENT ASSETS		
Cash and cash equivalents	$1,729,537	$170,106
Marketable securities	326,494	4,192,726
Restricted Cash	1,401,859	-
Grants receivable	-	767,163
Interest receivable	187	25,215
Prepaid expenses and other current assets	222,763	38,042
TOTAL CURRENT ASSETS	3,680,840	5,193,252
PROPERTY AND EQUIPMENT, at cost		
Furniture and equipment	38,850	29,623
Laboratory equipment	115,766	68,878
	154,616	98,501
Less accumulated depreciation	(80,429)	(64,558)
NET PROPERTY AND EQUIPMENT	74,187	33,943
OTHER ASSETS		
Patents, net of accumulated amortization of $32,475 and $28,145 respectively	227,207	178,307
Loan fees, net of accumulated amortization of $6,722 and $0, respectively	29,945	-
In-process research and development, net of accumulated amortization of $0	1,500,000	-
Deposits	25,728	18,088
TOTAL ASSETS	$5,537,907	$5,423,590
LIABILITIES AND SHAREHOLDERS' EQUITY		
CURRENT LIABILITIES		
Accounts payable and accrued expenses	$1,506,509	$264,707
Accounts payable and accrued expenses, related party	382,142	164,484
Sub-award payable, related party	41,855	75,072
Accrued royalties	122,416	24,904
TOTAL CURRENT LIABILITIES	2,052,922	529,167

LONG-TERM LIABILITIES		
Loan payable	3,961,733	-
Accrued interest	58,134	-
TOTAL LONG-TERM LIABILITIES	4,019,867	-
TOTAL LIABILITIES	6,072,789	529,167
SHAREHOLDERS' EQUITY		
Common stock, $0.001 par, 50,000,000 and 100,000,000 shares authorized, respectively, 11,687,747 and 10,351,294 shares issued and outstanding, respectively	11,687	10,351
Additional paid-in capital	15,552,946	12,114,689
Subscription receivable	-	(2,211)
Accumulated other comprehensive loss	(980)	(21,795)
Deficit accumulated during the development stage	(16,098,535)	(7,206,611)
TOTAL SHAREHOLDERS' EQUITY	(534,882)	4,894,423
TOTAL LIABILITIES AND SHAREHOLDERS' EQUITY	$5,537,907	$5,423,590

See accompanying notes to consolidated financial statements

CAPRICOR THERAPEUTICS, INC.

(A DEVELOPMENT STAGE COMPANY)

CONSOLIDATED STATEMENTS OF OPERATIONS AND COMPREHENSIVE LOSS

FOR THE YEARS ENDED DECEMBER 31, 2013 AND 2012 AND THE PERIOD

FROM JULY 5, 2005 (INCEPTION) THROUGH DECEMBER 31, 2013

	Years Ended December 31,		July 5, 2005 (inception) through December 31,
	2013	2012	2013
GRANT INCOME	$503,233	$1,898,764	$4,180,970
OPERATING EXPENSES			
Research and development	5,197,178	2,634,222	11,499,595
General and administrative	2,208,955	1,364,582	6,953,667
TOTAL OPERATING EXPENSES	7,406,133	3,998,804	18,453,262
LOSS FROM OPERATIONS	(6,902,900)	(2,100,040)	(14,272,292)
OTHER INCOME (EXPENSES)			
Investment income (loss)	(11,890)	28,785	150,891
Interest expense	(58,134)	-	(58,134)
Impairment of goodwill	(1,919,000)	-	(1,919,000)
TOTAL OTHER INCOME (EXPENSES)	(1,989,024)	28,785	(1,826,243)
NET LOSS	(8,891,924)	(2,071,255)	(16,098,535)
OTHER COMPREHENSIVE GAIN (LOSS)			
Net unrealized gain (loss) on marketable securities	20,815	(21,795)	(980)
COMPREHENSIVE LOSS	$(8,871,109)	$(2,093,050)	$(16,099,515)
Net loss per share, basic and diluted	$(0.85)	$(0.21)	
Weighted average number of shares, basic and diluted	10,501,416	9,945,251	

See accompanying notes to consolidated financial statements

CAPRICOR THERAPEUTICS, INC.

(A DEVELOPMENT STAGE COMPANY)

CONSOLIDATED STATEMENTS OF CHANGES IN SHAREHOLDERS' EQUITY

FOR THE PERIOD FROM JULY 5, 2005 (INCEPTION) THROUGH DECEMBER 31, 2013

	COMMON STOCK					
	SHARES	**AMOUNT**	**ADDITIONAL PAID-IN CAPITAL**	**SUBSCRIPTION RECEIVABLE**	**OTHER COMPREHENSIVE LOSS**	**DEFICIT ACCUMUL DURING T DEVELOP STAGE**
Balance, July 5, 2005	-	$-	$-	$-	$-	$-
Issuance of common shares to founders	3,734,740	3,735	(1,935)	(1,800)	-	-
Interest on subscription receivable	-	-	-	(36)	-	-
Net loss	-	-	-	-	-	36
Balance at December 31, 2005	3,734,740	3,735	(1,935)	(1,836)	-	36
Series A-1 preferred stock issuance for $1.54 per share, as converted	1,950,364	1,950	3,006,050	-	-	-
Interest on subscription receivable	-	-	-	(86)	-	-
Net loss	-	-	-	-	-	(1,171,419
Balance at December 31, 2006	5,685,104	5,685	3,004,115	(1,922)	-	(1,171,383
Interest on subscription receivable	-	-	-	(71)	-	-
Stock Based Compensation	-	-	5,820	-	-	-
Net loss	-	-	-	-	-	(979,076

Balance at December 31, 2007	5,685,104	5,685	3,009,935	(1,993)	-	(2,150,459
Common Stock issued for services at $0.15 per share	25,060	25	3,833	-	-	-
Interest on subscription receivable	-	-	-	(37)	-	-
Stock Based Compensation	-	-	16,422	-	-	-
Net loss	-	-	-	-	-	(630,859
Balance at December 31, 2008	5,710,164	5,710	3,030,190	(2,030)	-	(2,781,318
Series A-2 Preferred stock and warrants issued for cash at $1.83 per share, as converted	436,816	437	799,570	-	-	-
Interest on subscription receivable	-	-	-	(69)	-	-
Stock Based Compensation	-	-	8,251	-	-	-
Net loss	-	-	-	-	-	(148,970
Balance at December 31, 2009	6,146,980	6,147	3,838,011	(2,099)	-	(2,930,288
Series A-2 Preferred stock and warrants issued for cash at $1.83 per share, as converted	1,092,030	1,092	1,998,908	-	-	-
Equity Offering transaction costs	-	-	(91,155)	-	-	-
Interest on subscription receivable	-	-	-	(57)	-	-
Stock Based Compensation	-	-	24,163	-	-	-
Net loss	-	-	-	-	-	(1,055,748
	7,239,010	7,239	5,769,927	(2,156)	-	(3,986,036

Balance at December 31, 2010						
Series A-3 Preferred stock and warrants issued for cash at $1.93 per share, as converted	518,714	519	999,481	-	-	-
Interest on subscription receivable	-	-	-	(29)	-	-
Stock Based Compensation	-	-	15,527	-	-	-
Net loss	-	-	-	-	-	(1,149,320
Balance at December 31, 2011	7,757,724	7,758	6,784,935	(2,185)	-	(5,135,356
Series A-3 Preferred stock and warrants issued for cash at $1.93 per share, as converted	2,593,570	2,594	4,997,406	-	-	-
Interest on subscription receivable	-	-	-	(26)	-	-
Stock Based Compensation	-	-	332,347	-	-	-
Unrealized loss on marketable securities	-	-	-	-	(21,795)	-
Net loss	-	-	-	-	-	(2,071,255
Balance at December 31, 2012	10,351,294	10,351	12,114,689	(2,211)	(21,795)	(7,206,611
Interest on subscription receivable	-	-	-	(1)	-	-
Proceeds from subscription receivable	-	-	-	2,212	-	-
Stock Based Compensation	-	-	263,593	-	-	-
Reverse merger transaction	1,336,453	1,336	3,174,664	-	-	-

Reverse acquisition of Nile						
Unrealized gain (loss) on marketable securities	-	-	-	-	20,815	-
Net loss	-	-	-	-	-	(8,891,924
Balance at December 31, 2013	11,687,747	$11,687	$15,552,946	$-	$(980	) $(16,098,535

See accompanying notes to consolidated financial statements

CAPRICOR THERAPEUTICS, INC.

(A DEVELOPMENT STAGE COMPANY)

CONSOLIDATED STATEMENTS OF CASH FLOWS

FOR THE YEARS ENDED DECEMBER 31, 2013 AND 2012 AND THE PERIOD

FROM JULY 5, 2005 (INCEPTION) THROUGH DECEMBER 31, 2013

	Years Ended December 31,		July 5, 2005 (inception) through December 31,
	2013	2012	2013
CASH FLOWS FROM OPERATING ACTIVITIES:			
Net loss	$(8,891,924)	$(2,071,255)	$(16,098,535)
Adjustments to reconcile net loss to net cash used in operating activities:			
Gain on sale of property and equipment	-	-	(3,707)
Depreciation and amortization	26,923	20,337	164,732
Common stock issued for services	-	-	3,858
Impairment of goodwill	1,919,000	-	1,919,000
Stock-based compensation	263,593	332,347	666,123
Change in assets - (increase) decrease:			
Restricted cash	(1,401,859)	-	(1,401,859)
Grants receivable	767,163	(359,547)	-
Interest receivable	25,028	(25,215)	(187)
Prepaid expenses and other current assets	(161,617)	(26,684)	(199,659)
Deposits	(5,105)	(8,980)	(23,193)
Change in liabilities - increase (decrease):			
Accounts payable and accrued expenses	974,710	77,149	1,239,006
Accounts payable and accrued expenses, related party	217,658	4,554	382,142
Sub-award payable, related party	(33,217)	(5,349)	41,855
Accrued royalties	97,512	-	122,416
Accrued interest	58,134	-	58,134
NET CASH USED IN OPERATING ACTIVITIES	(6,144,001)	(2,062,643)	(13,129,874)
CASH FLOWS FROM INVESTING ACTIVITIES:			
Purchase of marketable securities	(226,998)	(4,214,521)	(4,441,519)
Proceeds from sales and maturities of marketable securities	4,114,045	-	4,114,045
Proceeds from sale of property and equipment	-	-	88,908
Payments for purchase of property and equipment	(56,115)	(13,428)	(284,923)
Proceeds from reverse merger	664	-	664
Payments for patents	(53,230)	(89,550)	(259,682)

NET CASH PROVIDED BY (USED IN) INVESTING ACTIVITIES	3,778,366	(4,317,499)	(782,507)
CASH FLOWS FROM FINANCING ACTIVITIES:			
Proceeds from the sale of series A-1 preferred stock	-	-	3,008,000
Proceeds from the sale of series A-2 preferred stock	-	-	2,800,007
Proceeds from the sale of series A-3 preferred stock	-	5,000,000	6,000,000
Proceeds from loan payable, net	3,925,066	-	3,925,066
Costs related to the issuance of preferred stock and warrants	-	-	(91,155)
NET CASH PROVIDED BY FINANCING ACTIVITIES	3,925,066	5,000,000	15,641,918
NET INCREASE (DECREASE) IN CASH AND CASH EQUIVALENTS	1,559,431	(1,380,142)	1,729,537
Cash and cash equivalents balance at beginning of period	170,106	1,550,248	-
Cash and cash equivalents balance at end of period	$1,729,537	$170,106	$1,729,537
SUPPLEMENTAL DISCLOSURES:			
Interest paid in cash	$-	$-	$-
Income taxes paid in cash	$-	$-	$-

See accompanying notes to consolidated financial statements

CAPRICOR THERAPEUTICS, INC.

(A DEVELOPMENT STAGE COMPANY)

NOTES TO CONSOLIDATED FINANCIAL STATEMENTS

DECEMBER 31, 2013 AND 2012

1. ORGANIZATION AND SUMMARY OF SIGNIFICANT ACCOUNTING POLICIES

Description of Business

Capricor Therapeutics, Inc., or the Company, is a development stage, biopharmaceutical company whose mission is to improve the treatment of cardiovascular diseases by commercializing innovative therapies. Capricor, Inc., or Capricor (a wholly-owned subsidiary of the Company), was founded in 2005 as a Delaware corporation based on the innovative work of its founder, Eduardo Marbán, M.D., Ph.D. After completion of a merger with Nile Therapeutics, Inc. or Nile, on November 20, 2013, Nile formally changed its name to Capricor Therapeutics, Inc. Capricor Therapeutics, together with our subsidiary, Capricor, currently have five drug candidates in various stages of development.

Consummation of Merger

On November 20, 2013, pursuant to that certain Agreement and Plan of Merger and Reorganization dated as of July 7, 2013, as amended by that certain First Amendment to Agreement and Plan of Merger and Reorganization, dated as of September 27, 2013 (as amended, the "Merger Agreement"), by and among Nile Therapeutics, Inc., a Delaware corporation ("Nile"), Bovet Merger Corp., a Delaware corporation and a wholly-owned subsidiary of Nile ("Merger Sub"), and Capricor, Merger Sub merged with and into Capricor and Capricor became a wholly-owned subsidiary of Nile (the "Merger"). Immediately prior to the effective time of the Merger (the "Effective Time") and in connection therewith, Nile filed certain amendments to its certificate of incorporation which, among other things (i) effected a 1-for-50 reverse split of its common stock (the "Reverse Stock Split"), (ii) changed its corporate name from "Nile Therapeutics, Inc." to "Capricor Therapeutics, Inc.," and (iii) effected a reduction in the total number of authorized shares of common stock from 100,000,000 to 50,000,000, and a reduction in the total number of authorized shares of preferred stock from 10,000,000 to 5,000,000.

At the Effective Time and in connection with the Merger, each outstanding share of Capricor's Series A-1, Series A-2 and Series A-3 Preferred Stock was converted into one share of common stock, par value $0.001 per share, of Capricor (the "Capricor Common Stock").

As a result of the Merger and in accordance with the terms of the Merger Agreement, each outstanding share of Capricor Common Stock was converted into the right to receive approximately 2.07 shares of the common stock of Capricor Therapeutics, par value $0.001 per share (the "Capricor Therapeutics Common Stock"), on a post 1-for-50 Reverse Stock Split basis. Immediately after the Effective Time and in accordance with the terms of the Merger Agreement, the former Capricor stockholders owned approximately 90% of the outstanding common stock of Capricor Therapeutics, and the Nile stockholders owned approximately 10% of the outstanding common stock of Capricor Therapeutics, in each case on a fully-diluted basis. For accounting purposes, the Merger is accounted for as a reverse merger with Capricor as the accounting acquiror (legal acquiree) and Nile as the accounting acquiree (legal acquiror).

Since Capricor was deemed to be the accounting acquiror in the merger, the historical financial information for periods prior to the merger reflect the financial information and activities solely of Capricor and not of Nile. The historical equity of Capricor has been retroactively adjusted to reflect the equity structure of Capricor Therapeutics using the respective exchange ratio established in the merger between Nile and Capricor, which reflects the number of shares Capricor Therapeutics issued to equity holders of Capricor as a result of the merger. The retroactive revision of Capricor's equity includes Capricor's preferred stock as if such shares of preferred stock had been converted into Capricor common stock at the respective dates of issuance, which is consistent with the terms of the merger. Accordingly, all common and preferred shares and per share amounts for all periods presented in the consolidated financial statements contained in this Annual Report on Form 10-K and notes thereto have been adjusted retrospectively, where applicable, to reflect the respective exchange ratio established in the merger.

