CAPRICOR THERAPEUTICS, INC.
Form 10-K
March 16, 2017

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, 2016

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, 2016: $32,566,107

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 14, 2017, there were 21,399,019 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 2017 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, 2016 are incorporated by reference into Part III of this Annual Report on Form 10-K.

TABLE OF CONTENTS

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

FORWARD-LOOKING STATEMENTS

This 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 and pre-clinical studies. 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, 2016 are not necessarily indicative of results that may be attained in the future.

PART I

ITEM 1. BUSINESS

Overview

Capricor Therapeutics, Inc. is a clinical-stage biotechnology company focused on the discovery, development and commercialization of first-in-class biological therapies for the treatment of cardiac and other medical conditions.

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, 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, or as amended, the Merger Agreement, by and among Nile, Nile's wholly-owned subsidiary, Bovet Merger Corp., a Delaware corporation, or Merger Sub, and Capricor, Inc., or Capricor, a Delaware corporation, Merger Sub merged with and into Capricor and Capricor became a wholly-owned subsidiary of Nile (referred to herein as the Merger). Immediately prior to the effective time of the Merger and in connection therewith, Nile filed certain amendments to its certificate of incorporation which, among other things, (i) effected a 1-for-50 reverse split of its common stock, (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 first-in-class biological therapies for the treatment of cardiac and other medical conditions. Our drug candidates in active development consist of CAP-1002 (allogeneic cardiosphere-derived cells, or CDCs) and CAP-2003 (CDC exosomes).

We are developing CAP-1002 for the treatment of certain conditions that result from damage to the heart muscle. We have conducted the DYNAMIC trial, a Phase I clinical trial of CAP-1002 in subjects with advanced heart failure, and we are currently conducting the ALLSTAR trial, a Phase II clinical trial of CAP-1002 in subjects who have suffered a myocardial infarction, or MI, which is commonly known as a heart attack. We are also currently conducting the HOPE trial, a Phase I/II clinical trial of CAP-1002 in subjects with heart disease associated with Duchenne muscular dystrophy, or DMD.

We are developing CAP-2003 for the treatment of certain cardiac and inflammatory conditions. CAP-2003 is currently in pre-clinical development and we expect to submit an Investigational New Drug application, or IND, to the U.S. Food and Drug Administration, or the FDA, in the second half of 2017.

These programs represent our core technology and products.

Background on Heart Disease, Heart Failure, and Duchenne Muscular Dystrophy

Heart Disease

Heart disease is the number one cause of death in the United States and in the world. According to the American Heart Association, an estimated 85 million people in the U.S. have some form of heart disease, representing over $207 billion in direct and indirect costs annually. Despite the availability of a variety of medical and surgical options by which many types of heart disease and the oft-associated adverse neurohormonal response may be managed, including medications such as beta-blockers, calcium channel blockers, angiotensin modulators, and aldosterone receptor antagonists and including implanted devices such as coronary stents, implanted pacemakers, resynchronization therapy and cardioverter-defibrillators, their collective ability to adequately address the heart disease population is limited by their degrees and durabilities of benefit as well as their tolerabilities and other risks. None of these interventions have reliably been shown to correct the underlying disease process, an important deficiency given the progressive nature of many types of heart disease. Mechanical circulatory support, and for selected patients, heart transplantation, may ultimately be necessary in those cases in which the utility of more conservative options is no longer sufficient.

The most common form of heart disease is coronary heart disease, characterized by a buildup of plaque inside the coronary arteries which supply blood to the heart. Plaque consists 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. If the flow of blood is not restored within a few minutes, heart muscle cells in the area of the blocked artery will die. This acute event is known as a myocardial infarction, the medical term for a heart attack. The area of infarct is eventually replaced by a permanent and non-contractile collagen scar that can adversely impact heart function. The size of the resulting scar has been shown to correlate with the pump function of the heart, with larger scars predicting worse outcomes. Despite best available therapy, patients who suffer an MI often continue to experience degeneration or weakening of their heart muscle, which can lead to heart failure and a shortened lifespan.

According to the American Heart Association, coronary heart disease afflicts over 15 million people in the U.S. and causes nearly 50% of heart disease deaths. 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 causes of hospitalization. Coronary heart disease is the most common cause of MI, which strikes approximately 750,000 Americans each year, often leading to repeated hospitalizations, a decrease in quality of life, and premature death. More than seven million people in the U.S. have had a heart attack.

Heart Failure & Dilated Cardiomyopathy

Heart failure, or HF, is a progressive condition in which the heart is unable to pump sufficiently to maintain blood flow to meet the body's needs. When the heart does not circulate blood adequately, the kidneys receive less blood and filter less fluid out of the circulation into the urine. The extra fluid in the circulation may build up in the lungs, the liver and in the legs. Signs and symptoms commonly include shortness of breath, progressive tiredness, and leg swelling, and can make everyday activities more difficult or impossible.

Dilated cardiomyopathy is a 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 MI, 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 failure worsens.

According to the American Heart Association, heart failure affects over five million Americans and is the fastest-growing clinical cardiac condition in the United States. The number of U.S. adults with heart failure is expected to increase to approximately eight million by 2030. Heart failure is responsible for over one million hospital admissions each year in the U.S. and generates annual inpatient costs of more than $20 billion. Among patients older than 65 years, heart failure is the most frequent cause of hospitalization. Of those patients who have been admitted,

approximately 24% are re-hospitalized in one month and approximately 50% are re-hospitalized in six months.

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 worldwide, and it is estimated that approximately 15,000 to 20,000 boys and young men are living with the disease in the U.S. DMD results from the lack of functional dystrophin protein 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 DMD patients, heart muscle cells progressively die and are replaced with scar tissue. This cardiomyopathy eventually leads to heart failure, which is currently the leading cause of death among those with DMD. There are no therapies that are currently approved to treat cardiomyopathy secondary to DMD.

Our Technology

Our core therapeutic technology is based on the cardiosphere-derived cell, or CDC, a type of cardiac progenitor cell that composes a minor fraction of the cardiac muscle cell population and was first identified in the academic laboratory of Capricor's scientific founder, Dr. Eduardo Marbán. Since their initial report in 2007, CDCs have been the subject of over 100 peer-reviewed scientific publications and have been administered to approximately 140 human subjects across several clinical trials. We are currently developing allogeneic CDCs (CAP-1002) as a product candidate for the treatment of cardiac disorders as well as exosomes produced by CDCs (CAP-2003) as a product candidate for the treatment of certain cardiac and inflammatory conditions.

Cardiosphere-Derived Cells

Preclinical and clinical data support the therapeutic concept of administering CDCs as a means to address conditions in which the heart muscle has been damaged. Although CDCs that are naturally present in the heart may serve to facilitate the repair of minor injury to the heart muscle as may occur in the course of daily living, for example as a result of intensive exercise, they may be insufficient to counteract catastrophic injury, such as that which occurs in a myocardial infarction, or chronic injury, such as that which occurs in heart failure or in DMD.

In a variety of experimental models of heart injury, CDCs have been shown to stimulate cell proliferation and blood vessel growth, to inhibit programmed cell death and scar formation, and to attract native progenitor cells to the site of injury.

In the CADUCEUS trial, a randomized clinical trial sponsored by Cedars-Sinai Medical Center in collaboration with The Johns Hopkins University and conducted in 25 patients who had recently suffered a heart attack, a single infusion of autologous CDCs (i.e., CDCs derived from the patient's own heart tissue) into the coronary artery associated with the infarcted region, compared to standard-of-care controls, demonstrated a statistically significant reduction in scar mass and increase viable muscle mass, as assessed by blinded cardiac MRI analysis at six and 12 months of follow-up. This trial was funded by the National Heart Lung and Blood Institute, or the NHLBI, Specialized Centers for Cell-Based Therapy.

In the DYNAMIC trial, an open-label, single administration, ascending dose clinical trial conducted in 14 patients with New York Heart Association, or NYHA, Class III heart failure secondary to dilated cardiomyopathy in which CAP-1002 (allogeneic CDCs, or CDCs derived from donor heart tissue) was infused into each of the three major coronary arteries, a pooled-dose analysis showed that measures of functional status and capacity, cardiac function and dimension, and quality-of-life broadly showed trends of improvement from baseline at six and 12 months of

follow-up. These results included the findings of statistically-significant improvements in NYHA Class, left ventricular ejection fraction, or LVEF, and the Minnesota Living with Heart Failure Questionnaire score at six months. The level of significance for LVEF improvement was maintained at 12 months.

CDCs are derived from cardiospheres, or CSps, which are self-assembling multicellular clusters which contain both primitive cells and committed progenitors for the three major cell types present in the heart. Although CSps have been demonstrated to possess regenerative properties in pre-clinical studies, their relatively large size makes them less suitable than CDCs for delivery into the coronary arteries due to the risk of intra-arterial obstruction. CDCs are sufficiently small that, within acceptable dose limits, they can be infused into a coronary artery. Capricor has performed clinical studies to establish the range of CDC dose levels that appear to be safe to deliver to the heart.

While CSps and their respective CDCs may originate from either a deceased human donor (allogeneic source) or from heart tissue taken directly from recipient patients themselves (autologous source), the methods for manufacturing CDCs from either source are similar.

Capricor's proprietary methods are focused on producing therapeutic doses of CDCs to boost the regenerative capacity of the heart, with the goal of improving cardiac function. Capricor has exclusively licensed intellectual property covering CDCs and CSps from three academic institutions and is also pursuing its own intellectual property rights relating to these product candidates.

Cardiosphere-Derived Cell Exosomes

Exosomes are nano-sized, membrane-enclosed vesicles, or "bubbles" that are secreted by essentially all cells and contain bioactive molecules, including proteins, RNAs and microRNAs. They act as messengers to regulate the functions of neighboring cells, and pre-clinical research has shown that exogenously-administered exosomes can direct or, in some cases, re-direct cellular activity, thereby supporting their therapeutic potential. Their size, ease of crossing cell membranes, and ability to communicate in native cellular language makes them an exciting, emerging class of potential therapeutic agents. Exosomes are a cell-free substance and may be stored, handled, reconstituted, and administered in similar fashion to common biopharmaceutical products such as antibodies.

Exosomes secreted by CDCs, or CDC exosomes, are capable of producing the effects observed with CDCs themselves, including anti-inflammatory, anti-angiogenic, anti-apoptotic, and anti-fibrotic effects. In pre-clinical models of ischemic heart disease, CDC exosomes prompt myocardial regeneration as well as various structural and functional improvements within the heart. These findings suggest that CDC exosomes may serve as a critical mediator of the actions of CDCs, and support the concept of their development as a therapeutic agent.

Our Product Candidates

We have four drug candidates, two of which are in various stages of active development. Our current research and development efforts are focused on CAP-1002 and CAP-2003. CAP-1002 is the subject of two ongoing clinical trials, and we expect to enter CAP-2003 into clinical development in the second half of 2017. CAP-1001 (autologous CDCs) was the subject of the CSMC and JHU-sponsored Phase I CADUCEUS trial and is not in active development. Both CAP-1002 and CAP-1001 are derived from CSps, and we do not plan to develop CSps as a therapeutic.

The following table summarizes our active product development programs:

Product	**Indication/Population**	**Development Stage**	**Commercial Rights***
CAP-1002	Post-Myocardial Infarction with Cardiac Dysfunction	Phase II	Capricor
	Advanced Heart Failure	Phase I completed	Capricor
	Duchenne Muscular Dystrophy-Associated Cardiomyopathy**	Phase I/II	Capricor
CAP-2003	Inflammatory conditions	Preclinical	Capricor
	Hypoplastic Left Heart Syndrome (HLHS)	Preclinical	Capricor

*Janssen Biotech, Inc. 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 CDCs in the field of cardiology, except as may otherwise be agreed with respect to certain indications to be determined.

** FDA has granted Orphan Drug designation to CAP-1002 for the treatment of DMD.

CAP-1002:

We are currently conducting two clinical trials of our lead product candidate, CAP-1002: the Phase II portion of the Phase I/II ALLSTAR trial in patients who have had an MI, and the Phase I/II HOPE-Duchenne trial in patients with DMD-associated cardiomyopathy. We have completed the Phase I portion of the Phase I/II DYNAMIC trial in patients with advanced heart failure.

Phase I/II ALLSTAR Clinical Trial

The Phase I portion of the ALLSTAR trial was a 14-patient, open-label, dose-escalation study that was conducted to evaluate the clinical safety of CAP-1002. Each patient received a single infusion of CAP-1002 into the coronary artery most closely associated with the location of their MI, at a dose level of either 12.5 million or 25 million cells. The primary safety endpoints focused on the potential adverse effects of CAP-1002 delivery, including potential immunologic consequences of infusing cells that had originated from an unrelated donor. Enrollment was completed in October 2013. Event rates observed for each of the four pre-specified safety endpoints (acute myocarditis possibly attributable to CAP-1002; death due to ventricular tachycardia or ventricular fibrillation; sudden death; and major adverse cardiac events) were 0% over one and 12 months following CAP-1002 infusion.

Updated preliminary 12-month magnetic resonance imaging, or MRI, data revealed that those Phase I patients who would have been eligible for randomization into the Phase II clinical study by virtue of dose and tissue type compatibility exhibited a reduction in infarct, or scar, size of 15% from baseline. These data also indicated a 4% improvement from baseline in ejection fraction, a global measure of the heart's pumping ability. Measurements of viable mass and regional function also showed quantifiable improvements. This Phase I study was funded in large part by a grant received from the National Institutes of Health, or NIH.

In December 2013, the Gene and Cell Therapy Data Safety Monitoring Board of the NHLBI notified Capricor that it had had met its safety endpoints and that Capricor was cleared to begin the Phase II portion of the ALLSTAR trial.

Capricor began enrollment of the Phase II ALLSTAR study in the first quarter of 2014. This randomized, double-blind, placebo-controlled trial is designed to determine if treatment with CAP-1002 can reduce scar size in patients who have suffered an MI. At the time of randomization, patients were stratified into one of two cohorts according to the time since the occurrence of their MI (either 30 to 90 days after the MI, or greater than 90 days up to one-year after the MI). Following infusion, patients are to be followed for periodic evaluations over the course of one year. As such, CAP-1002 is being evaluated in the setting of both acute MI, in which the scar has recently formed, and chronic MI, in which the scar is more established. Patients were randomized in a 2:1 ratio to receive an infusion of CAP-1002 (25 million cells) or placebo, respectively, into the coronary artery most closely associated with the region of their MI. The trial is powered to detect a reduction in scar size, relative to placebo, as measured by MRI at the 12-month follow-up. In addition to evaluating CAP-1002 according to changes in scar size, ALLSTAR will also evaluate CAP-1002 according to a variety of clinical and quality of life endpoints. The Phase II portion of the ALLSTAR trial is being funded in large part through the support of the California Institute for Regenerative Medicine, or CIRM.

Based on information available to us at the start of enrollment into the Phase II ALLSTAR trial, we initially designed this study to enroll up to 300 patients. Following the completion of statistical modeling of the design of ALLSTAR which incorporated the expanded dataset that had become available from other clinical trials of our CDCs, we 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 scar size as measured by MRI at 12 months. We have amended our clinical protocol to reflect these changes, which amendment was approved by the Data Safety Monitoring Board and was submitted to the FDA in February 2016.

In October 2016, we announced completion of enrollment of the Phase II portion of the ALLSTAR trial in which 142 subjects were randomized to the active or control treatment groups in a 2:1 ratio, respectively, and of whom 134 received a single infusion of either CAP-1002 or placebo into the infarct-associated coronary artery. Patients in the trial were enrolled at approximately 30 centers in the U.S. and in Canada.

