SECURITIES & EXCHANGE COMMISSION EDGAR FILING

CAPRICOR THERAPEUTICS, INC.

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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, 2015**
or
¨ **Transition Report Pursuant to 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 90211
(Address of principal executive offices, including zip code)

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

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

Title of Each Class	**Name of Each Exchange on Which Registered**
Common Stock, par value $0.001 per share	The Nasdaq Capital Market

Securities registered pursuant to Section 12(g) of the Act:
None

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

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

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

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

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

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

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

Indicate by check mark whether the registrant is a shell company (as defined in Rule 12b-2 of the Exchange 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, 2015: $32,449,891

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

As of March 29, 2016, there were 17,952,323 shares of the registrant's common stock, par value $0.001 per share, issued and outstanding.

DOCUMENTS INCORPORATED BY REFERENCE

Portions of the registrant's Definitive Proxy Statement for its 2016 Annual Meeting of Stockholders or an amendment to this Annual Report on Form 10-K to be filed with the Securities and Exchange Commission within 120 days of the registrant's fiscal year ended December 31, 2015 are incorporated by reference into Part III of this Annual Report on Form 10-K.

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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 Annual Report on 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 about the development of our drug candidates, including when we expect to undertake, initiate and complete clinical trials of our product candidates; expectation of or dates for commencement of clinical trials, investigational new drug filings, similar plans or projections; the regulatory approval of our drug candidates; our use of clinical research centers, third party manufacturers and other contractors; our ability to find collaborative partners for research, development and commercialization of potential products; our ability to manufacture products for clinical and commercial use; our ability to protect our patents and other intellectual property; our ability to market any of our products; our history of operating losses; our ability to compete against other companies and research institutions; the effect of potential strategic transactions on our business; acceptance of our products by doctors, patients or payors and the availability of reimbursement for our product candidates; our ability to attract and retain key personnel; the volatility of our stock price; and other risks and uncertainties detailed in the section of this Annual Report on Form 10-K entitled “Risk Factors”. 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, manufacture 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, (6) our ability to raise enough capital to fund our operations, (7) our ability to protect our intellectual property rights, and (8) our compliance with legal and regulatory requirements as a public company. 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, 2015 are not necessarily indicative of results that may be attained in the future.

PART I

ITEM 1. BUSINESS

Capricor Therapeutics, Inc. is a clinical-stage biotechnology company focused on the discovery, development and commercialization of first-in-class therapeutics. 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 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., or 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.

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 became Director of the Heart Institute at Cedars-Sinai Medical Center, or CSMC. Capricor's laboratories are located in space that Capricor leases from CSMC.

Our Strategy

Our strategy is to discover, develop and commercialize regenerative medicine and large molecule products for the treatment of disease, with a primary focus on the treatment of cardiovascular diseases including orphan indications. We currently have four ongoing clinical trials aiming to treat cardiovascular diseases in various progressions of the disease state.

CAP-1002, a cardiosphere-derived cell product, is currently being tested in the ALLSTAR Phase II clinical study on patients who have suffered a myocardial infarction (heart attack), while the DYNAMIC clinical study is testing CAP-1002 in patients who are in the advanced stages of heart failure. CAP-1002 is also being tested in the HOPE-Duchenne Phase I/II clinical study for use in connection with Duchenne muscular dystrophy-related cardiomyopathy.

Cenderitide, a dual receptor natriuretic peptide agonist developed at the Mayo Clinic, is currently being tested in a Phase II clinical study which is evaluating the safety and dose response of Cenderitide administered to patients with chronic heart failure.

Exosomes, which are are nano-sized, membrane-enclosed vesicles, or "bubbles," filled with select molecules, are being tested in pre-clinical studies to explore new therapies and indications. These programs represent our core technology and products.

Background on Heart Disease, Heart Failure and Duchenne Muscular Dystrophy

Heart Disease

Heart disease is a general term for many specific diseases or conditions relating to the heart. In the United States, heart disease costs over $207 billion in direct and indirect costs annually, according to the American Heart Association. Furthermore, heart disease is the number one cause of death in the world and in the United States. Treatment options for most types of heart disease typically include a life-long medication regimen. Other options include implanted devices such as coronary stents, pacemakers, and cardio-defibrillators, and for some patients, heart transplantation may be the only other option. The effectiveness of these interventions is limited. With an estimated 85 million Americans having some form of heart disease, according to the American Heart Association, the need for new, effective therapy is significant.

The most common form of heart disease is coronary heart disease, which is characterized by a buildup of plaque inside the coronary arteries which supply blood to the heart. Plaque is made up of fat, cholesterol, calcium, and other substances found in the blood. The plaque can eventually burst, tear or rupture, creating a “snag” where a blood clot forms and blocks blood flow in the artery, depriving part of the heart of oxygen and nutrients. This leads to a myocardial infarction (MI), the medical term for a heart attack. If the flow of blood is not restored within a few minutes heart muscle cells may die, causing permanent damage.

As the heart muscle begins to heal, a scar is formed that can impact normal heart function. Patients who suffer an MI often continue to experience degeneration or weakening of their heart muscle which can lead to heart failure and ultimately may shorten their lives.

According to the American Heart Association, coronary heart disease afflicts over 15 million people in the U.S. and causes almost 50% of heart disease deaths in the United States. In 2010, coronary heart disease was responsible for 1.3 million hospital stays. In 2011 heart attacks and coronary heart disease were two of the ten most expensive hospitalizations. Coronary heart disease is the primary cause of heart attack or MI, which strikes approximately 750,000 Americans each year, often leading to repeated hospitalizations, a decrease in quality of life, and premature death. In fact, more than seven million people in the U.S. have had a heart attack.

Capricor is evaluating CAP-1002 in the ALLSTAR Phase II clinical trial to determine its efficacy in reversing damage caused by heart attack.

Heart Failure & Dilated Cardiomyopathy

Heart failure, or HF, is a condition that exists when the heart cannot pump blood to the body as quickly as needed. The disease progresses over a long period of time and can make everyday activities more difficult. Blood returning to the heart faster than the heart can eject it, congests the system behind it. Decreased blood flow to organs, such as the kidneys, causes the body to retain more fluid, which further complicates the problem. As a result, HF can often cause damage to the kidneys and other organs, which in turn can worsen the condition of the heart. Dilated cardiomyopathy is another common cause of heart failure and is primarily characterized by the enlargement and weakening of the heart’s left ventricle, its main pumping chamber. The left ventricle becomes enlarged, or dilated, and cannot pump blood to the body with as much force as a healthy heart. Conditions such as coronary heart disease and heart attack, as well as viral infections, can cause dilated cardiomyopathy. While many people with dilated cardiomyopathy have minor or no symptoms, other people develop symptoms that may progress and worsen as heart function worsens.

HF is the fastest-growing clinical cardiac disease in the United States according to the American Heart Association, affecting over five million Americans. The number of U.S. adults with heart failure is expected to increase to approximately eight million people by 2030.

Capricor is evaluating CAP-1002 in the DYNAMIC clinical study to assess the safety and feasibility of delivering CAP-1002 to advanced heart failure patients. We initiated enrollment of the DYNAMIC trial in December 2014 and completed enrollment in April 2015. Initial top-line results showed that multi-vessel intracoronary infusion of CAP-1002 in subjects with dilated cardiomyopathy was shown to be safe with no major adverse cardiac events reported at one month or at six months post-infusion. Though this trial was intended as an early safety study, the six-month data demonstrated encouraging and congruent preliminary efficacy signals in multiple parameters, including subjective well-being, exercise capacity, ejection fraction and ventricular volumes.

Additionally, HF is the most frequent cause of hospital admissions in the U.S. for patients older than 65 years, generating annual inpatient costs of more than $20 billion, according to the American Heart Association. Furthermore, HF is responsible for over 1 million hospitalizations annually in the U.S. alone. Among those patients who have been admitted, approximately 24% are re-hospitalized in one month and approximately 50% are re-hospitalized in six months.

Acute Decompensated Heart Failure, or ADHF, is an acute exacerbation of HF requiring unplanned office visits, emergency room visits or hospitalization. Treatment options sometimes include diuretics to relieve the symptoms of ADHF by helping to remove excess fluid from the body which then helps to increase cardiac output. Despite aggressive therapies, one in three patients dies of the disease within a year of diagnosis, reflecting a substantial need for novel treatments.

Within 90 days following hospital admission for ADHF, which we refer to as the “post-acute” period, approximately 40% of patients with ADHF return to the hospital or die. To prevent re-hospitalization, post-acute patients need sustained heart and kidney function support to prevent a recurrence of their acute symptoms. While this post-acute indication is a novel indication in the HF space, we believe that post-acute patients represent one of the greatest areas of unmet need in the HF market. Cenderitide’s treatment goal and target indication is the prevention of re-hospitalization in heart failure patients during the post-acute hospitalization period.

Duchenne Muscular Dystrophy

Duchenne muscular dystrophy (DMD) is a rare form of muscular dystrophy which results in muscle degeneration and premature death. DMD affects approximately 1 in 3,600 male infants, and nearly 20,000 boys are living with the disease in the U.S. DMD results from a lack of a functional dystrophin protein as caused by a gene mutation. The lack of dystrophin, an important structural component of muscle cells, causes them to have increased susceptibility to damage and to progressively die. Patients with DMD experience progressive muscle weakness starting at an early age, loss of ambulation in the first decade of life, and eventual respiratory and cardiac failure. Their lifespan is abbreviated and averages less than three decades.

In the hearts of DMD patients, muscle is progressively replaced by scar tissue, often leading to eventual heart failure. This almost inevitable cardiomyopathy has become the leading cause of death in patients with DMD. However, patients with DMD may live longer following improvements in the treatment of their respiratory function. No therapies are currently approved to treat DMD cardiomyopathy. Capricor is evaluating CAP-1002 in the HOPE-Duchenne Phase I/II clinical trial to assess the safety and efficacy of delivering CAP-1002 to patients with DMD-related cardiomyopathy.

CDC (Cardiosphere-Derived Cell) Technology

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 pro-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 possibility 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 is also pursuing its own intellectual property rights relating to these product candidates.

Capricor’s proprietary methods are focused 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, leaving a scar. The larger the size of this 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 a 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 an 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 a significant increase in 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 such as 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 of the potential regenerative properties of CDCs.

Capricor's core technology is based on 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 CDCs, are 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. Although Capricor has experimented with direct intra-myocardial injection of CSps, it is not actively developing them for clinical use. 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.

Natriuretic Peptide Technology

Cenderitide is a novel chimeric natriuretic peptide being considered for the treatment of heart failure patients. Specifically, Cenderitide is a dual receptor agonist acting on both the A and B receptors. Cenderitide was rationally designed by scientists at the Mayo Clinic's cardio-renal research labs. Current therapies for acutely decompensated heart failure, or ADHF, including nesiritide, have been associated with favorable pharmacologic effects, but have also been associated with hypotension, which limits their utility outside the hospital setting. Cenderitide was designed to preserve the favorable effects of existing natriuretic peptide therapies while reducing or attenuating the hypotensive response and enhancing or preserving renal function. We believe that there may be a role for the use of Cenderitide in the outpatient treatment of heart failure.

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

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

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

Since the merger between Capricor, Inc. and Nile, we have decided to advance our Cenderitide development program in patients with HF. In October 2014, we entered into a Transfer Agreement with Medtronic pursuant to which we acquired certain intellectual property rights to patents and patent applications that were previously co-owned by Medtronic and Capricor. In addition, we acquired the rights to other patents and patent applications that were previously owned solely by Medtronic. In October 2014, we also entered into an Agreement for Investigator-Initiated Research Support with Insulet Corporation. Pursuant to the agreement with Insulet, Insulet supported Capricor's research by engaging in certain product development, project management and design control activities, in addition to supplying the OmniPod® product being used for our current studies of Cenderitide. In 2015, we completed a Phase II study in 14 patients with stable, chronic heart failure. Patients received up to eight consecutive days of Cenderitide through subcutaneous infusion using Insulet's drug delivery system based on the OmniPod technology. This trial assessed the safety and tolerability, pharmacokinetic profiles and pharmacodynamic response to increasing dose levels of open-label Cenderitide administered in a stepwise fashion. The drug was tolerated and there were no significant adverse events. Capricor has initiated an additional study to further assess the safety and efficacy of this product candidate, which will include higher dose levels of Cenderitide in patients with stable heart failure with moderate renal impairment. This study will assess the safety and tolerability, pharmacokinetic profiles and pharmacodynamic response to increasing dose levels of Cenderitide. Following these studies, Capricor will determine whether to conduct additional clinical studies to further assess the safety and efficacy of this product candidate. Cenderitide in the post-acute period has been granted Fast Track designation by the U.S. Food and Drug Administration (the "FDA").

Exosomes Technology

The CDC exosomes technology is based upon pre-clinical research by Dr. Eduardo Marbán and his colleagues at CSMC. Released by nearly every cell type in the body and a vital mediator of cellular activity, exosomes are nano-sized, membrane-enclosed vesicles, or "bubbles," that are filled with select molecules. These molecules include RNAs, proteins and microRNAs which, when released, send messages to neighboring cells to regulate cellular functions. They are present in bodily fluids, are accessible and can be readily isolated from cells.

Exosomes act as the transport vehicle out of the cell for segments of genetic material and proteins that act as messengers between cells, ultimately providing regulatory function for many cell processes, including inflammation, angiogenesis, programmed cell death (apoptosis), and scarring. Research has shown that exosomes derived from cultured cells can be used as therapeutic agents aimed to direct or, in some cases, re-direct cellular activities. Their size, ease in crossing cell membranes and their ability to communicate in the native cellular language of the cell makes them a class of exciting and potentially novel therapeutic agents.

As recently published research indicates, exosomes extracted from Capricor's CDCs, prompted myocardial regeneration in pre-clinical models of ischemic heart disease. Further, exosomes were shown to induce various structural and functional changes within the heart. We believe that these findings demonstrate for the first time that exosomes derived from CDCs may possess regenerative capabilities and may serve as proof of concept for the potential of these CDC-derived agents. We are hopeful that the unique properties of CDC-derived exosomes may allow us to develop novel cell-free therapeutics and expand our product portfolio. Though it is early in the development cycle, Capricor plans to explore the development of the exosomes technology as a next generation regenerative medicine portfolio in a variety of cardiovascular and non-cardiovascular areas.

Our Product Candidates

We currently have six 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 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 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 in October 2013. Preliminary 12 month MRI data collected on the patients in the Phase I open-label dose-escalation study revealed that those patients who would be included in the Phase II clinical study by virtue of dose and tissue type compatibility exhibited a 5.2% improvement in ejection fraction, a global measure of the heart's pumping ability. Additionally, there was a relative reduction in scar size of 20.7%. Measurements of viable mass and regional function also showed quantifiable improvements.

In December 2013, Capricor received notification from the National Heart Lung and Blood Institute, or the NHLBI, Gene and Cell Therapy Data Safety Monitoring Board 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 a 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. The Phase II portion of the trial was initially designed to enroll up to 300 patients.

We recently completed statistical modelling of the design of ALLSTAR. This modelling incorporated the expanded dataset that has become available from our other clinical trials of CAP-1002. Based on these results, we have elected to decrease the enrollment goal of ALLSTAR to approximately 120 patients, a sample size that is expected to maintain sufficient statistical power to detect a reduction in infarct, or scar, size as measured by MRI at twelve months. We have amended our clinical protocol to reflect these changes, which such amendment has been approved by the Data Safety Monitoring Board and submitted to the FDA. Phase II of the ALLSTAR study is being funded in large part through the support of the California Institute for Regenerative Medicine, or CIRM.

In December 2013, Capricor entered into a Collaboration Agreement and Exclusive License Option with Janssen Biotech, Inc., or Janssen. Under the agreement, Janssen has an exclusive option to enter into an exclusive license agreement with Capricor, pursuant to which, if exercised, 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, except as may otherwise be agreed with respect to certain indications. 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.

Capricor was awarded a grant for approximately $2.9 million from the NIH to support further development of the CAP-1002 product. In June 2014, we received approval from the NIH to use the funds from the grant for the first part of the DYNAMIC (dilated cardiomyopathy intervention with allogeneic myocardially-regenerative cells) trial, which is being sponsored by Capricor. The first part of the DYNAMIC trial used CAP-1002 to treat patients with advanced heart failure utilizing triple-vessel intracoronary infusion. We initiated enrollment of the DYNAMIC trial in December 2014 and completed enrollment in April 2015. Initial top-line results were presented at the American Heart Association's Annual Scientific Sessions in November 2015. Multi-vessel intracoronary infusion of CAP-1002 in subjects with dilated cardiomyopathy was shown to be safe in this study with no major adverse cardiac events reported at one month or at six months post-infusion. Though this trial was intended as an early safety study, the six-month data demonstrated encouraging and congruent preliminary efficacy signals in multiple parameters, including subjective well-being, exercise capacity, ejection fraction and ventricular volumes.

Additionally, we are currently enrolling the Phase I/II HOPE-Duchenne clinical trial, which is designed to enroll approximately 24 patients in a randomized, multi-center study evaluating the safety and preliminary efficacy of CAP-1002 in patients with cardiomyopathy related to Duchenne muscular dystrophy. Patients enrolled in the study who are randomized to receive CAP-1002 will be infused in all three coronary arteries, which will allow for CAP-1002 to be delivered to wide areas of the myocardium. Subject to finalization of definitive documents, this study will be funded in part through a grant award from CIRM in the amount of approximately $3.4 million. Both the milestones and the rate of disbursement of the award proceeds will be set forth in the definitive documents, which have not been determined as of the date of filing of this Annual Report on Form 10-K. In April 2015, the FDA granted orphan drug designation to CAP-1002 for the treatment of DMD.

- **Cenderitide (CD-NP)**: Cenderitide belongs to a class of drugs called natriuretic peptides. Preclinical and clinical data have shown that the natriuretic peptide class can act on multiple disease processes that play a role in negative outcomes associated with heart failure. Cenderitide's treatment goal and target indication is to provide a novel and effective therapeutic option for the outpatient treatment of heart failure, thereby addressing a critical unmet need. Cenderitide is being developed as an outpatient therapy to be delivered continuously using a validated subcutaneous infusion pump for up to 90 days (the "post-acute" period) following an acute heart failure hospital admission, as well as for other potential indications. Cenderitide was designed by scientists at the Mayo Clinic to be the only dual natriuretic peptide receptor agonist. In October 2014, we entered into an Agreement for Investigator-Initiated Research Support with Insulet Corporation, or Insulet, pursuant to, which Insulet supported Capricor's research by engaging in certain product development, project management and design control activities, in addition to supplying the OmniPod product being used for our current studies. In 2015, we completed a Phase II study in 14 patients with stable, chronic heart failure. Patients received up to eight consecutive days of Cenderitide through subcutaneous infusion using Insulet's drug delivery system based on the OmniPod technology. This trial assessed the safety and tolerability, pharmacokinetic profiles and pharmacodynamic response to increasing dose levels of open-label Cenderitide administered in a stepwise fashion. The drug was tolerated and there were no significant adverse events. Capricor has initiated an additional study to further assess the safety and efficacy of this product candidate, which will include higher dose levels of Cenderitide in patients with stable heart failure with moderate renal impairment. This study will assess the safety and tolerability, pharmacokinetic profiles and pharmacodynamic response to increasing dose levels of Cenderitide. Following these studies, Capricor will determine whether to conduct additional clinical studies to further assess the safety and efficacy of this product candidate. Cenderitide in the post-acute period has been granted Fast-Track designation by the FDA.

- **Exosomes**: Exosomes are nano-sized, membrane-enclosed vesicles, or “bubbles”, that are filled with select molecules, including proteins, RNAs and microRNAs, which, when released, send messages to neighboring cells to regulate cellular functions. Exosomes act as transport vehicles out of cells for microRNA, other fragments of genetic material and proteins that act as messengers between cells, ultimately providing regulatory function for many cell processes, including inflammation, angiogenesis, programmed cell death (apoptosis) and scarring. Pre-clinical research has shown that exogenous exosomes can be used as therapeutic agents aimed to direct or, in some cases, re-direct cellular activity. Their size, ease of crossing cell membranes, and ability to communicate in native cellular language makes them a class of exciting and novel therapeutic agents. We are currently in pre-clinical testing to explore the possible future therapeutic benefits that exosomes may possess and the indications in which they potentially may be investigated.

- **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, 17 of which 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 CDCs 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.

- **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. We are currently evaluating whether we will proceed with clinical development of this product.

- **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 asset, at present there is no plan to develop CSps as therapeutic agents.

The following table summarizes our product development programs:

Product	Indications	Commercial Rights	Ongoing Studies / Status
CAP-1002	Cardiovascular	Capricor	ALLSTAR Phase II trial is currently enrolling. DYNAMIC completed enrollment. HOPE-Duchenne Phase I/II trial is currently enrolling.
Cenderitide	Cardiovascular	Capricor Therapeutics	Second Phase II trial initiated in Q1 2016. First Phase II trial was completed in 2015.
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.
Exosomes	Cardiovascular and non-cardiovascular	Capricor	Preclinical.
CU-NP	Cardiovascular	Capricor Therapeutics	Preclinical.
CSps	Cardiovascular	Capricor	Preclinical.

Intellectual Property and Proprietary Know-How

Our goal is to obtain, maintain and enforce patent rights for our products, formulations, processes, methods of use 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. Our issued patents will expire on dates ranging from approximately 2019-2031.

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

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"), The Johns Hopkins University ("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, is currently paying minimum annual royalties in the amount of 20,000 Euros per year, and is obligated to pay a lower-end of a mid-range double-digit percentage on all royalties received as a result of sublicenses granted, which are net of any royalties paid to third parties under a license agreement from such third party to Capricor. 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 will 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 JHU 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 range from $5,000 on the first and second anniversary dates to $20,000 on the tenth anniversary date and thereafter. The minimum annual royalties are creditable against a low single-digit running royalty on net sales of products and net service revenues, which Capricor is also required to pay under the JHU License Agreement, which running royalty may be subject to further reduction in the event that Capricor is required to pay royalties on any patent rights to third parties in order to make or sell a licensed product. In addition, Capricor is required to pay a low double-digit 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 approval from the FDA. The development milestones range from $100,000 upon successful completion of a full Phase I clinical study to $1,000,000 upon full FDA market approval and are fully creditable against payments owed by Capricor to JHU on account of sublicense consideration attributable to milestone payments received from a sublicensee. The maximum aggregate amount of milestone payments payable under the JHU License Agreement, as amended, is $1,850,000.

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.

Cedars-Sinai Medical Center License Agreements

License Agreement for CDCs

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 patent 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 will 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 is required to meet certain spending and development milestones. The annual spending requirements range from $350,000 to $800,000 each year between 2010 and 2017 (with the exception of 2014, for which there was no annual spending requirement). Pursuant to the Amended CSMC License Agreement, Capricor remains obligated to pay low single-digit royalties on sales of royalty-bearing products as well as a low double-digit percentage of the consideration received from any sublicenses or other grant of rights. The above-mentioned royalties are subject to reduction in the event Capricor becomes obligated to obtain a license from a third party for patent rights in connection with the royalty-bearing product. 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.

On March 20, 2015, Capricor and CSMC entered into a First Amendment to the Amended CSMC License Agreement, pursuant to which the parties agreed to delete certain patent applications from the list of Scheduled Patents which Capricor determined not to be material to the portfolio.

License Agreement for Exosomes

On May 5, 2014, Capricor entered into an Exclusive License Agreement with CSMC (the “Exosomes License Agreement”), for certain intellectual property rights related to exosomes technology. The Exosomes License Agreement provides for the grant of an exclusive, world-wide, royalty-bearing license by CSMC to Capricor (with the right to sublicense) in order to conduct research using the patent rights and know-how and to develop and commercialize products in the field using the patent 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 Exosomes License Agreement, CSMC was paid a license fee and Capricor reimbursed CSMC for certain fees and costs incurred in connection with the prosecution of certain patent rights. Additionally, Capricor is required to meet certain non-monetary development milestones and is obligated to pay low single-digit royalties on sales of royalty-bearing products as well as a single-digit percentage of the consideration received from any sublicenses or other grant of rights. The above-mentioned royalties are subject to reduction in the event Capricor becomes obligated to obtain a license from a third party for patent rights in connection with the royalty bearing product.