The acquisition date fair value of the consideration transferred pursuant to the merger totaled $3,176,000. The preliminary goodwill recorded for the merger was $1,919,000. The initial fair values set forth below may be adjusted as additional information is obtained through the measurement period of the transaction and change the fair value allocation as of the acquisition date.

The following table summarizes the preliminary allocation of the purchase price on November 20, 2013 to the estimated fair values of the assets acquired and liabilities assumed in the merger:

CAPRICOR THERAPEUTICS, INC.

(A DEVELOPMENT STAGE COMPANY)

NOTES TO CONSOLIDATED FINANCIAL STATEMENTS

DECEMBER 31, 2013 AND 2012

1. ORGANIZATION AND SUMMARY OF SIGNIFICANT ACCOUNTING POLICIES (Continued)

Cash	$664
Prepaid expenses	25,639
In-process research and development	1,500,000
Accounts payable and accrued expenses	(269,303)
Net assets acquired	1,257,000
Goodwill	1,919,000
Total consideration	$3,176,000

Goodwill of $1,919,000 was comprised of the fair value of the stock issued in the merger of $3,176,000 less net assets acquired of $1,257,000. The Company determined goodwill to be fully impaired as of December 31, 2013. Since the acquisition date, the results of Nile have been included in the Company's consolidated financial results for the period from November 20, 2013 through December 31, 2013.

After the Effective Time, each then outstanding Capricor stock option, whether vested or unvested, was assumed by Capricor Therapeutics in accordance with the terms of (i) the 2006 Stock Option Plan, (ii) the 2012 Restated Equity Incentive Plan, or (iii) the 2012 Non-Employee Director Stock Option Plan, as applicable, and the stock option agreement under which each such option was issued. All rights with respect to Capricor Common Stock under outstanding Capricor options were converted into rights with respect to Capricor Therapeutics Common Stock.

Basis of Consolidation

Our consolidated financial statements include the accounts of the Company and our wholly-owned subsidiary. All intercompany transactions have been eliminated in consolidation.

Development Stage Activities

The Company is a development stage enterprise since it has not yet generated any revenue from the sale of products and, through December 31, 2013, its efforts have been principally devoted to developing its licensed technologies, recruiting personnel, developing its intellectual property portfolio, and raising capital. Accordingly, the accompanying financial statements have been prepared in accordance with the provisions of Accounting Standards Codification ("ASC") 915, "*Development Stage Entities*." The Company has experienced net losses since its inception and has an accumulated deficit of approximately $16.1 million at December 31, 2013. The Company expects to incur substantial and increasing losses and have negative net cash flows from operating activities as it expands its technology portfolio and engages in further research and development activities, particularly the conducting of pre-clinical and clinical trials.

Liquidity

The Company has historically financed its operations from equity financings. Since 2005, Capricor has used equity financed cash, government grant income and a CIRM loan award to finance its research and development activities as well as operational expenses.

Cash resources consisting of cash, cash equivalents and marketable securities as of December 31, 2013 were approximately $2.1 million, compared to $4.4 million as of December 31, 2012. Additionally, on January 7, 2014, Capricor received $12.5 million from Janssen Biotech, Inc. pursuant to the terms of the Collaboration Agreement and Exclusive License Option entered into on December 27, 2013. Furthermore, the Company will need substantial additional financing in the future until it can achieve profitability, if ever. The Company's continued operations will depend on its ability to raise additional funds through various potential sources, such as equity and debt financing, or to license its compounds to another pharmaceutical company. The Company will continue to fund operations from cash on hand and through sources of capital similar to those previously described, as well as government funded grants, and/or loans.

CAPRICOR THERAPEUTICS, INC.

(A DEVELOPMENT STAGE COMPANY)

NOTES TO CONSOLIDATED FINANCIAL STATEMENTS

DECEMBER 31, 2013 AND 2012

1. ORGANIZATION AND SUMMARY OF SIGNIFICANT ACCOUNTING POLICIES (Continued)

Use of Estimates

The preparation of financial statements in conformity with accounting principles generally accepted in the United States requires management to make estimates and assumptions that affect the reported amounts and disclosures. Management uses its historical records and knowledge of its business in making these estimates. Accordingly, actual results may differ from these estimates.

Cash and Cash Equivalents

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

Property and Equipment

Property and equipment are stated at cost. Repairs and maintenance costs are expensed in the period incurred. Depreciation is computed using the straight-line method over the related estimated useful lives.

Description	Estimated Useful Life
Office equipment, lab equipment and furniture	5 – 7 years

Government Research Grants

Government research grants that provide funding for research and development activities are recognized as income when the related expenses are incurred, when applicable.

Restricted Cash

As of December 31, 2013, restricted cash represents funds received under Capricor's Loan Agreement with the California Institute for Regenerative Medicine ("CIRM") (see note 2 below), to be allocated to the ALLSTAR clinical trial research costs as incurred.

Marketable Securities

At December 31, 2013, marketable securities consist primarily of United States treasuries. These investments are considered available-for-sale. Realized gains and losses on the sale of debt and equity securities are determined on the specific identification method. Unrealized gains and losses are presented as other comprehensive income (loss).

Intangible Assets

Amounts attributable to intellectual property consist primarily of the costs associated with the acquisition of certain technologies, patents, patents pending, and related intangible assets with respect to research and development activities. These long-term assets are stated at cost and are being amortized on a straight-line basis over the respective estimated useful lives of the assets ranging from five to fifteen years beginning on the date the patents become effective. Amortization expense was $4,330, $4,330 and $ 297,196 for the years ended December 31, 2013 and 2012 and for the period from July 5, 2005 (inception) through December 31, 2013, respectively. Future amortization expense for the next five years is estimated to be $4,330 per year. At December 31, 2013, the Company had $194,732 attributable to pending patents for which amortization has not begun.

As a result the merger, the Company recorded $1.5 million as in-process research and development, a component of intangible assets. An external valuation was performed to establish the value of the intellectual property primarily from licensed assets from the Mayo Foundation for Medical Education and Research that are currently being evaluated internally for future development plans. As of December 31, 2013, the Company has not begun amortizing the in-process research and development.

Long-Lived Assets

The Company accounts for the impairment and disposition of long-lived assets in accordance with guidance issued by the Financial Accounting Standards Board ("FASB"). Long-lived assets to be held and used are reviewed for events or changes in circumstances that indicate that their carrying value may not be recoverable, or annually. No impairment was recorded for the years ended December 31, 2013 and 2012 and for the period from July 5, 2005 (inception) through December 31, 2013.

CAPRICOR THERAPEUTICS, INC.

(A DEVELOPMENT STAGE COMPANY)

NOTES TO CONSOLIDATED FINANCIAL STATEMENTS

DECEMBER 31, 2013 AND 2012

1. ORGANIZATION AND SUMMARY OF SIGNIFICANT ACCOUNTING POLICIES (Continued)

Goodwill

The Company calculates goodwill as the difference between the acquisition date fair value of the estimated consideration paid in the merger and the values assigned to the assets acquired and liabilities assumed. Goodwill is not amortized but is generally subject to an impairment test annually or more frequently if an event or circumstance indicates that an impairment loss may have been incurred. The Company determined the goodwill balance of $1.9 million to be impaired as of December 31, 2013, and charged such amount to other expenses.

Income Taxes

Income taxes are recognized for the amount of taxes payable or refundable for the current year and deferred tax liabilities and assets are recognized for the future tax consequences of transactions that have been recognized in the Company's financial statements or tax returns. A valuation allowance is provided when it is more likely than not that some portion or the entire deferred tax asset will not be realized.

The Company uses guidance issued by the FASB that clarifies the accounting for uncertainty in income taxes recognized in an enterprise's financial statements and prescribes a recognition threshold of more likely than not and a measurement process for financial statement recognition and measurement of a tax position taken or expected to be taken in a tax return. In making this assessment, a company must determine whether it is more likely than not that a tax position will be sustained upon examination, based solely on the technical merits of the position and must assume that the tax position will be examined by taxing authorities. The Company’s policy is to include interest and penalties related to unrecognized tax benefits in income tax expense. Interest and penalties totaled $0 for the years ended December 31, 2013 and 2012 and for the period from July 5, 2005 (inception) through December 31, 2013. The Company files income tax returns with the Internal Revenue Service (“IRS”) and the California Franchise Tax Board. The Company’s net operating loss carryforwards are subject to IRS examination until they are fully utilized and such tax years are closed.

Loan Payable

The Company accounts for the funds advanced under its California Institute for Regenerative Medicine ("CIRM") Loan Agreement (note 2) as a loan payable as the eventual repayment of the loan proceeds or its forgiveness is contingent upon certain future milestones being met and other conditions. As the likelihood of whether or not the Company will ever achieve these milestones or satisfy these conditions cannot be reasonably predicted at this time, the Company records these amounts as a loan payable.

Research and Development

Costs relating to the design and development of new products are expensed as research and development as incurred in accordance with FASB Accounting Standards Codification ("ASC") 730-10, *Research and Development*. Research and development costs amounted to $5,197,178, $2,634,222 and $11,499,595 for the years ended December 31, 2013 and 2012 and for the period from July 5, 2005 (inception) through December 31, 2013, respectively.

Comprehensive Income (Loss)

Comprehensive income (loss) generally represents all changes in stockholders' equity during the period except those resulting from investments by, or distributions to, stockholders. For the years ended December 31, 2013 and 2012 and for the period from July 5, 2005 (inception) through December 31, 2013, the Company's comprehensive income (loss) was $20,815, $(21,795), and $(980), respectively. The Company's other comprehensive income (loss) is related to a net unrealized gain (loss) on marketable securities.

Stock-Based Compensation

The Company accounts for stock-based employee compensation arrangements in accordance with guidance issued by the FASB, which requires the measurement and recognition of compensation expense for all share-based payment awards made to employees, consultants, and directors based on estimated fair values.

The Company estimates the fair value of stock-based compensation awards on the date of grant using an option-pricing model. The value of the portion of the award that is ultimately expected to vest is recognized as expense over the requisite service periods in the Company's statements of operations.

50

CAPRICOR THERAPEUTICS, INC.

(A DEVELOPMENT STAGE COMPANY)

NOTES TO CONSOLIDATED FINANCIAL STATEMENTS

DECEMBER 31, 2013 AND 2012

1. ORGANIZATION AND SUMMARY OF SIGNIFICANT ACCOUNTING POLICIES (Continued)

The Company estimates the fair value of stock-based compensation awards using the Black-Scholes model. This model requires the Company to estimate the expected volatility and value of its common stock and the expected term of the stock options; all of which are highly complex and subjective variables. The variables take into consideration, among other things, actual and projected employee stock option exercise behavior. The Company calculates an average of historical volatility of similar companies as a basis for its expected volatility. Expected term is computed using the simplified method provided within Securities and Exchange Commission Staff Accounting Bulletin No. 110. The Company has selected a risk-free rate based on the implied yield available on U.S. Treasury securities with a maturity equivalent to the expected term of the options.

Earnings (Loss) per Share

Basic earnings (loss) per share is computed using the weighted-average number of common shares outstanding during the period. Diluted earnings (loss) per share are computed using the weighted-average number of common shares and dilutive potential common shares outstanding during the period. Dilutive potential common shares, which primarily consist of stock options issued to employees and warrants issued to third parties, have been excluded from the diluted loss per share calculation because their effect is anti-dilutive.

For the year ended December 31, 2013 and December 31, 2012, warrants and options to purchase 5,220,800 and 5,413,413 shares, respectively, have been excluded from the computation of potentially dilutive securities.

Fair Value Measurements

Assets and liabilities recorded at fair value in the balance sheet are categorized based upon the level of judgment associated with the inputs used to measure their fair value. The categories are as follows:

Level Input:	Input Definition:
Level I	Inputs are unadjusted, quoted prices for identical assets or liabilities in active markets at the measurement date.
Level II	Inputs, other than quoted prices included in Level I, that are observable for the asset or liability through corroboration with market data at the measurement date.
Level III	Unobservable inputs that reflect management's best estimate of what market participants would use in pricing the asset or liability at the measurement date.

The following table summarizes fair value measurements by level at December 31, 2013 and 2012 for assets and liabilities measured at fair value on a recurring basis:

	December 31, 2013			
	Level I	Level II	Level III	Total
Marketable securities	$326,494	$-	$-	$326,494

	December 31, 2012			
	Level I	Level II	Level III	Total
Marketable securities	$4,192,726	$ -	$ -	$4,192,726

Carrying amounts reported in the balance sheet of cash and cash equivalents, grants receivable and accounts payable and accrued expenses, approximate fair value due to their relatively short maturity. The carrying amounts of the Company’s marketable securities approximate fair value based on market quotations from national exchanges at the balance sheet date. Interest and dividend income are recognized separately on the income statement based on classifications provided by the brokerage firm holding the investments. The fair value of borrowings is not considered to be significantly different than its carrying amount because the stated rates for such debt reflect current market rates and conditions.

CAPRICOR THERAPEUTICS, INC.

(A DEVELOPMENT STAGE COMPANY)

NOTES TO CONSOLIDATED FINANCIAL STATEMENTS

DECEMBER 31, 2013 AND 2012

1. ORGANIZATION AND SUMMARY OF SIGNIFICANT ACCOUNTING POLICIES (Continued)

Warrant Liability

The Company accounts for some of its warrants issued in accordance with the guidance on Accounting for Certain Financial Instruments with Characteristics of both Liabilities and Equity, which provides that the Company classifies the warrant instrument as a liability at its fair value and adjusts the instrument to fair value at each reporting period. The fair value of warrants is estimated by management using Black-Scholes. 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. Prior to the merger between Nile and Capricor, the Company and holders of warrants to purchase shares of common stock entered into agreements pursuant to which such holders agreed to receive an aggregate of 59,546 shares of the Company's common stock in exchange for the cancellation and surrender of their warrants. No proceeds were received by the Company from these issuances. Management has determined the value of warrant liability to be insignificant at December 31, 2013.

2. LOAN PAYABLE

On February 5, 2013, Capricor entered into a Loan Agreement with CIRM (the "CIRM Loan Agreement"), pursuant to which CIRM agreed to disburse $19,782,136 to Capricor over a period of three and one-half years to support Phase II of the ALLSTAR clinical trial.

Under the CIRM Loan Agreement, Capricor is required to repay the CIRM loan with interest at the end of the loan period. The loan also provides for the payment of a risk premium whereby Capricor is required to pay CIRM a premium of up to 500% of the loan amount upon the achievement of certain revenue thresholds. The loan has a term of five years and is extendable annually up to ten years at Capricor's option if certain conditions are met. The interest rate for the initial term is set at the one-year LIBOR rate plus 2% ("base rate"), compounded annually, and becomes due at the end of the fifth year. After the fifth year, if the term of the loan is extended and if certain conditions are met, the interest rate will increase by 1% over the base rate each sequential year thereafter, with a maximum increase of 5% over the base rate in the tenth year. CIRM has the right to cease disbursements if a no-go milestone occurs or certain other conditions are not met. Under the terms of the CIRM Loan Agreement, CIRM deducted $36,667 from the initial

disbursement to cover its costs in conducting financial due diligence on Capricor. CIRM will also deduct $16,667 from each disbursement made in the second and third year of the loan period to cover its costs of continuing due diligence. So long as Capricor is not in default under the terms of the CIRM Loan Agreement, 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 also be forgiven if Capricor elects to abandon the project under certain circumstances. Under the CIRM Loan Agreement, Capricor is required to meet certain financial milestones by demonstrating to CIRM prior to each disbursement of loan proceeds that it has funds available sufficient to cover 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. Capricor will not issue stock, warrants or other equity to CIRM in connection with this award.

The timing of the distribution of funds pursuant to the CIRM Loan Agreement shall be 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.