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 CSps and CDCs in the field of cardiology, except as may otherwise be agreed with respect to certain indications to be determined. 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 the Phase II portion of the ALLSTAR clinical trial of CAP-1002. We expect to receive Janssen's decision with respect to this option in the third quarter of 2017 following the delivery of the six-month results from the ALLSTAR trial.

Phase I/II HOPE-Duchenne Clinical Trial

We are currently conducting the randomized, controlled, multi-center Phase I/II HOPE-Duchenne clinical trial which was designed to evaluate the safety and exploratory efficacy of CAP-1002 in approximately 24 patients with cardiomyopathy associated with DMD. Patients were randomized in a 1:1 ratio to receive either CAP-1002 or usual care available for DMD-associated cardiomyopathy. In patients receiving CAP-1002, a dose of 25 million cells was infused into each of the three main coronary arteries (75 million cells total), which allowed for CAP-1002 to be delivered to large areas of the myocardium. Patients are to be followed for periodic evaluations over the course of 12 months. Exploratory efficacy will be evaluated according to several different outcome measures, including cardiac MRI. This study is funded in part through a grant award from CIRM. Those patients who did not receive CAP-1002 may be eligible to receive open-label CAP-1002 after all participants have completed the controlled portion of the study and the Data Safety Monitoring Board has given the recommendation to proceed with the open-label extension. In April 2015, the FDA granted Orphan Drug designation to CAP-1002 for the treatment of DMD.

We announced the completion of enrollment of 25 patients in the HOPE-Duchenne trial in September 2016. To date, the Data Safety Monitoring Board has completed four safety reviews, and following each review, recommended that the trial continue. We expect to report top-line six-month results early in the second quarter of 2017 and report top-line 12-month results in the fourth quarter of 2017.

Additionally, depending upon trial results and available resources, we are planning to expand our CAP-1002 clinical development program in DMD beyond cardiac aspects of the disease. This expansion includes the conduct of a clinical trial which we plan to commence in the second half of 2017, subject to regulatory approval.

Phase I/II DYNAMIC Clinical Trial

The Phase I/II DYNAMIC trial, of which the Phase I portion has concluded, was designed to evaluate the safety and efficacy of CAP-1002 in the treatment of patients with advanced heart failure resulting from dilated cardiomyopathy of either ischemic or non-ischemic origin. This condition is characterized by chronic structural and functional abnormalities present throughout the heart's contractile tissue. In the DYNAMIC trial, CAP-1002 was infused into all three main coronary arteries to obtain broad exposure. Following infusion, patients were followed for one year. The trial was funded in part through a grant award from the NIH.

We initiated the open-label, dose-escalating Phase I portion of the DYNAMIC trial in December 2014 at a single center, CSMC, and in April 2015, completed enrollment with 14 patients with NYHA Class III heart failure. Each patient was administered CAP-1002 via a one-time, triple coronary infusion at one of several evenly-divided dose levels (37.5 million, 50 million, 62.5 million, or 75 million cells total). Initial top-line six-month 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. Although this trial was intended as a safety study, the six-month data demonstrated encouraging and congruent preliminary efficacy signals in multiple parameters, including ejection fraction, ventricular volumes, exercise capacity and subjective well-being.

In June 2016, Capricor reported positive 12-month data from the DYNAMIC study. For the 12 patients available for follow-up at one year, improvements from baseline in key cardiac function and dimensional indices that had been observed at six months were directionally maintained. Importantly, the change in median left ventricular ejection fraction from baseline to 12 months maintained its level of statistical significance that was shown at six months ($p=0.02$ at both time points) and, on an absolute basis, continued to improve from six to 12 months. Of the five NYHA Class III subjects who received the highest dose of CAP-1002 (75 million cells), two subjects improved by two Classes (to Class I) and three improved by one Class (to Class II) at six months. At 12 months, three of these five subjects were assessed as Class I and two as Class II, demonstrating further improvement and indicating durability of the benefit of CAP-1002 on heart failure status for as long as one year following administration. CAP-1002 infusion

was well-tolerated in DYNAMIC. Two of the 14 patients, who were in the lower two of the four dose cohorts, died from progressive heart failure approximately one and three months prior to study conclusion. Although we have designed a Phase II study to evaluate CAP-1002 in the heart failure population, at this time we have not made a determination with respect to conducting the Phase II portion of the DYNAMIC trial.

CAP-2003:

CAP-2003 comprises of exosomes secreted by CDCs, and is believed to mediate many of the effects that are observed with these cells, including anti-inflammatory, anti-angiogenic, anti-apoptotic, and anti-fibrotic effects. We are currently conducting studies in pre-clinical models of cardiac, inflammatory and various other conditions to explore the possible therapeutic benefits that CAP-2003 may possess. We are planning to evaluate CAP-2003 in preclinical studies for the treatment of HLHS. We hope to submit an IND for CAP-2003 to enable clinical development in the second half of 2017.

CAP-1001:

CAP-1001 consists of autologous CDCs. This product candidate was evaluated in the randomized, double-blind, placebo-controlled Phase I CADUCEUS clinical trial in patients who had recently experienced an MI. The study was sponsored and conducted by CSMC in collaboration with JHU. Of the 25 patients enrolled, 17 received an intracoronary infusion of CAP-1001 and eight received standard of care. 16 of the 17 patients treated with CAP-1001 showed a mean reduction of approximately 45% in scar mass and an increase in viable heart muscle at one-year following MI. The eight patients in the control group had no significant change in scar size. The data from CADUCEUS, using autologous CDCs, suggests that CDCs are effective in reducing scar size within several months of a heart attack. The design of our ongoing ALLSTAR trial of CAP-1002, an allogeneic product, is based on the results of CADUCEUS. In addition, ALLSTAR is evaluating the potential efficacy of CAP-1002 in patients between 90 days and one year post-MI, a patient population that CADUCEUS was not designed to study. At present, there is no plan for another clinical trial for CAP-1001.

CSps:

CSps are a 3D micro-tissue from which CDCs are derived, and have shown significant healing effects in pre-clinical models of heart failure. While we consider CSps an important asset, at present there is no plan to develop CSps as a therapeutic agent.

Natriuretic Peptides:

We have recently discontinued further development of two of our former natriuretic peptide product candidates, Cenderitide (CD-NP) and CU-NP, to more efficiently focus our resources and efforts on our cell therapy (CAP-1002) and CDC exosomes (CAP-2003) programs. For additional information, see “Intellectual Property and Proprietary Know-How — Company Technology – Cenderitide and CU-NP” contained in Part I, Item 1 to this Annual Report on Form 10-K and Note 10 to our accompanying consolidated financial statements included in Part II, Item 8 of this Annual Report on Form 10-K.

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 relevant to our technologies and 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 in 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. Our issued patents would expire as early as 2024 and as late as 2031 upon payment of patent maintenance fees. There are also limited opportunities to obtain extensions of patent terms in certain countries.

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 La Sapienza, or the University of Rome, JHU and CSMC. In addition, Capricor has filed patent applications related to enhancements or validation of the technology developed by its own scientists.

University of Rome License Agreement

Capricor and the University of Rome entered into a License Agreement, dated June 21, 2006, or 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, or 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. 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.

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, or the Original CSMC License Agreement, for certain intellectual property rights. In 2013, the Original 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, or 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 Original 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.

On August 5, 2016, Capricor and CSMC entered into a Second Amendment to the Amended CSMC License Agreement, or the Second License Amendment, pursuant to which the parties agreed to add certain patent families to the schedule of patent rights set forth in the agreement. Under the Second License Amendment, (i) the description of

patent rights in Schedule A has been replaced by a Revised Schedule A that includes two additional patent family applications; (ii) Capricor paid an upfront fee of $2,500; and (iii) Capricor reimbursed CSMC approximately $10,000 for attorneys' fees and filing fees that were incurred in connection with the additional patent families.

License Agreement for Exosomes

On May 5, 2014, Capricor entered into an Exclusive License Agreement with CSMC, or 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 Exosomes License Agreement, or the First Exosomes License Amendment. Under the First 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 Exosomes License Agreement, thereby amending the Exosomes License Agreement further to add an additional patent application to the Schedule of Patent Rights.

On August 5, 2016, Capricor and CSMC entered into a Third Amendment to the Exosomes License Agreement, or the Third Exosomes License Amendment pursuant to which the parties agreed to add certain patent families to the schedule of patent rights under the agreement. Under the Third Exosomes License Amendment, (i) the description of patent rights in Schedule A has been replaced by a Revised Schedule A that includes two additional patent family applications; (ii) Capricor paid CSMC an upfront fee of $2,500; and (iii) Capricor reimbursed CSMC approximately $16,000 for attorneys' fees and filing fees that were incurred in connection with the additional patent families.

Collaboration Agreement with Janssen Biotech, Inc.

On December 27, 2013, Capricor entered into a Collaboration Agreement and Exclusive License Option, or 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 agreed to contribute to the development of a chemistry, manufacturing and controls 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 CSps and CDCs in the field of cardiology, except as may otherwise be agreed with respect to certain indications to be determined. 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 entered into an exclusive license agreement for intellectual property rights related to natriuretic peptides with the Mayo Foundation for Medical Education and Research, or Mayo, a Clinical Trial Funding Agreement with Medtronic, Inc., or 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 SEC, on September 21, 2007, and which was amended on June 2, 2008, or 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, or 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, or the Amended Mayo Agreement. The Amended Mayo Agreement amended and restated in its entirety each of the CD-NP Agreement and the CU-NP Agreement, and created a single amended and restated license agreement between the Company and Mayo with respect to CD-NP and CU-NP.

On February 13, 2017, the Company provided Mayo with a notice of termination of the Amended Mayo Agreement pursuant to Section 7.03 of the Amended Mayo Agreement, thereby relinquishing all rights previously licensed by Mayo to Capricor with respect to CD-NP and CU-NP. The Company provided 90 days' notice of the effectiveness of termination, but Mayo has indicated to the Company that it considers the Amended Mayo Agreement to be terminated as of February 14, 2017 due to an ongoing dispute with Mayo regarding the payment of certain fees incurred in the prosecution of the intellectual property rights licensed by Mayo to the Company, which fees the Company does not deem to be material in amount. The Company elected to terminate the Amended Mayo Agreement so we may focus our resources and efforts on our cell therapy (CAP-1002) and CDC exosomes (CAP-2003) programs.

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, or 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 subsequently entered into a Transfer Agreement, described below.

Medtronic Transfer Agreement

On October 8, 2014, the Company entered into a Transfer Agreement, or 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, or the 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 with 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.

In light of our decision to terminate our development program with respect to natriuretic peptides, the Company is now considering whether or not to cease prosecution of some or all of the Natriuretic Peptide Patents and has offered to reassign to Medtronic rights to certain patent applications obtained through the Transfer Agreement.

Manufacturing

Capricor presently maintains its laboratory and research facilities in leased premises located at CSMC, or the CSMC Lease. We presently manufacture CAP-1002 and CAP-2003 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 current Good Manufacturing Practice, or cGMP, approved facility. Capricor manufactured CAP-1002 at this facility for its ongoing ALLSTAR and HOPE-Duchenne clinical studies. Capricor has commenced discussions on an amendment to the CSMC Lease with CSMC to extend the term of the CSMC Lease and include the manufacturing facility within its provisions. If CSMC revokes its permission to allow Capricor to utilize the manufacturing facility, Capricor would have to secure alternative facilities in which to manufacture its products, which would involve a significant monetary investment and would negatively impact the progress of our planned 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.

In addition to manufacturing CAP-1002 for its own clinical trials, Capricor has agreed, subject to final documentation, to provide CAP-1002 for investigational purposes in two clinical trials sponsored by CSMC. The first trial is known as "Regression of Fibrosis and Reversal of Diastolic Dysfunction in HFpEF Patients Treated with Allogeneic CDCs." Dr.

Eduardo Marbán is the named principal investigator under the study. The second trial is known as “Pulmonary Arterial Hypertension treated with Cardiosphere-derived Allogeneic Stem Cells.” In both studies, Capricor will provide the necessary number of doses and will receive a negotiated amount of monetary compensation therefor.

CAP-1001:

The manufacturing process for CAP-1001 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 approximately 6-8 weeks post-biopsy until the product can be administered to the patient.

CAP-1002:

The general 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 that was collected from an organ procurement organization, or 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.

CAP-2003:

The process for manufacturing CAP-2003 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 these 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 cell-derived product.

Research and Development

Capricor's research and development program has been advanced in part through federal and state grants and loan awards totaling over approximately $30.0 million to date. Our ongoing research and development activities primarily concern CDCs and CDC exosomes, and are focused on the characterization of their composition and actions, the evaluation of their therapeutic potential in selected disease settings, the development of next generation product candidates, and the identification of new technologies and indications. Capricor spent approximately $16.0 million and $13.8 million on research and development activities for the years ended December 31, 2016 and 2015, respectively.

Competition

We are engaged in fields that are characterized by extensive worldwide research and competition by pharmaceutical companies, medical device companies, specialized biotechnology companies, hospitals, physicians and academic institutions, both in the United States and abroad. The pharmaceutical industry is highly competitive, with a number of established, large pharmaceutical companies, as well as many smaller companies. Many of the organizations competing with us have substantially greater financial resources, larger research and development staffs and facilities, longer drug development history in obtaining regulatory approvals, and greater manufacturing and marketing capabilities than we do. There are many pharmaceutical companies, biotechnology companies, public and private universities, government agencies, and research organizations actively engaged in research and development of products which may target the same indications as our product candidates. We expect any future products and product candidates we develop to compete on the basis of, among other things, product efficacy and safety, time to market, price, extent of adverse side effects, and convenience of treatment procedures. The biotechnology and pharmaceutical industries are subject to rapid and significant technological change. The drugs that we are attempting to develop will have to compete with existing therapies. Our future success will depend in part on our ability to maintain a competitive position with respect to evolving cell therapy and exosome 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 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 the FDA's 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 IND, human clinical trials and filing and approval of either an NDA, for chemical pharmaceutical products, or a BLA for biological pharmaceutical products. The results of pre-clinical testing, which include laboratory evaluation of product chemistry and formulation, animal studies to assess the potential safety and efficacy of the product and its formulations, details concerning the drug manufacturing process and its controls, and a proposed clinical trial protocol and other information must be submitted to the FDA as part of an IND that must be reviewed and become effective before clinical testing can begin. The study protocol and informed consent information for patients in clinical trials must also be submitted to an independent Institutional Review Board, or IRB, for approval covering each institution at which the clinical trial will be conducted. Once a sponsor submits an IND, the sponsor must wait 30 calendar days before initiating any clinical trials. If the FDA has comments or questions within this 30-day period, the issue(s) must be resolved to the satisfaction of the FDA before clinical trials can begin. In addition, the FDA, an IRB or Capricor may impose a clinical hold on ongoing clinical trials due to safety concerns. If the FDA imposes a clinical hold, clinical trials can only proceed under terms authorized by the FDA. Our non-clinical and clinical studies must conform to the FDA's Good Laboratory Practice, or GLP, and Good Clinical Practice, or GCP, requirements, respectively, which are designed to ensure the quality and integrity of submitted data and protect the rights and well-being of study patients. Information for certain clinical trials also must be publicly disclosed within certain time limits on the clinical trial registry and results databank maintained by the NIH.

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

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

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- 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 Risk Evaluation and Mitigation Strategy 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.

Additionally, we will have to establish a collaboration agreement with a third party or build out our own manufacturing facility to support for a Phase III trial, or other registration trial or for commercialization purposes.

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. We have included our website address in this Annual Report on Form 10-K solely as an inactive textual reference.