The Exosomes 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 Exosomes 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.

On February 27, 2015, Capricor and CSMC entered into a First Amendment to Exclusive License Agreement, thereby amending the Exosomes License Agreement (the “Exosomes License Amendment”). Under the Exosomes License Amendment, (i) the description of patent rights in Schedule A has been replaced by a Revised Schedule A that includes four additional patent applications; (ii) Capricor was required to pay CSMC an upfront fee of $20,000; (iii) Capricor is required to reimburse CSMC approximately $34,000 for attorneys’ fees and filing fees that were incurred in connection with the additional patent rights; and (iv) Capricor is required to pay CSMC certain defined product development milestone payments upon reaching certain phases of its clinical studies and upon receiving approval for a product from the FDA. The product development milestones range from $15,000 upon the dosing of the first patient in a Phase I clinical trial of a product to $75,000 upon receipt of FDA approval for a product. The maximum aggregate amount of milestone payments payable under the Exosomes License Agreement, as amended, is $190,000. On June 10, 2015, Capricor and CSMC entered into a Second Amendment to Exclusive License Agreement, thereby amending the Exosomes License Agreement further to add an additional patent application to the Schedule of Patent Rights.

CSMC holds more than 10% of the outstanding capital stock of Capricor Therapeutics. Capricor is a party to a Facilities Lease Agreement with CSMC dated June 1, 2014. Capricor also manufactures CAP-1002 and Exosomes products in a manufacturing facility provided by CSMC. Additionally, Dr. Eduardo Marbán, who holds more than 10% of the outstanding capital stock of Capricor Therapeutics, is the Director of the Cedars-Sinai Heart Institute, the Co-Founder of Capricor and Chairman of Capricor's Scientific Advisory Board.

Collaboration Agreement with Janssen Biotech, Inc.

On December 27, 2013, Capricor entered into a Collaboration Agreement and Exclusive License Option (the "Janssen Agreement") with Janssen, a wholly-owned subsidiary of Johnson & Johnson. Under the terms of the Janssen Agreement, Capricor and Janssen agreed to collaborate on the development of Capricor's cell therapy program for cardiovascular applications, including its lead product candidate, CAP-1002. Capricor and Janssen further agreed to collaborate on the development of cell manufacturing in preparation for future clinical trials. Under the Janssen Agreement, Capricor was paid $12.5 million, and Capricor will contribute to the 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 royalty ranging from a low double-digit percentage to a lower-end of a mid-range double-digit percentage would be paid on sales of licensed products.

Company 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 ("Mayo"), a Clinical Trial Funding Agreement with Medtronic, Inc. ("Medtronic"), and a Transfer Agreement with Medtronic, all of which also include certain intellectual property licensing provisions.

Mayo License Agreement

The Company and 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 the 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 the CU-NP Agreement by, among other things, eliminating certain milestone payments and decreasing the royalty percentages payable upon the commercial sale of the products to low single-digit royalties on sales of CD-NP and CU-NP products. The Company is also obligated to pay to Mayo a low single-digit percentage on any upfront consideration or milestone payment received in connection with a sublicense. The Company is further obligated to pay to Mayo a low single-digit percentage on any consideration received in connection with an assignment of rights under the Amended Mayo Agreement. 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 (a) the expiration of the last to expire valid claim contained in the Mayo patents, or (b) 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 for 90 days' after 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. Such condition was satisfied when the Company initiated its clinical trial of Cenderitide in January 2015. The Company may terminate the Amended Mayo Agreement without cause upon 90 days' written notice.

Medtronic Clinical Trial Funding Agreement

In February 2011, the Company entered into a Clinical Trial Funding Agreement with Medtronic. Pursuant to the agreement, Medtronic provided funding and equipment necessary for the Company 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. 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. The Company and Medtronic have subsequently entered into a Transfer Agreement, described below.

Medtronic Transfer Agreement

On October 8, 2014, the Company entered into a Transfer Agreement (the "Transfer Agreement") with Medtronic to acquire patent rights relating to the formulation and pump delivery of natriuretic peptides. Pursuant to the Transfer Agreement, Medtronic has assigned to the Company all of its right, title and interest in all natriuretic peptide patents and patent applications previously owned by Medtronic or co-owned by Medtronic and the Company ("Natriuretic Peptide Patents"). Under the Transfer Agreement, the Company received all rights to the Natriuretic Peptide Patents, including the right to grant licenses and to make assignments without approval from Medtronic.

The Transfer Agreement became effective on October 8, 2014 and will expire simultaneously at the expiration of the last to expire of the valid claims. Both parties have the right to terminate the Transfer Agreement upon 30 days written notice to the other party in the event of a default which has not been cured within such 30-day period. In addition, Medtronic had the right to terminate the Transfer Agreement and to have the rights to the Natriuretic Peptide Patents reassigned to it by the Company if either the Company, an affiliate, or a non-party licensee failed to commence a clinical trial of a CD-NP product within 18 months from the effective date. Such condition was satisfied when the Company initiated its clinical trial of Cenderitide in January 2015.

In the event of a termination of the Transfer Agreement, (i) the Natriuretic Peptide Patents which were not owned or co-owned by the Company prior to the effective date of the Transfer Agreement shall be assigned back to Medtronic; (ii) the Company's rights in the Natriuretic Peptide Patents that were co-owned by Capricor pursuant to the Clinical Trial Funding Agreement will remain with the Company, subject to the surviving terms and provisions thereof; and (iii) the Company shall assign back to Medtronic those rights that were co-owned by Medtronic pursuant to the Clinical Trial Funding Agreement.

Pursuant to the Transfer Agreement, Medtronic was paid an upfront payment of $100,000, and the Company is obligated to pay Medtronic a mid-single-digit royalty on net sales of products, a low double-digit percentage of any consideration received from any sublicenses or other grant of rights, and a mid-double-digit percentage of any monetary awards or settlements received by the Company as a result of enforcement of the Natriuretic Peptide Patents against a non-party entity, less the costs and attorney's fees incurred to enforce the Natriuretic Peptide Patents. In addition, there are additional payments that may become due from the Company upon the achievement of certain defined milestones, which payments, in the aggregate, total up to $7.0 million.

Manufacturing

Capricor presently maintains its laboratory and research facilities in leased premises located at CSMC (the "CSMC Lease"). Additionally, Capricor presently manufactures its cells in a facility which is owned by and located within CSMC and in which we believe we follow current good manufacturing practices. It is Capricor's intention is to manufacture cells at this facility for its currently enrolling ALLSTAR and HOPE-Duchenne clinical studies. If the CSMC Lease is terminated or if CSMC revokes its permission to allow Capricor to utilize the manufacturing 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 our clinical trials and regulatory approvals. In addition, we would have to establish a collaboration agreement with a third party or build out our own manufacturing facility for any Phase III trial. We are actively in discussions with third parties regarding a potential technology transfer of our cell manufacturing processes in anticipation of potential advanced clinical studies and commercialization.

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. We believe that the allogeneic nature of CAP-1002 enables us to potentially 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 have established relationships with third-party manufacturers and other service providers to perform these services for us. We have historically relied on individual proposals and purchase orders to meet our needs and have typically relied on terms and conditions proposed by the third party or us to govern our rights and obligations under each order (including provisions with respect to intellectual property, if any). We do not have any material long-term agreements or commitments that are currently in place.

Exosomes:

The process for manufacturing exosomes starts with the proprietary process of creating a cell bank from donor heart tissue through the expansion of CDCs. Afterwards exosomes are isolated from the expanded CDCs. After CDC-derived exosomes are prepared, formulated, filled, tested, and validated, the exosomes product becomes available for therapeutic use. We believe that the allogeneic, acellular nature of exosomes enables us to potentially create a commercially scalable stem cell-derived product.

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. Because the Company is decreasing the number of patients to be enrolled in the ALLSTAR clinical trial, it is undetermined at the time of filing of this Annual Report on Form 10-K how much of the remaining CIRM loan award will ultimately be disbursed under the CIRM Loan Agreement. Our research and development efforts to date have led to the development of four product candidates which have reached various stages of pre-clinical and clinical development: autologous CDCs, allogeneic CDCs, Cenderitide and exosomes. Ongoing research focuses on in-depth product characterization, expanded use of current products, development of next generation products and identification of new technologies and indications. 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 is also exploring the use of natriuretic peptides for the treatment of patients with post-acute heart failure as well as potential indications for the use of exosomes. Capricor spent approximately $13.8 million and $7.8 million on research and development activities for the years ended December 31, 2015 and 2014, respectively. Subject to finalization of definitive documents, the HOPE-Duchenne clinical trial will be funded in part through a grant award from CIRM in the amount of approximately $3.4 million. Both the milestones and the rate of disbursement of the award proceeds will be set forth in the definitive documents, which have not been determined as of the date of filing of this Annual Report on Form 10-K.

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 our 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 new drug application, or NDA, or a pending biologics license application, 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 investigational new drug, or IND, application, 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 a facility which is owned by and located within CSMC and in which we believe we follow good manufacturing practices. Capricor's intention is to manufacture cells at this facility for its currently enrolling trials. If CSMC were to revoke its permission to allow Capricor to utilize the 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, we will have to establish a collaboration agreement with a third party or build out our own manufacturing facility for any Phase III trial.

As we proceed with the development of Cenderitide or possibly, 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.

Corporate Information

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.

Employees

Currently, we have 29 full-time employees and four part-time employees, although several of our full time employees also perform part-time services for CSMC, including our Chief Executive Officer, Linda Marbán, Ph.D., and our Chief Medical Officer, Deborah Ascheim, M.D., both of whom provide services on a minimal 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. The employees of Capricor, Inc. which is now a wholly-owned subsidiary of the Company, are continuing their employment relationship with Capricor. Certain officers of Capricor, Inc. are also serving as officers of the Company.

Description of Property

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 (the "Bubble Lease") which originally was set to expire on June 30, 2015, the base rent for the first 12-month period was $16,620 per month, and the base rent for the second 12-month period will be $17,285. On March 3, 2015, Capricor executed a Second Amendment to Lease with The Bubble Real Estate Company, LLC, pursuant to which additional space was added to the Bubble Lease and we exercised our option to extend the term of the Bubble Lease through June 30, 2016. Under the terms of the Second Amendment to the Bubble Lease, commencing February 2, 2015, the base rent increased to $17,957 for one month. Commencing on March 2, 2015, the base rent increased to $21,420 per month for the following four month period and commencing July 1, 2015, the base rent increased to $22,111 per month. At the time of filing of this Annual Report on Form 10-K, we are exploring different lease options, including renewing our current lease or moving to a different office location.

Capricor currently leases two research laboratories from CSMC under the terms of a three-year lease which expires on June 1, 2017. The rent expense for the first six-month period was approximately $15,461 per month. Commencing with the seventh month of the lease term, the rent expense increased to approximately $19,350 per month. The amount of rent expense is subject to annual adjustments according to increases in the Consumer Price Index.

With permission from CSMC, Capricor presently manufactures its cells and exosomes in a facility which is owned by and located within CSMC and in which we believe we follow good manufacturing practices. Our laboratories and manufacturing facility are located at 8700 Beverly Blvd., Los Angeles, California 90048. As our operations expand, we expect our space requirements and related expenses to increase.

ITEM 1A. 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 on Form 10-K, 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 condition, 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 Related 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, 2015, we had cash and cash resources, including marketable securities, totaling approximately $13.6 million. We have not generated any product revenues, and will not be able to generate any product revenues until, and only if, we receive approval to sell our drug candidates from the U.S. Food and Drug Administration, or 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, National Institutes of Health, or NIH, grants, and a California Institute for Regenerative Medicine, or CIRM, loan award. In March 2016, we were approved for a CIRM grant award for approximately $3.4 million to fund in part our HOPE-Duchenne trial of CAP-1002. In December 2013 we also entered into a collaboration agreement with Janssen Biotech, Inc., or Janssen, which provides for funding for the development 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 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 potentially initiate clinical development of CU-NP. Our research and development expenses will also increase as we further the development of our exosomes program and conduct additional studies with CAP-1002, such as our study of DMD. In addition, our expenses could increase beyond expectations if the FDA requires that we perform additional studies beyond those that we currently anticipate, which may also delay the timing of any potential product approval. Other than our cash on hand and the funds expected to be received from our CIRM Loan commitment and CIRM grant award, we currently have no commitments or arrangements for any additional financing to fund the research and development of Cenderitide, CU-NP, exosomes or CAP-1002 for DMD or any further DYNAMIC studies.

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 in 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 ALLSTAR clinical trial, our DYNAMIC trial, our Cenderitide trial, our HOPE-Duchenne trial and our planned exosomes program;

- the continued availability of funding from the NIH and CIRM;
- the costs of developing adequate manufacturing processes and facilities;
- the costs and timing of regulatory approval;
- the costs of filing, prosecuting, defending and enforcing any patent claims and other intellectual property rights;
- the costs and risks involved in conducting clinical trials and manufacturing operations internationally;
- 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 on Form 10-K:

- our need for substantial additional capital to fund our development programs;
- delays in the commencement, enrollment, and timing of clinical testing;
- the success of our ALLSTAR, DYNAMIC, Cenderitide and HOPE-Duchenne clinical trials through all stages of clinical development;
- the viability of CAP-1002 as a potential product candidate for the treatment of DMD and the success of all stages of its pre-clinical and clinical development, including through the HOPE-Duchenne trial;
- the success of clinical trials of our CU-NP product candidate, if any, through all stages of clinical development, if commenced;
- the viability of exosomes as a potential product candidate and the success of all stages of its pre-clinical and clinical development;
- 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 are in development or which may receive 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 ability to successfully manufacture our product candidates on a timely basis;
- 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 and obtain 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 members 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 six product candidates, CAP-1002, CAP-1001, cardiospheres, exosomes, Cenderitide and CU-NP, is in an early stage of development and requires extensive clinical testing before it may be approved by the FDA, or another regulatory authority in a jurisdiction outside the United States, which could take several years to complete, if ever. The 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 ALLSTAR trial, our DYNAMIC trial, our Cenderitide trial, or our HOPE-Duchenne trial. Additionally, we cannot predict with any certainty if, or when, we might commence any clinical trials of our product candidates other than the ALLSTAR trial, the DYNAMIC trial, the Cenderitide trial and the HOPE-Duchenne 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 agencies. We are also unable to predict whether our pre-clinical studies of our exosomes product will result in a viable clinical development program.

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, especially as we expand our business and operations internationally. 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 Related 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 a new drug application, or NDA, or a biologics license application, 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, testing and manufacturing. 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 potentially 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 sufficiently enroll or 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 our 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, delayed 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. We may be required to withdraw from a clinical trial as a result of changing standards of care, or we 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 inability of the sites to conduct trial procedures properly, 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 their participation in 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 on a timely basis;
- 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; positive results in FDA-required viral testing; karyotypic abnormalities in our cell product; or contamination in our manufacturing facilities, all of which events would necessitate disposal of all cells made from that source;
- availability of materials provided by third parties necessary to manufacture our product candidates;
- availability of adequate amounts of acceptable 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, which 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, once begun, 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 or maintain, clinical or 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 from those indications for which we sought approval.

Delays in our ability to enroll a sufficient number of patients in our ALLSTAR trial could cause CIRM to delay or discontinue the distribution of additional loan proceeds from the CIRM Loan Agreement. Because the Company will be decreasing the number of patients to be enrolled in the ALLSTAR clinical trial, it is undetermined at this time how much of the remaining CIRM loan award will ultimately be disbursed under the CIRM Loan Agreement. The loss of funding under the CIRM Loan Agreement could cause delays under our ALLSTAR trial.

Changes in regulatory requirements and guidance may occur, and we may need to amend clinical trial protocols to reflect these changes with appropriate regulatory authorities. Amendments may require us to resubmit our clinical trial protocols to IRBs for re-examination, which may impact the costs, timing, or successful completion of a clinical trial. If we experience delays in the completion of, or if we terminate, our clinical trials, the commercial prospects for our product candidates will be harmed, and our ability to generate product revenues will be delayed. In addition, many of the factors that cause, or lead to, a delay in the commencement or completion of clinical trials may also ultimately lead to the denial of regulatory approval of a product candidate. Even if we are able to ultimately commercialize our product candidates, other therapies for the same or similar indications may have been introduced to the market and already 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, our DYNAMIC trial, our HOPE-Duchenne clinical trial and our Cenderitide clinical trial, 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 do 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 II or 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 or cause us to refrain from 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 small patient populations. 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 with CAP-1002 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, our cells and the therapy could potentially be rendered ineffective.

Our business faces significant government regulation, and there is no guarantee that our product candidates 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 or as combination biological products/medical devices under the Federal Food, Drug and Cosmetic Act, the Public Health Service Act and other statutes, as outlined in the Code of Federal Regulations. 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, other federal agencies and corresponding state agencies to ensure strict compliance with good manufacturing practices, and other government regulations and corresponding foreign standards. We do not have control over third-party manufacturers' compliance with these regulations and standards, nor can we guarantee that we will maintain compliance with such regulations in regards to our own manufacturing processes. 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 IND or the product or require us to take our approved products off the market;
- we may be required to change the way the product is manufactured or administered and we may be required to 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 manufacturing, 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 or subsequent 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 FDA'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. New issues may arise during a product lifecycle that did not exist, or were unknown, at the time of product approval, such as adverse events of unanticipated severity or frequency, or problems with the facility where the product is manufactured. Since approved products, manufacturers, and manufacturers' facilities are subject to continuous review and periodic inspections, these new issues post-approval may result in voluntary actions by Capricor or may result in a regulatory agency imposing restrictions on that product or us, including requiring withdrawal of the product from the market or for use in a clinical study. If our product candidates fail to comply with applicable regulatory requirements, such as good manufacturing practices, 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 laboratories and research facilities in leased premises at Cedars-Sinai Medical Center, or CSMC, in Los Angeles, California. We presently manufacture our cells in a facility which is owned by and located within CSMC and in which we believe we follow good manufacturing practices, but which is not a GMP approved facility. Our intention is to manufacture cells at this facility for our ALLSTAR Phase II trial, our DYNAMIC trial and for our HOPE-Duchenne trial. These plans could change if we decide to expand any of our clinical trials to include international sites, such as in Europe. Currently, we also intend to utilize our premises at CSMC to develop and manufacture exosomes. If the facilities lease is terminated or if CSMC revokes its permission to allow us to utilize the manufacturing 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 may have to build out our own manufacturing facility or establish a collaboration agreement with a third party for any Phase III trial.

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 and a Provisional License for Tissue Bank Operation from the State of New York. 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, if a serious adverse event in any of our clinical trials 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. Other states may impose additional licensing requirements upon us which, until obtained, would limit our ability to conduct our trials in such states.

We obtain the donor hearts from which our CDCs are manufactured from organ procurement organizations, or OPOs. There is no guarantee that the OPOs which currently provide donor hearts to us will be able to continue to supply us with donor hearts in the future or, in that case, that an alternative OPO will be available to us. If those OPOs 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, OPOs are subject to regulations of various government agencies. There is no guarantee that laws and regulations pursuant to which our OPOs provide donor hearts will not change, making it more difficult or even impossible for the OPOs to continue to supply us with the hearts we need to produce our product.

There are additional risks involved in conducting trials internationally.

If we decide to expand one or more of our clinical trials to investigative sites in Europe or other countries outside of the United States, we will have additional regulatory requirements that we will have to meet in connection with our manufacturing, distribution, use of data and other matters. For example, if we decide to conduct our trials in Europe, we will have to either move our manufacturing facility to a facility located in Europe, enter into an agreement with a European manufacturer to manufacture our product candidates for us or enter into an agreement with a domestic manufacturer who maintains an acceptable GMP facility. Any of those options would involve a significant monetary investment, would involve increased risk and may impact the progress of our clinical trials and regulatory approvals. Our current and anticipated future reliance on a limited number of third-party manufacturers exposes us to the following additional risks:

- We may be unable to identify manufacturers needed to manufacture our product candidates or the necessary devices on acceptable terms or at all, because the number of potential manufacturers is limited, and before obtaining 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 or the devices intended for use, after receipt of FDA approval, if any.
- Our third-party manufacturers might be unable to manufacture our product candidates in the volume and of the quality required to meet our clinical and commercial needs, if any.
- Our third-party manufacturers might be unable to manufacture or supply us with sufficient quantities of devices or acceptable materials necessary for the development or use of our product candidates.
- Our product candidates may not perform well, or at all, with the devices received from third-party manufacturers.
- 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 or the materials or devices needed to manufacture or utilize our product candidates.
- Drug manufacturers are subject to ongoing periodic unannounced inspection by the FDA, the Drug Enforcement Agency, and their foreign counterparts 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.

Additionally, the U.S. Foreign Corrupt Practices Act, or FCPA, prohibits U.S. corporations and their representatives from offering, promising, authorizing or making payments to any foreign government official, government staff member, political party or political candidate in an attempt to obtain or retain business abroad. The scope of the FCPA includes interactions with certain healthcare professionals in many countries. Other countries have enacted similar anti-corruption laws and/or regulations. Ensuring compliance with the FCPA and the laws of other countries will involve additional monetary and time commitments on behalf of the Company.

Our risk mitigation measures and corporate compliance program cannot guarantee that we effectively manage all operational risks and that we are in compliance with all potentially applicable U.S. federal and state regulations and all potentially applicable foreign regulations and/or other requirements.

The development, manufacturing, distribution, pricing, sales, marketing and reimbursement of our product candidates, together with our general operations, are subject to extensive federal and state regulation in the United States and may be subject to extensive regulation in foreign countries. In addition, our business is complex, involves significant operational risks and includes the use of third parties to conduct business. While we intend to implement numerous risk mitigation measures to comply with such regulations in this complex operating environment, we cannot guarantee that we will be able to effectively mitigate all operational risks. We cannot guarantee that we, our employees, our consultants, our contractors or other third parties are or will be in compliance with all potentially applicable U.S. federal and state regulations and/or laws, and all potentially applicable foreign regulations and/or laws. If we fail to adequately mitigate our operational risks or if we or our agents fail to comply with any of those regulations or laws, a range of actions could result, including, but not limited to, the termination of clinical trials, the failure to approve a product candidate, restrictions on our products or manufacturing processes, withdrawal of our products from the market, significant fines, exclusion from government healthcare programs or other sanctions or litigation. Such occurrences could have a material and adverse effect on our business and results of operations.

Our employees and consultants may engage in misconduct or other improper activities, including noncompliance with regulatory standards and requirements.

We are exposed to the risk of employee or consultant fraud or other misconduct. Misconduct by our employees or consultants could include intentional failures to comply with FDA regulations, provide accurate information to the FDA, comply with manufacturing standards, comply with federal and state healthcare fraud and abuse laws and regulations, report financial information or data accurately or disclose unauthorized activities to us. Employee and consultant misconduct could involve the improper use of information obtained in the course of clinical trials, which could result in regulatory sanctions and serious harm to our reputation. It is not always possible to identify and deter such misconduct, and the precautions we take to detect and prevent this activity may not be effective in controlling unknown or unmanaged risks or losses or in protecting us from governmental investigations or other actions or lawsuits stemming from a failure to be in compliance with such laws or regulations. If any such actions are instituted against us, and we are not successful in defending ourselves or asserting our rights, those actions could have a material adverse effect on our business, financial condition and results of operations, and result in the imposition of significant fines or other sanctions against us.

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

Our manufacturing experience has been limited to manufacturing CAP-1002 for the ongoing ALLSTAR, DYNAMIC and HOPE-Duchenne clinical trials. 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 candidates have not previously been tested in any large trials to show safety or efficacy, nor are they available for commercial use. We face risks of manufacturing failures and risks of making products that are not proven to be safe or effective.