Capricor did not issue stock, warrants or other equity to CIRM in connection with this award. The due diligence costs to be deducted from each disbursement are capitalized and amortized to general and administrative expenses over the remaining term of the loan. As of December 31, 2013, $36,667 of loan costs were capitalized with $6,722, $0, and $6,722 expensed for the years ended December 31, 2013 and December 31, 2012 and the period from July 5, 2005 (inception) through December 31, 2013, respectively, with the balance of $29,945 to be amortized over the next 4.1 years.

On February 6, 2013, Capricor received loan proceeds of $857,267, net of loan costs. This loan amount will carry interest at the initial rate 2.77% per annum.

On July 8, 2013, Capricor received its second disbursement under the loan award for $3,067,799. This disbursement will carry interest at the initial rate of 2.45% per annum. A portion of the principle disbursed under the second disbursement is currently being recorded as restricted cash, as Capricor must expend for approved project costs in order to use these funds. For the year ended December 31, 2013 and for the period from July 5, 2005 (inception) through December 31, 2013, interest expense under the CIRM loan was $58,134 and $58,134, respectively.

CAPRICOR THERAPEUTICS, INC.

(A DEVELOPMENT STAGE COMPANY)

NOTES TO CONSOLIDATED FINANCIAL STATEMENTS

DECEMBER 31, 2013 AND 2012

3. STOCKHOLDER'S EQUITY

Reverse Stock Split

On November 20, 2013, we effected a reverse split of our common stock, par value $0.001 per share, at a ratio of one-for-fifty. Unless otherwise indicated, all share amounts, per share data, share prices, exercise prices and conversion rates set forth in these consolidated financial statements and related notes, where applicable, have been adjusted retroactively to reflect this reverse stock split.

Outstanding Shares

At December 31, 2013, there were 11,687,747 common shares issued and outstanding.

Conversion of all Convertible Preferred Stock at the Merger

Prior to the Merger and without giving effect to the applicable multiplier, Capricor was authorized to issue 5,426,844 shares of convertible preferred stock, which was allocated as follows: Series A-1: 940,000 shares, all of which were issued; Series A-2: 736,844 shares, all of which were issued; and Series A-3: 3,750,000 shares, of which 1,500,000 shares were issued. During 2011 and 2012, the 1,500,000 shares of Series A-3 convertible preferred stock, with a par value of $0.001 per share were issued for cash proceeds of $6,000,000. Immediately prior to the Effective Time, all shares of Capricor preferred stock were converted into shares of Capricor common stock pursuant to the terms of the Merger Agreement. The shares of Capricor preferred stock that were converted into Capricor common stock as a result of the Merger and in accordance with the terms of the Merger Agreement, were exchanged according to the applicable multiplier for 6,591,494 shares of common stock of the Company, and all rights and preferences (including dividends) attached to the shares of Capricor preferred stock were rendered void. The preferred shares are presented retrospectively as shares of common stock on an as-converted basis.

4.STOCK OPTIONS AND WARRANTS

Capricor, Inc. Warrants

During the year ended December 31, 2009, Capricor issued warrants to purchase shares of common stock in conjunction with the issuance of the Series A-2 Preferred Stock. Upon consummation of the merger on November 20, 2013, the warrants terminated per the terms of the original warrant agreement with no warrants being exercised prior to the termination.

Capricor Therapeutics, Inc. Warrants

In connection with its July 2009 private placement, the Company issued five-year warrants to purchase an additional 53,827 shares of common stock. The warrants were issued in three separate tranches, as follows:

- Warrants to purchase approximately 13,457 shares, representing 25% of the total warrant shares issued to investors, have an exercise price equal to $62.50
- Warrants to purchase approximately 13,457 shares, representing 25% of the total warrant shares issued to investors, have an exercise price equal to $85.50.
- Warrants to purchase approximately 26,913 shares, representing 50% of the total warrant shares issued to investors, have an exercise price equal to $114.00.

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

As consideration for its services as placement agent in connection with the July 2009 private placement, the Company also issued to designees of Riverbank Capital Securities, Inc. five-year warrants to purchase 4,366 shares of common stock at a price of $68.75 per share.

At the consummation of the merger, 317 shares of common stock were issued in exchange for the forfeiture of approximately 26,693 warrants issued as part of the July 2009 private placement. There are approximately 28,400 warrants remaining outstanding as of December 31, 2013 as part of the July 2009 private placement, with a weighted average exercise price of $94.00.

53

CAPRICOR THERAPEUTICS, INC.

(A DEVELOPMENT STAGE COMPANY)

NOTES TO CONSOLIDATED FINANCIAL STATEMENTS

DECEMBER 31, 2013 AND 2012

4. STOCK OPTIONS AND WARRANTS (continued)

In connection with the April 2010 Offering, the Company issued a total of 44,850 Unit Warrants, each of which has a term of five years and represents the right to purchase one share of the Company's common stock at an exercise price of $47.00 per share. In addition, the Company issued the underwriters a five-year warrant to purchase 7,800 shares of the Company's common stock at an exercise price of $47.00 per share. There are 52,650 warrants remaining outstanding as of December 31, 2013 as part of the April 2010 Offering, with a weighted average exercise price of $47.00.

In connection with the 2011 Offering, the Company issued a total of 50,000 warrants, each of which has a term of five years and represents the right to purchase one share of the Company's common stock at an exercise price of $30.00 per share. In addition, the Company issued to the Placement Agents a five-year warrant to purchase 5,000 shares of the Company's common stock at an exercise price of $30.00 per share. On August 1, 2013, the Company and the holders of warrants issued in connection with the Company's 2011 Offering entered into warrant exchange agreements whereby the Company issued a total of 9,166 shares of its common stock on a post-Reverse Stock Split basis. As a result, all of the warrants issued in connection with the June 2011 private placement were cancelled. No proceeds were received by the Company from this issuance.

In connection with the April 2012 financing, the Company issued a total of 50,250 warrants, each of which has a term of five years and represents the right to purchase one share of the Company's common stock at an exercise price of $25.00 per share. The warrants contained a non-standard anti-dilution features, such that, in the event the Company issues common shares at a price below the current exercise price of the warrants, the exercise price of the warrants will be adjusted based on the lower issuance price. This feature was triggered upon the conversion of the 2013 Notes. In previous years, management used a binomial option pricing model to determine the warrant liability. Upon consummation of the merger, 50,063 warrants were cancelled and exchanged for 50,063 shares of the Company's common stock. Management has determined that any additional liability is insignificant. There are 187 warrants remaining outstanding as of December 31, 2013 as part of the April 2012 financing, with a weighted average exercise price of $2.2725.

At the close of the merger between Nile and Capricor on November 20, 2013, certain convertible notes payable were converted into 251,044 shares of our common stock on a post-Reverse Stock Split basis. Additionally, 251,044

warrants to purchase shares of our common stock at a strike price of $2.2725, on a post-Reverse Stock Split basis, were issued to the holders of the 2013 Notes and certain additional notes issued in connection with the 2013 Notes.

The following schedule represents warrant activity for the year ended December 31, 2013:

	Warrants	Weighted Average Exercise Price
Outstanding at January 1, 2013	1,733,599	$ 3.38
Cancelled	(1,733,599)	3.38
Assumed from merger	81,237	63.33
Granted	251,044	2.27
Outstanding at December 31, 2013	332,281	$ 17.20

Stock Options

The Company’s Board of Directors has approved four stock option plans: (i) the Amended and Restated 2005 Stock Option Plan (ii) the 2006 Capricor Stock Option Plan, (iii) the 2012 Capricor Restated Equity Incentive Plan (which has superseded the 2006 Stock Option Plan) (the “2012 Plan”), and (iv) the 2012 Capricor Non-Employee Director Stock Option Plan (the “2012 Non-Employee Director Plan”).

The Company’s Amended and Restated 2005 Stock Option Plan (the “Plan”) was initially adopted by the Board of Directors on August 10, 2005. On July 26, 2010, the Company’s stockholders approved an amendment to the Plan increasing the total number of shares authorized for issuance thereunder to 190,000 after the effects of the Reverse Stock Split at the consummation of the merger. Under the Plan, incentives may be granted to officers, employees, directors, consultants, and advisors. Incentives under the Plan may be granted in any one or a combination of the following forms: (a) incentive stock options and non-statutory stock options, (b) stock appreciation rights, (c) stock awards, (d) restricted stock and (e) performance shares.

CAPRICOR THERAPEUTICS, INC.

(A DEVELOPMENT STAGE COMPANY)

NOTES TO CONSOLIDATED FINANCIAL STATEMENTS

DECEMBER 31, 2013 AND 2012

4.STOCK OPTIONS AND WARRANTS (continued)

After the effects of the Merger, the 2012 Plan reserved 4,149,710 shares for the grant of stock options, stock appreciation rights, restricted stock awards and performance unit/share awards to employees, consultants and other service providers. Included in the 2012 Plan are the shares that were originally reserved under the 2006 Stock Option Plan. Under the 2012 Plan, each option will be designated in the Award Agreement as either an Incentive Stock Option or a Nonstatutory Stock Option. Notwithstanding such designation, however, to the extent that the aggregate fair market value of the shares with respect to which Incentive Stock Options are exercisable for the first time by the participant during any calendar year (under all plans of the Company and any parent or subsidiary) exceeds one hundred thousand dollars ($100,000), such options will be treated as Nonstatutory Stock Options.

After the effects of the merger, the 2012 Non-Employee Director Plan reserved 2,697,311 shares for the grant of stock options to members of the Board of Directors, who are not employees of the Company.

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

The estimated weighted average fair values of the options granted during 2013 and 2012 were $0.53 and $0.60 per share, respectively.

The Company estimates the fair value of each option award using the Black-Scholes option-pricing model. The following assumptions we used for stock options issued in the year ended December 31, 2013 and December 31, 2012:

	December 31, 2013	December 31, 2012
Expected volatility	118%	100%
Expected term	0.1-7 years	5-7 years
Dividend yield	0%	0%
Risk-free interest rates	0.13-2.3%	0.63-1.34%

Employee stock-based compensation costs for the year ended December 31, 2013 and 2012 and for the cumulative period from July 5, 2005 (inception) through December 31, 2013, are as follows:

	Year ended December 31,		Period from July 5, 2005 (inception) through December 31, 2013
	2013	2012	
General and administrative	$263,593	$332,347	$ 666,123

The following table summarizes information about stock options outstanding and exercisable at December 31, 2013:

Shares Outstanding Range of Ex. Prices	Shares Outstanding	WA Term (yrs.)	WA Exercise Price
$0.16 - $0.19	100,627	4.80	$ 0.17
$0.30 - $0.37	4,709,838	8.36	$ 0.36
$0.87	56,021	4.95	$ 0.87
$18.50 - $28.50	10,330	1.89	$ 23.43
$34.00 - $44.50	11,703	0.59	$ 43.60
	4,888,519	8.22	$ 0.51

CAPRICOR THERAPEUTICS, INC.

(A DEVELOPMENT STAGE COMPANY)

NOTES TO CONSOLIDATED FINANCIAL STATEMENTS

DECEMBER 31, 2013 AND 2012

4. STOCK OPTIONS AND WARRANTS (continued)

Shares Exercisable			
Range of Ex. Prices	Shares Exercisable	WA Term (yrs.)	WA Exercise Price
$0.16 - $0.19	96,487	4.71	$ 0.17
$0.30 - $0.37	2,360,885	8.08	$ 0.37
$0.87	56,021	4.95	$ 0.87
$18.50 - $28.50	10,330	1.89	$ 23.43
$34.00 - $44.50	11,703	0.59	$ 43.60
	2,535,426	7.83	$ 0.67

As of December 31, 2013, the total unrecognized fair value compensation cost related to non-vested stock options was $600,539 which is expected to be recognized over approximately 2.7 years.

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

As of December 31, 2013, there were options granted and outstanding to purchase 4,888,519 shares of the Company’s common stock under the plans to employees and non-employees. During the year ended December 31, 2013 and 2012, 1,186,672 and 2,942,207 options, respectively, were granted to employees and non-employees under the plans.

The following is a schedule summarizing stock option activity for the year ended December 31, 2013:

	Number of Options	Weighted Average Exercise Price
Outstanding at January 1, 2013	3,679,814	$ 0.37
Granted	1,186,672	0.31
Assumed from merger	22,033	34.15
Exercised	-	-
Outstanding at December 31, 2013	4,888,519	$ 0.51
Exercisable at December 31, 2013	2,535,426	$ 0.67

5. CONCENTRATIONS

Cash Concentration

The Company has historically maintained checking accounts at two financial institutions. These accounts collectively are insured by the Federal Deposit Insurance Corporation up to $250,000. Historically, the Company has not experienced any losses in such accounts and believes it is not exposed to any significant credit risk on cash and cash equivalents. As of December 31, 2013 the Company maintained $3,274,631 of uninsured deposits.

6. COMMITMENTS AND CONTINGENCIES

Leases

Capricor leases space for its corporate offices pursuant to a lease effective for a two year period beginning July 1, 2013. The monthly payment will be $16,620 per month for the first twelve months of the term, and will increase to $17,285 per month for the second twelve months of the term. Capricor, Inc. also leases research facilities from Cedars-Sinai Medical Center, a shareholder of the Company, currently on a month-to-month basis.

Total rent expense to unrelated parties for the year ended December 31, 2013 and 2012 and for the period from July 5, 2005 (inception) through December 31, 2013 was $154,536, $61,782 and $216,318, respectively. Total rent expense to the related party for the year ended December 31, 2013 and 2012 and for the period from July 5, 2005 (inception) through December 31, 2013 was $54,648, $54,648, and $323,334, respectively.

CAPRICOR THERAPEUTICS, INC.

(A DEVELOPMENT STAGE COMPANY)

NOTES TO CONSOLIDATED FINANCIAL STATEMENTS

DECEMBER 31, 2013 AND 2012

6. COMMITMENTS AND CONTINGENCIES (continued)

Legal Contingencies

Periodically the Company may become involved in certain legal actions and claims arising in the ordinary course of business. There were no legal actions or claims reported at December 31, 2013.

7. LICENSE AGREEMENTS

Capricor's Technology - CAP-1002, CAP-1001 and CSPs

Capricor has entered into exclusive license agreements for intellectual property rights related to cardiac derived cells with Università Degli Studi Di Roma at la Sapienza (the University of Rome), JHU and CSMC. In addition, Capricor has filed patent applications related to enhancements or validation of the technology developed by its own scientists.

University of Rome License Agreement

Capricor and the University of Rome entered into a License Agreement, dated June 21, 2006 (the Rome License Agreement), which provides for the grant of an exclusive, world-wide, royalty-bearing license by the University of Rome to Capricor (with the right to sublicense) to develop and commercialize licensed products under the licensed patent rights in all fields. With respect to any new or future patent applications assigned to the University of Rome utilizing cardiac stem cells in cardiac care, Capricor has a first right of negotiation for a certain period of time to obtain a license thereto.

Pursuant to the Rome License Agreement, Capricor paid the University of Rome a license issue fee, as well as minimum annual royalties, and is obligated to pay a royalty received as a result of sublicenses granted. The minimum annual royalties are creditable against future royalty payments.

The Rome License Agreement will, unless extended or sooner terminated, remain in effect until the later of the last claim of any patent or until any patent application comprising licensed patent rights has expired or been abandoned. Under the terms of the Rome License Agreement, either party may terminate the agreement should the other party become insolvent or file a petition in bankruptcy. Either party shall have up to 90 days to cure its material breach.

The Johns Hopkins University License Agreement

Capricor and JHU entered into an Exclusive License Agreement, effective June 22, 2006 (the JHU License Agreement), which provides for the grant of an exclusive, world-wide, royalty-bearing license by JHU to Capricor (with the right to sublicense) to develop and commercialize licensed products and licensed services under the licensed patent rights in all fields and a nonexclusive right to the know-how. In May 2009, the JHU License Agreement was amended to add additional patent rights to the License Agreement in consideration of a payment to JHU and reimbursement of patent costs. Capricor and JHU executed a Second Amendment to the JHU License Agreement, effective as of December 20, 2013, pursuant to which, among other things, certain definitions were added or amended, the timing of certain obligations was revised and other obligations of the parties were clarified.