Employees

Currently, we have 38 full-time employees and two 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. Certain officers of Capricor 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. Capricor leases space for its corporate offices pursuant to a lease that was originally 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, or the Second Lease Amendment, 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 Lease 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 25, 2016, Capricor entered into a Third Amendment to Lease, or the Third Lease Amendment, with The Bubble Real Estate Company, LLC. Under the terms of the Third Lease Amendment, the lease term commenced on July 1, 2016 and will end on December 31, 2018. Commencing July 1, 2016, the base rent increased to $22,995 per month for the first twelve months of the term, will increase to $23,915 per month for the second twelve months of the term, and, thereafter, will increase to $24,872 for the remainder of the lease term.

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. Capricor is currently in discussions with CSMC regarding an amendment to extend the term of the CSMC Lease and include the manufacturing facility within its provisions.

With permission from CSMC, Capricor presently manufactures CAP-1002 and CAP-2003 in a facility which is owned by and located within CSMC. 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, 2016, we had cash and cash resources, including marketable securities and restricted cash, totaling approximately $17.5 million. We have not generated any product revenues, and we 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, or other regulatory authorities.

From inception, we have financed our operations through public and private sales of our equity and debt securities, grants from the National Institutes of Health, or NIH, and the Department of Defense, or DoD, and a loan commitment and grant award from the California Institute for Regenerative Medicine, or CIRM. In December 2013 we also entered into a collaboration agreement with Janssen Biotech, Inc., or Janssen, which provided funding for the development of our cell manufacturing program, 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 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 as we further the development of our exosomes program and conduct additional studies with CAP-1002. 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 supplying product for clinical trials sponsored by third parties, our CIRM loan commitment, CIRM grant award and the DoD grant award, we currently have no commitments or arrangements for any additional financing to fund the research and development of CAP-1002 or CAP-2003.

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.

Given our capital constraints, we need to prioritize spending on our clinical and pre-clinical programs. If we are unable to raise sufficient funds to support our current and planned operations, we may elect to discontinue certain of our ongoing activities or programs. For example, we recently discontinued development of two of our former natriuretic peptide product candidates, Cenderitide (CD-NP) and CU-NP, to more efficiently focus our resources and efforts on our CAP-1002 and CAP-2003 programs. Our inability to raise additional funds could also prevent us from taking advantage of opportunities to pursue promising new or existing programs in the future.

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 these estimates 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 HOPE-Duchenne trial, our planned Duchenne muscular dystrophy, or DMD, program and our planned exosomes program;
- the continued availability of funding from the NIH, DoD 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 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;
- the viability of CAP-2003 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 or to establish partnerships with other companies who have greater sales and marketing capabilities;
- 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 two active product candidates, CAP-1002 and CAP-2003, are 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 or our HOPE-Duchenne trial. Additionally, we cannot predict with any certainty if, or when, we might commence any additional clinical trials of our product candidates, or whether our current 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 if 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 several 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.

We may not be able to file INDs to commence additional clinical trials on the timelines we expect, and even if we are able to do so, the FDA may not permit us to proceed.

We expect to file a number of investigational new drug applications, or INDs, over the next several years. We expect to submit the first IND for our CAP-2003 product candidate and a potential new IND for our CAP-1002 product candidate by the end of 2017. However, our timing of filing for these INDs is primarily dependent on receiving further data from our preclinical studies, and our timing of filing on all product candidates is subject to further research. Additionally, our submission of INDs is contingent upon having sufficient financial resources to prepare and complete the application.

We cannot be sure that submission of an IND will result in the FDA allowing further clinical trials to begin, or that, once begun, issues will not arise that suspend or terminate such clinical trials. Any IND we submit could be denied by the FDA or the FDA could place any future investigation of ours on clinical hold until we provide additional information, either before or after clinical trials are initiated. Additionally, even if such regulatory authorities agree with the design and implementation of the clinical trials set forth in an IND or clinical trial application, we cannot guarantee that such regulatory authorities will not change their requirements in the future. Unfavorable future trial results or other factors, such as insufficient capital to continue development of a product candidate or program, could also cause us to voluntarily withdraw an effective IND.

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 the size of the 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.

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.

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 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.

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 and HOPE-Duchenne clinical trials, 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 trials we may conduct will demonstrate adequate efficacy and safety to result in regulatory approval to market our product candidates.

CAP-1002 for DMD has received orphan drug status, but we may be unable to maintain or receive the benefits associated with orphan drug status, including market exclusivity.

Under the Orphan Drug Act, the FDA may grant orphan designation to a drug or biologic intended to treat a rare disease or condition or for which there is no reasonable expectation that the cost of developing and making available in the United States a drug or biologic for a disease or condition will be recovered from sales in the United States for that drug or biologic. If a biological product that has orphan drug designation subsequently receives the first FDA approval for the disease for which it has such designation, the product is entitled to orphan product exclusivity, which

means that the FDA may not approve any other applications, including a full Biologics License Application, or BLA, to market the same biologic for the same indication for seven years, except in limited circumstances, such as a showing of clinical superiority to the product with orphan drug exclusivity.

We have received orphan drug status for CAP-1002 for the treatment of DMD, but exclusive marketing rights in the United States may be limited if we seek approval for an indication broader than the orphan designated indication and may be lost if the FDA later determines that the request for designation was materially defective or if we are unable to assure the availability of sufficient quantities of the product to meet the needs of patients with the rare disease or condition. Even though we have obtained orphan drug designation for CAP-1002 for a select indication, we may be unable to seek or obtain orphan drug designation for our future product candidates and we may not be the first to obtain marketing approval for any particular orphan indication.

Providing product for use in third party trials poses risks to our product candidates.

In addition to manufacturing CAP-1002 for its own clinical trials, Capricor, Inc., or Capricor, has agreed to provide CAP-1002 for investigational purposes, subject to final documentation, in two clinical trials sponsored by CSMC. The first trial is known as “Regression of Fibrosis and Reversal of Diastolic Dysfunction in HFpEF Patients Treated with Allogeneic CDCs.” Dr. Eduardo Marbán is the named principal investigator under the study. The second trial is known as “Pulmonary Arterial Hypertension treated with Cardiosphere-derived Allogeneic Stem Cells.” In both studies, Capricor will provide the necessary number of doses and will receive a negotiated amount of monetary compensation therefor.

Providing product for clinical trials sponsored by third parties poses significant risks for the Company as we will not have control over the conduct of the trial even though we have used our best efforts to ensure that the investigative sites are contractually bound to follow the protocol and other procedures established by Capricor. Additionally, even though the investigative sites have experience in conducting clinical trials, any adverse event that may occur during the trial may have a negative impact on our efforts to obtain regulatory approval for our product. There are no assurances that the clinical trial sites will perform in connection with the protocol, the manuals provided by Capricor or sponsor's instructions, or act in accordance with applicable law. There is no assurance that if research injuries are incurred, the third party's insurance carrier will compensate Capricor for any liabilities or other losses sustained by Capricor arising out of these injuries.

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. 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.

Risks Related to the Manufacturing of our Product Candidates

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 CAP-1002 and CAP-2003 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 current Good Manufacturing Practice, or cGMP, approved facility. We manufactured CAP-1002 at this facility for our ALLSTAR Phase I and Phase II trials, our DYNAMIC trial and our HOPE-Duchenne trial. Our plans to use this facility for future trials could change if we decide to expand any of our clinical trials to include international sites, such as in Europe or if we fail to meet the specifications necessary to produce our product in a qualified manner. Currently, we also intend to utilize our premises at CSMC to develop and manufacture CAP-2003. If the CSMC 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, or other registration trial or for commercialization purposes.

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 cGMP 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 delivery 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 delivery 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, sale, 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 ALLSTAR, DYNAMIC and HOPE-Duchenne clinical trials. Our experience in the manufacturing of exosomes is even more limited. 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.

If we continue with the development of CAP-1002 for a Phase III or other registration trial or for commercial purposes, we may need to rely exclusively on third parties to formulate and manufacture this product candidate and provide us with the devices and other products necessary to administer such a product.

We have not established our own manufacturing facilities for the production of CAP-1002 for a Phase III or other registration trial or for commercial purposes. Also, our resources and expertise to formulate or manufacture this product candidate are limited. If we were to conduct such a trial or reach the commercialization stage, we may have to engage one or more manufacturers to manufacture, supply, store, and distribute drug supplies for such purposes. If CAP-1002 receives FDA approval, we may need to rely on one or more third-party contractors to manufacture supplies of this drug candidate. Our current and anticipated future reliance on a limited number of third-party manufacturers exposes us to the following risks:

- We may be unable to identify manufacturers needed to manufacture our product candidates on acceptable terms or at all, because the number of potential manufacturers is limited, and subsequent to approval of an NDA or BLA, the FDA must approve any replacement contractor. This approval would require new testing and compliance inspections. In addition, a new manufacturer may have to be educated in, or develop substantially equivalent processes for, production of our products or the devices after receipt of FDA approval, if any.
- Our third-party manufacturers might be unable to formulate and manufacture our drugs in the volume and of the quality required to meet our clinical and commercial needs, if any.
- Our third-party manufacturers might be unable to manufacture or supply us with sufficient quantities of acceptable materials necessary for the development or use of our product candidates.
- 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 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.

The third parties we use in the manufacturing process for our product candidates may fail to comply with cGMP regulations.

If we decide to transfer the manufacturing of our product candidates for future clinical trials or for commercial supply, our contract manufacturers will be required to produce our drug products in compliance with cGMP. These contract manufacturers are subject to periodic unannounced inspections by the FDA and corresponding state and foreign

authorities to ensure strict compliance with cGMP and other applicable government regulations and corresponding foreign requirements. We do not have control over a third party manufacturer's compliance with these regulations and requirements. In addition, changes in cGMP could negatively impact the ability of our contract manufacturers to complete the manufacturing process of our product candidates in a compliant manner on the schedule we require for clinical trials or for potential commercial use. The failure to achieve and maintain high quality compliance, including failure to detect or control anticipated or unanticipated manufacturing errors, could result in patient injury or death or product recalls. Any difficulties or delays in our contractors' manufacturing and supply of product candidates, or any failure of our contractors to maintain compliance with the applicable regulations and requirements could increase our costs, make us postpone or cancel clinical trials, prevent or delay regulatory approvals by the FDA and corresponding state and foreign authorities, prevent the import and/or export of our products, cause us to lose revenue, result in the termination of the development of a product candidate, or have our product candidates recalled or withdrawn from use.

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, or at the facilities of any third party manufacturer, 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.

Our internal computer systems, or those used by our CROs or other contractors or consultants, may fail or suffer security breaches.

Despite the implementation of security measures, our internal computer systems and those of our current and future CROs and other contractors and consultants are vulnerable to damage from computer viruses and unauthorized access. While we have not experienced any such material system failure or security breach to date, if such an event were to occur and cause interruptions in our operations, it could result in a material disruption of our development programs and our business operations. For example, the loss of clinical trial data from completed or future clinical trials could result in delays in our regulatory approval efforts and significantly increase our costs to recover or reproduce the data. To the extent that any disruption or security breach were to result in a loss of, or damage to, our data or applications, or inappropriate disclosure of confidential or proprietary information, we could incur liability and the further development and commercialization of our product candidates could be delayed.

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.

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. There is no guarantee that Janssen will exercise its option for an exclusive license to CAP-1002 as well as certain allogeneic CSps and CDCs 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 license option, it could have a material adverse effect on the business, financial condition, or results of operations of the Company.

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, financial 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.

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. In light of our decision to terminate our development program with respect to natriuretic peptides, the Company is now considering whether or not to cease prosecution of some or all of the Natriuretic Peptide Patents and has offered to reassign to Medtronic rights to certain patent applications obtained through the Transfer Agreement.

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

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

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

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

Some jurisdictions in which we operate have enacted legislation which allows members of the public to access information under statutes similar to the U.S. Freedom of Information Act. Even though we believe our information would be excluded from the scope of such statutes, there are no assurances that we can protect our confidential information from being disclosed under the provisions of such laws. If any confidential or proprietary information is released to the public, such disclosures may negatively impact our ability to protect our intellectual property rights.

We may be subject to claims that our employees, consultants or independent contractors have wrongfully used or disclosed confidential information of third parties.

We have received confidential and proprietary information from third parties. In addition, we employ individuals who were previously employed at other biotechnology or pharmaceutical companies. We may be subject to claims that we or our employees, consultants or independent contractors have inadvertently or otherwise used or disclosed confidential information of these third parties or our employees' former employers. Litigation may be necessary to defend against these claims. Even if we are successful in defending against these claims, litigation could result in substantial cost and be a distraction to our management and employees.

We depend on intellectual property licensed from third parties and termination of any of these licenses could result in the loss of significant rights, which would harm our business.

We are dependent on patents, know-how and proprietary technology, both our own and licensed from others. We have several license agreements, including with University of Rome, JHU and CSMC. These licenses may be terminated upon certain conditions. Any termination of these licenses could result in the loss of significant rights and could harm our ability to commercialize our product candidates. Disputes may also arise between us and our licensors regarding intellectual property subject to a license agreement, including: the scope of rights granted under the license agreement and other interpretation-related issues; whether and the extent to which our technology and processes infringe on intellectual property of the licensor that is not subject to the licensing agreement; our right to sublicense patent and other rights to third parties under collaborative development relationships; our diligence obligations with respect to the use of the licensed technology in relation to our development and commercialization of our product candidates, and what activities satisfy those diligence obligations; and the ownership of inventions and know-how resulting from the joint creation or use of intellectual property by our licensors and us and our partners.

If disputes over intellectual property that we have licensed prevent or impair our ability to maintain our current licensing arrangements on acceptable terms, we may be unable to successfully develop and commercialize the affected product candidates. If we or our licensors fail to adequately protect this intellectual property, our ability to commercialize products could suffer.

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 cell therapy 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.

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 have received several grants from the NIH to fund various projects, including Phase I of the ALLSTAR trial and the DYNAMIC trial as well as a grant from the DoD. These awards are subject to annual and quarterly reporting requirements. If we fail to meet these requirements, the NIH or DoD 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 reduced the number of patients enrolled in the ALLSTAR clinical trial, CIRM and Capricor entered into a modification of the CIRM Loan Agreement.

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 CIRM Loan Agreement for failure to meet certain loan conditions.

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.

We rely and will rely on third parties to conduct our clinical trials. If these third parties do not successfully carry out their contractual duties or meet expected deadlines, we may not be able to obtain regulatory approval of or commercialize our product candidates.

We depend and will depend upon independent investigators and collaborators, such as universities, medical institutions, CROs and strategic partners to conduct our preclinical and clinical trials under agreements with us. We negotiate budgets and contracts with CROs and study sites, which may result in delays to our development timelines and increased costs. We rely heavily on these third parties over the course of our clinical trials, and we control only certain aspects of their activities. Nevertheless, we are responsible for ensuring that each of our studies is conducted in accordance with applicable protocol, legal, regulatory and scientific standards, and our reliance on third parties does not relieve us of our regulatory responsibilities. We and these third parties are required to comply with current good clinical practices, or cGCPs, which are regulations and guidelines enforced by the FDA and comparable foreign regulatory authorities for product candidates in clinical development. Regulatory authorities enforce these cGCPs through periodic inspections of trial sponsors, principal investigators and trial sites. If we or any of these third parties fail to comply with applicable cGCP regulations, the clinical data generated in our clinical trials may be deemed unreliable and the FDA or comparable foreign regulatory authorities may require us to perform additional clinical trials before approving our marketing applications. We cannot assure that, upon inspection, such regulatory authorities will determine that any of our clinical trials comply with the cGCP regulations. In addition, our clinical trials must be conducted with biologic product produced under cGMPs and will may require a large number of test patients. Our failure or any failure by these third parties to comply with these regulations or to recruit a sufficient number of patients may require us to repeat clinical trials, which would delay the regulatory approval process. Moreover, our business may be implicated if any of these third parties violates federal or state fraud and abuse or false claims laws and regulations or healthcare privacy and security laws.