We are subject to a number of manufacturing risks, any of which could substantially increase our costs and limit supply of our product candidates.

The process of manufacturing our product candidates is complex, highly regulated, and subject to several risks. For example, the process of manufacturing our product candidates is extremely susceptible to product loss due to contamination, equipment failure or improper installation or operation of equipment, or vendor or operator error. Even minor deviations from normal manufacturing processes for any of our product candidates could result in reduced production yields, product defects, and other supply disruptions. If microbial, viral, or other contaminations are discovered in our product candidates or in the manufacturing facilities in which our product candidates are made, such manufacturing facilities may need to be closed for an extended period of time to investigate and remedy the contamination. In addition, the manufacturing facilities in which our product candidates are made could be adversely affected by equipment failures, labor shortages, natural disasters, power failures and numerous other factors.

As we continue with the development of Cenderitide or CU-NP, we will rely exclusively on third parties to formulate and manufacture these product candidates and provide us with the devices and other products necessary to administer Cenderitide or CU-NP.

We 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 these product candidates. As we continue with our clinical trial of Cenderitide or the possible development of 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. In addition, these product candidates may require the use of one or more medical devices for infusion into patients. We have contracted with Insulet Corporation to supply us with its OmniPod pumps to utilize with Cenderitide for our current trial. We will have to enter into additional contracts with one or more device manufacturers to manufacture and supply the devices to be used in the dosing procedures for any future trials of Cenderitide or CU-NP. 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 or the necessary devices 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 or the devices 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 third-party manufacturers might be unable to manufacture or supply us with sufficient quantities of devices or acceptable materials necessary for the development or use of our product candidates.
- Our product candidates may not perform well, or at all, with the devices received from third-party manufacturers.
- 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 or the materials or devices needed to manufacture or utilize our product candidates.
- 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.

Business disruptions such as natural disasters could seriously harm our future revenues and financial condition and increase our costs and expenses.

Our corporate headquarters and manufacturing facilities are located in the greater Los Angeles, California area, a region known for seismic activity. A significant natural disaster, such as an earthquake, flood or fire, occurring at our headquarters or facilities could have a material and adverse effect on our business, financial condition and results of operations. In addition, terrorist acts or acts of war targeted at the U.S., and specifically the Los Angeles, California region, could cause damage or disruption to us, our employees, facilities and partners, which could have a material adverse effect on our business, financial condition and results of operations.

A breakdown or breach of our information technology systems could subject us to liability or interrupt the operation of our business.

We are increasingly dependent upon information technology systems and data, especially as we expand our clinical trials and therefore our databases of patient information. Our computer systems are potentially vulnerable to breakdown, malicious intrusion and random attack. Likewise, data privacy or security breaches by individuals authorized to access our information technology systems or others may pose a risk that sensitive data, including intellectual property, trade secrets or personal information belonging to us, our patients, customers or other business partners, may be exposed to unauthorized persons or to the public. Cyber-attacks are increasing in their frequency, sophistication and intensity. While we continue to build and improve our information systems and infrastructure and believe we have taken appropriate security measures to minimize these risks to our data and information technology systems, there can be no assurance that our efforts will prevent breakdowns or breaches in our systems that could adversely affect our business.

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, in-licensed 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, could have a material adverse effect, potentially 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 were to be 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 United States Patent and Trademark Office, or USPTO, and may become involved in opposition, derivation, reexamination, inter-partes 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 has developed new and untested regulations and procedures to govern the full implementation 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, only became effective in March 2013. The Leahy-Smith Act has also introduced procedures that may make it easier for third parties to challenge issued patents, as well as to intervene in the prosecution of patent applications. Finally, the Leahy-Smith Act contains new statutory provisions that still require the USPTO to issue new regulations for their implementation, and it may take the courts years to interpret the provisions of the new statute. 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 CAP-1002, CAP-1001, and CSps product candidates from University of Rome, The Johns Hopkins University, or JHU, and CSMC. We have also licensed certain patent and other intellectual property rights that cover exosomes from 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 our Amended and Restated Exclusive License Agreement with CSMC and our Exclusive License Agreement with CSMC, 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 also license certain patent and other intellectual property rights that cover our Cenderitide and CU-NP product candidates from the Mayo Foundation for Medical Education and Research, or Mayo. In the past, we have relied on Mayo to file, prosecute, and maintain patent applications, and otherwise protect the intellectual property to which we have a license, and, prior to our entry into the Amended and Restated License Agreement with Mayo, or 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. 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. With the execution of the Amended Mayo License Agreement, we are responsible for the prosecution and maintenance of the Mayo patents and patent applications covered by our license, and the associated costs and expenses. Our enforcement of certain of these licensed patents or defense of any claims asserting the invalidity of these patents would be subject to the cooperation of other parties.

In October 2014, we entered into a Transfer Agreement with Medtronic, Inc., or Medtronic, pursuant to which we received an assignment of patent rights that were owned or co-owned by Medtronic relating to natriuretic peptides. We have responsibility for the prosecution and maintenance of such patents and patent applications at our expense. We cannot be certain that the activities conducted by Medtronic prior to our acquisition of these patents and patent rights were conducted in compliance with applicable law and regulations, or will result in valid and enforceable patents. Our enforcement of certain of these assigned patents or defense of any claims asserting the invalidity of these patents would be subject to the cooperation of third parties.

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

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

- others may be able to make compounds that are similar to our product candidates but that are not covered by the claims of any of our patents;
- we might not have been the first to make the inventions covered by any issued patents or patent applications we may have (or third parties from whom we license intellectual property may have);
- 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. 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 are often limited in duration and 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. In addition, 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. 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 a third party from using the inventions claimed in our patents, that individual or company has the right to ask the court to rule that such 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 discontinuing the infringement of our 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 in the past invalidated tests used by the 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 could decide that we or our commercialization partners are infringing the third party's patents and order us or our partners to stop the activities covered by the patents. In addition, there is a risk that a court could 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.

As 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 applications 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, Inc.'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 or exosomes 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 the Amended Mayo Agreement, 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 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. In 2014, we received a grant from the NIH to fund the DYNAMIC 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 the CIRM Loan Agreement, pursuant to which CIRM agreed to disburse approximately $19.8 million to us over a period of approximately three and one-half years to support Phase II of our ALLSTAR clinical trial. Under the CIRM 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 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 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 CIRM 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 CIRM 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. We are also required to meet certain progress milestones specified in the CIRM Notice of Loan Award. Capricor and CIRM have agreed to adjust future disbursements of loan proceeds to align with actual patient enrollment. Because the Company is decreasing the number of patients to be enrolled in the ALLSTAR clinical trial, it is undetermined at this time how much of the remaining CIRM loan award will ultimately be disbursed under the CIRM Loan Agreement. The loss of funding under the CIRM Loan Agreement could cause delays under our ALLSTAR trial. There is no assurance that we will meet our milestones under the CIRM Loan Agreement, that CIRM will not delay or discontinue the disbursement of funds or that CIRM will not terminate the Loan Agreement for failure to meet certain loan conditions. If that were to happen, we may not have the funds necessary to complete the ALLSTAR Trial.

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 science 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.

There is a risk that Janssen may not exercise its option for an exclusive license.

The Company has entered into a Collaboration Agreement and Exclusive License Option with Janssen Biotech, Inc., or Janssen. There is no guarantee that Janssen will exercise its option for an exclusive license and enter into an agreement with the Company. Janssen has complete discretion as to whether it exercises its option for an exclusive license with the Company, and its decision is outside of our control. If Janssen declines to exercise the option it could have a material adverse effect on the business, financial condition, or results of operations of the Company.

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.

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 Dr. Deborah Ascheim, our Chief Medical Officer, also provide services on a limited part-time basis to CSMC as do several other of our employees. Dr. Frank Litvack, our Executive Chairman, 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.

All former employees of Nile Therapeutics, Inc., or Nile (our former corporate name), were terminated upon consummation of the merger between Nile and Capricor, Inc. We do not currently have any employees who have experience in the development of natriuretic peptides.

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 currently does 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.

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 potential 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 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 such collaborators 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 sufficient 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, if any, 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 payors, 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 or for its indemnification obligations. 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 significantly 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, 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, both federal and state 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, as well as the terms of that 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 or development 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;
- issues with the supply or manufacturing of any devices or materials needed to manufacture or utilize our drug candidates;
- FDA or other United States or foreign regulatory actions affecting us or our industry;
- the risks and costs of increased operations, including clinical and manufacturing operations, on an international basis;
- 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 or the operations of the Company;
- 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.

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. Additionally, the terms of our CIRM Loan Agreement restrict our ability to declare or pay dividends to our stockholders. 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 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 currently issued or currently outstanding. If issued, 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.

Market and economic conditions may adversely affect our industry, business and ability to obtain financing.

Recent global market and economic conditions have been unpredictable and challenging. These conditions and any adverse impact on the financial markets 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 securities analysts.

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 those contained in the projections. The inclusion of the projections in (or incorporated by reference in) this Annual Report on Form 10-K 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. Additionally, final data may differ significantly from preliminary reported data. Capricor has amended its protocol for the ALLSTAR trial which will result in a reduction in the number of patients necessary for potentially achieving statistical significance and meeting the primary endpoint. While we believe that this reduction will provide sufficient data to show statistically significant results, there is no assurance that the assumptions used for the reduction in sample size, which were based on prior trial results, will be replicated in this current trial.

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 or 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.

The former stockholders of Capricor, Inc., now a wholly-owned subsidiary of the Company, many of whom are executive officers and directors of the Company, together with their respective affiliates, beneficially own or control a majority of the outstanding shares of the Company. Accordingly, the stockholders, 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 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 Internal Revenue Code of 1986, as amended, or 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 an "ownership change" of Nile. In addition, previous or current changes in the Company's stock ownership may have triggered or, in the future, may trigger an "ownership change", some of which may be outside our control. 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.

The requirements of being a public company may strain our resources and divert management's attention.

As a public company, we are subject to the reporting requirements of the Securities Exchange Act of 1934, as amended, or the Exchange Act, and other applicable securities rules and regulations, and are subject to the listing requirements of The Nasdaq Stock Market LLC. Compliance with these rules and regulations will increase our legal and financial compliance costs, make some activities more difficult, time-consuming or costly and increase demand on our systems and resources. The Exchange Act requires, among other things, that we file annual, quarterly and current reports with respect to our business and operating results and maintain effective disclosure controls and procedures and internal control over financial reporting. In order to maintain and, if required, improve our disclosure controls and procedures and internal control over financial reporting to meet this standard, significant resources and management oversight may be required. As a result, management's attention may be diverted from other business concerns, which could harm our business and operating results. Although we have hired employees to comply with these requirements, we may need to hire more employees in the future, which will increase our costs and expenses.

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, as amended, or Sarbanes-Oxley, as well as rules implemented by the SEC, NASDAQ 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 Sarbanes-Oxley, 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 (the "Bubble Lease"), which was set to expire on June 30, 2015, the base rent for the first 12-month period was $16,620 per month, and the base rent for the second 12-month period was $17,285. On March 3, 2015, Capricor executed a Second Amendment to Lease with The Bubble Real Estate Company, LLC, pursuant to which additional space was added to the Bubble Lease and we exercised our option to extend the term of the Bubble Lease through June 30, 2016. Under the terms of the amendment to the Bubble Lease, commencing February 2, 2015, the base rent increased to $17,957 for one month. Commencing on March 2, 2015, the base rent increased to $21,420 per month for the subsequent four month period and commencing July 1, 2015, the base rent increased to $22,111 per month. At the time of filing of this Annual Report on Form 10-K, we are exploring different lease options, including renewing our current lease or moving to a different office location.

Capricor currently leases two research laboratories from CSMC under the terms of a three-year lease which expires on June 1, 2017. The rent expense for the first six-month period was approximately $15,461 per month. Commencing with the seventh month of the lease term, the rent expense increased to approximately $19,350 per month. The amount of rent expense is subject to annual adjustments according to increases in the Consumer Price Index.

With permission from CSMC, Capricor presently manufactures its cells and exosomes in a facility which is owned by and located within CSMC and in which we believe we follow good manufacturing practices. Our laboratories and manufacturing facility are located at 8700 Beverly Blvd., Los Angeles, California 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 Stock

Prior to March 9, 2015, our common stock traded on the OTCQB tier of the OTC Markets. Commencing March 9, 2015, our common stock began trading on the NASDAQ Capital Market under the symbol "CAPR". The following table lists the high and low prices of our common stock as quoted, in U.S. dollars, by NASDAQ or the OTCQB, as applicable, 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.

	High	Low
Year ended December 31, 2014		
First Quarter	$ 17.15	$ 2.50
Second Quarter	8.50	4.11
Third Quarter	4.45	3.51
Fourth Quarter	4.25	3.20
Year ended December 31, 2015		
First Quarter	$ 10.25	$ 3.43
Second Quarter	8.65	4.68
Third Quarter	5.10	3.86
Fourth Quarter	4.60	2.65

Holders

According to the records of our transfer agent, American Stock Transfer & Trust Company, as of March 29, 2016, we had 125 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. The ability of our Board of Directors to declare a dividend is subject to limits imposed by Delaware corporate law. Pursuant to the terms of our Loan Agreement with the California Institute for Regenerative Medicine, or CIRM, as amended, our Board of Directors also may not pay any dividends without the prior consent of CIRM; provided that our Board of Directors may pay dividends solely in shares of our common stock without such consent.

Performance Graph

We are a smaller reporting company, as defined by Rule 12b-2 of the Securities Exchange Act of 1934, as amended, and are not required to provide a performance graph.

Recent Sales of Unregistered Securities

On January 9, 2015, the Company entered into a Share Purchase Agreement with select investors pursuant to which the Company agreed to issue and sell to the investors, in a private placement ("PIPE 1"), an aggregate of 2,839,045 shares of its common stock at a price per share of $3.523 for an aggregate purchase price of approximately $10,000,000. The shares of common stock sold in PIPE 1 were issued and sold in reliance on the exemption from registration afforded by Section 4(2) of the Securities Act of 1933, as amended (the "Securities Act"), and Rule 506 of Regulation D promulgated under the Securities Act and corresponding provisions of state securities or "blue sky" laws. Each of the investors in PIPE 1 represented to the Company that it was acquiring the shares for investment only and not with a view towards, or for resale in connection with, the public sale or distribution thereof.

On February 3, 2015, the Company entered into a Share Purchase Agreement with certain accredited investors, pursuant to which the Company agreed to issue and sell to the investors, in a private placement ("PIPE 2"), an aggregate of 1,658,822 shares of its common stock, par value $0.001 per share, at a price per share of $4.25 for an aggregate purchase price of approximately $7,050,000. The shares of common stock sold in PIPE 2 were issued and sold to "accredited investors," as that term is defined in the Securities Act, and in reliance on the exemption from registration afforded by Section 4(2) of the Securities Act and Rule 506 of Regulation D promulgated under the Securities Act and corresponding provisions of state securities or "blue sky" laws. Each of the investors in PIPE 2 represented to the Company that it was acquiring the shares for investment only and not with a view towards, or for resale in connection with, the public sale or distribution thereof.

Issuer Purchases of Equity Securities

None.

ITEM 6. SELECTED FINANCIAL DATA

We are a smaller reporting company, as defined by Rule 12b-2 of the Securities Exchange Act of 1934, as amended, and are not required to provide the information required under this item.

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 audited consolidated financial statements and the audited 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

Our mission is to improve the treatment of diseases by discovering, developing and commercializing innovative therapies, with a primary focus on cardiovascular diseases. 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, or, as so amended, the Merger Agreement, by and among Nile Therapeutics, Inc., a Delaware corporation, or Nile, Bovet Merger Corp., a Delaware corporation and a wholly-owned subsidiary of Nile, or Merger Sub, and Capricor, Inc., or Capricor, Merger Sub merged with and into Capricor and Capricor became a wholly-owned subsidiary of Nile. 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, (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.

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 became Director of the Heart Institute at Cedars-Sinai Medical Center, or CSMC. Capricor's laboratories are located in space that Capricor leases from CSMC.

Drug Candidates

We currently have six 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 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 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 in October 2013. Preliminary 12 month MRI data collected on the patients in the Phase I open-label dose-escalation study revealed that those patients who would be included in the Phase II clinical study by virtue of dose and tissue type compatibility exhibited a 5.2% improvement in ejection fraction, a global measure of the heart's pumping ability. Additionally, there was a relative reduction in scar size of 20.7%. Measurements of viable mass and regional function also showed quantifiable improvements.

In December 2013, Capricor received notification from the National Heart Lung and Blood Institute, or the NHLBI, Gene and Cell Therapy Data Safety Monitoring Board 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 a 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. The Phase II portion of the trial was initially designed to enroll up to 300 patients.

We recently completed statistical modelling of the design of ALLSTAR. This modelling incorporated the expanded dataset that has become available from our other clinical trials of CAP-1002. Based on these results, we have elected to decrease the enrollment goal of ALLSTAR to approximately 120 patients, a sample size that is expected to maintain sufficient statistical power to detect a reduction in infarct, or scar, size as measured by MRI at twelve months. We have amended our clinical protocol to reflect these changes, which such amendment has been approved by the Data Safety Monitoring Board and submitted to the FDA. Phase II of the ALLSTAR study is being funded in large part through the support of the California Institute for Regenerative Medicine, or CIRM.

In December 2013, Capricor entered into a Collaboration Agreement and Exclusive License Option with Janssen Biotech, Inc., or Janssen. Under the agreement, Janssen has an exclusive option to enter into an exclusive license agreement with Capricor, pursuant to which, if exercised, 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, except as may otherwise be agreed with respect to certain indications. 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.

Capricor was awarded a grant for approximately $2.9 million from the NIH to support further development of the CAP-1002 product. In June 2014, we received approval from the NIH to use the funds from the grant for the first part of the DYNAMIC (dilated cardiomyopathy intervention with allogeneic myocardially-regenerative cells) trial, which is being sponsored by Capricor. The first part of the DYNAMIC trial used CAP-1002 to treat patients with advanced heart failure utilizing triple-vessel intracoronary infusion. We initiated enrollment of the DYNAMIC trial in December 2014 and completed enrollment in April 2015. Initial top-line results were presented at the American Heart Association's Annual Scientific Sessions in November 2015. Multi-vessel intracoronary infusion of CAP-1002 in subjects with dilated cardiomyopathy was shown to be safe in this study with no major adverse cardiac events reported at one month or at six months post-infusion. Though this trial was intended as an early safety study, the six-month data demonstrated encouraging and congruent preliminary efficacy signals in multiple parameters, including subjective well-being, exercise capacity, ejection fraction and ventricular volumes.

Additionally, we are currently enrolling the Phase I/II HOPE-Duchenne clinical trial, which is designed to enroll approximately 24 patients in a randomized, multi-center study evaluating the safety and preliminary efficacy of CAP-1002 in patients with cardiomyopathy related to Duchenne muscular dystrophy. Patients enrolled in the study who are randomized to receive CAP-1002 will be infused in all three coronary arteries, which will allow for CAP-1002 to be delivered to wide areas of the myocardium. Subject to finalization of definitive documents, this study will be funded in part through a grant award from CIRM in the amount of approximately $3.4 million. Both the milestones and the rate of disbursement of the award proceeds will be set forth in the definitive documents, which have not been determined as of the date of filing of this Annual Report on Form 10-K. In April 2015, the FDA granted orphan drug designation to CAP-1002 for the treatment of DMD.

- **Cenderitide (CD-NP)**: Cenderitide belongs to a class of drugs called natriuretic peptides. Preclinical and clinical data have shown that the natriuretic peptide class can act on multiple disease processes that play a role in negative outcomes associated with heart failure. Cenderitide's treatment goal and target indication is to provide a novel and effective therapeutic option for the outpatient treatment of heart failure, thereby addressing a critical unmet need. Cenderitide is being developed as an outpatient therapy to be delivered continuously using a validated subcutaneous infusion pump for up to 90 days (the "post-acute" period) following an acute heart failure hospital admission, as well as for other potential indications. Cenderitide was designed by scientists at the Mayo Clinic to be the only dual natriuretic peptide receptor agonist. In October 2014, we entered into an Agreement for Investigator-Initiated Research Support with Insulet Corporation, or Insulet, pursuant to, which Insulet supported Capricor's research by engaging in certain product development, project management and design control activities, in addition to supplying the OmniPod product being used for our current studies. In 2015, we completed a Phase II study in 14 patients with stable, chronic heart failure. Patients received up to eight consecutive days of Cenderitide through subcutaneous infusion using Insulet's drug delivery system based on the OmniPod technology. This trial assessed the safety and tolerability, pharmacokinetic profiles and pharmacodynamic response to increasing dose levels of open-label Cenderitide administered in a stepwise fashion. The drug was tolerated and there were no significant adverse events. Capricor has initiated an additional study to further assess the safety and efficacy of this product candidate, which will include higher dose levels of Cenderitide in patients with stable heart failure with moderate renal impairment. This study will assess the safety and tolerability, pharmacokinetic profiles and pharmacodynamic response to increasing dose levels of Cenderitide. Following these studies, Capricor will determine whether to conduct additional clinical studies to further assess the safety and efficacy of this product candidate. Cenderitide in the post-acute period has been granted Fast-Track designation by the FDA.

- **Exosomes**: Exosomes are nano-sized, membrane-enclosed vesicles, or “bubbles”, that are filled with select molecules, including proteins, RNAs and microRNAs, which, when released, send messages to neighboring cells to regulate cellular functions. Exosomes act as transport vehicles out of cells for microRNA, other fragments of genetic material and proteins that act as messengers between cells, ultimately providing regulatory function for many cell processes, including inflammation, angiogenesis, programmed cell death (apoptosis) and scarring. Pre-clinical research has shown that exogenous exosomes can be used as therapeutic agents aimed to direct or, in some cases, re-direct cellular activity. Their size, ease of crossing cell membranes, and ability to communicate in native cellular language makes them a class of exciting and novel therapeutic agents. We are currently in pre-clinical testing to explore the possible future therapeutic benefits that exosomes may possess and the indications in which they potentially may be investigated.

- **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, 17 of which 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 CDCs 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.

- **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. We are currently evaluating whether we will proceed with clinical development of this product.

- **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 asset, at present there is no plan to develop CSps as therapeutic agents.

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 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 explore other potential indications for CAP-1002, and as we further develop Cenderitide, exosomes and 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 to date have been proceeds from private and public equity sales, grants received from the NIH, a payment from Janssen and a loan and grant award from CIRM.

Research and development, or R&D, expenses consist primarily of salaries and related personnel costs, supplies, clinical trial costs, patient treatment costs, consulting fees, costs of personnel and supplies for manufacturing, costs of service providers for pre-clinical, clinical and manufacturing, and certain legal expenses resulting from intellectual property prosecution, stock compensation expense and other expenses relating to the design, development, testing and enhancement of our product candidates. Except for certain capitalized intangible assets, 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 due to 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 consolidated 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 for the fiscal years ended December 31, 2015 and 2014

General and Administrative Expenses. General and administrative, or G&A, expenses for the years ended December 31, 2015 and 2014 were approximately $4.4 million and $3.0 million, respectively. The increase of approximately $1.4 million in G&A expenses in the year ended December 31, 2015 compared to the year ended December 31, 2014 is primarily attributable to an increase of approximately $0.9 million related to stock-based compensation expense. Furthermore, there was an increase of approximately $0.3 million in compensation and recruiting costs related to increased headcount.

Research and Development Expenses. Research and development, or R&D, expenses for the years ended December 31, 2015 and 2014 were approximately $13.8 million and $7.8 million, respectively. The increase of approximately $6.0 million in R&D expenses in the year ended December 31, 2015 as compared to the year ended December 31, 2014 is primarily due to clinical development activities of CAP-1002 (ALLSTAR, DYNAMIC and HOPE-Duchenne) as well as Cenderitide, including continued research and development efforts. These activities resulted in an increase of approximately $4.5 million in clinical costs primarily related to contract research organizations and manufacturing costs associated with CAP-1002 and Cenderitide, as well as patient costs and expenses for the operational team that supports our clinical trials. Additionally, for the year ended December 31, 2015, there was an increase of approximately $0.5 million in R&D expenses related to our Janssen chemistry, manufacturing and controls development and process development work as compared to the year ended December 31, 2014. Furthermore, during 2015, there was an increase in R&D expenses related to our product candidates, including exosomes, of approximately $0.2 million and an increase of approximately $0.6 million related to salary increases and stock-based compensation for the year ended December 31, 2015 as compared to the year ended December 31, 2014.