Pursuant to the JHU License Agreement, JHU was paid an initial license fee and, thereafter, Capricor is required to pay minimum annual royalties on the anniversary dates of the JHU License Agreement. The minimum annual royalties are creditable against running royalties on net sales of products and net service revenues which Capricor is also required to pay under the JHU License Agreement. In addition, Capricor is required to pay a certain percentage of the consideration received by it from sublicenses granted, and is required to pay JHU certain defined development milestone payments upon the successful completion of certain phases of its clinical studies and upon receiving FDA approval. These milestone payments range from $100,000 at the time Phase I is fully complete to $1,000,000 if FDA approval has been received. As of December 31, 2013, $100,000 has been accrued as the Phase I enrollment has been completed.

The JHU License Agreement will, unless sooner terminated, continue in effect in each applicable country until the date of expiration of the last to expire patent within the patent rights, or, if no patents are issued, then for twenty years from the effective date. Under the terms of the JHU License Agreement, either party may terminate the agreement should the other party become insolvent or file a petition in bankruptcy, or fail to cure a material breach within 30 days after notice. In addition, Capricor may terminate for any reason upon 60 days’ written notice.

CAPRICOR THERAPEUTICS, INC.

(A DEVELOPMENT STAGE COMPANY)

NOTES TO CONSOLIDATED FINANCIAL STATEMENTS

DECEMBER 31, 2013 AND 2012

7. LICENSE AGREEMENTS (continued)

Cedars-Sinai Medical Center License Agreement

On January 4, 2010, Capricor entered into an Exclusive License Agreement with CSMC (the CSMC License Agreement), for certain intellectual property rights. In 2013, the CSMC License Agreement was amended twice resulting in, among other things, a reduction in the percentage of sublicense fees which would have been payable to CSMC. Effective December 30, 2013, Capricor entered into an Amended and Restated Exclusive License Agreement with CSMC (the Amended CSMC License Agreement) pursuant to which, among other things, certain definitions were added or amended, the timing of certain obligations was revised and other obligations of the parties were clarified.

The Amended CSMC License Agreement provides for the grant of an exclusive, world-wide, royalty-bearing license by CSMC to Capricor (with the right to sublicense) to conduct research using the patent rights and know-how and develop and commercialize products in the field using the patents rights and know-how. In addition, Capricor has the exclusive right to negotiate for an exclusive license to any future rights arising from related work conducted by or under the direction of Dr. Eduardo Marbán on behalf of CSMC. In the event the parties fail to agree upon the terms of an exclusive license, Capricor shall have a non-exclusive license to such future rights, subject to royalty obligations.

Pursuant to the CSMC License Agreement, CSMC was paid a license fee and Capricor was obligated to reimburse CSMC for certain fees and costs incurred in connection with the prosecution of certain patent rights. Additionally, Capricor was required to meet certain spending and development milestones. Pursuant to the Amended CSMC License Agreement, Capricor remains obligated to pay royalties on sales of royalty-bearing products as well as a percentage of the consideration received from any sublicenses or other grant of rights. In 2010, Capricor discontinued its research under some of the patents.

The Amended CSMC License Agreement will, unless sooner terminated, continue in effect on a country by country basis until the last to expire of the patents covering the patent rights or future patent rights. Under the terms of the Amended CSMC License Agreement, unless waived by CSMC, the agreement shall automatically terminate: (i) if

Capricor ceases, dissolves or winds up its business operations; (ii) in the event of the insolvency or bankruptcy of Capricor or if Capricor makes an assignment for the benefit of its creditors; (iii) if performance by either party jeopardizes the licensure, accreditation or tax exempt status of CSMC or the agreement is deemed illegal by a governmental body; (iv) within 30 days for non-payment of royalties; (v) within 90 days if Capricor fails to undertake commercially reasonable efforts to exploit the patent rights or future patent rights; (vi) if a material breach has not been cured within 90 days; or (vii) if Capricor challenges any of the CSMC patent rights. Capricor may terminate the agreement if CSMC fails to cure any material breach within 90 days after notice.

Collaboration Agreement with Janssen Biotech, Inc.

On December 27, 2013, Capricor entered into a Collaboration Agreement and Exclusive License Option with Janssen Biotech, Inc., or Janssen, a wholly-owned subsidiary of Johnson & Johnson. Under the terms of the agreement, Capricor and Janssen agreed to collaborate on the development of Capricor's cell therapy program for cardiovascular applications, including its lead product, CAP-1002. Capricor and Janssen further agreed to collaborate on the development of cell manufacturing in preparation for future clinical trials. Under the agreement, Capricor was paid $12.5 million in January 2014, and Capricor will contribute to the costs of development of a chemistry, manufacturing and controls (CMC) package. In addition, Janssen has the exclusive right to enter into an exclusive license agreement pursuant to which Janssen would receive a worldwide, exclusive license to exploit CAP-1002 as well as certain allogeneic cardiospheres and cardiosphere-derived cells in the field of cardiology. Janssen has the right to exercise the option at any time until 60 days after the delivery by Capricor of the six-month follow-up results from Phase II of Capricor's ALLSTAR clinical trial for CAP-1002. If Janssen exercises its option rights, Capricor would receive an upfront license fee and additional milestone payments which may total up to $325.0 million. In addition, a double-digit royalty would be paid on sales of licensed products.

Company's Technology – Cenderitide and CU-NP

The Company has entered into an exclusive license agreement for intellectual property rights related to natriuretic peptides with the Mayo Foundation for Medical Education and Research and a Clinical Trial Funding Agreement with Medtronic, Inc., which also includes certain intellectual property licensing provisions.

Mayo License Agreement

The Company and the Mayo Foundation for Medical Education and Research, or Mayo, previously entered into a Technology License Agreement with respect to cenderitide on January 20, 2006. On June 13, 2008, the Company and Mayo entered into a Technology License Agreement with respect to CU-NP (the CU-NP Agreement). On November 14, 2013, the Company entered into an Amended and Restated License Agreement with Mayo (the Amended Mayo Agreement). The Amended Mayo Agreement amends and restates in its entirety each of the CD-NP Agreement and the CU-NP Agreement, and creates a single amended and restated license agreement between the Company and Mayo with respect to CD-NP and CU-NP.

58

CAPRICOR THERAPEUTICS, INC.

(A DEVELOPMENT STAGE COMPANY)

NOTES TO CONSOLIDATED FINANCIAL STATEMENTS

DECEMBER 31, 2013 AND 2012

7. LICENSE AGREEMENTS (continued)

The Amended Mayo Agreement provides for the grant of an exclusive, world-wide, royalty-bearing license by Mayo to the Company (with the right to sublicense) under the Mayo patents, patent applications and improvements, and a nonexclusive right under the know-how, for the development and commercialization of CD-NP and CU-NP in all therapeutic indications. With respect to any future patents and any improvements related to cenderitide and CU-NP owned by or assigned to Mayo, the Company has the exclusive right of first negotiation for the exclusive or non-exclusive rights (at the Company's option) thereto. Such exclusive right of negotiation shall be effective as of June 1, 2016, or such earlier date when the Company has satisfied certain payment obligations to Mayo.

Under each of the previous CD-NP Agreement and CU-NP Agreement, the Company paid Mayo up-front cash payments and the Company agreed to make certain performance-based cash payments to Mayo upon successful completion of certain milestones. Additionally, the Company issued certain amounts of common stock of the Company to Mayo under each agreement. The Amended Mayo Agreement restructured the economic arrangements of the CD-NP Agreement and CU-NP Agreement by, among other things, eliminating certain milestone payments and decreasing the royalty percentages payable upon the commercial sale of the products. Pursuant to the terms of the Amended Mayo Agreement, the Company agreed to pay to Mayo an annual license maintenance fee and to issue to Mayo an additional 18,000 shares of the Company's common stock as additional consideration for the grant of certain rights. Mayo also agreed to waive or defer the payment of certain fees owed to Mayo. All breaches and defaults by the Company under the terms of the CD-NP Agreement and CU-NP Agreement were waived by Mayo in the Amended Mayo Agreement.

The Amended Mayo Agreement will, unless sooner terminated, expire on the later of (i) the expiration of the last to expire valid claim contained in the Mayo patents, or (ii) the 20th anniversary of the Amended Mayo Agreement. Under the terms of the Amended Mayo Agreement, Mayo may terminate the agreement earlier (i) for the Company's material breach of the agreement that remains uncured after 90 days' written notice to the Company, (ii) for the Company's insolvency or bankruptcy, (iii) if the Company challenges the validity or enforceability of any of the patent rights in any manner, or (iv) if the Company has not initiated either the next clinical trial of cenderitide within two years of the effective date of the Amended Mayo Agreement or a clinical trial of CU-NP within two and one-half years of the effective date. The Company may terminate the Amended Mayo Agreement without cause upon 90 days' written notice.

We license certain patent and other intellectual property rights that cover our cenderitide and CU-NP product candidates from Mayo. In the past, we have relied on Mayo to file, prosecute and maintain patent applications, and to otherwise protect the intellectual property to which we have a license. Prior to the Amended Mayo License Agreement, we did not have primary control over these activities for certain of these patents or patent applications and other intellectual property rights. With the execution of the Amended Mayo License Agreement, we have the responsibility for the prosecution and maintenance of the Mayo patents and patent applications at our expense. We cannot be certain that the activities conducted by Mayo have been or will be conducted in compliance with applicable laws and regulations, or will result in valid and enforceable patents and other intellectual property rights. Our enforcement of certain of these licensed patents or defense of any claims asserting the invalidity of these patents would also be subject to the cooperation of the third parties. We are also responsible for paying any prosecution and maintenance fees of all Mayo patents and Mayo patent applications now existing and included in the Amended Mayo License Agreement.

Medtronic Clinical Trial Funding Agreement

In February 2011, the Company entered into a Clinical Trial Funding Agreement with Medtronic, Inc. (Medtronic). Pursuant to the agreement, Medtronic provided 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 pump technology.

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. Although the Medtronic agreement expired, there are certain provisions that survive the expiration of the agreement, including the obligation to pay royalties on products that might be covered by the Joint Intellectual Property.

8. RELATED PARTY TRANSACTIONS

Lease and Sub-Lease Agreements

Capricor leases space for its research facilities from CSMC, a shareholder of Capricor Therapeutics, Inc. (see note 6).

CAPRICOR THERAPEUTICS, INC.

(A DEVELOPMENT STAGE COMPANY)

NOTES TO CONSOLIDATED FINANCIAL STATEMENTS

DECEMBER 31, 2013 AND 2012

8. RELATED PARTY TRANSACTIONS (continued)

Beginning May 1, 2012, pursuant to a sublease agreement, Capricor subleased part of its office space to Frank Litvack, the Company's Executive Chairman, for $2,500 per month. On April 1, 2013, Capricor entered into a sublease with Reprise Technologies, LLC, a limited liability company which is wholly owned by Dr. Litvack, for $2,500 per month. The sublease is on a month-to-month basis. Capricor recognized $30,000, $20,000 and $50,000 in sublease income from the related party during the year ended December 31, 2013 and 2012, and for the period from July 5, 2005 (inception) through December 31, 2013, respectively. Sublease income is recorded as a reduction to general and administrative expenses.

Consulting Agreements

Effective May 1, 2012 Frank Litvack, the Company's Executive Chairman entered into a consulting agreement for $4,000 per month for consulting services. Effective January 1, 2013, the payment amount was increased to $10,000 per month payable for consulting services. On March 24, 2014, Capricor entered into a consulting agreement with Dr. Litvack memorializing the $10,000 per month compensation arrangement described above. The agreement is terminable upon 30 days' notice.

Sub-Award Agreement

Effective January 30, 2012, Capricor, Inc. entered into a sub-award agreement with CSMC. Sub-award payments totaling approximately $249,019, $244,069 and $503,899 were paid to CSMC during the year ended December 31, 2013 and 2012, and for the period from July 5, 2005 (inception) through December 31, 2013, respectively. At December 31, 2013, the Company had sub-awards payable of $41,855.

Payables to Related Party

At December 31, 2013 and 2012, the Company had accounts payable and accrued expenses, which excludes the sub-award payable, to CSMC totaling $382,142 and $164,484, respectively.

9. SUBSEQUENT EVENTS

On January 7, 2014, Capricor received a payment from Janssen Biotech, Inc. for $12.5 million pursuant to the terms of the Collaboration Agreement and Exclusive License Option entered into on December 27, 2013.

Item 9. Changes in and Disagreements With Accountants on Accounting and Financial Disclosure

None.

Item 9A. Controls and Procedures

Evaluation of Disclosure Controls and Procedures

We have adopted and maintain disclosure controls and procedures that are designed to ensure that information required to be disclosed in our reports under the Securities Exchange Act of 1934, as amended, is recorded, processed, summarized and reported within the time periods specified in the SEC's rules and forms and that such information is accumulated and communicated to our management, including our Chief Executive Officer and Principal Financial Officer, as appropriate, to allow for timely decisions regarding required disclosure. In designing and evaluating the disclosure controls and procedures, management recognizes that controls and procedures, no matter how well designed and operated, cannot provide absolute assurance of achieving the desired control objectives.

As required by Rule 13a-15(b), under the Securities Exchange Act of 1934, as amended, we carried out an evaluation, under the supervision and with the participation of management, including our Chief Executive Officer and Principal Financial Officer, of the effectiveness of the design and operation of our disclosure controls and procedures as of the end of the period covered by this report. Based on the foregoing, our Chief Executive Officer and Principal Financial Officer concluded that as of December 31, 2013, our disclosure controls and procedures were effective at the reasonable assurance level.

Management's Report on Internal Control over Financial Reporting

Our management is responsible for establishing and maintaining adequate internal control over financial reporting as defined in Rule 13a-15(f) and 15d-15(f) of the Securities Exchange Act of 1934, as amended. Our internal control over financial reporting is a process designed to provide reasonable assurance to our management and Board of Directors regarding the reliability of financial reporting and the preparation of financial statements for external purposes in accordance with generally accepted accounting principles and includes policies and procedures that: (1) pertain to the maintenance of records that, in reasonable detail, accurately and fairly reflect the transactions and dispositions of our assets; (2) provide reasonable assurance that transactions are recorded as necessary to permit preparation of financial statements in accordance with generally accepted accounting principles, and that our receipts and expenditures are being made only in accordance with authorizations of our management and directors; and (3) provide reasonable assurance regarding prevention or timely detection of unauthorized acquisition, use or disposition of our assets that could have a material effect on the financial statements.

Because of its inherent limitations, internal control over financial reporting may not prevent or detect misstatements, errors or fraud. Also, projections of any evaluations of effectiveness to future periods are subject to the risk that controls may become inadequate because of changes in conditions, or that the degree of compliance with the policies or procedures may deteriorate.

Our management assessed the effectiveness of our internal control over financial reporting as of December 31, 2013. The assessment was based upon the framework described in the "Integrated Control-Integrated Framework" issued by the Committee of Sponsoring Organizations of the Treadway Commission (1992 Framework) ("COSO"). Based on that assessment, management has concluded that our internal control over financial reporting was effective as of December 31, 2013.

This Annual Report on Form 10-K does not include an attestation report of our registered public accounting firm regarding internal control over financial reporting. Management's report was not subject to attestation by our registered public accounting firm pursuant to rules of the SEC that permit smaller reporting companies to provide only management's report in this Annual Report on Form 10-K.