Any third parties conducting our clinical trials are not and will not be our employees and, except for remedies available to us under our agreements with such third parties, we cannot control whether or not they devote sufficient time and resources to our ongoing preclinical, clinical and nonclinical programs. These third parties may also have relationships with other commercial entities, including our competitors, for whom they may also be conducting clinical studies or other drug development activities, which could affect their performance on our behalf. If these third parties do not successfully carry out their contractual duties or obligations or meet expected deadlines, if they need to be replaced or if the quality or accuracy of the clinical data they obtain is compromised due to the failure to adhere to our clinical protocols or regulatory requirements or for other reasons, our clinical trials may be extended, delayed or terminated and we may not be able to complete development of, obtain regulatory approval of or successfully commercialize our product candidates. As a result, our financial results and the commercial prospects for our product candidates would be harmed, our costs could increase and our ability to generate revenue could be delayed. Switching or adding third parties to conduct our clinical trials involves substantial cost and requires extensive management time and focus. In addition, there is a natural transition period when a new third party commences work. As a result, delays occur, which can materially impact our ability to meet our desired clinical development timelines.

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.

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. There is a close working relationship between the academic lab at CSMC and our research and development team where employees and consultants of both entities contribute time and services to the research being performed by the other. 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.

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.

There have been recent public announcements by members of the U.S. Congress, President Trump and his administration regarding their plans to repeal and replace the Patient Protection and Affordable Care Act as well as to make changes to Medicare and Medicaid. While we cannot predict the timing or impact of any specific changes to applicable laws, the government has shown significant interest in pursuing healthcare reform and reducing healthcare costs. Any government-adopted reform measures could decrease the amount of reimbursement available from governmental and other third-party payors for our products.

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.

Our stock price may be impacted by the decision of Janssen Biotech, Inc. not to exercise its option to license CAP-1002.

We have entered into a Collaboration Agreement and Exclusive License Option with Janssen. Janssen's decision whether to exercise its option to license CAP-1002 may be influenced by factors which are out of our control. Even if the results of the ALLSTAR trial are positive, Janssen may still elect not to exercise its option due to factors that are pertinent to Janssen and/or Johnson and Johnson and not the prospects for CAP-1002. If the parties are unable to agree on the terms of the License Agreement or Janssen decides not to exercise, the price of our stock could be negatively impacted.

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.

If securities analysts do not publish research or reports about our business or if they publish negative evaluations of our stock, the price of our stock could decline.

The trading market for our common stock will rely in part on the research and reports that industry or financial analysts publish about us or our business. If no or few analysts maintain coverage of us, the trading price of our stock could decrease. If one or more of the analysts covering our business downgrade their evaluations of our stock, or cease to cover our stock altogether, the price of our stock could also decline. If one or more of these analysts cease to cover our stock, we could lose visibility in the market for our stock, which in turn could cause our stock price to decline.

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 amended its protocol for the ALLSTAR trial which resulted in a reduction in the number of patients necessary for potentially achieving statistical significance and meeting the primary endpoint. While we believe that the reduced sample size will provide sufficient power to show a statistically-significant effect, there is no assurance that the assumptions upon which the reduction in sample size was calculated, and which were based on prior CDC clinical trial results, will be replicated in the ALLSTAR 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.

A significant number of shares of our common stock are issuable pursuant to outstanding stock awards, and we expect to issue additional stock awards and shares of common stock in the future. Exercise of these awards and sales of shares will dilute the interests of existing security holders and may depress the price of our common stock.

As of December 31, 2016, there were approximately 21.4 million shares of common stock outstanding and outstanding awards to purchase approximately 6.6 million shares of common stock under various incentive stock

plans of the Company. Additionally as of December 31, 2016, there were approximately 0.5 million shares of common stock available for future issuance under various incentive plans. We may issue additional common stock and warrants from time to time to finance our operations. We may also issue additional shares to fund potential acquisitions or in connection with additional stock options or other equity awards granted to our employees, officers, directors and consultants under our various incentive plans. The issuance of additional shares of common stock or warrants to purchase common stock and the perception that such issuances may occur or exercise of outstanding warrants or options may have a dilutive impact on other stockholders and could have a material negative effect on the market price of our common stock.

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 Securities and Exchange Commission, 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. Capricor leases space for its corporate offices pursuant to a lease that was originally 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, or the Second Lease Amendment, 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 Lease 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 25, 2016, Capricor entered into a Third Amendment to Lease, or the Third Lease Amendment, with The Bubble Real Estate Company, LLC. Under the terms of the Third Lease Amendment, the lease term commenced on July 1, 2016 and will end on December 31, 2018. Commencing July 1, 2016, the base rent increased to $22,995 per month for the first twelve months of the term, will increase to $23,915 per month for the second twelve months of the term, and, thereafter, will increase to $24,872 for the remainder of the lease term.

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 CAP-1002 and CAP-2003 in a facility which is owned by and located within CSMC. 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. Capricor is currently in discussions with CSMC regarding an amendment to extend the term of the CSMC Lease and include the manufacturing facility within its provisions.

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 closing sales 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, 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
Year ended December 31, 2016		
First Quarter	$2.97	$2.01
Second Quarter	4.75	2.61
Third Quarter	4.27	3.21
Fourth Quarter	3.50	2.40

Holders

According to the records of our transfer agent, American Stock Transfer & Trust Company, as of March 14, 2017, we had 130 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

None.

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, focusing on cardiovascular disease as well as exploring other indications. 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 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. Capricor manufactures its CAP-1002 and exosomes product candidates in manufacturing facilities provided by CSMC.

Drug Candidates

We have four drug candidates, two of which are in various stages of active development. Our current research and development efforts are focused on CAP-1002 and CAP-2003. CAP-1002 is the subject of two ongoing clinical trials, and we expect to enter CAP-2003 into clinical development in the second half of 2017. CAP-1001 (autologous CDCs) was the subject of the CSMC and JHU-sponsored Phase I CADUCEUS trial and is not in active development. Both CAP-1002 and CAP-1001 are derived cardiospheres, or CSps, and we do not plan to develop CSps as a therapeutic.

CAP-1002:

Our core therapeutic technology is based on the cardiosphere-derived cell, or CDC, a type of cardiac progenitor cell that composes a minor fraction of the cardiac muscle cell population and was first identified in the academic laboratory of Capricor's scientific founder, Dr. Eduardo Marbán. Since their initial report in 2007, CDCs have been the subject of over 100 peer-reviewed scientific publications and have been administered to approximately 140 human subjects across several clinical trials. We are currently developing allogeneic CDCs (CAP-1002) as a product candidate for the treatment of cardiac disorders.

We are currently conducting two clinical trials of our lead product candidate, CAP-1002: the Phase II portion of the Phase I/II ALLSTAR trial in patients who have had a myocardial infarction, or MI, and the Phase I/II HOPE-Duchenne trial in patients with Duchenne muscular dystrophy-associated cardiomyopathy. We have completed the Phase I portion of the Phase I/II DYNAMIC trial in patients with advanced heart failure.

Phase I/II ALLSTAR Clinical Trial

The Phase I portion of the ALLSTAR trial was a 14-patient, open-label, dose-escalation study that was conducted to evaluate the clinical safety of CAP-1002. Each patient received a single infusion of CAP-1002 into the coronary artery most closely associated with the location of their MI, at a dose level of either 12.5 million or 25 million cells. The primary safety endpoints focused on the potential adverse effects of CAP-1002 delivery, including potential immunologic consequences of infusing cells that had originated from an unrelated donor. Enrollment was completed in October 2013. Event rates observed for each of the four pre-specified safety endpoints (acute myocarditis possibly attributable to CAP-1002; death due to ventricular tachycardia or ventricular fibrillation; sudden death; and major adverse cardiac events) were 0% over one and 12 months following CAP-1002 infusion.

Updated preliminary 12-month magnetic resonance imaging, or MRI, data revealed that those Phase I patients who would have been eligible for randomization into the Phase II clinical study by virtue of dose and tissue type compatibility exhibited a reduction in infarct, or scar, size of 15% from baseline. These data also indicated a 4% improvement from baseline in ejection fraction, a global measure of the heart's pumping ability. Measurements of viable mass and regional function also showed quantifiable improvements. This Phase I study was funded in large part by a grant received from the National Institutes of Health, or NIH.

In December 2013, the Gene and Cell Therapy Data Safety Monitoring Board of the National Heart Lung and Blood Institute notified Capricor that it had had met its safety endpoints and that Capricor was cleared to begin the Phase II portion of the ALLSTAR trial.

Capricor began enrollment of the Phase II ALLSTAR study in the first quarter of 2014. This randomized, double-blind, placebo-controlled trial is designed to determine if treatment with CAP-1002 can reduce scar size in patients who have suffered an MI. At the time of randomization, patients were stratified into one of two cohorts according to the time since the occurrence of their MI (either 30 to 90 days after the MI, or greater than 90 days up to one-year after the MI). Following infusion, patients are to be followed for periodic evaluations over the course of one year. As such, CAP-1002 is being evaluated in the setting of both acute MI, in which the scar has recently formed, and chronic MI, in which the scar is more established. Patients were randomized in a 2:1 ratio to receive an infusion of CAP-1002 (25 million cells) or placebo, respectively, into the coronary artery most closely associated with the region of their MI. The trial is powered to detect a reduction in scar size, relative to placebo, as measured by MRI at the 12-month follow-up. In addition to evaluating CAP-1002 according to changes in scar size, ALLSTAR will also evaluate CAP-1002 according to a variety of clinical and quality of life endpoints. The Phase II portion of the ALLSTAR trial is being funded in large part through the support of the California Institute for Regenerative Medicine, or CIRM.

Based on information available to us at the start of enrollment into the Phase II ALLSTAR trial, we initially designed this study to enroll up to 300 patients. Following the completion of statistical modeling of the design of ALLSTAR which incorporated the expanded dataset that had become available from other clinical trials of our CDCs, we 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 scar size as measured by MRI at 12 months. We have amended our clinical protocol to reflect these changes, which amendment was approved by the Data Safety Monitoring Board and was submitted to the U.S. Food and Drug Administration, or the FDA, in February 2016.

In October 2016, we announced completion of enrollment of the Phase II portion of the ALLSTAR trial in which 142 subjects were randomized to the active or control treatment groups in a 2:1 ratio, respectively, and of whom 134 received a single infusion of either CAP-1002 or placebo into the infarct-associated coronary artery. Patients in the trial were enrolled at approximately 30 centers in the U.S. and in Canada.

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 CSps and CDCs in the field of cardiology, except as may otherwise be agreed with respect to certain indications to be determined. 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 the Phase II portion of the ALLSTAR clinical trial of CAP-1002. We expect to receive Janssen’s decision with respect to this option in the third quarter of 2017 following the delivery of the six-month results from the ALLSTAR trial.

Phase I/II HOPE-Duchenne Clinical Trial

We are currently conducting the randomized, controlled, multi-center Phase I/II HOPE-Duchenne clinical trial which was designed to evaluate the safety and exploratory efficacy of CAP-1002 in approximately 24 patients with cardiomyopathy associated with Duchenne muscular dystrophy, or DMD. Patients were randomized in a 1:1 ratio to receive either CAP-1002 or usual care available for DMD-associated cardiomyopathy. In patients receiving CAP-1002, a dose of 25 million cells was infused into each of the three main coronary arteries (75 million cells total), which allowed for CAP-1002 to be delivered to large areas of the myocardium. Patients are to be followed for periodic evaluations over the course of 12 months. Exploratory efficacy will be evaluated according to several different outcome measures, including cardiac MRI. This study is funded in part through a grant award from CIRM. Those patients who did not receive CAP-1002 may be eligible to receive open-label CAP-1002 after all participants have completed the controlled portion of the study and the Data Safety Monitoring Board has given the recommendation to proceed with the open-label extension. In April 2015, the FDA granted Orphan Drug designation to CAP-1002 for the treatment of DMD.

We announced the completion of enrollment of 25 patients in the HOPE-Duchenne trial in September 2016. To date, the Data Safety Monitoring Board has completed four safety reviews, and following each review, recommended that the trial continue. We expect to report top-line six-month results early in the second quarter of 2017 and report top-line 12-month results in the fourth quarter of 2017.

Additionally, depending upon trial results and available resources, we are planning to expand our CAP-1002 clinical development program in DMD beyond cardiac aspects of the disease. This expansion includes the conduct of a clinical trial which we plan to commence in the second half of 2017, subject to regulatory approval.

Phase I/II DYNAMIC Clinical Trial

The Phase I/II DYNAMIC trial, of which the Phase I portion has concluded, was designed to evaluate the safety and efficacy of CAP-1002 in the treatment of patients with advanced heart failure resulting from dilated cardiomyopathy of either ischemic or non-ischemic origin. This condition is characterized by chronic structural and functional abnormalities present throughout the heart’s contractile tissue. In the DYNAMIC trial, CAP-1002 was infused into all three main coronary arteries to obtain broad exposure. Following infusion, patients were followed for one year. The trial was funded in part through a grant award from the NIH.

We initiated the open-label, dose-escalating Phase I portion of the DYNAMIC trial in December 2014 at a single center, CSMC, and in April 2015, completed enrollment with 14 patients with New York Heart Association, or

NYHA, Class III heart failure. Each patient was administered CAP-1002 via a one-time, triple coronary infusion at one of several evenly-divided dose levels (37.5 million, 50 million, 62.5 million, or 75 million cells total). Initial top-line six-month 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. Although this trial was intended as a safety study, the six-month data demonstrated encouraging and congruent preliminary efficacy signals in multiple parameters, including ejection fraction, ventricular volumes, exercise capacity and subjective well-being.

In June 2016, Capricor reported positive 12-month data from the DYNAMIC study. For the 12 patients available for follow-up at one year, improvements from baseline in key cardiac function and dimensional indices that had been observed at six months were directionally maintained. Importantly, the change in median left ventricular ejection fraction from baseline to 12 months maintained its level of statistical significance that was shown at six months ($p=0.02$ at both time points) and, on an absolute basis, continued to improve from six to 12 months. Of the five NYHA Class III subjects who received the highest dose of CAP-1002 (75 million cells), two subjects improved by two Classes (to Class I) and three improved by one Class (to Class II) at six months. At 12 months, three of these five subjects were assessed as Class I and two as Class II, demonstrating further improvement and indicating durability of the benefit of CAP-1002 on heart failure status for as long as one year following administration. CAP-1002 infusion was well-tolerated in DYNAMIC. Two of the 14 patients, who were in the lower two of the four dose cohorts, died from progressive heart failure approximately one and three months prior to study conclusion. Although we have designed a Phase II study to evaluate CAP-1002 in the heart failure population, at this time we have not made a determination with respect to conducting the Phase II portion of the DYNAMIC trial.

CAP-2003:

Exosomes are nano-sized, membrane-enclosed vesicles, or “bubbles” that are secreted by cells and contain bioactive molecules, including proteins, RNAs and microRNAs. They act as messengers to regulate the functions of neighboring cells, and pre-clinical research has shown that exogenously-administered exosomes can direct or, in some cases, re-direct cellular activity, supporting their therapeutic potential. Their size, ease of crossing cell membranes, and ability to communicate in native cellular language makes them an exciting class of potential therapeutic agents. We are currently developing exosomes produced by CDCs (CAP-2003) as a product candidate for the treatment of certain cardiac and other inflammatory conditions.