CAP-1002 – Although the development of CAP-1002 is in its early stages, we believe that it has the potential to treat heart disease and its complications. We expect to spend approximately $10.0 million to $13.0 million during 2016 on the development and manufacturing of CAP-1002, which expenses are primarily related to our Phase II ALLSTAR trial, the DYNAMIC trial and the HOPE-Duchenne trial. The Phase I portion of the ALLSTAR 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. Additionally, we have now completed statistical modelling of the design of ALLSTAR. This modelling incorporated the expanded dataset that has become available from our other clinical trials of CAP-1002. Based on these results, we have elected to decrease the enrollment goal of ALLSTAR to approximately 120 patients, a sample size that is expected to maintain sufficient statistical power to detect a reduction in infarct, or scar, size as measured by MRI at twelve months. We have amended our clinical protocol to reflect these changes, which such amendment has been approved by the Data Safety Monitoring Board and submitted to the FDA. Phase II is funded in large part 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. In regards to the DYNAMIC trial, Capricor recently announced top-line six-month data from the DYNAMIC trial. DYNAMIC was funded in large part through a grant award from the NIH.

Except as may otherwise be agreed with respect to certain indications, if Janssen exercises its exclusive option under the Collaboration Agreement and Exclusive License Option between the Company and Janssen, or the Janssen Agreement, 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 will thereafter be responsible for any additional trials and future development costs with respect to CAP-1002. Furthermore, as we proceed with the HOPE-Duchenne trial, which is designed to evaluate the treatment of cardiac dysfunction associated with DMD, we expect our expenses related to CAP-1002 to increase further. Our strategy for further development of CAP-1002 will depend to a large degree on the outcome of these planned studies and on Janssen's decision with respect to the option.

Cenderitide – We acquired the rights to Cenderitide in 2006, and have incurred substantial losses surrounding the development of the product to date. Prior to the merger between Capricor and Nile, Nile had incurred approximately $19.9 million in expenses directly relating to the Cenderitide development program through September 30, 2013. In March 2015, we completed enrollment of the Phase II trial, which enrolled 14 patients with stable, chronic heart failure. Capricor initiated an additional small study in 2016 to further assess the safety and efficacy of this product candidate, which will include higher dose levels of Cenderitide. We expect to spend approximately $0.5 million to $1.0 million during 2016 in development expenses related to the Cenderitide clinical program. Following these studies, Capricor will determine whether to conduct additional clinical studies to further assess the safety and efficacy of this product candidate.

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 patients 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 trials involving CAP-1002 and its ability to obtain significant capital to conduct further studies with CAP-1001.

Exosomes – Exosomes are nano-sized, membrane-enclosed vesicles, or "bubbles", that are filled with select molecules, including proteins, RNAs and microRNAs, which, when released, send messages to neighboring cells to regulate cellular functions. We expect to spend approximately $1.0 million to $2.0 million during 2016 in pre-clinical expenses related to the exosomes program. Capricor is currently in pre-clinical testing to explore the possible future therapeutic benefits that exosomes may possess.

CU-NP – Nile acquired the rights to CU-NP in September 2008. Prior to the merger between Capricor and Nile, Nile had incurred approximately $0.7 million in expenses 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 candidate.

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

Our expenditures on current and future clinical development programs, particularly our CAP-1002, Cenderitide and exosomes 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 product 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 manufacturing and clinical development and as a result of 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 product candidates; and
- the costs, requirements and timing of, and the ability to secure, regulatory approvals.

Grant Income. Grant income for the years ended December 31, 2015 and 2014 was approximately $1.7 million and $0.6 million, respectively. The increase in grant income in 2015 as compared to 2014 is due to the fact that the DYNAMIC clinical trial commenced in the third quarter of 2014, with the first patient being treated in late 2014, and the remaining patients in the clinical trial being treated throughout 2015.

Collaboration Income. As a result of the Janssen Agreement, collaboration income for the year ended December 31, 2015 and 2014 was approximately $3.8 million and $4.2 million, respectively. A ratable portion of the payment to Capricor under the Janssen Agreement was recognized in both the years ended December 31, 2015 and 2014 under the terms of the Janssen Agreement. The Company periodically reviews the estimated performance period of the Janssen Agreement based on the estimated progress of its project with Janssen.

Interest Expense. Interest expense for the years ended December 31, 2015 and 2014 was $248,626 and $200,505, respectively. The increase in interest expense in 2015 as compared to 2014 is due to accrued interest on the CIRM loan award.

Liquidity and Capital Resources for the fiscal years ended December 31, 2015 and 2014

The following table summarizes our liquidity and capital resources as of and for each of our last two fiscal years, and our net increase (decrease) in cash and cash equivalents as of and for each of our last two fiscal years, and is intended to supplement the more detailed discussion that follows. The amounts stated in the tables below are expressed in thousands.

Liquidity and capital resources	**December 31, 2015**	**December 31, 2014**
Cash and cash equivalents	$ 5,568	$ 8,035
Working capital	$ 7,461	$ 5,308
Stockholders' equity (deficit)	$ (1,032)	$ (6,249)

	Years ended December 31,	
Cash flow data	**2015**	**2014**
Cash provided by (used in):		
Operating activities	$ (10,817)	$ 959
Investing activities	(8,141)	141
Financing activities	16,492	5,206
Net increase (decrease) in cash and cash equivalents	$ (2,466)	$ 6,305

Our total cash and cash equivalents, not including restricted cash, as of December 31, 2015 was approximately $5.6 million compared to approximately $8.0 million as of December 31, 2014. The decrease in cash and cash equivalents for the year ended December 31, 2015 as compared to the year ended December 31, 2014 is due to an increase in operating expenses and an allocation of cash and cash equivalents to marketable securities. Total marketable securities, consisting primarily of United States treasuries, were approximately $8.0 million as of December 31, 2015, as compared to zero as of December 31, 2014. The increase in working capital and stockholders' equity as of December 31, 2015 is primarily due to the approximately $17.0 million received as a result of the two private placements of our common stock completed during the first quarter of fiscal year 2015. As of December 31, 2015, we had approximately $17.1 million in total liabilities, of which approximately $4.6 million was recorded as deferred income under the Janssen Agreement, and approximately $7.5 million in net working capital. We incurred a net loss of approximately $12.9 million for the year ended December 31, 2015.

Cash used in operating activities was approximately $10.8 million for the year ended December 31, 2015 and cash provided by operating activities was approximately $1.0 million for the year ended December 31, 2014. The difference of approximately $11.8 million in cash from operating activities is primarily due to the approximately $12.5 million received from Janssen in early 2014. To the extent we obtain sufficient capital and/or long-term debt funding and are able to continue developing our product candidates, including as we expand our technology portfolio and engage in further research and development activities, and, in particular, conduct pre-clinical studies and clinical trials, we expect to continue incurring substantial and increasing losses, which will generate negative net cash flows from operating activities.

We had cash flow used in investing activities of approximately $8.1 million for the year ended December 31, 2015 and cash flow provided by investing activities of approximately $0.1 million for the year ended December 31, 2014. The increase in cash used in investing activities for the year ended December 31, 2015 as compared to the year ended December 31, 2014 is primarily due to the net effect from purchases, sales, and maturities of marketable securities.

We had cash provided by financing activities of approximately $16.5 million and $5.2 million for the year ended December 31, 2015 and 2014, respectively. The increase in cash provided by financing activities for the year ended December 31, 2015 as compared to the year ended December 31, 2014 is primarily the result of the two private placements of our common stock completed during the first quarter of 2015.

Phase II of Capricor's ALLSTAR trial has been funded in large part through a loan award from CIRM. Because the Company is decreasing the number of patients to be enrolled in the ALLSTAR clinical trial, it is undetermined at this time how much of the remaining CIRM loan award will ultimately be disbursed under the CIRM Loan Agreement. The loss of funding under the CIRM Loan Agreement could cause delays under our ALLSTAR trial. Subject to sufficient funding, following completion of the Phase II trial there may be a Phase IIb and/or Phase III trial. If we continue with a Phase IIb and/or Phase III trial, we will need substantial additional capital in order to continue the development of CAP-1002. Pursuant to the Janssen Agreement, the chemistry, manufacturing and controls 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 option under the Janssen Agreement to enter into an exclusive license agreement with Capricor, Janssen will be responsible for any additional trials and future development costs with respect to CAP-1002, except for certain excluded indications.

Capricor's Phase I/II HOPE-Duchenne trial for the use of CAP-1002 to treat Duchenne muscular dystrophy cardiomyopathy will be funded in part through a grant award for approximately $3.4 million, subject to the finalization of definitive documents with CIRM. In April 2015, the FDA granted orphan drug designation to CAP-1002 for the treatment of DMD. Orphan drug designation is granted by the FDA's Office of Orphan Drug Products to drugs intended to treat a rare disease or condition affecting fewer than 200,000 people in the U.S. This designation confers special incentives to the drug developer, including tax credits on the clinical development costs and prescription drug user fee waivers and may allow for a seven year period of market exclusivity in the U.S. upon FDA approval.

We will need substantial additional capital in order to continue the development of Cenderitide. In March 2015, we completed enrollment of a Phase II clinical trial of Cenderitide and decided to conduct an additional small study to further assess the safety and efficacy of this product candidate, which will include higher dose levels of Cenderitide. The trial completed dosing of study participants in March 2016 and, depending on the outcome of these trials and the availability of resources, we will decide whether these trials will be followed by additional trials. In March 2011, the FDA granted fast track designation to Cenderitide in the post-acute period. According to the FDA's website, fast track designation facilitates the development and expeditious review of drugs and biologics intended to treat serious or life-threatening conditions and that demonstrate the potential to address unmet medical needs.

Our research and development expenses will also increase as we further develop our exosomes program and if we conduct additional studies with CAP-1002, such as a second part of the DYNAMIC study.

From inception through December 31, 2015, we financed our operations through private and public sales of our equity securities, NIH grants, a payment from Janssen and a CIRM loan award. In the first quarter of 2015, we completed two private placements, securing approximately $17.0 million in additional capital through the issuance of common equity. As we have not generated any revenue from the sale of our products 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 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 costs involved in prosecuting and enforcing patent claims and other intellectual property rights; and
- the costs and timing of regulatory approvals.

Financing Activities by the Company

March 2016 Financing On March 14, 2016, we entered into a Subscription Agreement, or the Subscription Agreement, with certain investors, or the Investors, pursuant to which, on March 16, 2016, we issued and sold to the Investors an aggregate of approximately $4.1 million of our registered and unregistered securities. On March 16, 2016, in accordance with the Subscription Agreement, we issued and sold to the Investors, and the Investors purchased from us, an aggregate of 1,692,151 shares, or the Shares, of our common stock at a purchase price of $2.40 per Share, or the Public Offering. The Shares were issued pursuant to our shelf registration statement on Form S-3 (File No. 333-207149), which was initially filed with the Securities and Exchange Commission, or the SEC, on September 28, 2015 and declared effective by the SEC on October 26, 2015. A prospectus supplement relating to the Public Offering was filed with the SEC on March 15, 2016.

Pursuant to the Subscription Agreement, we also issued and sold to the Investors, in a concurrent private placement, or the Private Placement and, together with the Public Offering, the Offerings, warrants to purchase up to an aggregate of 846,073 shares of our common stock, or the Warrants and, together with the Shares, the Securities. Each Warrant has an exercise price of $4.50 per share, will initially be exercisable on the date that is six months and one day from the date of issuance, and will expire on the date that is three years from the date of issuance.

We received net proceeds of approximately $3.9 million from the sale of the Securities in the Offerings, after deducting the placement agent fees and estimated offering expenses payable by us.

In connection with the Private Placement, we entered into a Registration Rights Agreement with the Investors on March 14, 2016, pursuant to which we agreed to (i) prepare and file with the SEC a registration statement to register for resale the shares of common stock issuable upon exercise of the Warrants within 90 calendar days following the closing of the Private Placement, and (ii) use our reasonable efforts to cause such registration statement to be declared effective by the SEC as soon as practicable.

SC&H Capital, or the Placement Agent, served as our placement agent for the Offerings. In consideration for services rendered as the Placement Agent in the Offerings, we paid to the Placement Agent upon the closings of the Offerings a cash fee equal to approximately $73,000, or 6.0% of the gross proceeds of the Shares sold to certain Investors identified by the Placement Agent. We also reimbursed the Placement Agent for its reasonable expenses actually and reasonably incurred in connection with its engagement, which such expenses did not exceed $5,000, and paid the reasonable legal fees of the Placement Agent's counsel, which such expenses did not exceed $10,000.

Certain of our officers and directors purchased Securities pursuant to the Offerings. Each of our officers and directors who purchased Warrants in the Private Placement paid a purchase price of $0.125 per share of common stock issuable upon exercise of such Warrants upon the closing of the Private Placement.

February 2015 Financing. On February 3, 2015, we entered into a Share Purchase Agreement with certain accredited investors pursuant to which we agreed to issue and sell, in a private placement, or PIPE 2, to the PIPE 2 investors an aggregate of 1,658,822 shares of our common stock at a price per share of $4.25 for an aggregate purchase price of approximately $7,050,000.

In connection with PIPE 2, we entered into a Registration Rights Agreement with the investors in PIPE 2 on February 3, 2015. Pursuant to the terms of the Registration Rights Agreement for PIPE 2, we were obligated (i) to prepare and file with the Securities and Exchange Commission a registration statement to register for resale the shares issued and sold in PIPE 2, and (ii) to use our reasonable best efforts to cause the applicable registration statement to be declared effective by the Securities and Exchange Commission as soon as practicable, in each case subject to certain deadlines. We filed a Registration Statement on Form S-1 (SEC File No. 333-202589), or the PIPE Form S-1, to register for resale the shares of common stock underlying the shares issued in PIPE 2, which such PIPE Form S-1 was declared effective by the Securities and Exchange Commission on March 30, 2015. On June 4, 2015, we filed a post-effective amendment to the PIPE Form S-1 to convert the PIPE Form S-1 to a Registration Statement on Form S-3, which post-effective amendment was declared effective by the Securities and Exchange Commission on June 11, 2015.

We may also be required to effect certain registrations to register for resale the shares issued and sold in PIPE 2 in connection with certain "piggy-back" registration rights granted to the PIPE 2 investors. We will be required to pay to each PIPE 2 investor liquidated damages equal to 1.0% of the aggregate purchase price paid by such investor pursuant to the PIPE 2 Share Purchase Agreement for the shares per month (up to a cap of 10.0%) if we do not meet certain obligations with respect to the registration of the shares, subject to certain conditions.

January 2015 Financing. On January 9, 2015, we entered into a Share Purchase Agreement with select investors pursuant to which we agreed to issue and sell to the investors, in a private placement, or PIPE 1, an aggregate of 2,839,045 shares of our common stock at a price per share of $3.523 for an aggregate purchase price of approximately $10,000,000.

In connection with PIPE 1, we also entered into a Registration Rights Agreement with the PIPE 1 investors on January 9, 2015. Pursuant to the terms of the Registration Rights Agreement, we were obligated (i) to prepare and file with the Securities and Exchange Commission a registration statement to register for resale the shares issued and sold in PIPE 1, and (ii) to use our reasonable best efforts to cause the applicable registration statement to be declared effective by the Securities and Exchange Commission as soon as practicable, in each case subject to certain deadlines. We filed the PIPE Form S-1to register for resale the shares of common stock underlying the shares issued in PIPE 1, which such PIPE Form S-1 was declared effective by the Securities and Exchange Commission on March 30, 2015. On June 4, 2015, we filed a post-effective amendment to the PIPE Form S-1 to convert the PIPE Form S-1 to a Registration Statement on Form S-3, which post-effective amendment was declared effective by the Securities and Exchange Commission on June 11, 2015.

We may also be required to effect certain registrations to register for resale the shares issued and sold in PIPE 1 in connection with certain "piggy-back" registration rights granted to the PIPE 1 investors. We will be required to pay to each PIPE 1 investor liquidated damages equal to 1.0% of the aggregate purchase price paid by such investor pursuant to the PIPE 1 Share Purchase Agreement for the shares per month (up to a cap of 10.0%) if we do not meet certain obligations with respect to the registration of the shares, subject to certain conditions.

On February 2, 2015, we entered into an amendment to the PIPE 1 Share Purchase Agreement with certain of the PIPE 1 investors, which amended certain provisions of such Share Purchase Agreement limiting our ability to issue additional shares of our common stock until the filing of an effective registration statement for the PIPE 1 shares. As a result of such amendment, the restriction on the issuance of additional shares was eliminated.

Financing Activities by Capricor, Inc.

CIRM Loan Agreement. On February 5, 2013, Capricor entered into a Loan Agreement with CIRM, or the CIRM Loan Agreement, pursuant to which CIRM agreed to disburse $19,782,136 to Capricor over a period of approximately three and one-half years to support Phase II of the ALLSTAR clinical trial. Because the Company is decreasing the number of patients to be enrolled in the ALLSTAR clinical trial, it is undetermined at this time how much of the remaining CIRM loan award will ultimately be disbursed under the CIRM Loan Agreement. The loss of funding under the CIRM Loan Agreement could cause delays under our ALLSTAR 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. The Company is also required to meet certain progress milestones set forth in the CIRM Notice of Loan Award with respect to the progress of the ALLSTAR clinical trial and manufacturing of the product. There is no assurance that CIRM will continue the disbursement of funds. Capricor and CIRM have agreed to adjust future disbursements of loan proceeds to align with actual patient enrollment.

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 terms of 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 sufficient funds available 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 did not issue stock, warrants or other equity to CIRM in connection with this award. Additionally, on September 30, 2015, we entered into a Joinder Agreement with Capricor, Inc. and CIRM, pursuant to which, among other things, we agreed to become a loan party under the CIRM Loan Agreement and to be jointly and severally responsible with Capricor for the performance of, and to be bound by the obligations and liabilities under, the CIRM Loan Agreement, subject to the rights and benefits afforded to a loan recipient thereunder. The balance of the loan with accrued interest is due in 2018, unless extended pursuant to the terms of the CIRM Loan Agreement.

In addition to the foregoing, the timing of the distribution of funds pursuant to the CIRM Loan Agreement is contingent upon the availability of funds in the California Stem Cell Research and Cures Fund in the California State Treasury, as determined by CIRM in its sole discretion.

CIRM Grant Award

On March 16, 2016, Capricor was informed by CIRM that its Application Review Subcommittee of the Independent Citizens' Oversight Committee approved a grant award in the amount of approximately $3.4 million to fund in part Capricor's Phase I/II HOPE-Duchenne clinical trial investigating CAP-1002 for the treatment of Duchenne muscular dystrophy-related cardiomyopathy. The terms of the award and the disbursement schedule have not yet been determined and the award is subject to the execution of definitive documents.

Grant Award

In August 2013, Capricor was approved for a Phase IIB Bridge grant through the NIH Small Business Innovation Research, or SBIR, program for continued development of its CAP-1002 product candidate. Under the terms of the grant, approximately $2,879,437 will be disbursed to us over a period of approximately three years, subject to annual and quarterly reporting requirements. In June 2014, Capricor received approval from the NIH to deploy this grant to fund the first part of the DYNAMIC trial. The first part of the DYNAMIC trial used CAP-1002 to treat patients with advanced heart failure. As of December 31, 2015, approximately $2.4 million had been incurred under the terms of the award.

Contractual Obligations and Commitments

We are a smaller reporting company, as defined by Rule 12b-2 of the Securities Exchange Act of 1934, as amended, and are not required to provide the information required under this item.

Off -Balance Sheet Arrangements

There were no off-balance sheet arrangements as described by Item 303(a)(4) of Regulation S-K as of December 31, 2015.

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, we recognize grant income in the period in which the expense is incurred for those expenses that are deemed reimbursable under the terms of the grant.

Income from Collaborative Agreement

Revenue from nonrefundable, up-front license or technology access payments under license and collaborative arrangements that are not dependent on any future performance by us is recognized when such amounts are earned. If we have continuing obligations to perform under the arrangement, such fees are recognized over the estimated period of the continuing performance obligation.

We account for multiple element arrangements, such as license and development agreements in which a customer may purchase several deliverables, in accordance with the Financial Accounting Standards Board ("FASB") Accounting Standards Codification ("ASC") Subtopic 605-25, *Multiple Element Arrangements.* For new or materially amended multiple element arrangements, we identify the deliverables at the inception of the arrangement and each deliverable within a multiple deliverable revenue arrangement is accounted for as a separate unit of accounting if both of the following criteria are met: (1) the delivered item or items have value to the customer on a standalone basis and (2) for an arrangement that includes a general right of return relative to the delivered item(s), delivery or performance of the undelivered item(s) is considered probable and substantially in our control. We allocate revenue to each non-contingent element based on the relative selling price of each element. When applying the relative selling price method, we determine the selling price for each deliverable using vendor-specific objective evidence ("VSOE") of selling price, if it exists, or third-party evidence ("TPE") of selling price, if it exists. If neither VSOE nor TPE of selling price exist for a deliverable, then we use the best estimated selling price for that deliverable. Revenue allocated to each element is then recognized based on when the basic four revenue recognition criteria are met for each element.

We determined the deliverables under Capricor's Collaboration Agreement with Janssen did not meet the criteria to be considered separate accounting units for the purposes of revenue recognition. As a result, we recognized revenue from non-refundable, upfront fees ratably over the term of our performance under the agreement. The upfront payments received, pending recognition as revenue, are recorded as deferred revenue and are classified as a short-term or long-term liability on the consolidated balance sheets and amortized over the estimated period of performance. We periodically review the estimated performance period of our contract based on the progress of our project.

Research and Development Expenses and Accruals

Research and development, or R&D, expenses consist primarily of salaries and related personnel costs, supplies, clinical trial costs, patient treatment costs, consulting fees, costs of personnel and supplies for manufacturing, costs of service providers for pre-clinical, clinical and manufacturing, and certain legal expenses resulting from intellectual property prosecution, stock compensation expense and other expenses relating to the design, development, testing and enhancement of our product candidates. Except for certain capitalized intangible assets, 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, or 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 general and administrative expense or research and development expense, as applicable, in the Statements of Operations. We expect to record additional non-cash compensation expense in the future, which may be significant.

Warrant Liability

We previously accounted for warrants issued in connection with the financing we completed in April 2012 and the embedded derivative warrant liability contained in the 2013 Notes in accordance with the guidance on Accounting for Certain Financial Instruments with Characteristics of both Liabilities and Equity, which provides that we classify the warrant instrument as a liability at its fair value and adjust the instrument to fair value at each reporting period. This liability is subject to re-measurement at each balance sheet date until exercised, and any change in fair value is recognized as a component of other income or expense. The 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 value of the warrant liability to be insignificant at December 31, 2015, and no such liability has been reflected on the consolidated balance sheet.

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 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. Generally, a reduction in restricted cash occurs when the Company deems certain costs are attributable to the ALLSTAR clinical trial.

Recently Issued or Newly Adopted Accounting Pronouncements

In May 2014, the FASB issued Accounting Standards Update ("ASU") 2014-09, *Revenue from Contracts with Customers* ("ASU 2014-09"). ASU 2014-09 will eliminate transaction- and industry-specific revenue recognition guidance under current generally accepted accounting principles in the United States of America ("U.S. GAAP") and replace it with a principle-based approach for determining revenue recognition. ASU 2014-09 will require that companies recognize revenue based on the value of transferred goods or services as they occur in the contract. ASU 2014-09 also will require additional disclosure about the nature, amount, timing and uncertainty of revenue and cash flows arising from customer contracts, including significant judgments and changes in judgments and assets recognized from costs incurred to obtain or fulfill a contract. ASU 2014-09 is effective for reporting periods beginning after December 15, 2017, and early adoption is not permitted. Entities can transition to the standard either retrospectively or as a cumulative-effect adjustment as of the date of adoption. The Company has not yet selected a transition method nor has it determined the effect of the standard on its ongoing financial reporting.