Changes in Internal Controls over Financial Reporting

There have been no changes in our internal control over financial reporting (as defined in Rules 13a-15(f) and 15d-15(f) under the Securities Exchange Act of 1934, as amended) during the fiscal year ended December 31, 2013 that have materially affected, or are reasonably likely to materially affect, our internal control over financial reporting.

ITEM 9B. OTHER INFORMATION

None.

Part III

ITEM 10. Directors, Executive Officers and Corporate Governance

Directors and Executive Officers

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

Name	Age	Positions Held
Linda Marbán, Ph.D.	50	President, Chief Executive Officer and Director
Anthony Bergmann, M.B.A.	28	Principal Financial Officer and Vice President of Finance
Karen G. Krasney, J.D.	61	Executive Vice President and General Counsel
Andrew Hamer, M.D.	52	Vice President of Medical Affairs
Anthony Davies, Ph.D.	49	Chief Technology Officer
Rachel Smith, Ph.D.	35	Vice President of Research and Development
Frank Litvack, M.D.	58	Executive Chairman and Director
Joshua Kazam	36	Director
Gregory W. Schafer	48	Director
Earl M. (Duke) Collier, Jr.	65	Director
David B. Musket	55	Director
Louis Manzo	76	Director
Louis J. Grasmick	89	Director
George W. Dunbar, Jr.	66	Director

Linda Marbán, Ph.D. Dr. Marbán is currently serving as our Chief Executive Officer. Co-founder of Capricor, Dr. Marbán has been with Capricor since 2005 and became its Chief Executive Officer in 2010. She combines her background in research with her business experience to lead Capricor and create a path to commercialization for its novel stem-cell cardiac therapies. Dr. Marbán was the lead negotiator in procuring the license agreements that are the foundation of Capricor's intellectual property portfolio. Under her direction as Chief Executive Officer, Capricor secured approximately $27.0 million in non-dilutive grants and a loan award which funds Capricor's R&D programs and clinical trials involving its CAP-1002 product. Dr. Marbán's deep knowledge of the cardiac space in particular, allows her to provide unique direction for the company's development and growth. From 2003 to 2009, Dr. Marbán was with Excigen, Inc., a biotechnology start-up company, where she was responsible for business development, operations, pre-clinical research, and supervising the development of gene therapy products in a joint development agreement with Genzyme Corp. While at Excigen, she also negotiated a joint development and sublicense agreement with Medtronic Corp. utilizing Excigen's technology and supervised the building of a lab in which the work was to be performed. Dr. Marbán began her career in academic science, first at the Cleveland Clinic Foundation working on the biophysical properties of cardiac muscle. That work continued when she moved to a postdoctoral fellowship at Johns Hopkins University, or JHU. While at JHU, she advanced to the rank of Research Assistant Professor in the

Department of Pediatrics, continuing her work on the mechanism of contractile dysfunction in heart failure. Her tenure at JHU ran from 2000 to 2003. Dr. Marbán earned a Ph.D. from Case Western Reserve University in cardiac physiology.

Anthony Bergmann, M.B.A. Mr. Bergmann currently serves as our Vice President of Finance. Mr. Bergmann previously worked at the business management firm, Gettleson, Witzer and O'Connor, in Beverly Hills, California beginning in 2008, where he focused on accounting and finance for several production studios generating motion picture releases and worldwide revenue exceeding $1 billion. The firm's clients included foundations, trusts, and independent actors, writers, producers and directors across the entertainment industry. While at the firm, he focused on budgeting, tax forecasting and asset management. Mr. Bergmann joined Capricor in 2011 and has served as the Director of Finance since 2012. He was recently made Vice President of Finance of Capricor. He also serves as Capricor's corporate treasurer. Mr. Bergmann was instrumental in facilitating the company's Series A-3 $6.0 million Preferred Stock offering and helped structure the company's successful $19.8 million budget proposal to the California Institute for Regenerative Medicine for the company's Phase II clinical trial. Mr. Bergmann is responsible for all aspects of the Company's finance, accounting and HR functions. Mr. Bergmann graduated from Providence College with a BS in Management, and a minor in Finance. He has an MBA from the University of Southern California's Marshall School of Business. He is actively involved in various venture capital and entrepreneurial associations throughout the Los Angeles area.

Karen G. Krasney, J.D. Ms. Krasney is currently serving as our Executive Vice President, Secretary and General Counsel. Ms. Krasney's career spans over 35 years serving as General Counsel for numerous corporations and private companies engaged in a wide variety of industries. Her extensive background and vast experience has been focused on domestic and international corporate and business law, as well as litigation. Ms. Krasney has been involved in the medical technology arena since the mid 1990's, representing several medical technology companies developing products for the treatment of cardiovascular disease. Commencing in 2002, Ms. Krasney served as legal counsel of Biosensors International Group Ltd., a multinational medical device company that develops, manufactures and sells medical devices for cardiology applications. In 2006, she accepted the position of General Counsel and Executive Vice President of Biosensors and served in that capacity until 2010. During her tenure at Biosensors, among other things, Ms. Krasney headed the legal team that facilitated the company's successful initial public offering in Singapore and was responsible for negotiating and documenting all agreements for the company worldwide, including licensing agreements with major medical device companies and agreements required for the company's international clinical trials. Ms. Krasney has been providing legal services to Capricor since 2011 and in 2012 joined Capricor as its Executive Vice President and General Counsel. Ms. Krasney also serves as a director on the Board of Cardiovascular Research Foundation, a non-profit research and education entity. Ms. Krasney received her Bachelor of Arts degree from the University of California, Los Angeles and her Juris Doctorate from the University of Southern California.

Andrew Hamer, M.D. Dr. Hamer is currently serving as our Vice President of Medical Affairs. He completed internal medicine and cardiology training at Green Lane Hospital in Auckland, New Zealand, having completed his degree in medicine from Otago University. Dr. Hamer also completed a Senior Cardiology Fellowship at the Deaconess Hospital and at Harvard Medical School in Boston. He served as Chairman of the New Zealand branch of the Cardiac Society of Australia and New Zealand from 2008 to 2009. In 2008, Dr. Hamer also co-chaired the Cardiac Surgery Services Development Working Group (CSSDG). In 2009, Dr. Hamer was selected by the Minister of Health to lead the development of the National Cardiac Surgery Clinical Network to oversee the implementation of the CSSDG recommendations, leading to substantial improvements in cardiac surgery delivery in New Zealand. In 2011, Dr. Hamer was asked to lead the expansion of the network to incorporate all of the cardiac services, forming the New Zealand Cardiac Clinical Network. In this role he led the implementation of national strategies to improve the equity and access to cardiac services and the establishment of national registries for acute coronary syndrome, percutaneous coronary intervention and cardiac surgery to enable continuous quality improvement from a local to national level. Dr. Hamer joined Capricor in November 2013 as the Vice President of Medical Affairs. Throughout this time, Dr. Hamer has been a cardiologist and internal medicine specialist at Nelson Hospital, where he has been a principal investigator for over 40 multi-center clinical trials in acute coronary syndrome, cholesterol, hypertension, heart failure, diabetes and atrial fibrillation management.

Anthony Davies, Ph.D. Dr. Davies joined Capricor in February, 2013 as the Chief Technology Officer, where he was responsible for the manufacturing, development and expansion of Capricor's cell-based therapeutic portfolio. From 2006 – 2012, Dr. Davies was Vice President, Product Development at Geron Corporation, a publicly traded biotechnology company with oncology and regenerative medicine programs. His team was responsible for multiple aspects of Geron's cell therapy portfolio development, including process and analytical development, device engineering, CMC regulatory interactions and manufacturing. During his tenure, his team supported multiple clinical trials and the first ever successful IND application for a human embryonic stem cell therapeutic. From 2005 to 2006, Dr. Davies was with Serologicals Corp. (now a division of EMD Millipore), a publicly traded diversified biological supply company, where he was responsible for global new product and process development. From 2004 to 2005, Dr. Davies was with Velico Medical, Inc. (formerly ZymeQuest, Inc.), a privately held transfusion medicine company, where he built manufacturing operations for all of the company's pre-commercial activities. Prior to Velico Medical, Dr. Davies worked at Onyx Pharmaceuticals, Inc., a publicly traded biopharmaceutical company, where he held positions of increasing responsibility while working on sorafenib, now co-marketed with Bayer as Nexavar®, a drug used in the treatment of multiple diseases with total worldwide sales in 2012 exceeding $1 billion. Dr. Davies received an MA in Biochemistry from the University of Cambridge and a Ph.D. from the University of Birmingham. He conducted postdoctoral research at the Institute of Virology at Oxford and the University of California, San Francisco. In January 2014, Dr. Davies resigned from his position as Chief Technology Officer of Capricor.

Rachel Smith, Ph.D. Dr. Smith is currently serving as our Vice President of Research and Development. Dr. Smith joined Capricor in 2008 and is a co-inventor of the CardiosphereTM technology that forms the core of Capricor's product portfolio. She also published the seminal proof-of-concept paper demonstrating the clinical utility of the Cardiosphere-derived stem cells in models of heart disease. Her research expertise encompasses the areas of stem cell biology, cardiac physiology, electrophysiology, as well as cell and tissue engineering. In 2012, Dr. Smith was appointed Vice President of Research and Development of Capricor and is responsible for developing the company's clinical trial protocols and managing its regulatory and research partner relationships. Dr. Smith obtained her Ph.D. in Biomedical Engineering from Johns Hopkins University under the advisement of Dr. Eduardo Marbán and with the support of a Whitaker Foundation Graduate Fellowship and a National Science Foundation Graduate Fellowship. She

received her undergraduate degree in Biomedical Engineering, Magna Cum Laude, from Tulane University.

Frank Litvack, M.D., FACC. Dr. Litvack is currently serving as our Executive Chairman and as a member of our Compensation Committee. Dr. Litvack is a native of Canada. He completed medical school and residency at McGill University in Montreal and a Cardiovascular Fellowship at Cedars Sinai Medical Center in Los Angeles, where he subsequently became co-director of the Cardiovascular Intervention Center and Professor of Medicine at UCLA. There he led a prominent clinical and research program known for its excellence in innovation, care and leadership in Translational Medicine. Dr. Litvack was Board certified in Internal Medicine, Cardiovascular Diseases and Interventional Cardiology. He has published more than one hundred research articles and chapters and is the recipient of several awards, including an American Heart Association Young Investigator Award, the Leon Goldman Medical Excellence Award for contributions to the field of biomedical optics and the United States Space Technology and Space Foundation Hall of Fame for pioneering work with the excimer laser. Dr. Litvack left full time practice and academics in 2000 to concentrate on entrepreneurial activities. Dr. Litvack has founded and operated several healthcare ventures, both as chairman and/or chief executive officer, including Progressive Angioplasty Systems Inc., a medical device company that was acquired by United States Surgical Corp. in 1998; Savacor, Inc., a medical device company that was acquired by St. Jude Medical in 2005; Conor Medsystems, Inc., a publicly traded medical device company that was acquired by Johnson & Johnson for $1.4 billion in 2007; and Entourage Medical Technologies Inc., a medical device company currently in development. He presently sits on the boards of several early stage healthcare companies and was a former director of publicly traded Nile Therapeutics, Inc. from 2009-2012. Dr. Litvack joined the Capricor Board as Executive Chairman in 2012. Dr. Litvack is currently a General Partner in Pura Vida Investment, LLC, a healthcare hedge fund and is serving as a Director on the Board of Cardiovascular Research Foundation, a non-profit research and education entity.

Joshua A. Kazam. Mr. Kazam served as Nile's non-employee President and Chief Executive Officer from June 2009 through August 2012, and has served as a director of the Company since inception in August 2005. In September 2004, Mr. Kazam co-founded Two River Group Holdings, LLC ("Two River"), and currently serves as Vice President and Director of Two River's managing member, Two River Group Management, LLC. Mr. Kazam also serves as an officer of the managing member of Two River Consulting, LLC, an organization that provides management, consulting and operational services for development stage biotechnology companies. 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 as the Director of Investment for the Orion Biomedical Fund, LP. 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.

Gregory W. Schafer. Mr. Schafer has served as a director of the Company since January 2008, and also serves as Chairman of the Audit Committee and as a member of the Nominating and Corporate Governance Committee. Mr. Schafer has served as Chief Financial Officer 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.

Earl M. (Duke) Collier, Jr. Mr. Collier joined the Capricor Board of Directors in 2011 and is a member of the Nominating and Corporate Governance Committee. He is currently the chief executive officer of 480 Biomedical, a medical device company developing products used in the treatment of peripheral artery disease, and serves as a Senior Advisor to Polaris Venture Partners, a venture capital firm focused on information technology and life sciences, and as executive chairman of Arsenal Medical, Inc., a medical device company. Mr. Collier was formerly Executive Vice President at Genzyme Corporation, a biotechnology company acquired by Sanofi for $20.1 billion in 2011. During his tenure at Genzyme, Mr. Collier was responsible for building the biosurgery business and overseeing the company's efforts in multiple sclerosis and other immune disorders. He has also led some of Genzyme's significant acquisitions and the formation of MG Biotherapeutics, Genzyme's joint venture with Medtronic Inc., which is focused on cardiac cell therapy. Mr. Collier also served as President of Vitas Healthcare, a hospice provider, as a partner at the Washington, DC-based law firm of Hogan and Hartson and as Deputy Administrator of the Health Care Finance Administration (now CMS) in the U.S. Department of Health & Human Services. Mr. Collier sits on the boards of several corporations including Arsenal Medical, Inc. and Pervasis Therapeutics, a biotechnology company. He is also chairman of the board for the Newton-Wellesley Hospital. From 2006 to 2009, Mr. Collier served as a director of publicly traded Decode Genetics Inc. (DGI Resolution, Inc.), a biopharmaceutical company. Mr. Collier earned a Bachelor of Arts degree at Yale University and received a law degree from the University of Virginia Law School.

64

David B. Musket. Mr. Musket joined the Capricor Board of Directors in 2012 and is a member of the Audit Committee and the Compensation Committee. Mr. Musket has vast experience in strategic finance and has been following developments in the pharmaceutical and medical device industries for over 30 years. Mr. Musket began his investment career as an equities research analyst at Goldman Sachs & Co. following the pharmaceutical industry. In 1991 he founded Musket Research Associates, a venture banking firm focused exclusively on emerging healthcare companies. In 1996 he co-founded ProMed Management, a healthcare-focused investment partnership. He is still actively involved with both of these entities. He has served on the boards of several private and public companies throughout his career, and is currently on the board of privately held TherOx, Inc., a medical device company. From 1999 to 2007, Mr. Musket served on the board of directors of publicly traded Conor MedSystems, Inc., a medical device company sold to Johnson & Johnson in 2007 for $1.4 billion. Mr. Musket holds a Bachelor of Arts degree in Biology and Psychology from Boston College.

Louis Manzo. Mr. Manzo was one of the initial investors in Capricor and joined the Capricor Board of Directors in 2006. Mr. Manzo is also a member of the Compensation Committee and the Nominating and Corporate Governance Committee. Mr. Manzo has been a prominent Baltimore entrepreneur for over three decades and has extensive experience in the area of finance. Mr. Manzo received his BS degree from the University of Notre Dame and his MBA from Harvard Business School. He served in the armed forces as an officer in the United States Navy. After completing his MBA at Harvard, Mr. Manzo joined, and in a few years became General Partner of, Baker, Watts & Co., a NYSE Member Firm. His experience there included being Director of Equity Research and later, the Head of Corporate Finance. During the 1980's, Mr. Manzo started his own private investment firm, LVM Venture Partners. Beginning in 1989, Mr. Manzo became part of the founders group which helped a Johns Hopkins cardiologist fund his launching of a research center for preventive cardiology. Mr. Manzo remained as an advisor during the center's formative years. His continued interest in preventive research included a major investment to research the use of protein modeling for early disease detection. Since 2002, he has been following and supporting research into the use of adult stem cells in the repair of spinal cord and heart damage. The list of private company boards, senior advisory roles, and charities that Mr. Manzo has been involved with over the years are numerous and varied, including: the Johns Hopkins Preventive Cardiology Center, a hospital center; Greater Baltimore Medical Center, a hospital; Goodwill Industries of Maryland, a non-profit organization; E.I.L Instruments, Inc., an instrument company; and Notre Dame University of Maryland, a private university.