CAP-2003 comprises of exosomes secreted by CDCs, and is believed to mediate many of the effects that are observed with these cells, including anti-inflammatory, anti-angiogenic, anti-apoptotic, and anti-fibrotic effects. We are currently conducting studies in pre-clinical models of cardiac, inflammatory and various other conditions to explore the possible therapeutic benefits that CAP-2003 may possess. We are planning to evaluate CAP-2003 in preclinical studies for the treatment of HLHS. We hope to submit an IND for CAP-2003 to enable clinical development in the second half of 2017.

CAP-1001:

CAP-1001 consists of autologous CDCs. This product candidate was evaluated in the randomized, double-blind, placebo-controlled Phase I CADUCEUS clinical trial in patients who had recently experienced an MI. The study was sponsored and conducted by CSMC in collaboration with JHU. Of the 25 patients enrolled, 17 received an intracoronary infusion of CAP-1001 and eight received standard of care. 16 of the 17 patients treated with CAP-1001 showed a mean reduction of approximately 45% in scar mass and an increase in viable heart muscle at one-year following MI. The eight patients in the control group had no significant change in scar size. The data from CADUCEUS, using autologous CDCs, suggests that CDCs are effective in reducing scar size within several months of a heart attack. The design of our ongoing ALLSTAR trial of CAP-1002, an allogeneic product, is based on the results of CADUCEUS. In addition, ALLSTAR is evaluating the potential efficacy of CAP-1002 in patients between 90 days and one year post-MI, a patient population that CADUCEUS was not designed to study. At present, there is no plan for another clinical trial for CAP-1001.

CSps:

CSps are a 3D micro-tissue from which CDCs are derived, and have shown significant healing effects in pre-clinical models of heart failure. While we consider CSps an important asset, at present there is no plan to develop CSps as a

therapeutic agent.

Natriuretic Peptides:

We have recently discontinued further development of two of our former natriuretic peptide product candidates, Cenderitide (CD-NP) and CU-NP, to more efficiently focus our resources and efforts on our CAP-1002 and CAP-2003 programs. In 2015, we completed a Phase II study in 14 patients with stable, chronic heart failure. The drug was tolerated and there were no significant adverse events. Capricor completed an additional study in 2016 to further assess the safety and efficacy of Cenderitide, which included higher dose levels of Cenderitide in patients with stable heart failure with moderate renal impairment. This study assessed the safety and tolerability, pharmacokinetic profiles and pharmacodynamic response to increasing dose levels of Cenderitide. For additional information, see "Intellectual Property and Proprietary Know-How — Company Technology – Cenderitide and CU-NP" contained in Part I, Item 1 to this Annual Report on Form 10-K and Note 10 to our accompanying consolidated financial statements included in Part II, Item 8 of this Annual Report on Form 10-K.

Financial Operations Overview

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 several years, if ever. To date, most of our development expenses have related to our product candidates, consisting of CAP-1002, CAP-2003 and our former product candidate, Cenderitide. As we proceed with the clinical development of CAP-1002 and explore other potential indications for CAP-1002, and as we further develop CAP-2003 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 and the Department of Defense, or DoD, 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, 2016 and 2015

General and Administrative Expenses. G&A expenses for the years ended December 31, 2016 and 2015 were approximately $4.9 million and $4.4 million, respectively. The increase of approximately $0.5 million in G&A expenses in the year ended December 31, 2016 compared to the year ended December 31, 2015 is primarily attributable to an increase of approximately $0.4 million related to compensation and recruiting costs related to increased headcount and payroll increases. Furthermore, there was an increase of approximately $0.1 million in stock-based compensation expense.

Research and Development Expenses. R&D expenses for the years ended December 31, 2016 and 2015 were approximately $16.0 million and $13.8 million, respectively. The increase of approximately $2.2 million in R&D expenses in the year ended December 31, 2016 as compared to the year ended December 31, 2015 is primarily due to clinical development activities of CAP-1002 (ALLSTAR and HOPE-Duchenne) and other continued research and development efforts. These activities resulted in an increase of approximately $2.1 million in clinical costs primarily related to contract research organizations and manufacturing for CAP-1002, as well as patient costs and expenses for the operational team that supports our clinical trials. Additionally, for the year ended December 31, 2016, there was an

increase of approximately $1.1 million in R&D expenses related to our product candidates, including exosomes. Furthermore, there was a decrease of approximately $1.3 million in clinical costs associated with our DYNAMIC and Cenderitide clinical trials and an increase of approximately $0.3 million in stock-based compensation for the year ended December 31, 2016 as compared to the year ended December 31, 2015.

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 $8.0 million to $12.0 million during 2017 on the development and manufacturing of CAP-1002, which expenses are primarily related to our Phase II ALLSTAR trial, the HOPE-Duchenne trial and additional planned studies in DMD. We began enrollment of the Phase II portion of the ALLSTAR trial in the first quarter of 2014 and announced the completion of enrollment in October 2016. Phase II is funded in large part through the support of a loan award from CIRM.

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 CSps and CDCs in the field of cardiology, except as may otherwise be agreed with respect to certain indications to be determined, 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 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 February 2017, we terminated the Amended and Restated Technology License Agreement with the Mayo Foundation for Medical Education and Research to more efficiently focus our resources and efforts on our CAP-1002 and CAP-2003 programs and we do not anticipate having any further material expenses in 2017 with this respect to this product candidate.

CAP-2003 –We expect to spend approximately $3.0 million to $5.0 million during 2017 in pre-clinical and other research expenses related to the CAP-2003 program. Capricor is currently engaged in pre-clinical testing of CAP-2003 to explore its therapeutic potential, including investigational new drug application-enabling studies.

CAP-1001 – In 2011, CSMC, in collaboration with JHU, completed the Phase I CADUCEUS trial. This study enrolled 25 patients who had suffered a heart attack within a mean of 65 days. Seventeen patients received CAP-1001 and eight received standard of care. Twelve months after the study had completed, no measurable adverse 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 scar size. While these data support CAP-1002 development as is currently being conducted through the ongoing Phase II ALLSTAR trial, at present there is no plan to conduct another clinical trial of CAP-1001.

CSps –CSps are at the pre-clinical stage of development. 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 and CAP-2003 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 independently or with a partner. 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, 2016 and 2015 was approximately $0.8 million and $1.7 million, respectively. The decrease in grant income in 2016 as compared to 2015 is primarily due to the fact that the DYNAMIC trial incurred more costs in 2015 than it did in 2016. The DYNAMIC trial was nearing its completion in 2016.

Collaboration Income. As a result of the Janssen Agreement, collaboration income for the years ended December 31, 2016 and 2015 was approximately $3.2 million and $3.8 million, respectively. A ratable portion of the payment to Capricor under the Janssen Agreement was recognized in both the years ended December 31, 2016 and 2015. The Company periodically reviews the estimated performance period of the Janssen Agreement based on the estimated progress of its project with Janssen.

Impairment Expense. Impairment expense, a non-cash expense, was $1.5 million for the year ended December 31, 2016. Impairment expense for the period related to acquired in-process research and development assets that were acquired in the merger with Nile in 2013. In February 2017, we announced the termination of our development plans for Cenderitide and CU-NP. Given this development, we have assessed the fair value of this indefinite-lived intangible asset to be $0 at December 31, 2016.

Interest Expense. Interest expense for the years ended December 31, 2016 and 2015 was $344,665 and $248,626, respectively. The increase in interest expense in 2016 as compared to 2015 is due to accrued interest on the CIRM Loan Award.

Liquidity and Capital Resources for the fiscal years ended December 31, 2016 and 2015

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, 2016	December 31, 2015
Cash and cash equivalents	$ 3,204	$ 5,568
Working capital	$ 13,213	$ 7,461
Stockholders' equity (deficit)	$ (4,003)	$ (1,032)

	Years ended December 31,	
Cash flow data	2016	2015
Cash provided by (used in):		
Operating activities	$ (15,802)	$ (10,817)
Investing activities	(5,191)	(8,141)
Financing activities	18,629	16,492
Net increase (decrease) in cash and cash equivalents	$ (2,364)	$ (2,466)

Our total cash and cash equivalents, not including restricted cash, as of December 31, 2016 was approximately $3.2 million compared to approximately $5.6 million as of December 31, 2015. The decrease in cash and cash equivalents for the year ended December 31, 2016 as compared to the year ended December 31, 2015 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 $13.0 million as of December 31, 2016, as compared to approximately $8.0 million as of December 31, 2015. The increase in working capital as of December 31, 2016 is primarily due to the approximately $3.9 million received in net proceeds in the first quarter of 2016 as a result of a registered direct offering of our common stock and concurrent private placement of warrants to purchase shares of our common stock and the approximate $9.9 million received in net proceeds as a result of an underwritten registered public offering and concurrent registered direct offering of our common stock completed in the third quarter of 2016 coupled with operational expenditures. As of December 31, 2016, we had approximately $22.8 million in total liabilities, of which approximately $1.4 million was recorded as deferred income under the Janssen Agreement. As of December 31, 2016, we had approximately $13.2 million in net working capital. We incurred a net loss of approximately $18.8 million for the year ended December 31, 2016.

Cash used in operating activities was approximately $15.8 million and $10.8 million for the years ended December 31, 2016 and 2015, respectively. The difference of approximately $5.0 million in cash from operating activities is primarily due to an increase in net loss for the year ended December 31, 2016 of approximately $5.9 million as compared to the same period of 2015. Additionally, for the year ended December 31, 2015, cash provided by the release of restricted cash totaled approximately $3.0 million as compared to a net change of cash received of approximately $1.3 million in restricted cash for the same period of 2016. Furthermore, for the year ended December 31, 2016, we received $3.1 million from our CIRM Award and had a non-cash impairment of $1.5 million related to the termination of our natriuretic peptides program. 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, 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 $5.2 million and $8.1 million for the years ended December 31, 2016 and 2015, respectively. The decrease in cash used in investing activities for the year ended December 31, 2016 as compared to the year ended December 31, 2015 is primarily due to the net effect from purchases, sales, and maturities of marketable securities.

We had cash provided by financing activities of approximately $18.6 million and $16.5 million for the years ended December 31, 2016 and 2015, respectively. The increase in cash provided by financing activities for the year ended December 31, 2016 as compared to the year ended December 31, 2015 is primarily the result of approximately $4.8 million in loan proceeds from our CIRM Loan Award. Furthermore, we received net proceeds from issuances of common stock of approximately $13.9 million in 2016, compared to net proceeds of issuances of common stock of approximately $16.4 million in 2015.

Phase II of Capricor's ALLSTAR trial has been funded in large part through a loan award from CIRM. The Company and CIRM entered into an amendment to the CIRM Loan Agreement pursuant to which the parties agreed upon a schedule for future disbursements of the proceeds of the loan amount based upon the achievement of specified operational milestones. As a result of the CIRM Loan Amendment and because the Company decreased the number of patients to be enrolled in the ALLSTAR clinical trial, the Company will not need to take down the full amount available for disbursement under the CIRM Loan Agreement, and in addition certain of the operational milestones tied to patient enrollment will not be met. The amount that will ultimately be disbursed will be approximately 70-75% of the total amount specified in the CIRM Loan Agreement, thus reducing the total amount of debt incurred thereunder. 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 is being developed by the joint efforts of Janssen and Capricor. Capricor is 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 to be determined.

Our Phase I/II HOPE-Duchenne trial of CAP-1002 in DMD-associated cardiomyopathy is being funded in part through a grant award from CIRM for approximately $3.4 million, which was entered into in June 2016. 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.

Our research and development expenses will continue to increase as we further develop our exosomes program and if we conduct additional studies with CAP-1002.

From inception through December 31, 2016, we financed our operations through private and public sales of our equity securities, NIH and DoD grants, a payment from Janssen, a CIRM loan and a CIRM grant award. In the first quarter of 2016, we completed a registered direct offering of our common stock and a concurrent private placement of warrants to purchase shares of our common stock, securing approximately $4.1 million in additional capital through the

issuance of securities. Additionally, in the third quarter of 2016, we completed an underwritten and concurrent registered direct offering of our common stock to purchase shares of our common stock, securing approximately $10.9 million in additional capital through the issuance of securities. Furthermore, in 2016 we received approximately $4.8 million in loan proceeds from our CIRM Loan Award as well as $3.1 million in disbursements from our CIRM Award. 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 become 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 and success 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;
- the costs of manufacturing our product candidates;
- 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

September 2016 Financing. On September 21, 2016, the Company completed an underwritten registered public offering and concurrent registered direct offering in which the Company issued an aggregate of 3,403,125 shares of its common stock at a price per share of $3.20 for an aggregate purchase price of $10,890,000. Fees paid in conjunction with the underwritten deal and registered direct offering, which included underwriter commissions and estimated offering expenses, amounted to approximately $1.0 million in the aggregate resulting in net proceeds of approximately $9.9 million. 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 underwritten offering and a prospectus supplement relating to the registered direct offering were filed with the SEC on September 16, 2016.

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. This offering included participation from certain of the Company’s officers and directors. The Shares were issued pursuant to our shelf registration statement on Form S-3 (File No. 333-207149), which was initially filed with 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, initially become exercisable on September 17, 2016, and will expire on March 16, 2019.

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. In accordance with the terms of the Registration Rights Agreement, we registered for resale the shares of common stock issuable upon exercise of the Warrants pursuant to our registration statement on Form S-3 (File No. 333-212017), which was filed with the SEC on June 14, 2016 and declared effective by the SEC on June 30, 2016.

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 SEC 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 SEC 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 SEC 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 SEC on June 11, 2015.

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 SEC 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 SEC as soon as practicable, in each case subject to certain deadlines. We filed the PIPE Form S-1 to 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 SEC 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 SEC on June 11, 2015.

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 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. On May 12, 2016, we and CIRM entered into an amendment to the CIRM Loan Agreement, or the CIRM Loan Amendment, pursuant to which the parties agreed upon a schedule for future disbursements of the proceeds of the loan amount based upon the achievement of specified operational milestones. As a result of the CIRM Loan Amendment and because we decreased the number of patients enrolled in the ALLSTAR clinical trial, we will not need to take down the full amount available for disbursement under the CIRM Loan Agreement and in addition certain of the operational milestones tied to patient enrollment will not be met. We believe that the amount that will ultimately be disbursed will be approximately 70-75% of the total amount specified in the CIRM Loan Agreement, thus reducing the total amount of debt incurred thereunder.

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%, or the 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. We are 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.

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 loan award. Additionally, on September 30, 2015, we entered into a Joinder Agreement with Capricor 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 June 16, 2016, Capricor entered into the CIRM Award with CIRM 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-associated cardiomyopathy. Pursuant to terms of the CIRM Award, the disbursements will be tied to the achievement of specified operational milestones. If CIRM determines, in its sole discretion, that Capricor has not complied with the terms and conditions of the CIRM Award, CIRM may suspend or permanently cease disbursements or pursue other remedies as allowed by law. In addition, the terms of the CIRM Award include a co-funding requirement pursuant to which Capricor is required to spend approximately $2.3 million of its own capital

to fund the HOPE-Duchenne clinical trial. If Capricor fails to satisfy its co-funding requirement, the amount of the CIRM Award may be proportionately reduced. The CIRM Award is further subject to the conditions and requirements set forth in the CIRM Grants Administration Policy for Clinical Stage Projects. Such requirements include, without limitation, the filing of quarterly and annual reports with CIRM, the sharing of intellectual property pursuant to Title 17, CCR Sections 100600-100612, and the sharing with the State of California of a fraction of licensing revenue received from a CIRM funded research project and net commercial revenue from a commercialized product which resulted from CIRM funded research as set forth in Title 17, CCR Section 100608. The maximum royalty on net commercial revenue that Capricor may be required to pay to CIRM is equal to nine times the total amount awarded and paid to Capricor.