In August 2014, the FASB issued ASU 2014-15, *Presentation of Financial Statements – Going Concern (Topic 915): Disclosure of Uncertainties about an Entity's Ability to Continue as a Going Concern,* which states that in connection with preparing financial statements for each annual and interim reporting period, an entity's management should evaluate whether there are conditions or events, considered in the aggregate, that raise substantial doubt about the entity's ability to continue as a going concern within one year after the date that the financial statements are issued (or within one year after the date that the financial statements are available to be issued when applicable). The adoption of this update is not expected to have a material effect on our financial statements.

In February 2015, the FASB issued ASU 2015-02, *Consolidation (Topic 810): Amendments to the Consolidation Analysis.* This standard modifies existing consolidation guidance for reporting organizations that are required to evaluate whether they should consolidate certain legal entities. ASU 2015-02 is effective for fiscal years and interim periods within those years beginning after December 15, 2015, and requires either a retrospective or a modified retrospective approach to adoption. Early adoption is permitted. The Company is currently evaluating the potential impact of this standard on its consolidated financial statements, as well as the available transition methods.

In February 2015, the FASB issued ASU 2015-03, *Simplifying the Presentation of Debt Issuance Costs.* This update changes the presentation of debt issuance costs in the balance sheet. ASU 2015-03 requires debt issuance costs related to a recognized debt obligation to be presented in the balance sheet as a direct deduction from the carrying amount of the related debt liability rather than being presented as an asset. Amortization of debt issuance costs will continue to be reported as interest expense. In August 2015, the FASB issued ASU 2015-15, "Presentation and Subsequent Measurement of Debt Issuance Costs Associated with Line-of Credit Arrangements." This ASU clarified guidance in ASC 2015-03 stating that the SEC staff would not object to a company presenting debt issuance costs related to a line-of-credit arrangement on the balance sheet as a deferred asset, regardless of whether there were any outstanding borrowings at period-end. This update is effective for annual and interim periods beginning after December 15, 2015, which will require us to adopt these provisions in the first quarter of 2016. This update will be applied on a retrospective basis, wherein the balance sheet of each period presented will be adjusted to reflect the effects of applying the new guidance.

In February 2016, the FASB issued 2016-02, *Leases (Topic 842),* which supersedes existing guidance on accounting for leases in "Leases (Topic 840)" and generally requires all leases to be recognized in the consolidated balance sheet. ASU 2016-02 is effective for annual and interim reporting periods beginning after December 15, 2018; early adoption is permitted. The provisions of ASU 2016-02 are to be applied using a modified retrospective approach. The Company is currently evaluating the impact of the adoption of this standard on its consolidated financial statements.

Other recent accounting pronouncements issued by the FASB, including its Emerging Issues Task Force, the American Institute of Certified Public Accountants, and the Securities and Exchange Commission, did not or are not believed by management to have a material impact on the Company's present or future consolidated financial statement presentation or disclosures.

ITEM 7A. QUANTITATIVE AND QUALITATIVE DISCLOSURES ABOUT MARKET RISK

Interest Rate Sensitivity

Our exposure to market risk for changes in interest rates relates primarily to our marketable securities and cash and cash equivalents. As of December 31, 2015, the fair value of our cash, cash equivalents, including restricted cash, and marketable securities was approximately $13.6 million. Additionally, as of December 31, 2015, Capricor's portfolio was classified as cash, cash equivalents and marketable securities, which consist primarily of money market funds and bank money market, which included short term United States treasuries, bank savings and checking accounts. Capricor did not have any investments with significant exposure to the subprime mortgage market issues.

The goal of our investment policy is to place our 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. Our 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 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

CAPRICOR THERAPEUTICS, INC.
INDEX TO FINANCIAL STATEMENTS

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 Subsidiary as of December 31, 2015 and 2014, and the related consolidated statements of operations and comprehensive loss, shareholders' equity, and cash flows for each of the years in the two-year period ended December 31, 2015. Capricor Therapeutics, Inc.'s management is responsible for these consolidated financial statements. Our responsibility is to express an opinion on these consolidated 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 consolidated 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 consolidated financial statements, assessing the accounting principles used and significant estimates made by management, as well as evaluating the overall consolidated 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 Subsidiary as of December 31, 2015 and 2014, and the results of their operations and their cash flows for the years in the two-year period ended December 31, 2015, 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 28, 2016

CAPRICOR THERAPEUTICS, INC.
CONSOLIDATED BALANCE SHEETS
DECEMBER 31, 2015 AND 2014

ASSETS

	2015	2014
CURRENT ASSETS		
Cash and cash equivalents	$ 5,568,306	$ 8,034,765
Marketable securities	7,999,010	-
Restricted cash	-	2,977,024
Grant receivable	211,938	360,233
Prepaid expenses and other current assets	210,603	235,523
TOTAL CURRENT ASSETS	13,989,857	11,607,545
PROPERTY AND EQUIPMENT, net	318,566	229,455
OTHER ASSETS		
Intangible assets, net of accumulated amortization of $98,679 and $49,930, respectively	191,003	239,752
In-process research and development, net of accumulated amortization of $0	1,500,000	1,500,000
Other assets	70,146	55,320
TOTAL ASSETS	$ 16,069,572	$ 13,632,072
LIABILITIES AND STOCKHOLDERS' EQUITY (DEFICIT)		
CURRENT LIABILITIES		
Accounts payable and accrued expenses	$ 2,530,500	$ 1,699,254
Accounts payable and accrued expenses, related party	352,334	433,712
Deferred revenue, current	3,645,834	4,166,667
TOTAL CURRENT LIABILITIES	6,528,668	6,299,633
LONG-TERM LIABILITIES		
Deferred revenue, net of current portion	911,458	4,166,666
Loan payable	9,155,857	9,155,857
Accrued interest	505,363	258,639
TOTAL LONG-TERM LIABILITIES	10,572,678	13,581,162
TOTAL LIABILITIES	17,101,346	19,880,795
COMMITMENTS AND CONTINGENCIES (NOTE 6)		
STOCKHOLDERS' EQUITY (DEFICIT)		
Preferred stock, $0.001 par value, 5,000,000 shares authorized, none issued and outstanding	-	-
Common stock, $0.001 par value, 50,000,000 shares authorized, 16,254,985 and 11,707,051 shares issued and outstanding, respectively	16,255	11,707
Additional paid-in capital	34,115,052	16,054,697
Accumulated other comprehensive income	9,385	-
Accumulated deficit	(35,172,466)	(22,315,127)
TOTAL STOCKHOLDERS' EQUITY (DEFICIT)	(1,031,774)	(6,248,723)
TOTAL LIABILITIES AND STOCKHOLDERS' EQUITY (DEFICIT)	$ 16,069,572	$ 13,632,072

See accompanying notes to the audited consolidated financial statements.

CAPRICOR THERAPEUTICS, INC.
CONSOLIDATED STATEMENTS OF OPERATIONS AND COMPREHENSIVE LOSS
FOR THE YEARS ENDED DECEMBER 31, 2015 AND 2014

	Years ended December 31,	
	2015	2014
INCOME		
Collaboration income	$ 3,776,041	$ 4,166,667
Grant income	1,741,607	620,033
TOTAL INCOME	5,517,648	4,786,700
OPERATING EXPENSES		
Research and development	13,757,279	7,787,384
General and administrative	4,372,195	3,017,301
TOTAL OPERATING EXPENSES	18,129,474	10,804,685
LOSS FROM OPERATIONS	(12,611,826)	(6,017,985)
OTHER INCOME (EXPENSE)		
Investment income	3,113	1,898
Interest expense	(248,626)	(200,505)
TOTAL OTHER INCOME (EXPENSE)	(245,513)	(198,607)
NET LOSS	(12,857,339)	(6,216,592)
OTHER COMPREHENSIVE GAIN		
Net unrealized gain on marketable securities	9,385	980
COMPREHENSIVE LOSS	$ (12,847,954)	$ (6,215,612)
Net loss per share, basic and diluted	$ (0.81)	$ (0.53)
Weighted average number of shares, basic and diluted	15,902,133	11,696,980

See accompanying notes to the audited consolidated financial statements.

CAPRICOR THERAPEUTICS, INC.
CONSOLIDATED STATEMENTS OF CHANGES IN STOCKHOLDERS' EQUITY (DEFICIT)
FOR THE PERIOD FROM DECEMBER 31, 2013 THROUGH DECEMBER 31, 2015

	COMMON STOCK		ADDITIONAL PAID-IN CAPITAL	OTHER COMPREHENSIVE INCOME (LOSS)	ACCUMULATED DEFICIT	TOTAL STOCKHOLDERS' EQUITY (DEFICIT)
	SHARES	AMOUNT				
Balance at December 31, 2013	11,687,747	$ 11,687	$ 15,552,946	$ (980)	$ (16,098,535)	$ (534,882)
Stock-based compensation	4,165	5	496,934	-	-	496,939
Unrealized gain on marketable securities	-	-	-	980	-	980
Stock awards, warrants and options exercised	15,139	15	4,817	-	-	4,832
Net loss	-	-	-	-	(6,216,592)	(6,216,592)
Balance at December 31, 2014	11,707,051	$ 11,707	$ 16,054,697	$ -	$ (22,315,127)	$ (6,248,723)
Issuance of common stock, net of fees	4,497,867	4,498	16,441,720	-	-	16,446,218
Stock-based compensation	1,666	2	1,573,222	-	-	1,573,224
Unrealized gain on marketable securities	-	-	-	9,385	-	9,385
Stock awards, warrants and options exercised	48,401	48	45,413	-	-	45,461
Net loss	-	-	-	-	(12,857,339)	(12,857,339)
Balance at December 31, 2015	16,254,985	$ 16,255	$ 34,115,052	$ 9,385	$ (35,172,466)	$ (1,031,774)

See accompanying notes to the audited consolidated financial statements.

CAPRICOR THERAPEUTICS, INC.
CONSOLIDATED STATEMENTS OF CASH FLOWS
FOR THE YEARS ENDED DECEMBER 31, 2015 AND 2014

	Years ended December 31,	
	2015	2014
CASH FLOWS FROM OPERATING ACTIVITIES:		
Net loss	$ (12,857,339)	$ (6,216,592)
Adjustments to reconcile net loss to net cash provided by (used in) operating activities:		
Depreciation and amortization	110,865	41,896
Stock-based compensation	1,573,224	496,939
Change in assets - (increase) decrease:		
Restricted cash	2,977,024	(1,575,165)
Receivables	148,295	(360,233)
Prepaid expenses and other current assets	24,920	(12,573)
Other assets	(14,826)	(29,592)
Change in liabilities - increase (decrease):		
Accounts payable and accrued expenses	831,246	70,329
Accounts payable and accrued expenses, related party	(81,378)	9,715
Accrued interest	246,724	200,505
Deferred revenue	(3,776,041)	8,333,333
NET CASH PROVIDED BY (USED IN) OPERATING ACTIVITIES	(10,817,286)	958,562
CASH FLOWS FROM INVESTING ACTIVITIES:		
Purchase of marketable securities	(17,989,625)	-
Proceeds from sales and maturities of marketable securities	10,000,000	327,474
Purchases of property and equipment	(129,697)	(162,687)
Payments for leasehold improvements	(21,530)	(23,744)
NET CASH PROVIDED BY (USED IN) INVESTING ACTIVITIES	(8,140,852)	141,043
CASH FLOWS FROM FINANCING ACTIVITIES:		
Net proceeds from sale of common stock	16,446,218	-
Proceeds from loan payable, net	-	5,200,791
Proceeds from stock awards, warrants and options	45,461	4,832
NET CASH PROVIDED BY FINANCING ACTIVITIES	16,491,679	5,205,623
NET INCREASE (DECREASE) IN CASH AND CASH EQUIVALENTS	(2,466,459)	6,305,228
Cash and cash equivalents balance at beginning of period	8,034,765	1,729,537
Cash and cash equivalents balance at end of period	$ 5,568,306	$ 8,034,765
SUPPLEMENTAL DISCLOSURES:		
Interest paid in cash	$ 2,685	$ -
Income taxes paid in cash	$ -	$ -

See accompanying notes to the audited consolidated financial statements.

1. ORGANIZATION AND SUMMARY OF SIGNIFICANT ACCOUNTING POLICIES

Description of Business

The mission of Capricor Therapeutics, Inc., a Delaware corporation (referred to herein as "Capricor Therapeutics" or the "Company"), is to improve the treatment of diseases by commercializing innovative therapies, with a primary focus on cardiovascular diseases. Capricor, Inc., a privately-held company and a wholly-owned subsidiary of Capricor Therapeutics (referred to herein as "Capricor"), 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 between Capricor and a subsidiary of Nile Therapeutics, Inc., a Delaware corporation ("Nile"), on November 20, 2013, Capricor became a wholly-owned subsidiary of Nile and Nile formally changed its name to Capricor Therapeutics, Inc. Capricor Therapeutics, together with its subsidiary, Capricor, currently has six drug candidates in various stages of development.

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.

Liquidity

The Company has historically financed its research and development activities as well as operational expenses from equity financings, government grants, a payment from Janssen Biotech, Inc. ("Janssen") pursuant to a Collaboration Agreement with Janssen and a loan award from the California Institute for Regenerative Medicine ("CIRM").

Cash, cash equivalents and marketable securities as of December 31, 2015 were approximately $13.6 million, compared to $8.0 million as of December 31, 2014. In January 2015, the Company entered into a Share Purchase Agreement with select investors, pursuant to which the Company issued an aggregate of 2,839,045 shares of its common stock at a price per share of $3.523 for an aggregate purchase price of approximately $10,000,000. In February 2015, the Company entered into a Share Purchase Agreement with select investors, pursuant to which the Company issued an aggregate of 1,658,822 shares of its common stock at a price per share of $4.25 for an aggregate purchase price of approximately $7,050,000. In March 2016, the Company entered into a Subscription Agreement with certain investors pursuant to which the Company issued an aggregate of 1,692,151 shares of common stock at a price per share of $2.40 for an aggregate purchase price of approximately $4.1 million. Pursuant to the Subscription Agreement, the Company also issued to the Investors warrants to purchase up to an aggregate of 846,073 shares of Common Stock. Each warrant has an exercise price of $4.50 per share, will initially be exercisable on the date that is six months and one day from the date of issuance, and will expire on the date that is three years from the date of issuance. Furthermore, in March 2016, Capricor was informed by CIRM that it was approved for a grant award in the amount of approximately $3.4 million to fund in part Capricor's Phase I/II HOPE-Duchenne clinical trial. The terms of the award and the disbursement schedule have not been determined as of the date of filing of this Annual Report on Form 10-K and the award is subject to the execution of definitive documents. The Company's principal uses of cash are for research and development expenses, general and administrative expenses, capital expenditures and other working capital requirements.

The Company's future expenditures and capital requirements may be substantial and will depend on many factors, including but not limited to the following:

- the timing and costs associated with commercialization of its product candidates;
- the timing and costs associated with its clinical trials and preclinical studies;
- the number and scope of its research programs; and
- the costs involved in prosecuting and enforcing patent claims and other intellectual property rights.

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

The Company's cash requirements are expected to continue to increase as it advances its research, development and commercialization programs and the Company expects to seek additional financing primarily from, but not limited to, the sale and issuance of equity or debt securities, the licensing or sale of its technology and from government grants. The Company cannot provide assurances that financing will be available when and as needed or that, if available, financing will be available on favorable or acceptable terms or at all. If the Company is unable to obtain additional financing when and if required, it would have a material adverse effect on the Company's business and results of operations and could include reducing expenses and curtailing operations. To the extent the Company issues additional equity securities, its existing stockholders could experience substantial dilution.

Use of Estimates

The preparation of financial statements in conformity with generally accepted accounting principles in the United States of America ("U.S. GAAP") requires management to make estimates and assumptions that affect the reported amounts of assets and liabilities and disclosure of contingent assets and liabilities at the date of the consolidated financial statements. Estimates also affect the reported amounts of revenues and expenses during the reporting period. The most sensitive estimates relate to the period over which the collaboration revenue is recognized and the stock-based compensation. 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.

Restricted Cash

As of December 31, 2014, restricted cash represented funds received under Capricor's Loan Agreement with CIRM (see Note 2 – "Loan Payable"), which are to be allocated to the ALLSTAR clinical trial research costs as incurred. Generally, a reduction of restricted cash occurs when the Company deems certain costs are attributable to the ALLSTAR clinical trial.

Marketable Securities

The Company determines the appropriate classification of its marketable securities at the time of purchase and reevaluates such designation at each balance sheet date. All of the Company's marketable securities are considered as available-for-sale and carried at estimated fair values. Realized gains and losses on the sale of debt and equity securities are determined using the specific identification method. Unrealized gains and losses on available-for-sale securities are excluded from net income and reported in accumulated other comprehensive income (loss) as a separate component of stockholders' equity.

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 life of the asset, which such estimated useful lives range from five to seven years. Leasehold improvements are depreciated on a straight-line basis over the shorter of the useful life of the asset or the lease term. Depreciation was approximately $62,116 and $32,163 for the years ended December 31, 2015 and 2014, respectively.

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

Property and equipment consisted of the following at December 31:

	2015	2014
Furniture and fixtures	$ 59,128	$ 38,850
Laboratory equipment	387,872	278,453
Leasehold improvements	45,274	23,744
	492,274	341,047
Less accumulated depreciation	(173,708)	(111,592)
Property and equipment, net	$ 318,566	$ 229,455

Intangible Assets

Amounts attributable to intellectual property consist primarily of the costs associated with the acquisition of certain technologies, patents, pending patents and related intangible assets with respect to research and development activities. Intellectual property assets are stated at cost and are amortized on a straight-line basis over the respective estimated useful lives of the assets ranging from five to fifteen years. Also, the Company recorded capitalized loan fees as a component of intangible assets on the consolidated balance sheet (see Note 2 – "Loan Payable"). Total amortization expense was approximately $48,749 and $10,733 for the years ended December 31, 2015 and 2014, respectively. A summary of future amortization expense as of December 31, 2015 is as follows:

Years ended	Amortization Expense
2016	$ 48,749
2017	48,749
2018	43,733
2019	43,277
2020	4,330
Thereafter	2,165

As a result of the merger in 2013 between Capricor and Nile, the Company recorded $1.5 million as in-process research and development in accordance with Financial Accounting Standards Board ("FASB") Accounting Standards Codification ("ASC") 805, *Business Combinations*. The in-process research and development asset is subject to impairment testing until completion or abandonment of research and development efforts associated with the project. Upon successful completion of the project, the Company will make a determination as to the then remaining useful life of the intangible asset and begin amortization.

The Company reviews indefinite-lived intangible assets at least annually for possible impairment. Goodwill and indefinite-lived intangible assets are reviewed for possible impairment between annual tests if an event occurs or circumstances change that would more likely than not reduce the fair value of the reporting unit below its carrying value. As of December 31, 2015, the Company deemed the assets to not be impaired and did not begin 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 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, 2015 and 2014.

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

Government Research Grants

Generally, government research grants that provide funding for research and development activities are recognized as income when the related expenses are incurred, as applicable. In August 2013, Capricor was approved for a Phase IIB Bridge grant through the NIH Small Business Innovation Research, or SBIR, program for continued development of its CAP-1002 product candidate. Under the terms of the grant, disbursements are being made to Capricor over a period of approximately three years, in an aggregate amount of approximately $2.9 million, subject to annual and quarterly reporting requirements. As of December 31, 2015, approximately $2.4 million had been incurred under the terms of the award.

Income from Collaborative Agreement

Revenue from nonrefundable, up-front license or technology access payments under license and collaborative arrangements that are not dependent on any future performance by the Company is recognized when such amounts are earned. If the Company has continuing obligations to perform under the arrangement, such fees are recognized over the estimated period of the continuing performance obligation.

The Company accounts for multiple element arrangements, such as license and development agreements in which a customer may purchase several deliverables, in accordance with FASB ASC Subtopic 605-25, Multiple Element Arrangements. For new or materially amended multiple element arrangements, the Company identifies the deliverables at the inception of the arrangement and each deliverable within a multiple deliverable revenue arrangement is accounted for as a separate unit of accounting if both of the following criteria are met: (1) the delivered item or items have value to the customer on a standalone basis and (2) for an arrangement that includes a general right of return relative to the delivered item(s), delivery or performance of the undelivered item(s) is considered probable and substantially in the Company's control. The Company allocates revenue to each non-contingent element based on the relative selling price of each element. When applying the relative selling price method, the Company determines the selling price for each deliverable using vendor-specific objective evidence ("VSOE") of selling price, if it exists, or third-party evidence ("TPE") of selling price, if it exists. If neither VSOE nor TPE of selling price exist for a deliverable, then the Company uses the best estimated selling price for that deliverable. Revenue allocated to each element is then recognized based on when the basic four revenue recognition criteria are met for each element.

The Company determined the deliverables under its Collaboration Agreement with Janssen (see Note 7 – "License Agreements") did not meet the criteria to be considered separate accounting units for the purposes of revenue recognition. As a result, the Company recognized revenue from non-refundable, upfront fees ratably over the term of its performance under the agreement with Janssen. The upfront payments received, pending recognition as revenue, are recorded as deferred revenue and are classified as a short-term or long-term liability on the condensed consolidated balance sheets of the Company and amortized over the estimated period of performance. The Company periodically reviews the estimated performance period of its contract based on the estimated progress of its project.

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. The Company incurred no interest or penalties for the years ended December 31, 2015 and 2014. 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.

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

Loan Payable

The Company accounts for the funds advanced under its Loan Agreement with CIRM (see Note 2 – "Loan Payable") as a loan payable as the eventual repayment of the loan proceeds or forgiveness of the loan 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.

Rent

Rent expense for the Company's leases, which generally have escalating rentals over the term of the lease, is recorded on a straight-line basis over the lease term. The difference between the rent expense and rent paid has been recorded as deferred rent in the accounts payable and accrued expenses, related party in the consolidated balance sheet. Rent is amortized on a straight-line basis over the term of the applicable lease, without consideration of renewal options.

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 ASC 730-10, *Research and Development*. Research and development costs amounted to approximately $13.8 million and $7.8 million for the years ended December 31, 2015 and 2014, 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. The Company's comprehensive loss was approximately $12.8 million and $6.2 million for the years ended December 31, 2015 and 2014, respectively. The Company's other comprehensive income is related to a net unrealized gain on marketable securities. For the years ended December 31, 2015 and 2014, the Company's other comprehensive gain was $9,385 and $980, respectively.

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.

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 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 ("SEC") 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.

Basic and Diluted Loss per Share

Basic loss per share is computed using the weighted-average number of common shares outstanding during the period. Diluted loss per share is 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, consultants and directors as well as warrants issued to third parties, have been excluded from the diluted loss per share calculation because their effect is anti-dilutive.

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

For the years ended December 31, 2015 and 2014, warrants and options to purchase 6,233,153 and 5,308,581 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, 2015 for assets and liabilities measured at fair value on a recurring basis:

	December 31, 2015			
	Level I	Level II	Level III	Total
Marketable securities	$ 7,999,010	$ -	$ -	$ 7,999,010

Carrying amounts reported in the balance sheet of cash and cash equivalents, grants receivable, accounts payable and accrued expenses approximate fair value due to their relatively short maturity. The carrying amounts of the Company's marketable securities are 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.

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 must classify the warrant instrument as a liability at its fair value and adjust the instrument to fair value at each reporting period. The fair value of warrants is estimated by management using the Black-Scholes option-pricing model. 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. Management has determined the value of the warrant liability to be insignificant at December 31, 2015, and no such liability has been reflected on the balance sheet.