Louis J. Grasmick. Mr. Grasmick was one of the initial investors in Capricor and joined the Capricor Board of Directors in 2006. Mr. Grasmick is a prominent Baltimore philanthropist and entrepreneur with over fifty years of executive experience. He is the chief executive officer of the Louis J. Grasmick Lumber Company, a supplier of industrial lumber, which he founded after playing professional baseball for seven years. His many accomplishments and positions include being director of the Harbor Bank of Maryland's Executive Committee, as well as past president of Signal 13, a non-profit organization. Mr. Grasmick currently sits on the board of directors for The Johns Hopkins Hospital Broccoli Center. Voted "Man of the Year" by both the Baltimore Junior Association of Commerce and the Variety Club, he was also honored by the Children's Guild of Maryland in 2009 with their award for "Making the Impossible Possible."

George W. Dunbar, Jr. Mr. Dunbar joined the Capricor Board of Directors in 2012 and is a member of the Audit Committee. Mr. Dunbar is currently President and Chief Executive Officer of ISTO Technologies. Inc., a

privately-held biotechnology company. Mr. Dunbar has extensive healthcare and life sciences operating experience, and has served as a former Director or CEO with a number of private and public life science companies. Prior to joining ISTO, commencing in 2010, Mr. Dunbar served as a Venture Partner with Arboretum Ventures, a leading healthcare venture capital firm. He has served as a board member for the following portfolio companies: IntelliCyt, a provider of high throughput screening and analytics for aiding drug discovery, KFx Medical, a medical device company (as chair), and CerviLenz, Inc., a medical device company (as executive chair). He was a past director and executive chair of Accuri Cytometers (now Becton Dickinson & Co.), a cell analysis and flow cytometer company. Mr. Dunbar has also served as the chief executive officer and/or a director of several publicly traded companies, all of which are involved in the healthcare industry. Previously, he served as chairman and chief executive officer of publicly traded Aastrom Biosciences, a biotechnology company developing therapies for severe, chronic cardiovascular diseases; as a director and chief executive officer of publicly traded Stem Cells Inc. (formerly Cyto Therapeutics), a company engaged in the development of stem cell therapies; as a director and chief executive officer of publicly traded Metra Biosystems, a bio-marker discovery company; as a director of publicly traded DepoTech, a biotechnology company; as a director of publicly traded LJL Biosystems, a provider of drug discovery automated systems to the life sciences industry; and as a director of publicly traded Quidel Corporation, a company which develops and markets diagnostic testing solutions. Mr. Dunbar has also worked with several venture capital groups and served as an advisor, director, or chief executive officer to several private life sciences companies, including Quantum Dot, a Versant Ventures/MPM Capital company; Targesome, an Alloy Ventures/CHL Medical Partners company; and Epic Therapeutics, an MPM Capital/Proquest Investments company. He has also held senior leadership positions with Ares-Serono, now Merck- Serono, and Amersham International, now GE Healthcare. Mr. Dunbar attended Auburn University where he graduated with a BS in Electrical Engineering and later received his MBA. He currently serves on the Harbert College of Business MBA Advisory Board and is an advisor to Vanderbilt University’s Center for Technology Transfer and Commercialization.

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 and other companies and professional backgrounds which we require to continue to grow and bring value to our stockholders. Dr. Frank Litvack, our Executive Chairman, has a wealth of business building experience and medical expertise that ensures that our activities are anchored in sound scientific research and solid business planning and practices. As an accomplished veteran of the healthcare industry who has orchestrated the founding, development and sale of several medical technology companies, we believe that Dr. Litvack provides invaluable knowledge and leadership to the company. Dr. Linda Marbán brings a wealth of knowledge in research and development especially for the treatment of cardiovascular disease. She has over a decade of experience in early stage life sciences companies, as well as business development expertise. Mr. Kazam and Mr. Musket have venture capital or investment banking backgrounds and offer expertise in financing and growing small biopharmaceutical companies. Each of Mr. Collier, Dunbar, Kazam, Manzo, Grasmick, Musket, 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. Dunbar and Mr. Collier have extensive experience in the pharmaceutical industry, allowing them to contribute their 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.

Section 16(a) Beneficial Ownership Reporting Compliance

Section 16(a) of the Securities Exchange Act of 1934, as amended, requires the Company's directors and officers and persons who own more than ten percent of a registered class of the Company's equity securities to file reports of ownership and reports of changes in the ownership with the SEC. Such persons are required by SEC regulations to furnish the Company with copies of all Section 16(a) forms they file. Based solely on its review of the copies of the forms submitted to it during the last fiscal year, the Company believes that, during the last fiscal year, all such reports were timely filed, except for a Form 4 filed by Joshua A. Kazam, a director, reporting the cancellation of warrants in exchange for common stock of the Company, effected on each of November 13, 2013 and November 20, 2013; a Form 3 filed by Cedars-Sinai Medical Center, a holder of more than 10% of the outstanding shares of common stock of the Company; and a Form 3 filed by MD BTI, LLC, a holder of more than 10% of the outstanding shares of common stock of the Company, all of which were inadvertently filed late.

Code of Business Conduct and Ethics

The Board of Directors has adopted a Code of Business Conduct and Ethics (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 to 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 violations of the Code, fair dealing and protection and use of Company assets.

A copy of the Code, as adopted by the Board of Directors, is available at the Corporate Governance page of our website at *www.capricor.com.* Please note that information contained on our website is not incorporated by reference in, or considered to be a part of, this Annual Report on Form 10-K. 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.

Audit Committee

The current members of our Audit Committee are Mr. Gregory Schafer (Chair), Mr. George Dunbar and Mr. David Musket. Our Board of Directors has determined that Mr. Schafer qualifies as an “audit committee financial expert,” as defined by the applicable rules of the SEC. Although our shares are not listed on the NASDAQ Stock Market, the Board has determined that all members are “independent” within the meaning of the applicable listing standard of the NASDAQ Stock Market.

Compensation Committee

The current members of our Compensation Committee are Dr. Frank Litvack, Mr. Louis Manzo and Mr. David Musket. Although our shares are not listed on the NASDAQ Stock Market, the Board has determined that all members are “independent” within the meaning of the applicable listing standard of the NASDAQ Stock Market.

Nominating and Corporate Governance Committee

The current members of our Nominating and Corporate Governance Committee are Mr. Earl Collier, Mr. Gregory Schafer and Mr. Louis Manzo. Although our shares are not listed on the NASDAQ Stock Market, the Board has determined that all members are “independent” within the meaning of the applicable listing standard of the NASDAQ Stock Market.

ITEM 11. EXECUTIVE COMPENSATION

The following summary compensation table reflects cash and non-cash compensation for the 2013 and 2012 fiscal years awarded to or earned by (i) each individual serving as our principal executive officer during the fiscal year ended December 31, 2013; and (ii) the two most highly-compensated individuals, other than our principal executive officer, that served as an executive officer at the end of the fiscal year ended December 31, 2013 and who received in excess of $100,000 in total compensation during 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 ($)
Linda Marbán, Ph.D.	2012	$ 190,313	–	–	–	$190,313
Chief Executive Officer	2013	$ 232,344	–	$ 108,000	–	$340,344
Karen Krasney, J.D.	2012	$ 130,000	–	$ 54,747	$ 1,000(2)	$185,747
Executive Vice President & General Counsel	2013	$ 189,390	–	–	$ 1,000(2)	$190,390
Anthony Davies, Ph.D.	2012	$ –	–	–	–	–
Chief Technology Officer	2013	$ 213,083	–	$ 49,272	$ 40,554(3)	$302,909
Darlene Horton, M.D.	2012	$ 81,439	–	–	–	$81,439
Former Chief Executive Officer	2013	$ 1,000	239,345(4)	–	–	$240,345

(1) Amounts reflect the grant date fair value of awards granted under the Capricor, Inc. 2012 Restated Equity Incentive 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 4 of the Notes to Consolidated Financial Statements included in this Annual Report on Form 10-K. See the *"Outstanding Equity Awards at Fiscal Year-End"* table, below, for information regarding all option awards outstanding as of December 31, 2013.

(2) Represents premiums contributed by Capricor for the employee's Health Flexible Spending account.

(3) Represents all amounts reimbursed to Mr. Davies during his employment relationship with Capricor for commuting expenses and a housing allowance.

(4) Represents the change of control bonus paid to Ms. Horton as part of the Employment Agreement between her and the Company dated August 3, 2012, as amended from time to time. As part of the change of control bonus and in connection with the merger between Nile and Capricor, the Company issued 77,208 shares of the Company's common stock on a post-Reverse Stock Split basis following completion of the merger between Nile and Capricor. The value of the compensation is derived using the closing price of the Company's common stock, as reported on the OTCQB, on November 27, 2013, the date seven days after the separation agreement between the Company and Ms. Horton was deemed effective. The shares were issued pursuant to the Company's Amended and Restated 2005 Stock Option Plan.

Employment Agreements and Post-Termination Benefits

Linda Marbán, Ph.D. — President and Chief Executive Officer

Dr. Linda Marbán's employment as our Chief Executive Officer is subject to the terms of that certain employment agreement dated September 1, 2010, by and between Capricor and Dr. Marbán. In accordance with the agreement, Dr. Marbán is required to devote three-fourths of her time to the position of Chief Executive Officer and is entitled to an annual salary of $150,000, which salary was increased to $232,344 for the period ended December 31, 2013. Dr. Marbán's employment is at-will, and she has also signed an employee invention assignment, non-disclosure, non-solicitation, and non-competition agreement. In addition, in 2010, Capricor issued to Dr. Marbán a 10-year stock option to purchase 414,971 shares of our common stock at an exercise price of $0.37 per share calculated after giving effect to the merger between Nile and Capricor. The vesting schedule for that grant is as follows: 25% of the shares of common stock subject to the option vested immediately; 20% of the remaining shares of common stock subject to the option have vested or will vest on each of September 1, 2011, September 1, 2012, September 1, 2013, September 1, 2014 and September 1, 2015. In 2013, Dr. Marbán was granted a second 10-year stock option to purchase 414,971 shares of our common stock at an exercise price of $0.30 per share calculated after giving effect to the merger between Nile and Capricor and which vests over a four-year period at the rate of 25% per year commencing June 1, 2014. Notwithstanding the vesting schedule, early exercise of options is permissible pursuant to her option agreement. The first grant was awarded pursuant to Capricor's 2006 Stock Option Plan and the second grant was awarded pursuant to Capricor's 2012 Restated Equity Incentive Plan. In the event the employment agreement is terminated during the term other than for cause, death or disability, she would be entitled to receive a severance payment equal to three months' salary then in effect. In addition, if upon the hiring of a new Chief Executive Officer, Capricor does not employ Dr. Marbán at a level of at least a vice-president, she would be entitled to receive a severance payment equal to three months' salary and the vesting of her then unvested options would be accelerated by six months.

Karen Krasney, J.D. — Executive Vice President, General Counsel

Karen Krasney's employment as our Executive Vice President and General Counsel is pursuant to an oral agreement which commenced March 1, 2012. Ms. Krasney's current base salary is $250,000 per year. In addition, Ms. Krasney has signed an at-will employment, confidential information, and invention assignment agreement, and an arbitration agreement. Additionally, in 2012, Ms. Krasney was granted a 10-year option to purchase 189,320 shares of our common stock at an exercise price of $0.37 per share calculated after giving effect to the merger between Nile and Capricor. 25% of the option shares vested November 1, 2012 and the remainder is vesting at the rate of 1/36 per month on the first day of each month commencing December 1, 2012. Notwithstanding the vesting schedule, early exercise of options is permissible pursuant to her option agreement. The grant was awarded pursuant to Capricor's 2012 Restated Equity Incentive Plan.

Anthony Davies, Ph.D. — Chief Technology Officer

Anthony Davies' employment as our Chief Technology Officer was subject to the terms of that certain employment agreement dated February 18, 2013, by and between Capricor and Mr. Davies. In accordance with the agreement, Dr. Davies was required to devote his full time to the position of Chief Technology Officer and was entitled to an annual salary of $260,000. In addition, Dr. Davies was to be considered for a discretionary annual bonus in an amount up to 20% of his base salary, commuting expenses during the period in which he was to relocate to Los Angeles, and a housing allowance of $4,000 per month for nine months effective after his relocation to Los Angeles. In addition, Dr. Davies signed an at-will employment, confidential information, and invention assignment agreement, and an arbitration agreement. In 2013, Capricor issued Dr. Davies a 10-year stock option to purchase 189,320 shares of our common stock at an exercise price of $0.30 per share calculated after giving effect to the merger between Nile and Capricor, which option was to vest at the rate of 25% per year commencing March 1, 2014. The grant was awarded pursuant to Capricor's 2012 Restated Equity Incentive Plan. Notwithstanding the vesting schedule, early exercise of options was permissible pursuant to his option agreement. Dr. Davies resigned from his position as Chief Technology Officer of Capricor in January 2014 and his contract terminated. No portion of his option shares was deemed vested.

Darlene Horton, M.D. — Former Chief Executive Officer

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

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

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

The agreement further provided that if, prior to December 31, 2013, the Company completed a Change of Control Transaction other than as described in the preceding paragraph, then Dr. Horton would 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).

Upon the consummation of the merger between Nile and Capricor, Dr. Horton executed a Separation Agreement and Release with the Company, in consideration for which she received the change of control bonus due pursuant to the terms of the March 21, 2013 letter agreement. As part of the change of control bonus and in connection with the Merger, the Company issued 77,208 shares of the Company's common stock on a post-Reverse Stock Split basis following completion of the merger. The shares were issued pursuant to the Company's Amended and Restated 2005 Stock Option Plan.

The foregoing summary of the March 21, 2013 letter agreement is qualified in its entirety by reference to the complete letter agreement, a copy of which is attached as Exhibit 10.3 to the Company's Current Report on Form 8-K, filed with the SEC on March 22, 2013. Additionally, the foregoing summary of the Separation Agreement and Release is qualified in its entirety by reference to the complete agreement, a copy of which is attached as Exhibit 10.10 to this Annual Report on Form 10-K.

Outstanding Equity Awards at Fiscal Year-End

The following table sets forth information concerning unexercised stock options held by the named executive officers at December 31, 2013:

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	
Linda Marbán, Ph.D.	290,480	124,491	—	0.37	09/01/2020	(1)
	—	414,971	—	0.30	05/14/2023	(2)(6)
Karen Krasney, J.D.	118,325	70,995	—	0.37	11/13/2022	(3)(6)
Anthony Davies, Ph.D.	—	189,320	—	0.30	02/22/2023	(4)(6)
Darlene Horton, M.D.	—	—	—	—	—	(5)

(1) Vesting schedule is as follows: 25% of the shares of common stock subject to this option vested immediately. 20% of the remaining shares of common stock subject to this option have vested or will vest on each of September 1, 2011, September 1, 2012, September 1, 2013, September 1, 2014 and September 1, 2015.

(2) Vesting schedule is as follows: The shares of common stock subject to this option vest 25% per year over 4 years commencing June 1, 2014.

(3) Vesting schedule is as follows: 25% of the shares of common stock subject to this option vested immediately, with the remainder vesting over 36 months commencing December 1, 2012.

(4) Vesting schedule is as follows: This shares of common stock subject to this option vest over 4 years with the first 25% of the shares of common stock subject to the option vesting on February 22, 2014. Dr. Davies resigned in January 2014, and no further options vested under the terms of his award.