After completing the CIRM funded research project and after the award period end date, estimated to be in late 2017 or in 2018, Capricor has the right to convert the CIRM Award into a loan, the terms of which will be determined based on various factors, including the stage of the research and development of the program at the time the election is made. On June 20, 2016, Capricor entered into a Loan Election Agreement with CIRM whereby, among other things, CIRM and Capricor agreed that, if converted, the term of the loan would be five years from the date of execution of the applicable loan agreement; provided that the term of the loan will not exceed ten years from the date on which the CIRM Award was granted. Beginning on the date of the loan, the loan shall bear interest on the unpaid principal balance plus the interest that was accrued prior to the election point according to the terms set forth in CIRM's Loan Policy, or the New Loan Balance, at a per annum rate equal to the LIBOR rate for a three-month deposit in U.S. dollars, as published by the Wall Street Journal on the loan date, plus one percent. Interest shall be compounded annually on the outstanding New Loan Balance commencing with the loan date and the interest shall be payable, together with the New Loan Balance, upon the due date of the loan. If Capricor elects to convert the CIRM Award into a loan, certain requirements of the CIRM Award will no longer be applicable, including the revenue sharing requirements. Capricor will not make its decision as to whether it will elect to convert the CIRM Award into a loan until after the end of the HOPE-Duchenne trial. Since Capricor may be required to repay some or all of the amounts awarded by CIRM, the Company will account for this award as a liability rather than income. If Capricor were to lose this funding, it may be required to delay, postpone, or cancel its HOPE-Duchenne trial or otherwise reduce or curtail its operations, unless it was able to obtain adequate financing for its clinical trial from alternative sources. In July 2016, Capricor received the first disbursement of $2.0 million under the terms of the CIRM Award.

Additionally, in September 2016, we completed the first operational milestone which was tied to the completion of enrollment of the HOPE-Duchenne clinical trial for which $1.1 million was received by Capricor in November 2016.

NIH Grant Award (DYNAMIC)

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 NIH grant, disbursements were 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, 2016, the full award of $2.9 million has been disbursed.

NIH Grant Award (HLHS)

In September 2016, Capricor was approved for a grant from the NIH to study CAP-2003 for hypoplastic left heart syndrome (HLHS). Under the terms of the NIH grant, disbursements will be made to Capricor in an amount up to approximately $4.2 million, subject to annual and quarterly reporting requirements as well as completion of the study objectives. As of December 31, 2016, no disbursements have been made under the terms of the NIH grant award.

U.S. Department of Defense Grant Award

In September 2016, Capricor was approved for a grant award from the DoD in the amount of approximately $2.4 million to be used toward developing a scalable, commercially-ready process to manufacture CAP-2003. Under the terms of the award, disbursements will be made to Capricor over a period of approximately two years, subject to annual and quarterly reporting requirements. As of December 31, 2016, approximately $0.3 million has 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, 2016.

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.

CIRM Grant Award

Capricor will account for the disbursements under its CIRM Award as long-term liabilities. Capricor will recognize the CIRM grant disbursements as a liability as the principal is disbursed rather than recognizing the full amount of the grant award. After completing the CIRM funded research project and after the award period end date, Capricor has the right to convert the CIRM Award into a loan, the terms of which will be determined based on various factors, including the stage of the research and the stage of development at the time the election is made. Since Capricor may be required to repay some or all of the amounts awarded by CIRM, the Company accounts for this award as a liability rather than income.

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, or FASB, Accounting Standards Codification, or 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, or VSOE, of selling price, if it exists, or third-party evidence, or TPE, of selling price, if it exists. If neither VSOE nor TPE of selling price exists 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

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 (which has now expired), (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 secured convertible promissory notes we issued in March 2013, or 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, 2016, 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.

Impairment Expense

During the year ended December 31, 2016, we recorded total impairment charges, a non-cash expense, of $1.5 million. The Company determined that the carrying value of the acquired in-process research and development assets from Nile which included Cenderitide and CU-NP may not be recoverable and should be fully impaired.

Restricted Cash

We have two awards with CIRM designated for specific use, the CIRM Loan Agreement in connection with the ALLSTAR Phase II clinical trial and the CIRM Award related to the HOPE Phase I/II clinical trial. Restricted cash represents funds received under these awards which are to be allocated to the research costs as incurred. Generally, a reduction of restricted cash occurs when we deem certain costs are attributable to the respective award.

Recently Issued or Newly Adopted Accounting Pronouncements

In May 2014, the FASB issued Accounting Standards Update, or ASU, 2014-09, *Revenue from Contracts with Customers*, or 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 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. We have not yet selected a transition method nor have we determined the effect of the standard on our 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,* or ASU 2014-15, 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). ASU 2014-15 is effective for the annual period ending after December 15, 2016 and for annual and interim periods thereafter. Early adoption is permitted. 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*, or ASU 2015-02. 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. We adopted this standard effective December 31, 2015.

In April 2015, the FASB issued ASU 2015-03, *Simplifying the Presentation of Debt Issuance Costs*, or ASU 2015-03. 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*, or ASU 2015-15. ASU 2015-15 clarified guidance in ASU 2015-03 by providing 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 required us to adopt these provisions in the first quarter of 2016. This update was applied on a retrospective basis, wherein the balance sheet of each period presented was adjusted to reflect the effects of applying the new guidance.

In February 2016, the FASB issued ASU 2016-02, *Leases (Topic 842)*, or ASU 2016-02*,* 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. We are currently evaluating the impact of the adoption of this standard on our consolidated financial statements.

In March 2016, the FASB issued ASU 2016-09, *Compensation — Stock Compensation (Topic 718): Improvements to Employee Share-Based Payment Accounting*, which outlines new provisions intended to simplify various aspects related to accounting for share-based payments and their presentation in the financial statements. The standard is effective for us beginning December 15, 2016 and for interim periods within those annual periods. Early adoption is permitted. We are evaluating the impact of the adoption of this guidance on our financial statements.

In April 2016, the FASB issued ASU 2016-10, *Revenue from Contracts with Customers (Topic 606)*, which amends certain aspects of the FASB's and International Accounting Standards Board's new revenue standard, ASU 2014-09, *Revenue from Contracts with Customers*. The standard should be adopted concurrently with the adoption of ASU 2014-09, which is effective for annual and interim periods beginning after December 15, 2017. Early adoption is permitted. We have not yet selected a transition method nor have we determined the effect of the standard on our ongoing financial reporting.

In November 2016, the FASB issued ASU 2016-18, *Statement of Cash Flows (Topic 230): Restricted Cash*, a consensus of the FASB Emerging Issues Task Force, which requires that a statement of cash flows explain the change during the period in the total of cash, cash equivalents, and amounts generally described as restricted cash or restricted cash equivalents. Therefore, amounts generally described as restricted cash and restricted cash equivalents should be included with cash and cash equivalents when reconciling the beginning-of-period and end-of period total amounts shown on the statement of cash flows. The standard is effective for the Company for fiscal years beginning after

December 15, 2017, and interim periods within those fiscal years. Early adoption is permitted. The Company is evaluating the impact of the adoption of this guidance on its 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 SEC, 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, 2016, the fair value of our cash, cash equivalents, including restricted cash, and marketable securities was approximately $17.5 million. Additionally, as of December 31, 2016, Capricor's portfolio was classified as cash, cash equivalents and marketable securities, which consisted 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, 2016 and 2015, and the related consolidated statements of operations and comprehensive loss, shareholders' equity (deficit), and cash flows for each of the years in the two-year period ended December 31, 2016. Capricor Therapeutics, Inc. and Subsidiary'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, 2016 and 2015, and the results of their operations and their cash flows for the years in the two-year period ended December 31, 2016, 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 14, 2017

F-1

CAPRICOR THERAPEUTICS, INC.

CONSOLIDATED BALANCE SHEETS

DECEMBER 31, 2016 AND 2015

ASSETS	2016	2015
CURRENT ASSETS		
Cash and cash equivalents	$3,204,378	$5,568,306
Marketable securities	12,990,510	7,999,010
Restricted cash	1,347,225	-
Awards receivable	223,335	211,938
Prepaid expenses and other current assets	342,892	210,603
TOTAL CURRENT ASSETS	18,108,340	13,989,857
PROPERTY AND EQUIPMENT, net	435,336	318,566
OTHER ASSETS		
Intangible assets, net of accumulated amortization of $147,429 and $98,679, respectively	142,253	191,003
In-process research and development, net of accumulated amortization of $0	-	1,500,000
Other assets	61,426	70,146
TOTAL ASSETS	$18,747,355	$16,069,572
LIABILITIES AND STOCKHOLDERS' EQUITY (DEFICIT)		
CURRENT LIABILITIES		
Accounts payable and accrued expenses	$3,038,780	$2,530,500
Accounts payable and accrued expenses, related party	489,217	352,334
Deferred revenue, current	1,367,186	3,645,834
TOTAL CURRENT LIABILITIES	4,895,183	6,528,668
LONG-TERM LIABILITIES		
Deferred revenue, net of current portion	-	911,458
Loan payable	13,905,857	9,155,857
CIRM liability	3,100,000	-
Accrued interest	849,469	505,363
TOTAL LONG-TERM LIABILITIES	17,855,326	10,572,678
TOTAL LIABILITIES	22,750,509	17,101,346

COMMITMENTS AND CONTINGENCIES (NOTE 7)		
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, 21,399,019 and 16,254,985 shares issued and outstanding, respectively	21,399	16,255
Additional paid-in capital	49,951,165	34,115,052
Accumulated other comprehensive income	3,524	9,385
Accumulated deficit	(53,979,242)	(35,172,466)
TOTAL STOCKHOLDERS' EQUITY (DEFICIT)	(4,003,154)	(1,031,774)
TOTAL LIABILITIES AND STOCKHOLDERS' EQUITY (DEFICIT)	$18,747,355	$16,069,572

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, 2016 AND 2015

	Years ended December 31,	
	2016	2015
INCOME		
Collaboration income	$3,190,106	$3,776,041
Grant income	808,512	1,741,607
TOTAL INCOME	3,998,618	5,517,648
OPERATING EXPENSES		
Research and development	16,042,082	13,757,279
General and administrative	4,933,054	4,372,195
TOTAL OPERATING EXPENSES	20,975,136	18,129,474
LOSS FROM OPERATIONS	(16,976,518)	(12,611,826)
OTHER INCOME (EXPENSE)		
Investment income	14,407	3,113
Interest expense	(344,665)	(248,626)
Impairment of in-process research and development	(1,500,000)	-
TOTAL OTHER INCOME (EXPENSE)	(1,830,258)	(245,513)
NET LOSS	(18,806,776)	(12,857,339)
OTHER COMPREHENSIVE GAIN (LOSS)		
Net unrealized gain (loss) on marketable securities	(5,861)	9,385
COMPREHENSIVE LOSS	$(18,812,637)	$(12,847,954)
Net loss per share, basic and diluted	$(1.01)	$(0.81)
Weighted average number of shares, basic and diluted	18,551,013	15,902,133

See accompanying notes to the audited consolidated financial statements.

F-3

CAPRICOR THERAPEUTICS, INC.

CONSOLIDATED STATEMENTS OF CHANGES IN STOCKHOLDERS' EQUITY (DEFICIT)

FOR THE PERIOD FROM DECEMBER 31, 2014 THROUGH DECEMBER 31, 2016

	COMMON STOCK		ADDITIONAL PAID-IN	OTHER COMPREHENSIVE	ACCUMULATED	TOTAL STOCKHOLDERS' EQUITY
	SHARES	AMOUNT	CAPITAL	INCOME (LOSS)	DEFICIT	(DEFICIT)
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 loss 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)
Issuance of common stock, net of fees	5,095,276	5,095	13,859,722	-	-	13,864,817
Stock-based compensation	-	-	1,962,465	-	-	1,962,465
Unrealized loss on marketable securities	-	-	-	(5,861)	-	(5,861)
Stock options exercised	48,758	49	13,926	-	-	13,975
Net loss	-	-	-	-	(18,806,776)	(18,806,776)
Balance at December 31, 2016	21,399,019	$21,399	$49,951,165	$3,524	$(53,979,242)	$(4,003,154)

See accompanying notes to the audited consolidated financial statements.

F-4

CAPRICOR THERAPEUTICS, INC.

CONSOLIDATED STATEMENTS OF CASH FLOWS

FOR THE YEARS ENDED DECEMBER 31, 2016 AND 2015

	Years ended December 31,	
	2016	2015
CASH FLOWS FROM OPERATING ACTIVITIES:		
Net loss	$(18,806,776)	$(12,857,339)
Adjustments to reconcile net loss to net cash used in operating activities:		
Depreciation and amortization	125,719	110,865
Stock-based compensation	1,962,465	1,573,224
Non-cash impairment	1,500,000	-
Change in assets - (increase) decrease:		
Restricted cash	(1,347,225)	2,977,024
Receivables	(11,397)	148,295
Prepaid expenses and other current assets	(132,289)	24,920
Other assets	8,720	(14,826)
Change in liabilities - increase (decrease):		
Accounts payable and accrued expenses	508,280	831,246
Accounts payable and accrued expenses, related party	136,883	(81,378)
Accrued interest	344,106	246,724
CIRM liability	3,100,000	-
Deferred revenue	(3,190,106)	(3,776,041)
NET CASH USED IN OPERATING ACTIVITIES	(15,801,620)	(10,817,286)
CASH FLOWS FROM INVESTING ACTIVITIES:		
Purchase of marketable securities	(17,997,361)	(17,989,625)
Proceeds from sales and maturities of marketable securities	13,000,000	10,000,000
Purchases of property and equipment	(191,970)	(129,697)
Payments for leasehold improvements	(1,769)	(21,530)
NET CASH USED IN INVESTING ACTIVITIES	(5,191,100)	(8,140,852)
CASH FLOWS FROM FINANCING ACTIVITIES:		
Net proceeds from sale of common stock	13,864,817	16,446,218
Proceeds from loan payable	4,750,000	-
Proceeds from stock awards, warrants, and options	13,975	45,461
NET CASH PROVIDED BY FINANCING ACTIVITIES	18,628,792	16,491,679
NET DECREASE IN CASH AND CASH EQUIVALENTS	(2,363,928)	(2,466,459)

Cash and cash equivalents balance at beginning of period	5,568,306	8,034,765
Cash and cash equivalents balance at end of period	$3,204,378	$5,568,306
SUPPLEMENTAL DISCLOSURES:		
Interest paid in cash	$1,343	$2,685
Income taxes paid in cash	$-	$-

See accompanying notes to the audited consolidated financial statements.

CAPRICOR THERAPEUTICS, INC.

NOTES TO CONSOLIDATED FINANCIAL STATEMENTS

DECEMBER 31, 2016 AND 2015

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, focusing on cardiovascular diseases as well as exploring other indications. Capricor, Inc. ("Capricor"), a privately-held company and a wholly-owned subsidiary of Capricor Therapeutics, 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, have four drug candidates, two of which are in various stages of active 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 and a grant from the California Institute for Regenerative Medicine ("CIRM").

Cash, cash equivalents and marketable securities as of December 31, 2016 were approximately $16.2 million, compared to approximately $13.6 million as of December 31, 2015. 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 its 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 its common stock. Each warrant has an exercise price of $4.50 per share, became exercisable on September 17, 2016, and will expire on March 16, 2019. In September 2016, the Company completed an underwritten registered public offering and concurrent registered direct offering in which the Company issued an aggregate of 3,403,125 shares of its common stock at a price per share of $3.20 for an aggregate purchase price of approximately $10.9 million.