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

Recent Accounting Pronouncements

In May 2014, the FASB issued Accounting Standards Update ("ASU") 2014-09, *Revenue from Contracts with Customers* ("ASU 2014-09"). ASU 2014-09 will eliminate transaction- and industry-specific revenue recognition guidance under current generally accepted accounting principles in the United States of America ("U.S. GAAP") and replace it with a principle-based approach for determining revenue recognition. ASU 2014-09 will require that companies recognize revenue based on the value of transferred goods or services as they occur in the contract. ASU 2014-09 also will require additional disclosure about the nature, amount, timing and uncertainty of revenue and cash flows arising from customer contracts, including significant judgments and changes in judgments and assets recognized from costs incurred to obtain or fulfill a contract. ASU 2014-09 is effective for reporting periods beginning after December 15, 2017, and early adoption is not permitted. Entities can transition to the standard either retrospectively or as a cumulative-effect adjustment as of the date of adoption. The Company has not yet selected a transition method nor has it determined the effect of the standard on its ongoing financial reporting.

In August 2014, the FASB issued ASU 2014-15, *Presentation of Financial Statements – Going Concern (Topic 915): Disclosure of Uncertainties about an Entity's Ability to Continue as a Going Concern,* which states that in connection with preparing financial statements for each annual and interim reporting period, an entity's management should evaluate whether there are conditions or events, considered in the aggregate, that raise substantial doubt about the entity's ability to continue as a going concern within one year after the date that the financial statements are issued (or within one year after the date that the financial statements are available to be issued when applicable). The adoption of this update is not expected to have a material effect on our financial statements.

In February 2015, the FASB issued ASU 2015-02, *Consolidation (Topic 810): Amendments to the Consolidation Analysis.* This standard modifies existing consolidation guidance for reporting organizations that are required to evaluate whether they should consolidate certain legal entities. ASU 2015-02 is effective for fiscal years and interim periods within those years beginning after December 15, 2015, and requires either a retrospective or a modified retrospective approach to adoption. Early adoption is permitted. The Company is currently evaluating the potential impact of this standard on its consolidated financial statements, as well as the available transition methods.

In February 2015, the FASB issued ASU 2015-03, *Simplifying the Presentation of Debt Issuance Costs.* This update changes the presentation of debt issuance costs in the balance sheet. ASU 2015-03 requires debt issuance costs related to a recognized debt obligation to be presented in the balance sheet as a direct deduction from the carrying amount of the related debt liability rather than being presented as an asset. Amortization of debt issuance costs will continue to be reported as interest expense. In August 2015, the FASB issued ASU 2015-15, "Presentation and Subsequent Measurement of Debt Issuance Costs Associated with Line-of Credit Arrangements." This ASU clarified guidance in ASC 2015-03 stating that the SEC staff would not object to a company presenting debt issuance costs related to a line-of-credit arrangement on the balance sheet as a deferred asset, regardless of whether there were any outstanding borrowings at period-end. This update is effective for annual and interim periods beginning after December 15, 2015, which will require us to adopt these provisions in the first quarter of 2016. This update will be applied on a retrospective basis, wherein the balance sheet of each period presented will be adjusted to reflect the effects of applying the new guidance.

In February 2016, the FASB issued 2016-02, *Leases (Topic 842),* which supersedes existing guidance on accounting for leases in "Leases (Topic 840)" and generally requires all leases to be recognized in the consolidated balance sheet. ASU 2016-02 is effective for annual and interim reporting periods beginning after December 15, 2018; early adoption is permitted. The provisions of ASU 2016-02 are to be applied using a modified retrospective approach. The Company is currently evaluating the impact of the adoption of this standard on its consolidated financial statements.

Other recent accounting pronouncements issued by the FASB, including its Emerging Issues Task Force, the American Institute of Certified Public Accountants, and the Securities and Exchange Commission, did not or are not believed by management to have a material impact on the Company's present or future consolidated financial statement presentation or disclosures.

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 approximately three and one-half years to support Phase II of Capricor's ALLSTAR clinical trial. Because the Company is decreasing the number of patients to be enrolled in the ALLSTAR clinical trial, it is undetermined at this time how much of the remaining CIRM loan award will ultimately be disbursed under the CIRM Loan Agreement.

2. LOAN PAYABLE (Continued)

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. The Company is also required to meet certain progress milestones set forth in the CIRM Notice of Loan Award with respect to the progress of the ALLSTAR clinical trial and manufacturing of the product. There is no assurance that CIRM will continue the disbursement of funds. Capricor and CIRM have agreed to adjust future disbursements of loan proceeds to align with actual patient enrollment.

Under the terms of the CIRM Loan Agreement, if Capricor is not in default, the loan may be forgiven during the term of the project period if Capricor abandons the trial due to the occurrence of a no-go milestone. After the end of the project period, the loan may also be forgiven if Capricor elects to abandon the project under certain circumstances. Under the terms of 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 sufficient funds available 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 did not issue stock, warrants or other equity to CIRM in connection with this award. Additionally, on September 30, 2015, the Company entered into a Joinder Agreement with Capricor, Inc. and CIRM, pursuant to which, among other things, the Company agreed to become a loan party under the CIRM Loan Agreement and to be jointly and severally responsible with Capricor for the performance of, and to be bound by the obligations and liabilities under, the CIRM Loan Agreement, subject to the rights and benefits afforded to a loan recipient thereunder.

In addition to the foregoing, 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 California State Treasury, as determined by CIRM in its sole discretion. Disbursements from time to time may be delayed or suspended in order to coincide with projected expenditures and patient estimated enrollment of Capricor's ALLSTAR clinical trial.

The due diligence costs are recorded as a discount on the loan and amortized to general and administrative expenses over the remaining term of the loan. As of December 31, 2015, $30,000 of loan costs were capitalized with the balance of $11,402 to be amortized over approximately 2.1 years.

In 2013, Capricor received loan proceeds of $3,925,066, net of loan costs. The disbursements carried an initial interest rate of approximately 2.5% - 2.8% per annum.

In April 2014, Capricor received the third disbursement under the loan award of $4,679,947. This disbursement carries interest at the initial rate of approximately 2.6% per annum.

In July 2014, Capricor received the fourth disbursement under the loan award of $514,177, which includes previously deducted due diligence costs that were refunded. This disbursement carries interest at the initial rate of approximately 2.6% per annum. For the years ended December 31, 2015 and 2014, interest expense under the CIRM loan was $246,724 and $200,505, respectively. The principal balance outstanding under the CIRM loan was $9,155,857 at each of December 31, 2015 and December 31, 2014. The balance of the loan with accrued interest is due in 2018, unless extended pursuant to the terms of the CIRM Loan Agreement.

3. STOCKHOLDER'S EQUITY

Private Placements

On January 9, 2015, the Company entered into a Share Purchase Agreement with select investors, pursuant to which the Company agreed to issue and sell to the investors, in a private placement ("PIPE 1"), an aggregate of 2,839,045 shares of its common stock at a price per share of $3.523 for an aggregate purchase price of approximately $10,000,000.

3. STOCKHOLDER'S EQUITY (Continued)

On February 3, 2015, the Company entered into a Share Purchase Agreement with certain accredited investors, pursuant to which the Company agreed to issue and sell to the investors, in a private placement ("PIPE 2"), an aggregate of 1,658,822 shares of its common stock at a price per share of $4.25 for an aggregate purchase price of approximately $7,050,000.

Fees paid in conjunction with PIPE 1 and PIPE 2 amounted to $605,736 in the aggregate and were recorded as a reduction to additional paid-in capital.

Outstanding Shares

At December 31, 2015, the Company had 16,254,985 shares of common stock issued and outstanding.

4. STOCK AWARDS, WARRANTS AND OPTIONS

Warrants

The following table summarizes all warrant activity for the years ended December 31, 2015 and 2014:

	Warrants	Weighted Average Exercise Price
Outstanding at January 1, 2014	332,281	$ 17.20
Expired	(28,400)	94.00
Outstanding at December 31, 2014	303,881	$ 10.02
Exercised	(15,401)	2.27
Expired	(52,650)	47.00
Outstanding at December 31, 2015	235,830	$ 2.27

The following table summarizes all outstanding warrants to purchase shares of the Company's common stock as of December 31, 2015:

At December 31, 2015			
Grant Date	Warrants Outstanding	Weighted Average Exercise Price	Expiration Date
4/4/2012	187	$ 2.27	4/4/2017
11/20/2013	235,643	$ 2.27	11/20/2018
	235,830		

Restricted Stock

In August 2014, the Company granted 10,000 shares of restricted stock to one of its consultants in consideration of services to be rendered. This restricted stock grant was to vest monthly over a period of one year. In February 2015, the Company terminated the agreement with the consultant effective March 2015 and therefore, no additional shares will be issued pursuant to the restricted stock grant. For the year ended December 31, 2015, the Company issued 1,666 shares of that restricted common stock grant, which were valued at approximately $8,588 in the aggregate. The fair value of the restricted stock was determined using the Company's closing stock price on the vesting date.

4. STOCK AWARDS, WARRANTS AND OPTIONS (Continued)

Stock Options

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

On August 10, 2005, the Company adopted the 2005 Plan. On July 26, 2010, the Company's stockholders approved an amendment to the 2005 Plan increasing the total number of shares authorized for issuance thereunder to 190,000. Under the 2005 Plan, incentives may be granted to officers, employees, directors, consultants and advisors. Incentives under the 2005 Plan may be granted in any one or a combination of the following forms: (i) incentive stock options and non-statutory stock options, (ii) stock appreciation rights, (iii) stock awards, (iv) restricted stock, and (v) performance shares.

At the time the merger between Capricor and Nile became effective, 4,149,710 shares of common stock were reserved under the 2012 Plan for the issuance 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 of common stock that were originally reserved under the 2006 Stock Option Plan. Under the 2012 Plan, each stock option granted 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 $100,000, such options will be treated as nonstatutory stock options.

At the time the merger between Capricor and Nile became effective, 2,697,311 shares of common stock were reserved under the 2012 Non-Employee Director Plan for the issuance of stock options to members of the Board whom are not employees of the Company.

Each of the Company's stock option plans are administered by the Board, 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 the 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 value of the options granted during 2015 and 2014 were approximately $3.84 and $4.40 per share, respectively.

The Company estimates the fair value of each option award using the Black-Scholes option-pricing model. The Company used the following assumptions to estimate the fair value of stock options issued in the years ended December 31, 2015 and 2014:

	December 31, 2015	December 31, 2014
Expected volatility	76% - 82%	112% - 117%
Expected term	5-7 years	7 years
Dividend yield	0%	0%
Risk-free interest rates	0.3% - 2.1%	2.2%

Employee and non-employee stock-based compensation expense for the years ended December 31, 2015 and 2014 was as follows:

	2015	2014
General and administrative	$ 1,276,370	$ 345,682
Research and development	288,265	134,555
Total	$ 1,564,635	$ 480,237

4. STOCK AWARDS, WARRANTS AND OPTIONS (Continued)

The following table summarizes information about stock options outstanding and exercisable at December 31, 2015:

Shares Outstanding

Range of Ex. Prices	Shares Outstanding	Weighted Average Term (yrs.)	Weighted Average Exercise Price
$0.16 - $0.19	100,627	2.80	$ 0.17
$0.30 - $0.37	4,360,116	6.36	0.36
$0.87	56,021	2.95	0.87
$3.58 - $5.78	1,443,948	9.25	5.15
$9.14 - $12.00	33,011	8.38	11.34
$18.50 - $28.50	3,600	0.28	28.08
	5,997,323	6.97	$ 1.59

Shares Exercisable

Range of Ex. Prices	Shares Exercisable	Weighted Average Term (yrs.)	Weighted Average Exercise Price
$0.16 - $0.19	100,627	2.80	$ 0.17
$0.30 - $0.37	3,999,627	6.28	0.36
$0.87	56,021	2.95	0.87
$3.58 - $5.78	346,586	9.04	5.32
$9.14 - $12.00	6,341	8.12	12.00
$18.50 - $28.50	3,600	0.28	28.08
	4,512,802	6.37	$ 0.78

As of December 31, 2015, the total unrecognized fair value compensation cost related to non-vested stock options was approximately $4.2 million, which is expected to be recognized over approximately 3.0 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 an expense over the applicable vesting periods.

The following is a schedule summarizing employee and non-employee stock option activity for the years ended December 31, 2015 and 2014:

	Number of Options	Weighted Average Exercise Price	Aggregate Intrinsic Value
Outstanding at January 1, 2014	4,888,519	$ 0.51	
Granted	368,154	5.01	
Exercised	(15,139)	0.32	
Expired/Cancelled	(236,834)	2.39	
Outstanding at December 31, 2014	5,004,700	$ 0.75	$ 15,014,100
Granted	1,311,137	5.31	
Exercised	(33,000)	0.32	
Expired/Cancelled	(285,514)	4.03	
Outstanding at December 31, 2015	5,997,323	$ 1.59	$ 8,876,038
Exercisable at December 31, 2015	4,512,802	$ 0.78	$ 10,334,317

4. STOCK AWARDS, WARRANTS AND OPTIONS (Continued)

The aggregate intrinsic value represents the difference between the exercise price of the options and the estimated fair value of the Company's common stock for each of the respective periods.

The aggregate intrinsic value of options exercised was $131,708 and $82,058 for the years ended December 31, 2015 and 2014, respectively.

5. CONCENTRATIONS

Cash Concentration

The Company has historically maintained checking accounts at two financial institutions. These accounts are each insured by the Federal Deposit Insurance Corporation for up to $250,000. Historically, the Company has not experienced any significant losses in such accounts and believes it is not exposed to any significant credit risk on cash, cash equivalents and marketable securities. As of December 31, 2015, the Company maintained approximately $13.6 million of uninsured deposits.

6. COMMITMENTS AND CONTINGENCIES

Leases

Capricor leases space for its corporate offices pursuant to a lease that is effective for a two year period beginning July 1, 2013 with an option to extend the lease for an additional twelve months. The monthly lease payment was $16,620 per month for the first twelve months of the term and increased to $17,285 per month for the second twelve months of the term. On March 3, 2015, Capricor executed a Second Amendment to Lease with The Bubble Real Estate Company, LLC, pursuant to which (i) additional space was added to the Company's corporate office lease and (ii) the Company exercised its option to extend the lease term through June 30, 2016. Under the terms of the Second Amendment, commencing February 2, 2015, the base rent was $17,957 for one month, and, commencing March 2, 2015, the base rent increased to $21,420 per month for four months. Commencing July 1, 2015, the base rent increased to $22,111 per month for the remainder of the lease term.

On May 14, 2014, Capricor entered into a facilities lease with Cedars-Sinai Medical Center ("CSMC"), a shareholder of the Company, for two research labs (the "Facilities Lease"). The Facilities Lease is for a term of three years commencing June 1, 2014 and replaces the month-to-month lease that was previously in effect between CSMC and Capricor. The monthly lease payment under the Facilities Lease was approximately $15,461 per month for the first six months of the term and increased to approximately $19,350 per month for the remainder of the term. The amount of rent expense is subject to annual adjustments according to increases in the Consumer Price Index.

Unless renewed, each of the leases described above will not be in effect for fiscal year 2018. A summary of future minimum rental payments required under operating leases as of December 31, 2015 is as follows:

Years ended	Operating Leases
2016	$ 364,866
2017	96,750
Total minimum lease payments	**$ 461,616**

Expenses incurred under operating leases to unrelated parties for the years ended December 31, 2015 and 2014 were approximately $255,942 and $203,430, respectively. Expenses incurred under operating leases to related parties for the years ended December 31, 2015 and 2014 were approximately $224,421 and $153,682, respectively.

Legal Contingencies

Periodically, the Company may become involved in certain legal actions and claims arising in the ordinary course of business. There were no material legal actions or claims reported at December 31, 2015.

7. LICENSE AGREEMENTS

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

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"), The Johns Hopkins University ("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, is currently paying minimum annual royalties in the amount of 20,000 Euros per year, and is obligated to pay a lower-end of a mid-range double-digit percentage on all royalties received as a result of sublicenses granted, which are net of any royalties paid to third parties under a license agreement from such third party to Capricor. 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 will 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 JHU 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 range from $5,000 on the first and second anniversary dates to $20,000 on the tenth anniversary date and thereafter. The minimum annual royalties are creditable against a low single-digit running royalty on net sales of products and net service revenues, which Capricor is also required to pay under the JHU License Agreement, which running royalty may be subject to further reduction in the event that Capricor is required to pay royalties on any patent rights to third parties in order to make or sell a licensed product. In addition, Capricor is required to pay a low double-digit 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 approval from the U.S. Food and Drug Administration (the "FDA"). The development milestones range from $100,000 upon successful completion of a full Phase I clinical study to $1,000,000 upon full FDA market approval and are fully creditable against payments owed by Capricor to JHU on account of sublicense consideration attributable to milestone payments received from a sublicensee. The maximum aggregate amount of milestone payments payable under the JHU License Agreement, as amended, is $1,850,000. As of December 31, 2014, $100,000 was recorded within accounts payable and accrued expenses as a development milestone due to the fact that Phase I of the ALLSTAR study enrollment had been completed. In May 2015, Capricor paid the development milestone related to Phase I that was owed to JHU pursuant to the terms of the JHU License Agreement.

7. LICENSE AGREEMENTS (Continued)

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.

Cedars-Sinai Medical Center License Agreements

License Agreement for CDCs

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 patent 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 will 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 is required to meet certain spending and development milestones. The annual spending requirements range from $350,000 to $800,000 each year between 2010 and 2017 (with the exception of 2014, for which there was no annual spending requirement). Pursuant to the Amended CSMC License Agreement, Capricor remains obligated to pay low single-digit royalties on sales of royalty-bearing products as well as a low double-digit percentage of the consideration received from any sublicenses or other grant of rights. The above-mentioned royalties are subject to reduction in the event Capricor becomes obligated to obtain a license from a third party for patent rights in connection with the royalty-bearing product. 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.

On March 20, 2015, Capricor and CSMC entered into a First Amendment to the Amended CSMC License Agreement, pursuant to which the parties agreed to delete certain patent applications from the list of Scheduled Patents which Capricor determined not to be material to the portfolio.

7. LICENSE AGREEMENTS (Continued)

License Agreement for Exosomes

On May 5, 2014, Capricor entered into an Exclusive License Agreement with CSMC (the "Exosomes License Agreement"), for certain intellectual property rights related to exosomes technology. The Exosomes License Agreement provides for the grant of an exclusive, world-wide, royalty-bearing license by CSMC to Capricor (with the right to sublicense) in order to conduct research using the patent rights and know-how and to develop and commercialize products in the field using the patent 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 Exosomes License Agreement, CSMC was paid a license fee and Capricor reimbursed CSMC for certain fees and costs incurred in connection with the prosecution of certain patent rights. Additionally, Capricor is required to meet certain non-monetary development milestones and is obligated to pay low single-digit royalties on sales of royalty-bearing products as well as a single-digit percentage of the consideration received from any sublicenses or other grant of rights. The above-mentioned royalties are subject to reduction in the event Capricor becomes obligated to obtain a license from a third party for patent rights in connection with the royalty bearing product.

The Exosomes 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 Exosomes 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.

On February 27, 2015, Capricor and CSMC entered into a First Amendment to Exclusive License Agreement, thereby amending the Exosomes License Agreement (the "Exosomes License Amendment"). Under the Exosomes License Amendment, (i) the description of patent rights in Schedule A has been replaced by a Revised Schedule A that includes four additional patent applications; (ii) Capricor was required to pay CSMC an upfront fee of $20,000; (iii) Capricor is required to reimburse CSMC approximately $34,000 for attorneys' fees and filing fees that were incurred in connection with the additional patent rights; and (iv) Capricor is required to pay CSMC certain defined product development milestone payments upon reaching certain phases of its clinical studies and upon receiving approval for a product from the FDA. The product development milestones range from $15,000 upon the dosing of the first patient in a Phase I clinical trial of a product to $75,000 upon receipt of FDA approval for a product. The maximum aggregate amount of milestone payments payable under the Exosomes License Agreement, as amended, is $190,000. On June 10, 2015, Capricor and CSMC entered into a Second Amendment to Exclusive License Agreement, thereby amending the Exosomes License Agreement further to add an additional patent application to the Schedule of Patent Rights.

As noted above, Capricor is party to lease agreements with CSMC, which holds more than 10% of the outstanding capital stock of Capricor Therapeutics (see Note 6 – "Commitments and Contingencies"). Additionally, Dr. Eduardo Marbán, who holds more than 10% of the outstanding capital stock of Capricor Therapeutics, is the Director of the Cedars-Sinai Heart Institute, the Co-Founder of Capricor and Chairman of Capricor's Scientific Advisory Board.

7. LICENSE AGREEMENTS (Continued)

Collaboration Agreement with Janssen Biotech, Inc.

On December 27, 2013, Capricor entered into a Collaboration Agreement and Exclusive License Option (the "Janssen Agreement") with Janssen, a wholly-owned subsidiary of Johnson & Johnson. Under the terms of the Janssen Agreement, Capricor and Janssen agreed to collaborate on the development of Capricor's cell therapy program for cardiovascular applications, including its lead product candidate, CAP-1002. Capricor and Janssen further agreed to collaborate on the development of cell manufacturing in preparation for future clinical trials. Under the Janssen Agreement, Capricor was paid $12.5 million, and Capricor will contribute to the 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 royalty ranging from a low double-digit percentage to a lower-end of a mid-range double-digit percentage would be paid on sales of licensed products.

Company 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 ("Mayo"), a Clinical Trial Funding Agreement with Medtronic, Inc. ("Medtronic"), and a Transfer Agreement with Medtronic, all of which also include certain intellectual property licensing provisions.

Mayo License Agreement

The Company and 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 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.

7. LICENSE AGREEMENTS (Continued)

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 the CU-NP Agreement by, among other things, eliminating certain milestone payments and decreasing the royalty percentages payable upon the commercial sale of the products to low single-digit royalties on sales of CD-NP and CU-NP products. The Company is also obligated to pay to Mayo a low single-digit percentage on any upfront consideration or milestone payment received in connection with a sublicense. The Company is further obligated to pay to Mayo a low single-digit percentage on any consideration received in connection with an assignment of rights under the Amended Mayo Agreement. 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 (a) the expiration of the last to expire valid claim contained in the Mayo patents, or (b) 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 for 90 days' after 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. Such condition was satisfied when the Company initiated its clinical trial of Cenderitide in January 2015. The Company may terminate the Amended Mayo Agreement without cause upon 90 days' written notice.

Medtronic Clinical Trial Funding Agreement

In February 2011, the Company entered into a Clinical Trial Funding Agreement with Medtronic. Pursuant to the agreement, Medtronic provided funding and equipment necessary for the Company 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. 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. The Company and Medtronic have subsequently entered into a Transfer Agreement, described below.

Medtronic Transfer Agreement

On October 8, 2014, the Company entered into a Transfer Agreement (the "Transfer Agreement") with Medtronic to acquire patent rights relating to the formulation and pump delivery of natriuretic peptides. Pursuant to the Transfer Agreement, Medtronic has assigned to the Company all of its right, title and interest in all natriuretic peptide patents and patent applications previously owned by Medtronic or co-owned by Medtronic and the Company ("Natriuretic Peptide Patents"). Under the Transfer Agreement, the Company received all rights to the Natriuretic Peptide Patents, including the right to grant licenses and to make assignments without approval from Medtronic.

7. LICENSE AGREEMENTS (Continued)

The Transfer Agreement became effective on October 8, 2014 and will expire simultaneously at the expiration of the last to expire of the valid claims. Both parties have the right to terminate the Transfer Agreement upon 30 days written notice to the other party in the event of a default which has not been cured within such 30-day period. In addition, Medtronic had the right to terminate the Transfer Agreement and to have the rights to the Natriuretic Peptide Patents reassigned to it by the Company if either the Company, an affiliate, or a non-party licensee failed to commence a clinical trial of a CD-NP product within 18 months from the effective date. Such condition was satisfied when the Company initiated its clinical trial of Cenderitide in January 2015.