(5) Darlene Horton was the former Chief Executive Officer of Nile Therapeutics, Inc. prior to the merger between Capricor and Bovet Merger Corp.

(6) The options issued under the 2012 Restated Equity Incentive Plan are subject to early exercise. If the option holder elects to take advantage of the early exercise feature and purchase shares prior to the vesting of such shares, the shares will be deemed restricted stock and will be subject to a repurchase option in favor of the Company if the option holder’s service to the Company terminates prior to vesting.

Compensation of Directors

The following table sets forth the compensation received by our directors for their service in 2013. Dr. Marbán is not listed below since she is an employee of Capricor Therapeutics and receives no additional compensation for serving on our Board of Directors or its committees. Additionally, Ms. Horton, the Company's former Chief Executive Officer, is not listed in the below table as she received no compensation for her service on the Board during the fiscal year ended December 31, 2013.

Name	Fees Earned or Paid in Cash	Option Awards (1)	Total
Frank Litvack, M.D. (2)	$ 120,000	$ 88,479	$208,479
George Dunbar	—	3,513	3,513
Louis Manzo	—	3,513	3,513
Louis Grasmick	—	3,445	3,445
Earl Collier	—	3,513	3,513
David Musket	—	3,513	3,513
Joshua Kazam (3)	—	—	—
Gregory Schafer (4)	—	—	—
Arie S. Belldegrun, M.D. (5)	—	—	—
Pedro Granadillo (5)	—	—	—
Peter M. Kash, Ed.D. (5)	—	—	—
Paul A. Mieyal, Ph.D. (5)	—	—	—

(1) Amounts reflect the grant date fair value of awards granted under the 2012 Restated Equity Incentive Plan and the 2012 Non-Employee Director 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 4 of the Notes to the Consolidated Financial Statements included in this Annual Report on Form 10-K.

(2) Dr. Litvack served on the Board of Directors of Nile Therapeutics, Inc. until October 28, 2012 and is currently the Executive Chairman of the Board of Directors of Capricor Therapeutics, Inc.

(3) Mr. Kazam was previously a member of the Nile Therapeutics, Inc. Board, and was not compensated for his services in 2013. Upon his appointment to the Capricor Therapeutics Board, he forfeited all prior options held. Pursuant to the terms of Nile's services agreement with Two River Consulting, LLC, or TRC, Mr. Kazam served as Nile's 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. The TRC agreement was terminated at

the close of the merger between Nile and Capricor. 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) Mr. Schafer was previously a member of the Nile Therapeutics, Inc. Board, and was not compensated for his services in 2013. Upon his appointment to the Capricor Therapeutics Board, he forfeited all prior options held.

(5) These directors resigned from the Board effective upon completion of the merger between Nile and Capricor on November 20, 2013.

ITEM 12. SECURITY OWNERSHIP OF CERTAIN BENEFICIAL OWNERS AND MANAGEMENT

The following table sets forth certain information known to us regarding the beneficial ownership of our common stock as of March 26, 2014 by:

- each of our directors,
- each named executive officer as defined and named in the Summary Compensation Table appearing herein,
- all of our directors and executive officers as a group, and,
- each person known by us to beneficially own more than five percent of our common stock (based on information supplied in Schedules 13D and 13G filed with the Securities and Exchange Commission).

Except as indicated by footnote, and subject to applicable community property laws, each person identified in the table possesses sole voting and investment power with respect to all capital stock shown to be held by that person. The address of each named executive officer and director, unless indicated otherwise, is c/o Capricor Therapeutics, Inc., 8840 Wilshire Blvd., 2nd Floor, Beverly Hills, CA 90211

Name of Beneficial Owner	Shares of Common Stock Beneficially Owned (1)	Percentage of Common Stock Beneficially Owned (1)
Named Executive Officers and Directors:		
Frank Litvack, M.D. (2)	1,316,145	10.1
George Dunbar (3)	87,784	*
Louis Manzo (4)	954,172	8.0
Louis Grasmick (5)	1,213,529	10.1
Earl Collier (6)	126,415	1.1
David Musket (7)	87,784	*
Joshua Kazam (8)	50,184	*
Gregory Schafer (9)	2	*
Linda Marbán, Ph.D. (10)	549,837	4.6
Karen Krasney, J.D. (11)	118,325	1.0
Darlene Horton, M.D. (12)	77,208	*
Anthony Davies Ph. D. (13)	-	-
Directors and executive officers as a group (13 individuals)	4,578,351	31.7

5% Stockholders:		
Dr. Eduardo Marbán (14)		
c/o 8840 Wilshire Blvd., 2nd Floor		
Beverly Hills, CA 90211	3,164,154	27.1
MD BTI, LLC (15)		
2560 Lord Baltimore Drive		
Baltimore, MD 21244	1,934,939	16.6
Cedars-Sinai Medical Center (16)		
8700 Beverly Blvd.		
West Hollywood, CA 90048	1,324,086	11.3

* Represents less than 1%.

(1) Based on 11,690,859 shares of our common stock outstanding as of March 26, 2014. Beneficial ownership is determined in accordance with Rule 13d-3 under the Exchange Act, and includes any shares as to which the security or stockholder has sole or shared voting power or investment power, and also any shares which the security or stockholder has the right to acquire within 60 days of March 26, 2014, whether through the exercise or conversion of any stock option, convertible security, warrant or other right. The indication herein that shares are beneficially owned is not an admission on the part of the security or stockholder that he, she or it is a direct or indirect beneficial owner of those shares.

(2) Includes 1,316,145 shares issuable upon the exercise of stock options that are exercisable or will become exercisable within 60 days of March 26, 2014.

(3) Includes 87,784 shares issuable upon the exercise of stock options that are exercisable or will become exercisable within 60 days of March 26, 2014.

(4) Includes (i) 638,155 shares held by Coniston Corporation, an entity of which Mr. Manzo was the sole owner. In December 2012, Mr. Manzo transferred 99% of the non-voting shares of Coniston Corporation to several irrevocable trusts established for the benefit of his children. Mr. Manzo retained the remaining 1% of the shares of Coniston and retains all voting power with respect to Coniston shares; and (ii) 316,017 shares issuable upon the exercise of options held individually by Mr. Manzo that are exercisable or will become exercisable within 60 days of March 26, 2014.

(5) Includes (i) 897,512 shares held by Nancelou Inc., an entity of which 50% is owned by Louis Grasmick and Nancy Grasmick, husband and wife, as tenants by the entirety, and the other 50% of which is owned by Grant Grasmick, the son of Louis Grasmick and Nancy Grasmick, and, as a result, Louis Grasmick, Nancy Grasmick and Grant Grasmick may be deemed to have shared voting and dispositive power with respect to the shares beneficially owned by Nancelou, Inc.; and (ii) 316,017 shares issuable upon the exercise of options held individually by Mr. Grasmick that are exercisable or will become exercisable within 60 days of March 26, 2014.

(6) Includes 126,415 shares issuable upon the exercise of stock options which are exercisable or will become exercisable within 60 days of March 26, 2014.

(7) Includes 87,784 shares issuable upon the exercise of stock options which are exercisable or will become exercisable within 60 days of March 26, 2014.

(8) Includes (i) 30,988 shares held by Mr. Kazam; (ii) 300 shares issuable upon the exercise of outstanding warrants held by Mr. Kazam; (iii) 12,276 shares held by the Kazam Family Trust, of which Mr. Kazam’s spouse is the trustee and his children are beneficiaries, and as to which Mr. Kazam disclaims beneficial ownership except to the extent of any pecuniary interest therein; (iv) 3,310 shares held by Mr. Kazam’s spouse as custodian for the benefit of their minor children, to which Mr. Kazam disclaims beneficial ownership except to the extent of his pecuniary interest therein; and (v) 3,310 shares held by the Kash Family Foundation, of which Mr. Kazam is trustee but as to which he has no pecuniary interest.

(9) Includes 2 shares held by Mr. Schafer.

(10) Includes (i) 259,357 shares held by Dr. Linda Marbán, and (ii) 290,480 shares issuable upon the exercise of options held by Dr. Marbán which are exercisable or will become exercisable within 60 days of March 26, 2014. Dr. Linda Marbán is our Chief Executive Officer.

(11) Includes 118,325 shares issuable upon the exercise of stock options which are exercisable or will become exercisable within 60 days of March 26, 2014.

(12) Represents the change of control bonus paid to Ms. Horton as part of the Employment Agreement between her and the Company dated August 3, 2012, as amended from time to time. As part of the change of control bonus and in connection with the merger between Nile and Capricor, the Company issued to Ms. Horton 77,208 shares of the Company's common stock on a post-Reverse Stock Split basis following completion of the merger between Nile and Capricor. The shares were issued pursuant to the Company's Amended and Restated 2005 Stock Option Plan.

(13) All of Mr. Davies' outstanding options expired unexercised upon the termination of his employment with the Company in January 2014.

(14) Includes 3,164,154 shares held by Dr. Eduardo Marbán.

(15) Includes (i) 1,556,141 shares held by MD BTI, LLC, which has the sole power to vote or direct the vote of, and sole power to dispose or direct the disposition of, all 1,556,141 shares held by it, (ii) 324,196 shares held by MD BTI, Inc.; and (iii) 54,602 shares held individually by Edward A. St. John. Edward St. John, LLC, a Delaware limited liability company, is the company manager (the "Company Manager") of MD BTI, LLC. Edward A. St. John, an individual, is the general manager of Company Manager. As the company manager of MD BTI, LLC, Company Manager is deemed to be the beneficial owner of the shares held by MD BTI, LLC and is therefore deemed to have shared voting and dispositive power over the 1,556,141 shares held by MD BTI, LLC. Mr. St. John is the sole member and general manager of Company Manager and is therefore deemed to be the beneficial owner of the shares held by Company Manager. Additionally, Mr. St. John is the president of MD BTI, Inc. and is therefore deemed to be the beneficial owner of the shares held by MD BTI, Inc. As a result of the foregoing, Mr. St. John has the sole power to vote or direct the vote of 54,602 Shares; has the shared power to vote or direct the vote of 1,880,337 Shares; has the sole power to dispose or direct the disposition of 54,602 Shares; and has the shared power to dispose or direct the disposition of 1,880,337 Shares.

(16) Includes 1,324,086 shares held by Cedars-Sinai Medical Center.

Securities Authorized for Issuance Under Equity Compensation Plans

Capricor Therapeutics, Inc. has three equity-incentive plans that have been approved by stockholders: (i) the Amended and Restated 2005 Stock Option Plan (the former Nile plan); (ii) the 2006 Stock Option Plan; and (iii) the 2012 Restated Equity Incentive Plan. The Company also has maintains the 2012 Non-Employee Director Stock Option Plan, which has not been approved by stockholders. The following table sets forth certain information as of December 31, 2013 with respect to the Company's equity incentive plans:

	Number of Securities to be Issued Upon Exercise of Outstanding Options	**Weighted-Average Exercise Price of Outstanding Options**	**Number of Securities Remaining Available for Future Issuance Under Equity Compensation Plans (Excluding Securities Reflected in Column)**
Plan category			
Equity compensation plans approved by security holders:			
The Amended and Restated 2005 Stock Option Plan	22,033	$ 34.15	21,272
The 2006 Stock Option Plan	737,607	$ 0.38	-
The 2012 Restated Equity Incentive Plan	1,491,612	$ 0.32	1,920,491
Equity compensation plans not approved by stockholders:			
2012 Non-employee Director Stock Option Plan	2,637,267	$ 0.37	60,044
Total	**4,888,519**	**$ 0.51**	**2,001,807**

ITEM 13. certain relationships and related transactions, and director independence

Certain Relationships and Related Transactions

Cedars-Sinai Medical Center

On July 27, 2010, Cedars-Sinai Medical Center ("CSMC") acquired 263,158 shares of Capricor, Inc.'s Series A-2 Convertible Preferred Stock and on April 20, 2012 acquired 375,000 shares of Capricor, Inc.'s A-3 Convertible Preferred Stock, which were exchanged for 1,324,086 shares of common stock of the Company after the effects of the merger between Nile and Capricor.

On January 4, 2010, Capricor entered into an Exclusive License Agreement with CSMC, (the CSMC License Agreement), for certain intellectual property rights. In 2013, the CSMC License Agreement was amended twice resulting in, among other things, a reduction in the percentage of sublicense fees which would have been payable to CSMC. Effective December 30, 2013, Capricor entered into an Amended and Restated Exclusive License Agreement with CSMC (the Amended CSMC License Agreement) pursuant to which, among other things, certain definitions were added or amended, the timing of certain obligations was revised and other obligations of the parties were clarified. The Amended CSMC License Agreement provides for the grant of an exclusive, world-wide, royalty-bearing license by CSMC to Capricor (with the right to sublicense) to conduct research using the patent rights and know-how and develop and commercialize products in the field using the patents rights and know-how. In addition, Capricor has the exclusive right to negotiate for an exclusive license to any future rights arising from work conducted by or under the direction of Dr. Eduardo Marbán on behalf of CSMC. In the event the parties fail to agree upon the terms of an exclusive license, Capricor shall have a non-exclusive license to such future rights, subject to royalty obligations. Pursuant to the CSMC License Agreement, CSMC was paid a license fee and Capricor was obligated to reimburse CSMC for certain fees and costs incurred in connection with the prosecution of certain patent rights. Additionally, Capricor was required to meet certain spending and development milestones. Pursuant to the Amended CSMC License Agreement, Capricor remains obligated to pay royalties on sales of royalty-bearing products as well as a percentage of the consideration received from any sublicenses or other grant of rights. In 2010, Capricor discontinued its research under some of the patents.

Capricor presently maintains its laboratory 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 30 days' notice to Capricor. With the permission of CSMC, 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 its Phase II trial.

Dr. Frank Litvack (Executive Chairman)

Since April, 2012, Dr. Frank Litvack has been serving as Capricor's Executive Chairman. In April 2012, Dr. Frank Litvack was given a director package when he agreed to serve as the Executive Chairman of Capricor, Inc. Pursuant to that Board package, Dr. Litvack was paid a consulting fee of $4,000 per month commencing upon his election to the Board. Such compensation increased to $10,000 per month upon Capricor, Inc.'s receipt of a CIRM award. Dr. Litvack was granted an option for a number of shares of Company common stock equal to ten percent (10%) of the outstanding shares of all Company stock on a fully diluted basis (the "Initial Option"), calculated as if all options and warrants granted or contemplated to be granted to Company employees, directors and other eligible participants had been granted and exercised as of the grant date of the Initial Option. 25% of the Initial Option vested on the first day of the month after his election to the Capricor, Inc. Board of Directors. The remainder was to vest at the rate of 1/36 per month over the following 36 month period. In connection with the merger between Nile and Capricor, Dr. Litvack's options were converted into options for the Company's common stock. He thus holds the following option grants for (i) 1,545,435 shares at $0.37 per share (ii) 140,270 at $0.37 per share (iii) 207,485 at $0.30 per share calculated after giving effect to the merger between Nile and Capricor.

Under Dr. Litvack's previous agreement with Capricor, Inc., upon the closing of each Qualified Financing until such time that Capricor, Inc. reached a threshold of $10 million financing (including the sums previously received from sales of Series A-3 shares), Dr. Litvack was to be granted an additional option to purchase that number of shares of Capricor, Inc. common stock necessary to maintain Dr. Litvack's equity position at ten percent (10%) of the outstanding shares of all Capricor, Inc. stock on a fully diluted basis (the "Anti-Dilution Rights"). On August 21, 2013, Capricor, Inc. entered into an agreement and release of all claims pursuant to which Dr. Litvack was granted an additional option to purchase 207,485 option shares calculated after giving effect to the merger between Nile and Capricor in exchange for forfeiture of these Anti-Dilution Rights. In addition, the terms of each of Dr. Litvack's stock option agreements were modified to extend the exercise period during which he has to exercise his options for Company common stock after he ceases to be a service provider to the Company from 90 days to one year.