Additionally, under the terms of the Company's ALLSTAR Loan Award with CIRM (see Note 2 – "Loan Payable"), Capricor received $4.8 million in additional disbursements over the course of 2016. Also, in June 2016, Capricor entered into a Grant Award with CIRM in the amount of approximately $3.4 million (the "CIRM Award") to fund, in part, Capricor's Phase I/II HOPE-Duchenne clinical trial (see Note 6 – "Government Grant Awards"). Pursuant to the terms of the CIRM Award, the disbursements are tied to the achievement of specified operational milestones. In addition, the terms of the CIRM Award include a co-funding requirement pursuant to which Capricor is required to spend a minimum of approximately $2.3 million of its own capital to fund the HOPE-Duchenne clinical trial. In 2016, Capricor received two disbursements under the terms of the CIRM Award totaling $3.1 million. Additionally, in September, the Company was awarded a U.S. Department of Defense ("DoD") grant award in the amount of approximately $2.4 million (see Note 6 – "Government Grant Awards").

The Company's principal uses of cash are for research and development expenses, general and administrative expenses, capital expenditures and other working capital requirements.

CAPRICOR THERAPEUTICS, INC.

NOTES TO CONSOLIDATED FINANCIAL STATEMENTS

DECEMBER 31, 2016 AND 2015

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

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 the manufacturing of its product candidates;
- 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.

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 the Company could be required to reduce expenses and curtail 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 U.S. generally accepted accounting principles ("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 collaboration revenue is recognized, recoverability and fair value of intangible assets, and the assumptions used to estimate stock-based compensation expense. 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

The Company has two awards with CIRM designated for specific use, a Loan Agreement with CIRM (the "CIRM Loan Agreement") entered into on February 5, 2013 (see Note 2 – "Loan Payable") in connection with the ALLSTAR Phase II clinical trial and the CIRM Award (see Note 6 – "Government Grant Awards") related to the HOPE Phase I/II clinical trial. Restricted cash represents funds received under these awards which are to be allocated to the research costs as incurred. Generally, a reduction of restricted cash occurs when the Company deems certain costs are attributable to the respective award. The restricted cash balance was approximately $1.3 million and $0 as of December 31, 2016 and 2015, respectively.

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.

CAPRICOR THERAPEUTICS, INC.

NOTES TO CONSOLIDATED FINANCIAL STATEMENTS

DECEMBER 31, 2016 AND 2015

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

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 $85,888 and $62,116 for the years ended December 31, 2016 and 2015, respectively.

Property and equipment consisted of the following at December 31:

	2016	2015
Furniture and fixtures	$51,161	$59,128
Laboratory equipment	587,809	387,872
Leasehold improvements	47,043	45,274
	686,013	492,274
Less accumulated depreciation	(250,677)	(173,708)
Property and equipment, net	$435,336	$318,566

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. Certain 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 for the years ended December 31, 2016 and 2015. A summary of future amortization expense as of December 31, 2016 is as follows:

Years ended	Amortization Expense
2017	$ 48,749
2018	43,733
2019	43,276
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. The Company reviews intangible assets at least annually for possible impairment. 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. In February 2017, the Company announced the termination of its development program for Cenderitide and CU-NP. As of December 31, 2016, the Company deemed the in-process research and development assets to be impaired. As of December 31, 2016, the Company recognized an impairment expense of $1.5 million shown within the statement of operations and comprehensive loss as an other expense.

CAPRICOR THERAPEUTICS, INC.

NOTES TO CONSOLIDATED FINANCIAL STATEMENTS

DECEMBER 31, 2016 AND 2015

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

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 related to long-lived assets was recorded for the years ended December 31, 2016 and 2015.

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. Because the terms of the CIRM Award allow Capricor to elect to convert the grant into a loan at the end of the project period, the CIRM Award is being classified as a liability rather than income (see Note 6 - “Government Grant Awards”).

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 that the deliverables under its Collaboration Agreement with Janssen (see Note 8 – "License Agreements") did not meet the criteria to be considered separate accounting units for the purposes of revenue recognition. As a result, the Company recognizes 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 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.

CAPRICOR THERAPEUTICS, INC.

NOTES TO CONSOLIDATED FINANCIAL STATEMENTS

DECEMBER 31, 2016 AND 2015

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

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.

As of December 31, 2016, the Company had federal net operating loss carryforwards of approximately $84.2 million, available to reduce future taxable income, which will begin to expire in 2026. As of December 31, 2016, the Company had state net operating loss carryforwards of approximately $80.0 million, available to reduce future taxable income, which will begin to expire in 2017. Utilization of these net operating losses could be limited under Section 382 of the Internal Revenue Code of 1986, as amended (the “Code”) and similar state laws based on ownership changes and the value of the Company’s stock. Additionally, currently, the Company has approximately $1.4 million of federal research and development credits and approximately $0.1 million of federal orphan drug credits, available to offset future taxable income. These federal research and development and orphan drug credits begin to expire in 2027 and 2035, respectively.

Under Section 382 of the Code, the Company’s ability to utilize NOL carryforwards or other tax attributes, such as federal tax credits, in any taxable year may be limited if the Company has experienced an “ownership change.” Generally, a Section 382 ownership change occurs if one or more stockholders or groups of stockholders who owns at least 5% of a corporation’s stock increases its ownership by more than 50 percentage points over its lowest ownership percentage within a specified testing period. Similar rules may apply under state tax laws. We have experienced an ownership change that we believe under Section 382 of the Code will result in limitation in our ability to utilize net operating losses and credits. In addition, the Company may experience future ownership changes as a result of future offerings or other changes in ownership of its stock. As a result, the amount of the NOLs and tax credit carryforward presented in the financial statement could be limited and may expire unutilized. The Company’s net operating loss carryforwards are subject to Internal Revenue Service (“IRS”) examination until they are fully utilized and such tax years are closed.

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, 2016 and 2015. The Company files income tax returns with the IRS and the California Franchise Tax Board.

Loan Payable

The Company accounts for the funds advanced under the CIRM Loan Agreement (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 rental amounts 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 consolidated balance sheet accounts payable and accrued expenses, related party. 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 $16.0 million and $13.8 million for the years ended December 31, 2016 and 2015, respectively.

CAPRICOR THERAPEUTICS, INC.

NOTES TO CONSOLIDATED FINANCIAL STATEMENTS

DECEMBER 31, 2016 AND 2015

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

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 $18.8 million and $12.8 million for the years ended December 31, 2016 and 2015, respectively. The Company's other comprehensive income (loss) is related to a net unrealized gain (loss) on marketable securities. For the years ended December 31, 2016 and 2015, the Company's other comprehensive gain (loss) was $(5,861) and $9,385, 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 an 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.

For the years ended December 31, 2016 and 2015, warrants and options to purchase 7,690,285 and 6,233,153 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.

CAPRICOR THERAPEUTICS, INC.

NOTES TO CONSOLIDATED FINANCIAL STATEMENTS

DECEMBER 31, 2016 AND 2015

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

The following tables summarize the fair value measurements by level for assets and liabilities measured at fair value on a recurring basis:

	December 31, 2016			
	Level I	Level II	Level III	Total
Marketable securities	$12,990,510	$ -	$ -	$12,990,510

	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 from 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, 2016, and no such liability has been reflected on the balance sheet.

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 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* ("ASU 2014-15"), 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). ASU 2014-15 is effective for the annual period ending after December 15, 2016 and for annual and interim periods thereafter. Early adoption is permitted. The adoption of this update is not expected to have a material effect on the Company's financial statements.

CAPRICOR THERAPEUTICS, INC.

NOTES TO CONSOLIDATED FINANCIAL STATEMENTS

DECEMBER 31, 2016 AND 2015

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

In February 2015, the FASB issued ASU 2015-02, *Consolidation (Topic 810): Amendments to the Consolidation Analysis* ("ASU 2015-02"). 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. The Company adopted this standard effective December 31, 2015.

In April 2015, the FASB issued ASU 2015-03, *Simplifying the Presentation of Debt Issuance Costs* ("ASU 2015-03"). 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* ("ASU 2015-15"). ASU 2015-15 clarified guidance in ASU 2015-03 by providing 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 required the Company to adopt these provisions in the first quarter of 2016. This update was applied on a retrospective basis, wherein the balance sheet of each period presented was adjusted to reflect the effects of applying the new guidance.

In February 2016, the FASB issued ASU 2016-02, *Leases (Topic 842)* ("ASU 2016-02"), 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.

In March 2016, the FASB issued ASU 2016-09, *Compensation — Stock Compensation (Topic 718): Improvements to Employee Share-Based Payment Accounting*, which outlines new provisions intended to simplify various aspects related to accounting for share-based payments and their presentation in the financial statements. The standard is effective for the Company beginning December 15, 2016 and for interim periods within those annual periods. Early adoption is permitted. The Company is evaluating the impact of the adoption of this guidance on its financial statements.

In April 2016, the FASB issued ASU 2016-10, *Revenue from Contracts with Customers (Topic 606)*, which amends certain aspects of the FASB's and International Accounting Standards Board's new revenue standard, ASU 2014-09, *Revenue from Contracts with Customers* ("ASU 2014-09"). The standard should be adopted concurrently with the adoption of ASU 2014-09, which is effective for annual and interim periods beginning after December 15, 2017. Early adoption is permitted. The Company has not yet selected a transition method nor has it determined the effect of the standard on its ongoing financial reporting.

In November 2016, the FASB issued ASU 2016-18, *Statement of Cash Flows (Topic 230): Restricted Cash*, a consensus of the FASB Emerging Issues Task Force, which requires that a statement of cash flows explain the change during the period in the total of cash, cash equivalents, and amounts generally described as restricted cash or restricted cash equivalents. Therefore, amounts generally described as restricted cash and restricted cash equivalents should be included with cash and cash equivalents when reconciling the beginning-of-period and end-of period total amounts shown on the statement of cash flows. The standard is effective for the Company for fiscal years beginning after December 15, 2017, and interim periods within those fiscal years. Early adoption is permitted. The Company is evaluating the impact of the adoption of this guidance on its 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 SEC, 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.

CAPRICOR THERAPEUTICS, INC.

NOTES TO CONSOLIDATED FINANCIAL STATEMENTS

DECEMBER 31, 2016 AND 2015

2. LOAN PAYABLE

On February 5, 2013, Capricor entered into 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. On May 12, 2016, the Company and CIRM entered into an amendment to the CIRM Loan Agreement (the "CIRM Loan Amendment") pursuant to which the parties agreed, among other things, upon a schedule for future disbursements of the proceeds of the loan amount based upon the achievement of specified operational milestones. As a result of the CIRM Loan Amendment and because the Company decreased the number of patients enrolled in the ALLSTAR clinical trial, the Company will not need to take down the full amount available for disbursement under the CIRM Loan Agreement and certain operational milestones tied to patient enrollment will not be met. The Company believes that the amount that will ultimately be disbursed will be approximately 70-75% of the total amount specified in the CIRM Loan Agreement, thus reducing the total amount of debt incurred thereunder.

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.

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 loan award. Additionally, on September 30, 2015, the Company entered into a Joinder Agreement with Capricor 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.

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, 2016, $30,000 of loan costs were capitalized with the balance of $5,929 to be amortized over approximately one year and one months.

In 2013, Capricor received disbursements pursuant to the terms of the CIRM Loan Agreement of $3,925,066, net of loan costs. The disbursements carried an initial interest rate of approximately 2.5% - 2.8% per annum.

In 2014, Capricor received disbursements pursuant to the terms of the CIRM Loan Agreement of $5,194,124, which includes previously deducted due diligence costs that were refunded. The disbursements carried an initial interest rate of approximately 2.6% per annum.

In 2016, Capricor received disbursements pursuant to the terms of the CIRM Loan Agreement of $4,750,000. The disbursements carried an initial interest rate of approximately 3.2% - 3.4% per annum.

CAPRICOR THERAPEUTICS, INC.

NOTES TO CONSOLIDATED FINANCIAL STATEMENTS

DECEMBER 31, 2016 AND 2015

2. LOAN PAYABLE (Continued)

For the years ended December 31, 2016 and 2015, interest expense under the CIRM loan was $344,106 and $246,724, respectively. The principal balance outstanding under the CIRM loan was $13,905,857 and $9,155,857 for the years ended December 31, 2016 and December 31, 2015, respectively. 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

March 2016 Registered Direct Offering

On March 16, 2016, the Company issued and sold to certain investors an aggregate of 1,692,151 shares of the Company's common stock at a purchase price of $2.40 per share for an aggregate purchase price of $4,060,000. This offering included participation from some of the Company's officers and directors. Fees paid in conjunction with the registered direct offering, which included placement agent fees and estimated offering expenses, amounted to approximately $0.1 million in the aggregate and were recorded as a reduction to additional paid-in capital, resulting in net proceeds of approximately $3.9 million.

In connection with the sale of shares of the Company's common stock, on March 16, 2016, 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, became initially exercisable on September 17, 2016, and will expire on March 16, 2019. Pursuant to the terms of each warrant, if, on or after the original exercise date of such warrant, the Volume Weighted Average Price of the Common Stock (as defined in each warrant) equals or exceeds $7.50 per share for any period of 20 consecutive trading days, the Company shall have the right, but not the obligation, to redeem any unexercised portion of such warrant for a redemption fee of $0.001 per share of common stock underlying such warrant.

September 2016 Underwritten Public and Registered Direct Offering

In September 2016, the Company completed an underwritten registered public offering and concurrent registered direct offering pursuant to which the Company issued an aggregate of 3,403,125 shares of its common stock at a price per share of $3.20 for an aggregate purchase price of $10,890,000. Fees paid in conjunction with the underwritten deal and registered direct offering, which included underwriter commissions and estimated offering expenses, amounted to approximately $1.0 million in the aggregate and were recorded as a reduction to additional paid-in capital, resulting in net proceeds of approximately $9.9 million.

Outstanding Shares

At December 31, 2016, the Company had 21,399,019 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, 2016 and 2015:

	Warrants	Weighted Average Exercise Price
Outstanding at January 1, 2015	303,881	$ 10.02
Exercised	(15,401)	2.27
Expired	(52,650)	47.00
Outstanding at December 31, 2015	235,830	$ 2.27
Granted	846,073	4.50
Outstanding at December 31, 2016	1,081,903	$ 4.01

CAPRICOR THERAPEUTICS, INC.

NOTES TO CONSOLIDATED FINANCIAL STATEMENTS

DECEMBER 31, 2016 AND 2015

4. STOCK AWARDS, WARRANTS AND OPTIONS (Continued)

The following table summarizes all outstanding warrants to purchase shares of the Company's common stock:

	Warrants Outstanding			
Grant Date	December 31, 2016	December 31, 2015	Exercise Price per Share	Expiration Date
4/4/2012	187	187	$ 2.27	4/4/2017
11/20/2013	235,643	235,643	$ 2.27	11/20/2018
3/16/2016	846,073	-	$ 4.50	3/16/2019
	1,081,903	235,830		

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 (which has now expired), (ii) the 2006 Stock Option Plan, (iii) the 2012 Restated Equity Incentive Plan (which 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").

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.

On June 2, 2016 at the Company's annual stockholder meeting, the stockholders approved a proposal to amend the 2012 Plan, to, among other things, increase the number of shares of common stock of the Company that may be issued

under the 2012 Plan to equal the sum of 4,149,710 plus 2% of the outstanding shares of common stock as of December 31, 2015, with the number of shares that may be issued under the 2012 Plan automatically increasing thereafter on January 1 of each year, commencing with January 1, 2017, by 2% of the outstanding shares of common stock as of the last day of the immediately preceding fiscal year (rounded down to the nearest whole share). Additionally, in connection with the proposed increase in the total number of shares of common stock that may be issued under the 2012 Plan, the Company increased the number of shares of common stock that may be issued pursuant to options that are intended to qualify as incentive stock options from 4,149,710 shares to 4,474,809 shares. The Third Amendment to the 2012 Plan provided that an additional 325,099 shares be added to the 2012 Plan for the fiscal year 2016. In addition, for the fiscal year beginning on January 1, 2017 the amount of shares that were added was equal to 427,980 shares.