In the event of a termination of the Transfer Agreement, (i) the Natriuretic Peptide Patents which were not owned or co-owned by the Company prior to the effective date of the Transfer Agreement shall be assigned back to Medtronic; (ii) the Company's rights in the Natriuretic Peptide Patents that were co-owned by Capricor pursuant to the Clinical Trial Funding Agreement will remain with the Company, subject to the surviving terms and provisions thereof; and (iii) the Company shall assign back to Medtronic those rights that were co-owned by Medtronic pursuant to the Clinical Trial Funding Agreement.

Pursuant to the Transfer Agreement, Medtronic was paid an upfront payment of $100,000, and the Company is obligated to pay Medtronic a mid-single-digit royalty on net sales of products, a low double-digit percentage of any consideration received from any sublicenses or other grant of rights, and a mid-double-digit percentage of any monetary awards or settlements received by the Company as a result of enforcement of the Natriuretic Peptide Patents against a non-party entity, less the costs and attorney's fees incurred to enforce the Natriuretic Peptide Patents. In addition, there are additional payments that may become due from the Company upon the achievement of certain defined milestones, which payments, in the aggregate, total up to $7.0 million.

8. RELATED PARTY TRANSACTIONS

Lease and Sub-Lease Agreement

As noted above, Capricor Therapeutics is party to lease agreements with CSMC, which holds more than 10% of the outstanding capital stock of Capricor Therapeutics (see Note 6 – "Commitments and Contingencies"). Additionally, Dr. Eduardo Marbán, who holds more than 10% of the outstanding capital stock of Capricor Therapeutics, is the Director of the Cedars-Sinai Heart Institute, the Co-Founder of Capricor and the Chairman of Capricor's Scientific Advisory Board.

Beginning May 1, 2012, pursuant to a sublease agreement, Capricor subleased part of its office space to Frank Litvack, the Company's Executive Chairman and a member of its Board of Directors, 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. For both the years ended December 31, 2015 and 2014, Capricor recognized $30,000 in sublease income from the related party. Sublease income is recorded as a reduction to general and administrative expenses.

Consulting Agreements

Effective January 1, 2013, Frank Litvack, the Company's Executive Chairman and a member of its Board of Directors, entered into an oral Consulting Agreement with Capricor whereby Capricor agreed to pay Dr. Litvack fees of $10,000 per month for consulting services. On March 24, 2014, Capricor entered into a written Consulting Agreement with Dr. Litvack memorializing the $10,000 per month compensation arrangement described above. The agreement is terminable upon 30 days' notice.

Payables to Related Party

At December 31, 2015 and 2014, the Company had accounts payable and accrued expenses to related parties totaling $352,334 and $433,712, respectively. CSMC accounts for approximately $352,334 and $421,328 of the total accounts payable and accrued expenses to related parties as of December 31, 2015 and 2014, respectively. CSMC expenses relate to the ongoing clinical trials costs and deferred rent on our research lab space.

9. SUBSEQUENT EVENTS

March 2016 Financing

On March 14, 2016, the Company entered into a Subscription Agreement with certain investors pursuant to which, on March 16, 2016, the Company issued and sold to the investors an aggregate of approximately $4.1 million of registered and unregistered securities of the Company. On March 16, 2016, in accordance with the Subscription Agreement, the Company issued and sold to the investors, and the investors purchased from the Company, an aggregate of 1,692,151 shares of the Company's common stock at a purchase price of $2.40 per share. The shares were issued pursuant to the Company's shelf registration statement on Form S-3 (File No. 333-207149), which was initially filed with the Securities and Exchange Commission (the "SEC") on September 28, 2015 and declared effective by the SEC on October 26, 2015. A prospectus supplement relating to the Public Offering was filed with the SEC on March 15, 2016.

Pursuant to the Subscription Agreement, the Company also issued and sold to the investors, in a concurrent private placement, warrants to purchase up to an aggregate of 846,073 shares of the Company's common stock. Each warrant has an exercise price of $4.50 per share, will initially be exercisable on the date that is six months and one day from the date of issuance, and will expire on the date that is three years from the date of issuance.

The Company received net proceeds of approximately $3.9 million from the sale of the securities in the offerings, after deducting the placement agent fees and estimated offering expenses payable by the Company.

In connection with the private placement of the warrants, the Company entered into a Registration Rights Agreement with the investors on March 14, 2016, pursuant to which the Company agreed to (i) prepare and file with the SEC a registration statement to register for resale the shares of common stock issuable upon exercise of the warrants within 90 calendar days following the closing of the private placement, and (ii) use its reasonable efforts to cause such registration statement to be declared effective by the SEC as soon as practicable.

Additional CIRM Disbursement

On March 11, 2016, Capricor received an additional disbursement from CIRM for $1.0 million pursuant to the achievement of an enrollment milestone in connection with the ALLSTAR project.

CIRM Grant Award

On March 16, 2016, Capricor was informed by CIRM that its Application Review Subcommittee of the Independent Citizens' Oversight Committee approved a grant award in the amount of approximately $3.4 million to fund in part Capricor's Phase I/II HOPE-Duchenne clinical trial investigating CAP-1002 for the treatment of Duchenne muscular dystrophy-related cardiomyopathy. The terms of the award and the disbursement schedule have not yet been determined and the award is subject to the execution of definitive documents.

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 Chief 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 Chief 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 Chief Financial Officer concluded that as of December 31, 2015, 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.

Management assessed the effectiveness of our internal control over financial reporting as of December 31, 2015 based on the framework set forth by the Committee of Sponsoring Organizations of the Treadway Commissions in Internal Control-Integrated Framework. Based on that assessment, management has concluded that our internal control over financial reporting was effective as of December 31, 2015.

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, 2015 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.

The information required by this item will be set forth in the sections entitled “Information Regarding the Board of Directors and Corporate Governance”, “Information Regarding Executive Officers” and “Section 16(a) Beneficial Ownership Reporting Compliance” in our Definitive Proxy Statement for our 2016 Annual Meeting of Stockholders, or our 2016 Proxy Statement, to be filed with the SEC within 120 days after the end of the fiscal year ended December 31, 2015, and is incorporated herein by reference.

Item 11. Executive Compensation.

The information required by this item will be set forth in the section entitled “2015 Executive Compensation” and “Compensation of Directors” in our 2016 Proxy Statement and is incorporated herein by reference.

Item 12. Security Ownership of Certain Beneficial Owners and Management and Related Stockholder Matters.

The information required by this item will be set forth in the sections entitled “Securities Authorized for Issuance Under Equity Compensation Plans” and “Security Ownership of Certain Beneficial Owners and Management” in our 2016 Proxy Statement and is incorporated herein by reference.

Item 13. Certain Relationships and Related Transactions, and Director Independence.

The information required by this item will be set forth in the sections entitled “Certain Relationships and Related Party Transactions” and “Information Regarding the Board of Directors and Corporate Governance” in our 2016 Proxy Statement and is incorporated herein by reference.

Item 14. Principal Accounting Fees and Services.

The information required by this item will be set forth in the section entitled “Principal Accountant Fees and Services” in our 2016 Proxy Statement and is incorporated herein by reference.

PART IV

ITEM 15. EXHIBITS AND FINANCIAL STATEMENT SCHEDULES

(a)(1) Financial Statements

The financial statements required by this item are included in a separate section of this Annual Report on Form 10-K beginning on page F-1.

(a)(2) Financial Statement Schedules

Financial Statement Schedules have been omitted because they are either not applicable or the required information is included in the consolidated financial statements or notes thereto listed in (a)(1) above.

(a)(3) Exhibits

The following exhibits are filed herewith or incorporated herein by reference:

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	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).
4.2	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).
4.3	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).
4.4	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).
4.5	Form of Warrant, issued by the Company to the Investors on March 16, 2016 (incorporated by reference to Exhibit 4.2 to the Company's Amendment No. 1 to Current Report on Form 8-K/A, filed with the Commission on March 16, 2016).

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 (incorporated by reference to Exhibit 10.7 to the Company's Annual Report on Form 10-K, filed with the Commission on March 31, 2014). †
10.8	Employment Agreement between Capricor, Inc. and Anthony Davies, dated February 18, 2013 (incorporated by reference to Exhibit 10.8 to the Company's Annual Report on Form 10-K, filed with the Commission on March 31, 2014). †
10.9	Consulting Agreement between Capricor, Inc. and Frank Litvack, dated March 24, 2014 (incorporated by reference to Exhibit 10.9 to the Company's Annual Report on Form 10-K, filed with the Commission on March 31, 2014). †
10.10	Separation Agreement and Release between the Company and Darlene Horton, M.D., dated November 20, 2013 (incorporated by reference to Exhibit 10.10 to the Company's Annual Report on Form 10-K, filed with the Commission on March 31, 2014). †
10.11	Form of Indemnification Agreement (incorporated by reference to Exhibit 10.11 to the Company's Annual Report on Form 10-K, filed with the Commission on March 31, 2014). †
10.12	Amended and Restated 2005 Stock Option Plan (incorporated by reference to Exhibit 10.9 to the Company's Current Report on Form 8-K, filed with the Commission on September 21, 2007). †
10.13	Form of Stock Option Agreement (incorporated by reference to Exhibit 10.10 to the Company's Current Report on Form 8-K, filed with the Commission on September 21, 2007). †
10.14	Form of Incentive Stock Option Agreement (incorporated by reference to Exhibit 10.11 to the Company's Current Report on Form 8-K, filed with the Commission on September 21, 2007). †
10.15	Capricor, Inc. 2006 Stock Option Plan (incorporated by reference to Exhibit 4.4 to the Company's Registration Statement on Form S-8, filed with the Commission on March 4, 2014). †
10.16	Capricor, Inc. 2012 Restated Equity Incentive Plan (incorporated by reference to Exhibit 4.5 to the Company's Registration Statement on Form S-8, filed with the Commission on March 4, 2014). †
10.17	Capricor, Inc. 2012 Non-Employee Director Stock Option Plan (incorporated by reference to Exhibit 4.6 to the Company's Registration Statement on Form S-8, filed with the Commission on March 4, 2014). †

10.18	First Amendment to Capricor, Inc. 2006 Stock Option Plan (incorporated by reference to Exhibit 4.11 to the Company's Registration Statement on Form S-8, filed with the Commission on March 4, 2014). †
10.19	First Amendment to Capricor, Inc. 2012 Restated Equity Incentive Plan (incorporated by reference to Exhibit 4.12 to the Company's Registration Statement on Form S-8, filed with the Commission on March 4, 2014). †
10.20	First Amendment to Capricor, Inc. 2012 Non-Employee Director Stock Option Plan (incorporated by reference to Exhibit 4.13 to the Company's Registration Statement on Form S-8, filed with the Commission on March 4, 2014). †
10.21	Form of Incentive Stock Option Agreement for the Capricor, Inc. 2006 Stock Option Plan (incorporated by reference to Exhibit 4.7 to the Company's Registration Statement on Form S-8, filed with the Commission on March 4, 2014). †
10.22	Form of Non-Qualified Stock Option Agreement for the Capricor, Inc. 2006 Stock Option Plan (incorporated by reference to Exhibit 4.8 to the Company's Registration Statement on Form S-8, filed with the Commission on March 4, 2014). †
10.23	Form of Stock Option Agreement for the Capricor, Inc. 2012 Restated Equity Incentive Plan (incorporated by reference to Exhibit 4.9 to the Company's Registration Statement on Form S-8, filed with the Commission on March 4, 2014). †
10.24	Form of Stock Option Agreement for the Capricor, Inc. 2012 Non-Employee Director Stock Option Plan (incorporated by reference to Exhibit 4.10 to the Company's Registration Statement on Form S-8, filed with the Commission on March 4, 2014). †
10.25	Form of Securities Purchase Agreement entered into among the Company and Various Accredited Investors on July 7, 2009 (incorporated by reference to Exhibit 10.1 to the Company's Current Report on Form 8-K, filed with the Commission on July 13, 2009).
10.26	Form of Securities Purchase Agreement entered into among the Company and Various Accredited Investors on June 20, 2011 (incorporated by reference to Exhibit 10.1 to the Company's Current Report on Form 8-K, filed with the Commission on June 24, 2011).
10.27	Form of Security Agreement, by and among the Company and Various Accredited Investors, dated March 15, 2013 (incorporated by reference to Exhibit 10.2 to the Company's Current Report on Form 8-K, filed with the Commission on March 22, 2013).
10.28	Placement Agent Agreement dated March 30, 2012, between the Company and Roth Capital Partners, LLC (incorporated by reference to Exhibit 1.1 to the Company's Current Report on Form 8-K, filed with the Commission on April 2, 2012).
10.29	Form of Subscription Agreement, entered into on March 30, 2012, between the Company and Various Investors (incorporated by reference to Exhibit 10.1 to the Company's Current Report on Form 8-K, filed with the Commission on April 2, 2012).
10.30	Clinical Trial Funding Agreement, dated February 25, 2011, between the Company and Medtronic, Inc. (incorporated by reference to Exhibit 10.1 to the Company's Quarterly Report on Form 10-Q, filed with the Commission on May 16, 2011). +
10.31	Exclusive License Agreement, dated June 21, 2006, between Capricor, Inc. and the Universita Degli Studi Di Roma "La Sapienza" (incorporated by reference to Exhibit 10.31 to the Company's Annual Report on Form 10-K, filed with the Commission on March 31, 2014). +
10.32	Exclusive License Agreement, dated June 22, 2006, between Capricor, Inc. and the Johns Hopkins University(incorporated by reference to Exhibit 10.32 to the Company's Annual Report on Form 10-K, filed with the Commission on March 31, 2014) . +

10.33	First Amendment to the Exclusive License Agreement, dated May 13, 2009, between Capricor, Inc. and the Johns Hopkins University (incorporated by reference to Exhibit 10.33 to the Company's Annual Report on Form 10-K, filed with the Commission on March 31, 2014). +
10.34	Second Amendment to the Exclusive License Agreement, dated December 20, 2013, between Capricor, Inc. and the Johns Hopkins University (incorporated by reference to Exhibit 10.34 to the Company's Annual Report on Form 10-K, filed with the Commission on March 31, 2014). +
10.35	Amended and Restated License Agreement, dated November 14, 2013, between the Company and Mayo Foundation for Medical Education and Research (incorporated by reference to Exhibit 10.35 to the Company's Annual Report on Form 10-K, filed with the Commission on March 31, 2014) . +
10.36	Amended and Restated Exclusive License Agreement, dated December 20, 2013, between Capricor, Inc. and Cedars-Sinai Medical Center (incorporated by reference to Exhibit 10.36 to the Company's Annual Report on Form 10-K, filed with the Commission on March 31, 2014) . +
10.37	Collaboration Agreement and License Option, dated December 27, 2013, between Capricor, Inc. and Janssen Biotech, Inc. (incorporated by reference to Exhibit 10.37 to the Company's Annual Report on Form 10-K, filed with the Commission on March 31, 2014). +
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10.43	Sublease Agreement, dated May 1, 2012, between Capricor, Inc. and Frank Litvack (incorporated by reference to Exhibit 10.43 to the Company's Annual Report on Form 10-K, filed with the Commission on March 31, 2014).
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10.49	Registration Rights Agreement, dated as of January 9, 2015, by and among Capricor Therapeutics, Inc. and the Investors (incorporated by reference to Exhibit 10.2 to the Company's Amendment No. 1 to Current Report on Form 8-K/A, filed with the Commission on January 22, 2015).
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10.52	Amendment dated February 2, 2015 to Share Purchase Agreement dated as of January 9, 2015, by and among Capricor Therapeutics, Inc. and the purchaser signatories thereto (incorporated by reference to Exhibit 10.3 to the Company's Amendment No. 1 to Current Report on Form 8-K/A, filed with the Commission on February 6, 2015).
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10.57	Joinder Agreement, dated as of September 30, 2015, by and among the Company, Capricor, Inc. and the California Institute For Regenerative Medicine (incorporated by reference to Exhibit 10.1 to the Company's Quarterly Report on Form 10-Q, filed with the Commission on November 13, 2015).
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21.1	List of Subsidiaries.*
23.1	Consent of Rose Snyder & Jacobs, LLP.*

24.1	Power of Attorney (included on signature page hereof).*
31.1	Certification of Principal Executive Officer.*
31.2	Certification of Principal Financial Officer.*
32.1	Certification of Principal Executive Officer pursuant to Section 906 of the Sarbanes-Oxley Act of 2002.*
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101	The following financial information formatted in eXtensible Business Reporting Language (XBRL): (i) Consolidated Balance Sheets as of December 31, 2015 and 2014, (ii) Consolidated Statements of Operations for the years ended December 31, 2015 and 2014, (iii) Consolidated Statement of Stockholders' Equity (Deficit) for the period from December 31, 2013 through December 31, 2015, (iv) Consolidated Statements of Cash Flows for the years ended December 31, 2015 and 2014, and (v) Notes to Consolidated Financial Statements.*

* Filed herewith.
† Indicates management contract or compensatory plan or arrangement.
+ The Company has received confidential treatment with respect to certain portions of this exhibit. Omitted portions have been filed separately with the SEC.

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 30, 2016.

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 Leland Gershell, M.D., Ph.D. 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 Annual Report on 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
/s/ Linda Marbán, Ph.D. Linda Marbán, Ph.D.	Chief Executive Officer and Director *(Principal Executive Officer)*	March 30, 2016
/s/ Leland Gershell, M.D., Ph.D. Leland Gershell, M.D., Ph.D.	Chief Financial Officer *(Principal Financial Officer)*	March 30, 2016
/s/ Anthony J. Bergmann Anthony J. Bergmann	Vice President of Finance *(Principal Accounting Officer)*	March 30, 2016
/s/ Frank Litvack, M.D. Frank Litvack, M.D.	Executive Chairman	March 30, 2016
/s/ Joshua A. Kazam Joshua A. Kazam	Director	March 30, 2016
/s/ Earl M. Collier Earl M. Collier	Director	March 30, 2016
/s/ Louis V. Manzo Louis V. Manzo	Director	March 30, 2016
/s/ Louis J. Grasmick Louis J. Grasmick	Director	March 30, 2016
/s/ Gregory W. Schafer Gregory W. Schafer	Director	March 30, 2016
/s/ George W. Dunbar George W. Dunbar	Director	March 30, 2016
/s/ David B. Musket David B. Musket	Director	March 30, 2016

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 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).

4.2 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).

4.3 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).

4.4 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).

4.5 Form of Warrant, issued by the Company to the Investors on March 16, 2016 (incorporated by reference to Exhibit 4.2 to the Company's Amendment No. 1 to Current Report on Form 8-K/A, filed with the Commission on March 16, 2016).

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 (incorporated by reference to Exhibit 10.7 to the Company's Annual Report on Form 10-K, filed with the Commission on March 31, 2014). †
10.8	Employment Agreement between Capricor, Inc. and Anthony Davies, dated February 18, 2013 (incorporated by reference to Exhibit 10.8 to the Company's Annual Report on Form 10-K, filed with the Commission on March 31, 2014). †
10.9	Consulting Agreement between Capricor, Inc. and Frank Litvack, dated March 24, 2014 (incorporated by reference to Exhibit 10.9 to the Company's Annual Report on Form 10-K, filed with the Commission on March 31, 2014). †
10.10	Separation Agreement and Release between the Company and Darlene Horton, M.D., dated November 20, 2013 (incorporated by reference to Exhibit 10.10 to the Company's Annual Report on Form 10-K, filed with the Commission on March 31, 2014). †
10.11	Form of Indemnification Agreement (incorporated by reference to Exhibit 10.11 to the Company's Annual Report on Form 10-K, filed with the Commission on March 31, 2014). †
10.12	Amended and Restated 2005 Stock Option Plan (incorporated by reference to Exhibit 10.9 to the Company's Current Report on Form 8-K, filed with the Commission on September 21, 2007). †
10.13	Form of Stock Option Agreement (incorporated by reference to Exhibit 10.10 to the Company's Current Report on Form 8-K, filed with the Commission on September 21, 2007). †
10.14	Form of Incentive Stock Option Agreement (incorporated by reference to Exhibit 10.11 to the Company's Current Report on Form 8-K, filed with the Commission on September 21, 2007). †
10.15	Capricor, Inc. 2006 Stock Option Plan (incorporated by reference to Exhibit 4.4 to the Company's Registration Statement on Form S-8, filed with the Commission on March 4, 2014). †
10.16	Capricor, Inc. 2012 Restated Equity Incentive Plan (incorporated by reference to Exhibit 4.5 to the Company's Registration Statement on Form S-8, filed with the Commission on March 4, 2014). †
10.17	Capricor, Inc. 2012 Non-Employee Director Stock Option Plan (incorporated by reference to Exhibit 4.6 to the Company's Registration Statement on Form S-8, filed with the Commission on March 4, 2014). †
10.18	First Amendment to Capricor, Inc. 2006 Stock Option Plan (incorporated by reference to Exhibit 4.11 to the Company's Registration Statement on Form S-8, filed with the Commission on March 4, 2014). †
10.19	First Amendment to Capricor, Inc. 2012 Restated Equity Incentive Plan (incorporated by reference to Exhibit 4.12 to the Company's Registration Statement on Form S-8, filed with the Commission on March 4, 2014). †
10.20	First Amendment to Capricor, Inc. 2012 Non-Employee Director Stock Option Plan (incorporated by reference to Exhibit 4.13 to the Company's Registration Statement on Form S-8, filed with the Commission on March 4, 2014). †
10.21	Form of Incentive Stock Option Agreement for the Capricor, Inc. 2006 Stock Option Plan (incorporated by reference to Exhibit 4.7 to the Company's Registration Statement on Form S-8, filed with the Commission on March 4, 2014). †
10.22	Form of Non-Qualified Stock Option Agreement for the Capricor, Inc. 2006 Stock Option Plan (incorporated by reference to Exhibit 4.8 to the Company's Registration Statement on Form S-8, filed with the Commission on March 4, 2014). †

10.23 Form of Stock Option Agreement for the Capricor, Inc. 2012 Restated Equity Incentive Plan (incorporated by reference to Exhibit 4.9 to the Company's Registration Statement on Form S-8, filed with the Commission on March 4, 2014). †

10.24 Form of Stock Option Agreement for the Capricor, Inc. 2012 Non-Employee Director Stock Option Plan (incorporated by reference to Exhibit 4.10 to the Company's Registration Statement on Form S-8, filed with the Commission on March 4, 2014). †

10.25 Form of Securities Purchase Agreement entered into among the Company and Various Accredited Investors on July 7, 2009 (incorporated by reference to Exhibit 10.1 to the Company's Current Report on Form 8-K, filed with the Commission on July 13, 2009).

10.26 Form of Securities Purchase Agreement entered into among the Company and Various Accredited Investors on June 20, 2011 (incorporated by reference to Exhibit 10.1 to the Company's Current Report on Form 8-K, filed with the Commission on June 24, 2011).

10.27 Form of Security Agreement, by and among the Company and Various Accredited Investors, dated March 15, 2013 (incorporated by reference to Exhibit 10.2 to the Company's Current Report on Form 8-K, filed with the Commission on March 22, 2013).

10.28 Placement Agent Agreement dated March 30, 2012, between the Company and Roth Capital Partners, LLC (incorporated by reference to Exhibit 1.1 to the Company's Current Report on Form 8-K, filed with the Commission on April 2, 2012).

10.29 Form of Subscription Agreement, entered into on March 30, 2012, between the Company and Various Investors (incorporated by reference to Exhibit 10.1 to the Company's Current Report on Form 8-K, filed with the Commission on April 2, 2012).

10.30 Clinical Trial Funding Agreement, dated February 25, 2011, between the Company and Medtronic, Inc. (incorporated by reference to Exhibit 10.1 to the Company's Quarterly Report on Form 10-Q, filed with the Commission on May 16, 2011). +

10.31 Exclusive License Agreement, dated June 21, 2006, between Capricor, Inc. and the Universita Degli Studi Di Roma "La Sapienza" (incorporated by reference to Exhibit 10.31 to the Company's Annual Report on Form 10-K, filed with the Commission on March 31, 2014). +

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* Filed herewith.
† Indicates management contract or compensatory plan or arrangement.
+ The Company has received confidential treatment with respect to certain portions of this exhibit. Omitted portions have been filed separately with the SEC.