On March 24, 2014, the Company entered into a consulting agreement with Dr. Litvack memorializing the $10,000 per month compensation arrangement described above. The agreement is terminable upon 30 days' notice.

On May 1, 2012, Dr. Litvack entered into a sublease with Capricor pursuant to which he subleased from Capricor an office and an administrative bay located within Capricor's leased premises in Beverly Hills, California for a monthly rate of $2,500. On April 1, 2013, the foregoing sublease was terminated and Reprise Technologies LLC, a limited liability company which is wholly owned by Dr. Litvack, executed a new sublease for an office and administrative bay within Capricor's leased premises for a monthly rate of $2,500. Such sublease is on a month-to-month basis and is terminable upon 30 days' written notice by either party.

Director Independence

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, which requires that a majority of the board of directors qualify as independent, as determined by the board of directors. After considering all relevant relationships and transactions, our board of directors, in consultation with legal counsel, has determined that Messrs. Schafer, Dunbar, Musket, Collier, Manzo, Grasmick and Dr. Litvack are "independent" within the meaning of the applicable listing standards of the NASDAQ Stock Market. In making this determination, the board of directors found that none of these directors had a material or other disqualifying relationship with us. In addition to transactions required to be disclosed under SEC rules, the board of directors considered certain other relationships in making its independence determinations, and determined in each case that such other relationships did not impair the director's ability to exercise independent judgment on our behalf.

Dr. Marbán, our Chief Executive Officer, is not an independent director by virtue of her employment with us. Mr. Kazam is also deemed not an independent director due to his previous relationship, and that of his consulting firm Two River Consulting, LLC, with Nile Therapeutics, Inc.

ITEM 14. PRINCIPAL ACCOUNTANT FEES AND SERVICES

Auditor Fees

The following is a summary of the fees billed to us by Rose, Snyder & Jacobs LLP and Crowe Horwath LLP, our independent registered public accounting firms, for professional services rendered for fiscal years ended December 31, 2013 and 2012:

	Fiscal Year Ended December 31,	
Service Category	2013	2012
Audit Fees	$194,150	$100,880
Audit-Related Fees	—	2,044
Tax Fees	14,720	6,500
All Other Fees	—	—
Total Fees	$208,870	$109,424

In the above table, in accordance with the SEC's definitions and rules, "audit fees" are fees for professional services for the audit and review of our annual financial statements, as well as the audit and review of our financial statements included in our registration statements filed under the Securities Act and issuance of consents and for services that are normally provided by the accountant in connection with statutory and regulatory filings or engagements except those not required by statute or regulation; "audit-related fees" are fees for assurance and related services that were reasonably related to the performance of the audit or review of our financial statements, including attestation services that are not required by statute or regulation, due diligence and services related to acquisitions; "tax fees" are fees for tax compliance, tax advice and tax planning; and "all other fees" are fees for any services not included in the first three categories.

Audit Committee Pre-Approval Process

Pursuant to our Audit Committee Charter, before the independent registered public accounting firm is engaged by the Company or its subsidiaries to render audit or non-audit services, the Audit Committee pre-approves the engagement. Audit Committee pre-approval of audit and non-audit services is not required if the engagement for the services is entered into pursuant to pre-approval policies and procedures established by the Audit Committee regarding the Company's engagement of the independent registered public accounting firm, provided the policies and procedures are detailed as to the particular service, the Audit Committee is informed of each service provided and such policies and procedures do not include delegation of the Audit Committee's responsibilities under the Exchange Act to the Company's management. The Audit Committee may delegate to one or more designated members of the Audit

Committee the authority to grant pre-approvals, provided such approvals are presented to the Audit Committee at a subsequent meeting. If the Audit Committee elects to establish pre-approval policies and procedures regarding non-audit services, the Audit Committee must be informed of each non-audit service provided by the independent registered public accounting firm. Audit Committee pre-approval of non-audit services (other than review and attest services) also is not be required if such services fall within available exceptions established by the SEC. None of the services provided by our independent registered public accounting firm for fiscal 2013 or 2012 were obtained in reliance on the waiver of the pre-approval requirement afforded in SEC regulations.

PART IV

ITEM 15. EXHIBITS AND FINANCIAL STATEMENT SCHEDULES

2.1	Agreement and Plan of Merger, dated as of August 15, 2007, by and among SMI Products, Inc., Nile Merger Sub, Inc. and Nile Therapeutics, Inc. (incorporated by reference to Exhibit 2.1 to the Company's Current Report on Form 8-K, filed with the Commission on August 17, 2007).
2.2	Agreement and Plan of Merger and Reorganization, dated as of July 7, 2013, by and among Nile Therapeutics, Inc., Bovet Merger Corp. and Capricor, Inc. (incorporated by reference to Exhibit 2.1 to the Company's Current Report on Form 8-K, filed with the Commission on July 9, 2013).
2.3	First Amendment to Agreement and Plan of Merger and Reorganization, dated as of September 27, 2013, by and between Nile Therapeutics, Inc., Bovet Merger Corp. and Capricor, Inc. (incorporated by reference to Exhibit 2.1 to the Company's Current Report on Form 8-K, filed with the Commission on October 3, 2013).
3.1	Certificate of Incorporation of the Company (incorporated by reference to Exhibit 3.1 to the Company's Current Report on Form 8-K, filed with the Commission on February 9, 2007).
3.2	Certificate of Amendment of Certificate of Incorporation of the Company (incorporated by reference to Exhibit 3.1 to the Company's Current Report on Form 8-K, filed with the Commission on November 26, 2013).
3.3	Bylaws of the Company (incorporated by reference to Exhibit 3.2 to the Company's Current Report on Form 8-K, filed with the Commission on February 9, 2007).
4.1	Form of Warrant issued to Investors in July 2009 Private Placement (incorporated by reference to Exhibit 4.1 to the Company's Registration Statement on Form S-3, filed with the Commission on August 13, 2009).
4.2	Form of Warrant issued to Placement Agent in July 2009 Private Placement (incorporated by reference to Exhibit 4.2 to the Company's Registration Statement on Form S-3, filed with the Commission on August 13, 2009).
4.3	Warrant Agreement, dated April 21, 2010, between the Company and American Stock Transfer & Trust Company, LLC, as Warrant Agent (incorporated by reference to Exhibit 4.1 to the Company's Current Report on Form 8-K, filed with the Commission on April 22, 2010).
4.4	Form of Unit Warrant issued to Investors in April 2010 Public Offering (incorporated by reference to Exhibit 4.5 to the Company's Annual Report on Form 10-K, (included as part of Exhibit 4.4 thereof) filed with the Commission on June 21, 2013).

4.5	Form of Representative's Warrant issued to Maxim Group, LLC in connection with April 2010 Public Offering (incorporated by reference to Exhibit 4.3 to the Company's Current Report on Form 8-K, filed with the Commission on April 22, 2010).
4.6	Form of Warrant issued to Investors in June 2011 Private Placement (incorporated by reference to Exhibit 4.1 to the Company's Current Report on Form 8-K, filed with the Commission on June 24, 2011).
4.7	Form of Warrant issued to Investors in March 2012 Registered Offering (incorporated by reference to Exhibit 4.1 to the Company's Current Report on Form 8-K, filed with the Commission on April 2, 2012).
10.1	Form of Convertible Note Purchase Agreement entered into among the Company and various accredited investors on March 15, 2013 (incorporated by reference to Exhibit 10.1 to the Company's Current Report on Form 8-K filed with the Commission on March 22, 2013).
10.2	Form of Note issued to Various Accredited Investors on March 15, 2013 (includes Form of Warrant as Exhibit A) (incorporated by reference to Exhibit 4.1 to the Company's Current Report on Form 8-K, filed with the Commission on March 22, 2013).
10.3	First Amendment to the Secured Convertible Promissory Notes (incorporated by reference to Exhibit 10.1 to the Company's Current Report on Form 8-K, filed with the Commission on October 3, 2013).

10.4	Letter Agreement between Nile Therapeutics, Inc. and Darlene Horton, M.D., dated August 3, 2012 (incorporated by reference to Exhibit 10.1 to the Company's Current Report on Form 8-K, filed with the Commission on August 7, 2012). †
10.5	Letter Agreement between Nile Therapeutics, Inc. and Darlene Horton, M.D., dated November 2, 2012 (incorporated by reference to Exhibit 10.1 to the Company's Current Report on Form 8-K, filed with the Commission November 5, 2012). †
10.6	Letter Agreement between Nile Therapeutics, Inc. and Darlene Horton, M.D., dated March 21, 2013 (incorporated by reference to Exhibit 10.3 to the Company's Current Report on Form 8-K, filed with the Commission on March 22, 2013). †
10.7	Employment Agreement by and between Capricor, Inc. and Linda Marbán, dated September 1, 2010. *†
10.8	Employment Agreement between Capricor, Inc. and Anthony Davies, dated February 18, 2013. *†
10.9	Consulting Agreement between Capricor, Inc. and Frank Litvack, dated March 24, 2014. *†
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82

SIGNATURES

Pursuant to the requirements of Section 13 or 15(d) of the Securities Exchange Act of 1934, the registrant has duly caused this report to be signed on its behalf by the undersigned, thereunto duly authorized, on March 31, 2014.

CAPRICOR
THERAPEUTICS, INC.

By: /s/ Linda Marbán, Ph.D.
Linda Marbán, Ph.D.

Chief Executive Officer

KNOW ALL MEN BY THESE PRESENTS, that we, the undersigned officers and directors of Capricor Therapeutics, Inc., hereby severally constitute Linda Marbán, Ph.D. and Anthony Bergmann, and each of them singly, our true and lawful attorneys with full power to them, and each of them singly, to sign for us and in our names in the capacities indicated below, any and all amendments to said Form 10-K, and generally to do all such things in our names and in our capacities as officers and directors to enable Capricor Therapeutics, Inc. to comply with the provisions of the Securities Exchange Act of 1934, and all requirements of the U.S. Securities and Exchange Commission, hereby ratifying and confirming our signatures as they may be signed by our said attorneys, or any of them, to any and all amendments hereto.

Pursuant to the requirements of the Securities Exchange Act of 1934, this report has been signed below by the following persons on behalf of the registrant and in the capacities and on the dates indicated.

Signature	**Title**	**Date**
		March 31, 2014
/s/ Linda Marbán, Ph.D.	Chief Executive Officer and Director	
Linda Marbán, Ph.D.	*(Principal Executive Officer)*	
/s/ Anthony J. Bergmann	Vice President of Finance	March 31, 2014
Anthony J. Bergmann	*(Principal Financial and Accounting Officer)*	

/s/ Frank Litvack, M.D. Frank Litvack, M.D.	Executive Chairman	March 31, 2014
/s/ Joshua A. Kazam Joshua A. Kazam	Director	March 31, 2014
/s. Earl M. Collier Earl M. Collier	Director	March 31, 2014
/s/ Louis V. Manzo Louis V. Manzo	Director	March 31, 2014
/s/ Louis J. Grasmick Louis J. Grasmick	Director	March 31, 2014
/s/ Gregory W. Schafer Gregory W. Schafer	Director	March 31, 2014
/s/ George W. Dunbar George W. Dunbar	Director	March 31, 2014

/s/ David B. Musket March 31, 2014

Director

David B. Musket

INDEX OF EXHIBITS FILED WITH THIS REPORT

Exhibit No.	Description
2.1	Agreement and Plan of Merger, dated as of August 15, 2007, by and among SMI Products, Inc., Nile Merger Sub, Inc. and Nile Therapeutics, Inc. (incorporated by reference to Exhibit 2.1 to the Company's Current Report on Form 8-K, filed with the Commission on August 17, 2007).
2.2	Agreement and Plan of Merger and Reorganization, dated as of July 7, 2013, by and among Nile Therapeutics, Inc., Bovet Merger Corp. and Capricor, Inc. (incorporated by reference to Exhibit 2.1 to the Company's Current Report on Form 8-K, filed with the Commission on July 9, 2013).
2.3	First Amendment to Agreement and Plan of Merger and Reorganization, dated as of September 27, 2013, by and between Nile Therapeutics, Inc., Bovet Merger Corp. and Capricor, Inc. (incorporated by reference to Exhibit 2.1 to the Company's Current Report on Form 8-K, filed with the Commission on October 3, 2013).
3.1	Certificate of Incorporation of the Company (incorporated by reference to Exhibit 3.1 to the Company's Current Report on Form 8-K, filed with the Commission on February 9, 2007).
3.2	Certificate of Amendment of Certificate of Incorporation of the Company (incorporated by reference to Exhibit 3.1 to the Company's Current Report on Form 8-K, filed with the Commission on November 26, 2013).
3.3	Bylaws of the Company (incorporated by reference to Exhibit 3.2 to the Company's Current Report on Form 8-K, filed with the Commission on February 9, 2007).
4.1	Form of Warrant issued to Investors in July 2009 Private Placement (incorporated by reference to Exhibit 4.1 to the Company's Registration Statement on Form S-3, filed with the Commission on August 13, 2009).
4.2	Form of Warrant issued to Placement Agent in July 2009 Private Placement (incorporated by reference to Exhibit 4.2 to the Company's Registration Statement on Form S-3, filed with the Commission on August 13, 2009).
4.3	Warrant Agreement, dated April 21, 2010, between the Company and American Stock Transfer & Trust Company, LLC, as Warrant Agent (incorporated by reference to Exhibit 4.1 to the Company's Current Report on Form 8-K, filed with the Commission on April 22, 2010).
4.4	Form of Unit Warrant issued to Investors in April 2010 Public Offering (incorporated by reference to Exhibit 4.5 to the Company's Annual Report on Form 10-K (included as part of Exhibit 4.4 thereof), filed with the Commission on June 21, 2013).

4.5	Form of Representative's Warrant issued to Maxim Group, LLC in connection with April 2010 Public Offering (incorporated by reference to Exhibit 4.3 to the Company's Current Report on Form 8-K, filed with the Commission on April 22, 2010).
4.6	Form of Warrant issued to Investors in June 2011 Private Placement (incorporated by reference to Exhibit 4.1 to the Company's Current Report on Form 8-K, filed with the Commission on June 24, 2011).
4.7	Form of Warrant issued to Investors in March 2012 Registered Offering (incorporated by reference to Exhibit 4.1 to the Company's Current Report on Form 8-K, filed with the Commission on April 2, 2012).
10.1	Form of Convertible Note Purchase Agreement entered into among the Company and various accredited investors on March 15, 2013 (incorporated by reference to Exhibit 4.1 to the Company's Current Report on Form 8-K filed with the Commission on March 22, 2013).
10.2	Form of Note issued to Various Accredited Investors on March 15, 2013 (includes Form of Warrant as Exhibit A) (incorporated by reference to Exhibit 4.1 to the Company's Current Report on Form 8-K, filed with the Commission on March 22, 2013).
10.3	First Amendment to the Secured Convertible Promissory Notes (incorporated by reference to Exhibit 10.1 to the Company's Current Report on Form 8-K, filed with the Commission on October 3, 2013).
10.4	Letter Agreement between Nile Therapeutics, Inc. and Darlene Horton, M.D., dated August 3, 2012 (incorporated by reference to Exhibit 10.1 to the Company's Current Report on Form 8-K, filed with the Commission on August 7, 2012). †

10.5	Letter Agreement between Nile Therapeutics, Inc. and Darlene Horton, M.D., dated November 2, 2012 (incorporated by reference to Exhibit 10.1 to the Company's Current Report on Form 8-K, filed with the Commission November 5, 2012). †
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