EMPLOYMENT AGREEMENT

THIS EMPLOYMENT AGREEMENT ("**Agreement**") is made and shall be effective as of February 22, 2016 (the " **Effective Date**"), by and between **CAPRICOR, INC**., a Delaware corporation, whose offices are located at 8840 Wilshire Blvd., 2nd Floor, Beverly Hills, California 90211 (the " **Company**"), and **LELAND JAMES GERSHELL, MD**, **Ph.D.,** whose address is 205 East 85th Street, Apt. 3G, New York, NY 10028 (" **Employee**").

A. The Company is engaged in the business of developing and commercializing novel therapies for the treatment of diseases and desires to assure itself of the services of Employee by engaging Employee to perform services under the terms of this Agreement;

B. Employee has a medical background and experience serving as a Chief Financial Officer of a publicly traded corporation and Employee desires to provide services to the Company on the terms herein provided; and

C. The parties now desire to enter into an Employment Agreement which shall set forth the full terms and conditions of Employee's employment.

NOW, **THEREFORE**, in consideration of the mutual covenants, promises, and agreements set forth herein and for good and valuable consideration, the receipt and sufficiency of which are hereby acknowledged, the parties hereby mutually agree as follows:

1. EMPLOYMENT. The Company hereby agrees to employ Employee, and Employee hereby agrees to accept employment with the Company, upon the terms and conditions herein set forth. Employee's start date shall be February 22, 2016.

2. DUTIES AND POWERS OF EMPLOYEE

2.1 Duties of Employee. Employee shall serve as the Company's Chief Financial Officer reporting directly to the Chief Executive Officer or to such other person designated from time to time by the Chief Executive Officer. In that capacity, Employee shall serve as a key member of the Executive Management team and will assume a strategic role in the overall management of the Company. Employee will have primary responsibility for planning, implementing, managing and controlling all financial-related activities of the Company, including responsibility and oversight for accounting, finance, forecasting, strategic planning, deal analysis, investor relationships and private and institutional financings. Employee will also be expected to represent the Company, along with the Chief Executive Officer, at meetings with investment bankers and investors. Employee's responsibilities shall include, without limitation, performing those Services set forth on **Exhibit A**, attached hereto and incorporated herein, which may be amended from time at the discretion of the Chief Executive Officer (collectively, the "**Services**"). Except as otherwise specifically set forth in this Agreement, during the duration of his employment, and except for periods of illness, personal time off, or reasonable leaves of absence, Employee shall devote his full time and attention to the business and affairs of the Company, as such business and affairs now exist and as they hereafter may be changed or added to, under and pursuant to the general direction of the Company's Board of Directors (the "**Board**").

2.2 Place of Performance. Employee shall be permitted to work from his home office in New York. However, Employee will be expected to spend the time necessary (which could be as much as one to two weeks each month working in the Company's offices located in Beverly Hills, California) and otherwise as may be required from time to time. If at some time in the future the Company believes it is necessary for you to relocate to California, the Company shall have the right to request that of you.

2.3 Other Activities. During the continuation of his employment hereunder, Employee shall not provide any work or services to any other person or organization without the prior written consent of the Chief Executive Officer, which consent may be withheld in the Chief Executive Officer's sole and absolute discretion. Nothing contained herein shall prohibit Employee from making passive personal investments in publicly traded companies so long as Employee's investment does not constitute an equity position greater than five percent (5%) of such company's outstanding securities.

2.4 Company Policies. By execution of this Agreement, Employee is agreeing to comply with all Company policies, procedures and standards of conduct that are currently in effect or that may be established or modified by the Company from time to time.

3. COMPENSATION

3.1 Base Salary. In consideration of the Services to be provided by Employee during his employment hereunder, Employee shall receive a base salary of two hundred fifty thousand dollars ($250,000) per annum (the "**Base Salary**"), which sum shall be payable in semi-monthly installments consistent with Company pay practices.

3.2 Grant of Stock Options. As further consideration for the Services to be provided by Employee hereunder, subject to the approval of the Company's Board, Employee shall be granted a stock option under Capricor Therapeutics' 2012 Restated Equity Incentive Plan (the "**Stock Plan**") to purchase an aggregate of 166,500 shares of Common Stock of Capricor Therapeutics, Inc. (the "**Option Shares**"). If granted, 25% of the Option Shares shall vest on the first anniversary of the first day of the month following the date of grant ("**Grant Date**") and the remainder will vest at the rate of 1/36 per month on the first day of each succeeding month thereafter over a three-year period. The exercise price for the Option Shares shall be not less than the fair market value of the shares on the Grant Date which will be determined by the closing price of the Common Stock on the Grant Date. The Option Shares shall be further subject to the provisions of the Stock Plan and the applicable Stock Option Agreement to be executed by the Capricor Therapeutics and Employee.

3.3 Additional Compensation. Along with other Executives of the Company, Employee shall be considered for Base Salary increases, bonuses or additional stock options, the granting of which shall be determined in the sole discretion of the Company's Compensation Committee and Board of Directors taking into consideration Employee's performance and the performance of the Company as a whole.

3.4 Deduction of Taxes. The Company shall have the right to deduct or withhold from the compensation due to Employee hereunder any and all sums required for Federal Income and Social Security taxes and all other federal, state or local taxes now applicable or that may be enacted and become applicable in the future.

4. OTHER BENEFITS

4.1 Insurance. Commencing on the first day of the month following the thirty (30) day period after the commencement of employment and so long as Employee remains employed by the Company, Employee shall be entitled to participate in the medical, dental and vision insurance plans which are from time to time made available to other employees of the Company in accordance with the Company's policies then in effect. The right to receive such insurance benefits shall vest if and only if any of the foregoing types of insurance plans are adopted and maintained by the Company. In addition, commencing in the second year of Employee's employment, the sum of one thousand dollars ($1,000) shall be deposited into a flexible spending account each year earmarked for Employee's benefit to be used only for qualified medical expenses. If Employee's employment is terminated for whatever reason before such sum is expended by him, any remaining balance will be cancelled upon termination of employment. The insurance provided to Employee shall be consistent with that afforded to other C-level executives of the Company.

4.2 Paid Time Off and Sick Pay.

(a) Paid Time Off. Employee shall be entitled to a maximum of twenty (20) working days' off during each one-year period of this Agreement without loss of compensation, to be taken at a time or times mutually agreed upon by the Company and Employee. Paid time off days may be taken only at such times as are mutually convenient for the Company and Employee. Employee acknowledges that all matters regarding paid time off will be subject to the Company's written policy with respect thereto, a copy of which shall be provided to Employee upon commencement of his employment.

(b) Sick Days. Commencing after the first sixty (60) calendar days of Employee's employment, Employee shall be entitled to take a maximum of four (4) sick days per calendar year without loss of compensation. Employee acknowledges that all matters regarding sick leave will be subject to the Company's written policy with respect thereto, a copy of which shall be provided to Employee upon commencement of his employment.

4.3 Business Expenses. The Company shall reimburse Employee monthly for all reasonable business expenses incurred by Employee in performing the Services hereunder, including, without limitation: (a) expenses incurred for business travel; (b) meals, lodging, and ground transportation expenses incurred during business travel; (c) pre-approved promotional expenses; (d) long distance telephone charges; and (e) any other expenses which the Company determines is necessary in connection with the performance of Employee's Services hereunder. Each such expense shall be reimbursable only if it is of such a nature qualifying it as a proper deduction on the federal and state income tax returns of the Company and has been pre-approved in writing by the Company. Employee shall furnish to the Company adequate records, receipts and other documentary evidence required by federal and state statutes and regulations issued by the appropriate taxing authorities for the substantiation of that expenditure as an income tax deduction. Notwithstanding the foregoing, Employee shall not be required to obtain prior written approval for expenditures under the sum of $500. All travel shall be in accordance with the Company's Travel Policy applicable to other C-level executives of the Company.

4.4 Sarbanes-Oxley Act of 2002. Notwithstanding anything herein to the contrary, if the Company determines, in its good faith judgment, that any provision of this Agreement is likely to be interpreted as a personal loan prohibited by the Sarbanes-Oxley Act of 2002 and the rules and regulations promulgated thereunder (the "**Act**"), then such provision shall be modified as necessary or appropriate so as to not violate the Act and if this cannot be accomplished, then the Company shall use its reasonable efforts to provide Employee with similar, but lawful, substitute benefits at a cost to the Company not to significantly exceed the amount the Company would have otherwise paid to provide such benefit(s) to Employee.

4.5 Modification of Benefits. The Company reserves the right from time to time to alter, modify or eliminate benefits offered to it employees under any of the Company's policies or plans.

5. OBLIGATIONS OF EMPLOYEE

5.1 Confidential and Proprietary Information. Employee acknowledges and agrees that he has been given, and during the continuance of this Agreement and in the course of discharging his duties hereunder he will have access to and become acquainted with, information and know-how concerning the operations, products and processes of the Company which are confidential and/or proprietary to the Company (and/or its licensors and affiliates). As a condition of Employee's employment, Employee agrees to execute an At-Will Employment, Confidential Information, and Invention Assignment Agreement (the "**Proprietary Rights Agreement**") which, among other things, shall set forth Employee's obligations with respect to the Company's confidential and proprietary information. An executed copy of the Proprietary Rights Agreement shall be attached hereto as **Exhibit B** and incorporated herein by reference.

5.2 Non-Competition and Non-Solicitation By Employee. Employee acknowledges and agrees that his duty of loyalty to the Company is of paramount importance. As a condition of Employee's employment, Employee acknowledges and agrees to abide by the provisions regarding non-competition and non-solicitation set forth in the Proprietary Rights Agreement attached hereto as **Exhibit B**.

5.3 Equitable Remedies. In the event of a breach or threatened breach of the provisions of Section 5 of this Agreement, including its subsections, the Company shall be entitled to an injunction enjoining Employee from such breach, but nothing herein shall be construed as prohibiting the Company from pursuing in addition any other remedies available for such breach or threatened breach.

6. COMPLIANCE AND REPRESENTATIONS; ETHICAL CONDUCT

6.1 Ethical Conduct. It is the policy of Capricor to conduct its business at all times in accordance with the highest standards of corporate, business and medical ethics. Employee agrees to comply with those standards as more particularly set forth in the Company's Code of Conduct and Ethics in all matters relating to the Services and all other performance under or pursuant to this Agreement.

6.2 Compliance with Laws. In the performance of the Services hereunder, Employee will comply with all applicable laws, rules and regulations of any government or governmental body or board having jurisdiction and all professional standards and guidelines or any code of conduct which may be applicable to persons involved in the conduct of clinical trials.

6.3 No Improper Payments. Employee agrees that he will not, either on his own behalf or on behalf of the Company, make any improper payment or make any donation, or give anything of value, either directly or indirectly, to an official of any government for the purpose of improperly influencing an act or decision of the official in his or her official capacity or inducing the official to use his or her influence to assist Employee or the Company in obtaining or maintaining business or for any other improper purpose prohibited by applicable law or the public policies of the U.S. or any country in which the Company's clinical trials are conducted.

6.4 No Political Payments. Employee shall not, in the name, on behalf or for the benefit of the Company or any of its affiliates or in respect any clinical trial which it is conducting, offer, pay, give, promise to pay or give, or authorize the payment or gift of money or anything of value to any official, political party (or employee of a customer) or to any other person at the request, suggestion or direction of any official, political party (or employee of a customer) or when all or a portion of such money or thing of value will be offered, given or promised, directly or indirectly, to any such person for the purpose of improperly obtaining or retaining business or favorable governmental action.

6.5 **No Debarment**. Employee represents that as of the time of the signing of this Agreement, he has not been debarred in the conduct of clinical trials and he will not knowingly use the services of any debarred person in connection with any work on any clinical trial conducted by the Company. If at any time after execution of this Agreement and continuing for a period of one (1) year after the termination hereof, Employee becomes aware that he or any person utilized for the conduct of any of the Company's clinical trials is, or is knowingly in the process of being debarred, Employee shall so notify the Company in writing immediately.

7. TERMINATION OF EMPLOYMENT

7 . 1 **At-Will Employment**. The employment of Employee shall commence on the Effective Date and shall continue in effect until the termination hereof by either party. The employment of Employee is "At-Will" and may be terminated at the will of either the Company or Employee, with or without cause or notice.

7.2 **Payments Due Upon Termination**. Upon termination of Employee's employment, the Company shall pay to Employee on such date required by applicable law, a lump sum amount in cash equal to Employee's Base Salary and other payments due through the date of termination to the extent not theretofore paid.

8. GENERAL PROVISIONS

8 . 1 **Notices**. Any notices to be given by either party to the other may be effected either by personal delivery in writing, by facsimile or electronic transmission or by mail, registered or certified, postage prepaid. Mailed notices shall be addressed to the parties at the addresses appearing in the introductory paragraph of this Agreement or such other address on file for Employee in Employee's personnel records, but each party may change its address by written notice in accordance with this section. Notices personally delivered or sent by facsimile transmission shall be deemed communicated as of the date of actual receipt; mailed notices shall be deemed communicated two (2) days after the date on which they are mailed.

8 . 2 **Entire Agreement**. This Agreement supersedes any and all other agreements, either oral or in writing, between the parties with respect to the employment of Employee by the Company, excluding any Nondisclosure Agreement previously signed by Employee, the Proprietary Rights Agreement, the written policies adopted by the Company from time to time, and a Dispute Resolution and Mutually Binding Arbitration Agreement to be executed by the parties contemporaneous herewith, and contains all of the covenants and agreements between the parties with respect to that employment in any manner whatsoever. Each party acknowledges that no representations, inducements, promises, or agreements, orally or otherwise, other than those set forth herein, have been made by any party, or anyone acting on behalf of any party, and that no other agreement, statement, or promise between the parties not contained in this Agreement shall be valid or binding on the parties. Any modification of this Agreement will be effective only if it is in writing signed by the party to be charged.

8.3 **Severability.** If any one or more provisions in this Agreement is held by a court of competent jurisdiction to be invalid, void, or unenforceable, such provision shall be judicially modified accordingly to make such provision enforceable and if not possible to reasonably do so, such provision shall be deemed excluded from this Agreement. In such case, the balance of this Agreement shall be interpreted as if such provision were so excluded and shall be enforceable in accordance with its terms.

8.4 **Waiver.** The failure of either party to insist on strict compliance with any of the terms, covenants, or conditions of this Agreement by the other party shall not be deemed a waiver of that term, covenant, or condition, nor shall any waiver or relinquishment of any right or power at any one time or times be deemed a waiver or relinquishment of that right or power for all or any other times.

8.5 **Governing Law**. This Agreement and each of its provisions shall be governed by and construed in accordance with the laws of the State of California (without regard to its conflict of law principles), except that the laws of the State of Delaware shall govern all matters as to the Stock Plan and Stock Option Agreement. The state and federal courts of the State of California in Los Angeles County shall have exclusive jurisdiction to determine any controversies arising in connection with this Agreement or the relationship of the parties.

8.6 **Agreement Binding.** This Agreement shall inure to the benefit of and be binding upon the Company and its affiliates, successors and assigns. The Company will require any successor (whether direct or indirect, by purchase, merger, consolidation or otherwise) to all or substantially all of the business and/or assets of the Company to assume expressly and agree to perform this Agreement in the same manner and to the same extent that the Company would be required to perform it as if no such succession had taken place.

8.7 **Survival**. Notwithstanding any provision of this Agreement to the contrary, the provisions of Sections 5, 6 and 8 (and each of their subsections) shall survive the expiration or termination of this Agreement as necessary to give full effect to all of the provisions contained herein.

8.8 **Headings and Captions**. Section headings and captions used in this Agreement are for reference only and shall not affect the construction of this Agreement.

Signature Page Follows

IN WITNESS WHEREOF, the parties have caused this Agreement to be executed as of the Effective Date.

Capricor, Inc.

By: /s/ Karen Krasney

Name: Karen Krasney

Title: EVP, General Counsel

Employee:

/s/ Leland Gershell, MD, Ph.D.

Leland James Gershell, MD, Ph.D.

Exhibit 21.1

SUBSIDIARIES OF THE REGISTRANT

Legal Name	Jurisdiction of Organization
Capricor, Inc.	Delaware

Exhibit 23.1

CONSENT OF INDEPENDENT REGISTERED PUBLIC ACCOUNTING FIRM

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

We consent to the incorporation by reference in the Registration Statements of Capricor Therapeutics, Inc. on Form S-8 (File Nos. 333-152283, 333-175727, and 333-194317) and Form S-3 (File Nos. 333- 207149, 333-195385, and 333-202589) of our report dated March 28, 2016, relating to the consolidated financial statements, appearing in this Annual Report on Form 10-K.

/s/ Rose, Snyder & Jacobs LLP

Rose, Snyder & Jacobs LLP
Encino, California

March 28, 2016

Exhibit 31.1

CERTIFICATION OF PRINCIPAL EXECUTIVE OFFICER

I, Linda Marbán, Ph.D., certify that:

1. I have reviewed this Annual Report on Form 10-K of Capricor Therapeutics, Inc.;

2. Based on my knowledge, this report does not contain any untrue statement of a material fact or omit to state a material fact necessary to make the statements made, in light of the circumstances under which such statements were made, not misleading with respect to the period covered by this report;

3. Based on my knowledge, the financial statements, and other financial information included in this report, fairly present in all material respects the financial condition, results of operations and cash flows of the registrant as of, and for, the periods presented in this report;

4. The registrant's other certifying officer and I are responsible for establishing and maintaining disclosure controls and procedures (as defined in Exchange Act Rules 13a-15(e) and 15d-15(e)) and internal control over financial reporting (as defined in Exchange Act Rules 13a-15(f) and 15d-15(f)) for the registrant and have:

a) Designed such disclosure controls and procedures, or caused such disclosure controls and procedures to be designed under our supervision, to ensure that material information relating to the registrant, including its consolidated subsidiaries, is made known to us by others within those entities, particularly during the period in which this report is being prepared;

b) Designed such internal control over financial reporting, or caused such internal control over financial reporting to be designed under our supervision, to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements for external purposes in accordance with generally accepted accounting principles;

c) Evaluated the effectiveness of the registrant's disclosure controls and procedures and presented in this report our conclusions about the effectiveness of the disclosure controls and procedures, as of the end of the period covered by this report based on such evaluation; and

d) Disclosed in this report any change in the registrant's internal control over financial reporting that occurred during the registrant's most recent fiscal quarter (the registrant's fourth fiscal quarter in the case of an annual report) that has materially affected, or is reasonably likely to materially affect, the registrant's internal control over financial reporting.

5. The registrant's other certifying officer and I have disclosed, based on our most recent evaluation of internal control over financial reporting, to the registrant's auditors and the audit committee of the registrant's board of directors (or persons performing the equivalent functions):

a) All significant deficiencies and material weaknesses in the design or operation of internal control over financial reporting which are reasonably likely to adversely affect the registrant's ability to record, process, summarize and report financial information; and

b) Any fraud, whether or not material, that involves management or other employees who have a significant role in the registrant's internal control over financial reporting.

Date: March 30, 2016

/s/ Linda Marbán, Ph.D.
Name: Linda Marbán, Ph.D.
Title: Chief Executive Officer and Principal Executive Officer

Exhibit 31.2

CERTIFICATION OF PRINCIPAL FINANCIAL OFFICER

I, Leland Gershell, M.D., Ph.D. certify that:

1. I have reviewed this Annual Report on Form 10-K of Capricor Therapeutics, Inc.;

2. Based on my knowledge, this report does not contain any untrue statement of a material fact or omit to state a material fact necessary to make the statements made, in light of the circumstances under which such statements were made, not misleading with respect to the period covered by this report;

3. Based on my knowledge, the financial statements, and other financial information included in this report, fairly present in all material respects the financial condition, results of operations and cash flows of the registrant as of, and for, the periods presented in this report;

4. The registrant's other certifying officer and I are responsible for establishing and maintaining disclosure controls and procedures (as defined in Exchange Act Rules 13a-15(e) and 15d-15(e)) and internal control over financial reporting (as defined in Exchange Act Rules 13a-15(f) and 15d-15(f)) for the registrant and have:

a) Designed such disclosure controls and procedures, or caused such disclosure controls and procedures to be designed under our supervision, to ensure that material information relating to the registrant, including its consolidated subsidiaries, is made known to us by others within those entities, particularly during the period in which this report is being prepared;

b) Designed such internal control over financial reporting, or caused such internal control over financial reporting to be designed under our supervision, to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements for external purposes in accordance with generally accepted accounting principles;

c) Evaluated the effectiveness of the registrant's disclosure controls and procedures and presented in this report our conclusions about the effectiveness of the disclosure controls and procedures, as of the end of the period covered by this report based on such evaluation; and

d) Disclosed in this report any change in the registrant's internal control over financial reporting that occurred during the registrant's most recent fiscal quarter (the registrant's fourth fiscal quarter in the case of an annual report) that has materially affected, or is reasonably likely to materially affect, the registrant's internal control over financial reporting.

5. The registrant's other certifying officer and I have disclosed, based on our most recent evaluation of internal control over financial reporting, to the registrant's auditors and the audit committee of the registrant's board of directors (or persons performing the equivalent functions):

a) All significant deficiencies and material weaknesses in the design or operation of internal control over financial reporting which are reasonably likely to adversely affect the registrant's ability to record, process, summarize and report financial information; and

b) Any fraud, whether or not material, that involves management or other employees who have a significant role in the registrant's internal control over financial reporting.

Date: March 30, 2016

/s/ Leland Gershell, M.D., Ph.D.
Name: Leland Gershell, M.D., Ph.D.
Title: Chief Financial Officer and Principal Financial Officer

Exhibit 32.1

CERTIFICATION OF PRINCIPAL EXECUTIVE OFFICER
PURSUANT TO
18 U.S.C. SECTION 1350,
AS ADOPTED PURSUANT TO
SECTION 906 OF THE SARBANES-OXLEY ACT OF 2002

Pursuant to 18 U.S.C. § 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002, Linda Marbán, Ph.D., the Principal Executive Officer of Capricor Therapeutics, Inc. (the "**Company**"), hereby certifies, to her knowledge, that:

(1) the Annual Report on Form 10-K of the Company for the quarterly period ended December 31, 2015 (the " **Report**") fully complies with the requirements of Section 13(a) or Section 15(d), as applicable, of the Securities Exchange Act of 1934, as amended; and

(2) the information contained in the Report fairly presents, in all material respects, the financial condition and results of operations of the Company for the period covered by the Report.

Date: March 30, 2016

/s/ Linda Marbán, Ph.D.
Name: Linda Marbán, Ph.D.
Title: Chief Executive Officer and Principal Executive Officer

Exhibit 32.2

CERTIFICATION OF PRINCIPAL FINANCIAL OFFICER
PURSUANT TO
18 U.S.C. SECTION 1350,
AS ADOPTED PURSUANT TO
SECTION 906 OF THE SARBANES-OXLEY ACT OF 2002

Pursuant to 18 U.S.C. § 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002, Leland Gershell, M.D., Ph.D., the Principal Financial Officer of Capricor Therapeutics, Inc. (the "**Company**"), hereby certifies, to his knowledge, that:

(1) the Annual Report on Form 10-K of the Company for the quarterly period ended December 31, 2015 (the " **Report**") fully complies with the requirements of Section 13(a) or Section 15(d), as applicable, of the Securities Exchange Act of 1934, as amended; and

(2) the information contained in the Report fairly presents, in all material respects, the financial condition and results of operations of the Company for the period covered by the Report.

Date: March 30, 2016

/s/ Leland Gershell, M.D., Ph.D.
Name: Leland Gershell, M.D., Ph.D.
Title: Chief Financial Officer and Principal Financial Officer