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 2016 and 2015 were approximately $2.09 and $3.84 per share, respectively.

CAPRICOR THERAPEUTICS, INC.

NOTES TO CONSOLIDATED FINANCIAL STATEMENTS

DECEMBER 31, 2016 AND 2015

4. STOCK AWARDS, WARRANTS AND OPTIONS (Continued)

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, 2016 and 2015:

	December 31, 2016	December 31, 2015
Expected volatility	78% - 82%	76% - 82%
Expected term	5-7 years	5-7 years
Dividend yield	0%	0%
Risk-free interest rates	0.5% - 2.3%	0.3% - 2.1%

Employee and non-employee stock-based compensation expense for the years ended December 31, 2016 and 2015 was as follows:

	2016	2015
General and administrative	$1,400,059	$1,284,959
Research and development	562,406	288,265
Total	$1,962,465	$1,573,224

The following table summarizes information about stock options outstanding and exercisable at December 31, 2016:

Shares Outstanding			
Range of Ex. Prices	Shares Outstanding	Weighted Average Term (yrs.)	Weighted Average Exercise Price
$0.16 - $0.19	78,842	1.33	$ 0.17
$0.30 - $0.37	4,331,069	5.35	0.36
$0.87	56,021	1.95	0.87
$3.58 - $5.78	2,138,301	8.67	4.23
$9.14	4,149	8.23	9.14

	6,608,382	6.35	$ 1.62

Shares Exercisable

Range of Ex. Prices	Shares Exercisable	Weighted Average Term (yrs.)	Weighted Average Exercise Price
$0.16 - $0.19	78,842	1.33	$ 0.17
$0.30 - $0.37	4,220,843	5.32	0.36
$0.87	56,021	1.95	0.87
$3.58 - $5.78	829,979	8.39	4.62
$9.14	1,729	8.23	9.14
	5,187,414	5.72	$ 1.05

As of December 31, 2016, the total unrecognized fair value compensation cost related to non-vested stock options was approximately $3.5 million, which is expected to be recognized over a weighted average period of approximately 1.4 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.

CAPRICOR THERAPEUTICS, INC.

NOTES TO CONSOLIDATED FINANCIAL STATEMENTS

DECEMBER 31, 2016 AND 2015

4. STOCK AWARDS, WARRANTS AND OPTIONS (Continued)

The following is a schedule summarizing employee and non-employee stock option activity for the years ended December 31, 2016 and 2015:

	Number of Options	Weighted Average Exercise Price	Aggregate Intrinsic Value
Outstanding at January 1, 2015	5,004,700	$ 0.75	
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
Granted	980,000	2.98	
Exercised	(48,758)	0.29	
Expired/Cancelled	(320,183)	5.45	
Outstanding at December 31, 2016	6,608,382	$ 1.62	$ 6,874,063
Exercisable at December 31, 2016	5,187,414	$ 1.05	$ 8,365,442

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 approximately $142,031 and $131,708 for the years ended December 31, 2016 and 2015, 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, 2016, the Company maintained approximately $17.3 million of uninsured deposits.

6. GOVERNMENT GRANT AWARDS

CIRM Grant Award (HOPE)

On June 16, 2016, Capricor entered into the CIRM Award with CIRM in the amount of approximately $3.4 million to fund, in part, Capricor's Phase I/II HOPE-Duchenne clinical trial investigating CAP-1002 (allogeneic cardiosphere-derived cells) for the treatment of Duchenne muscular dystrophy-associated cardiomyopathy. Pursuant to terms of the CIRM Award, the disbursements will be tied to the achievement of specified operational milestones. If CIRM determines, in its sole discretion, that Capricor has not complied with the terms and conditions of the CIRM Award, CIRM may suspend or permanently cease disbursements or pursue other remedies as allowed by law. In addition, the terms of the CIRM Award include a co-funding requirement pursuant to which Capricor is required to spend approximately $2.3 million of its own capital to fund the HOPE-Duchenne clinical trial. If Capricor fails to satisfy its co-funding requirement, the amount of the CIRM Award may be proportionately reduced. The CIRM Award is further subject to the conditions and requirements set forth in the CIRM Grants Administration Policy for Clinical Stage Projects. Such requirements include, without limitation, the filing of quarterly and annual reports with CIRM, the sharing of intellectual property pursuant to Title 17, CCR Sections 100600-100612, and the sharing with the State of California of a fraction of licensing revenue received from a CIRM funded research project and net commercial revenue from a commercialized product which resulted from CIRM funded research as set forth in Title 17, CCR Section 100608. The maximum royalty on net commercial revenue that Capricor may be required to pay to CIRM is equal to nine times the total amount awarded and paid to Capricor.

CAPRICOR THERAPEUTICS, INC.

NOTES TO CONSOLIDATED FINANCIAL STATEMENTS

DECEMBER 31, 2016 AND 2015

6. GOVERNMENT GRANT AWARDS (Continued)

After completing the CIRM funded research project and after the award period end date, estimated to be in late 2017 or in 2018, Capricor has the right to convert the CIRM Award into a loan, the terms of which will be determined based on various factors, including the stage of the research and the stage of development at the time the election is made. On June 20, 2016, Capricor entered into a Loan Election Agreement with CIRM whereby, among other things, CIRM and Capricor agreed that, if converted, the term of the loan would be five years from the date of execution of the applicable loan agreement; provided that the term of the loan will not exceed ten years from the date on which the CIRM Award was granted. Beginning on the date of the loan, the loan shall bear interest on the unpaid principal balance plus the interest that was accrued prior to the election point according to the terms set forth in CIRM's Loan Policy ("New Loan Balance") at a per annum rate equal to the LIBOR rate for a three-month deposit in U.S. dollars, as published by the Wall Street Journal on the loan date, plus one percent. Interest shall be compounded annually on the outstanding New Loan Balance commencing with the loan date and the interest shall be payable, together with the New Loan Balance, upon the due date of the loan. If Capricor elects to convert the CIRM Award into a loan, certain requirements of the CIRM Award will no longer be applicable, including the revenue sharing requirements. Capricor will not make its decision as to whether it will elect to convert the CIRM Award into a loan until after the end of the HOPE-Duchenne trial. Since Capricor may be required to repay some or all of the amounts awarded by CIRM, the Company will account for this award as a liability rather than income. If Capricor were to lose this funding, it may be required to delay, postpone, or cancel its HOPE-Duchenne trial or otherwise reduce or curtail its operations, unless it was able to obtain adequate financing for its clinical trial from alternative sources. In July 2016, Capricor received the first disbursement of $2.0 million under the terms of the CIRM Award. Additionally, in September 2016, we completed the first operational milestone which was tied to the completion of enrollment of the HOPE-Duchenne clinical trial for which $1.1 million was received by Capricor in November 2016. As of December 31, 2016, our CIRM liability balance for the CIRM Award was $3.1 million.

NIH Grant Award (DYNAMIC)

In August 2013, Capricor was approved for a Phase IIB bridge grant through the National Institutes of Health ("NIH") Small Business Innovation Research ("SBIR") program for continued development of its CAP-1002 product candidate. Under the terms of the NIH grant, disbursements were 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. During the years ended December 31, 2016 and 2015, approximately $0.5 million and $1.7 million, respectively, were incurred under the terms of the NIH grant. As of December 31, 2016, the full award of $2.9 million has been disbursed.

NIH Grant Award (HLHS)

In September 2016, Capricor was approved for a grant from the NIH to study CAP-2003 (cardiosphere-derived cell exosomes) for hypoplastic left heart syndrome (HLHS). Under the terms of the NIH grant, disbursements will be made to Capricor in an amount up to approximately $4.2 million, subject to annual and quarterly reporting requirements as well as completion of the study objectives. As of December 31, 2016, no disbursements have been made under the terms of the NIH grant award.

U.S. Department of Defense Grant Award

In September 2016, Capricor was approved for a grant award from the DoD in the amount of approximately $2.4 million to be used toward developing a scalable, commercially-ready process to manufacture CAP-2003. Under the terms of the award, disbursements will be made to Capricor over a period of approximately two years, subject to annual and quarterly reporting requirements. As of December 31, 2016, approximately $0.3 million has been incurred under the terms of the award.

CAPRICOR THERAPEUTICS, INC.

NOTES TO CONSOLIDATED FINANCIAL STATEMENTS

DECEMBER 31, 2016 AND 2015

7. COMMITMENTS AND CONTINGENCIES

Leases

Capricor leases space for its corporate offices pursuant to a lease that was originally 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 (the "Second Lease Amendment") 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 Lease 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 25, 2016, Capricor entered into a Third Amendment to Lease (the "Third Lease Amendment") with The Bubble Real Estate Company, LLC. Under the terms of the Third Lease Amendment, the lease term commenced on July 1, 2016 and will end on December 31, 2018. Commencing July 1, 2016, the base rent increased to $22,995 per month for the first twelve months of the term, will increase to $23,915 per month for the second twelve months of the term, and, thereafter, will increase to $24,872 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. At the time of filing of this Annual Report on Form 10-K, the Company is currently in discussions with CSMC regarding an amendment to extend the term of the CSMC Lease and include the manufacturing facility within its provisions.

Unless renewed, each of the leases described above will not be in effect for fiscal year 2019. Included within the table below, future minimum rental payments to related parties totaled approximately $96,750. A summary of future minimum rental payments required under operating leases as of December 31, 2016 is as follows:

Years ended	Operating Leases

2017	$ 378,210
2018	292,722
Total minimum lease payments	$ 670,932

Expenses incurred under operating leases to unrelated parties for the years ended December 31, 2016 and 2015 were approximately $272,607 and $255,942, respectively. Expenses incurred under operating leases to related parties for each of the years ended December 31, 2016 and 2015 were approximately $224,421.

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, 2016.

8. 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 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.

CAPRICOR THERAPEUTICS, INC.

NOTES TO CONSOLIDATED FINANCIAL STATEMENTS

DECEMBER 31, 2016 AND 2015

8. LICENSE AGREEMENTS (Continued)

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 (“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. 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.

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

CAPRICOR THERAPEUTICS, INC.

NOTES TO CONSOLIDATED FINANCIAL STATEMENTS

DECEMBER 31, 2016 AND 2015

8. LICENSE AGREEMENTS (Continued)

Cedars-Sinai Medical Center License Agreements

License Agreement for CDCs

On January 4, 2010, Capricor entered into an Exclusive License Agreement with CSMC (the "Original CSMC License Agreement") for certain intellectual property rights. In 2013, the Original 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 Original 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.

On August 5, 2016, Capricor and CSMC entered into a Second Amendment to the Amended CSMC License Agreement (the “Second License Amendment”), pursuant to which the parties agreed to add certain patent families to the schedule of patent rights set forth in the agreement. Under the Second License Amendment, (i) the description of patent rights in Schedule A has been replaced by a Revised Schedule A that includes two additional patent family applications; (ii) Capricor paid an upfront fee of $2,500; and (iii) Capricor reimbursed CSMC approximately $10,000 for attorneys’ fees and filing fees that were incurred in connection with the additional patent families.

CAPRICOR THERAPEUTICS, INC.

NOTES TO CONSOLIDATED FINANCIAL STATEMENTS

DECEMBER 31, 2016 AND 2015

8. 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 Exosomes License Agreement (the "First Exosomes License Amendment"). Under the First 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 Exosomes License Agreement, thereby amending the Exosomes License Agreement further to add an additional patent application to the Schedule of Patent Rights.

On August 5, 2016, Capricor and CSMC entered into a Third Amendment to the Exosomes License Agreement (the "Third Exosomes License Amendment"), pursuant to which the parties agreed to add certain patent families to the schedule of patent rights under the agreement. Under the Third Exosomes License Amendment, (i) the description of patent rights in Schedule A has been replaced by a Revised Schedule A that includes two additional patent family applications; (ii) Capricor paid CSMC an upfront fee of $2,500; and (iii) Capricor reimbursed CSMC approximately $16,000 for attorneys' fees and filing fees that were incurred in connection with the additional patent families.

CAPRICOR THERAPEUTICS, INC.

NOTES TO CONSOLIDATED FINANCIAL STATEMENTS

DECEMBER 31, 2016 AND 2015

8. 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 agreed to contribute to the development of a chemistry, manufacturing and controls 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 CSps and CDCs in the field of cardiology, except as may otherwise be agreed with respect to certain indications to be determined. 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 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 (see Note 10 – "Subsequent Events").

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 subsequently entered into a Transfer Agreement, described below.

CAPRICOR THERAPEUTICS, INC.

NOTES TO CONSOLIDATED FINANCIAL STATEMENTS

DECEMBER 31, 2016 AND 2015

8. LICENSE AGREEMENTS (Continued)

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 (the "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 with 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.

In light of our decision to terminate our development program with respect to natriuretic peptides, the Company is now considering whether or not to cease prosecution of some or all of the Natriuretic Peptide Patents and has offered to reassign to Medtronic rights to certain patent applications obtained through the Transfer Agreement.

9. RELATED PARTY TRANSACTIONS

Lease and Sub-Lease Agreement

As noted above, Capricor is a party to lease agreements with CSMC, which holds more than 10% of the outstanding capital stock of Capricor Therapeutics (see Note 7 – "Commitments and Contingencies"), and CSMC has served and continues to serve as an investigative site in Capricor's clinical trials. Additionally, Dr. Eduardo Marbán, who holds more than 10% of the outstanding capital stock of Capricor Therapeutics and participates as an observer at the Company's meetings of the Board of Directors, is the Director of the Cedars-Sinai Heart Institute, a Co-Founder of Capricor and the Chairman of the Company's Scientific Advisory Board.

On April 1, 2013, Capricor entered into a sublease with Reprise Technologies, LLC, a limited liability company which is wholly owned by Dr. Frank Litvack, the Company's Executive Chairman and member of its Board of Directors, for $2,500 per month. The sublease is on a month-to-month basis. For both the years ended December 31, 2016 and 2015, Capricor recognized $30,000 in sublease income from the related party. Sublease income is recorded as a reduction to general and administrative expenses.

CAPRICOR THERAPEUTICS, INC.

NOTES TO CONSOLIDATED FINANCIAL STATEMENTS

DECEMBER 31, 2016 AND 2015

9. RELATED PARTY TRANSACTIONS (Continued)

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. Additionally, in 2016, Capricor retained the services of Lit Digital Media, LLC whose sole member is Harry Litvack, the son of Frank Litvack. Lit Digital Media provides services to the Company related to social media and public relations, and the Company pays Lit Digital Media approximately $1,500 per month for such services.

Payables to Related Party

At December 31, 2016 and 2015, the Company had accounts payable and accrued expenses to related parties totaling $489,217 and $352,334, respectively. CSMC accounts for approximately $477,907 and $352,334 of the total accounts payable and accrued expenses to related parties as of December 31, 2016 and 2015, respectively. CSMC expenses relate to the ongoing clinical trials costs and deferred rent on our research lab space.

Related Party Clinical Trials

Capricor has agreed to provide cells for investigational purposes in two clinical trials sponsored by CSMC, subject to final documentation. The first trial is known as "Regression of Fibrosis and Reversal of Diastolic Dysfunction in HFpEF Patients Treated with Allogeneic CDCs." Dr. Eduardo Marbán is the named principal investigator under the study. The second trial is known as "Pulmonary Arterial Hypertension treated with Cardiosphere-derived Allogeneic Stem Cells." In both studies, Capricor will provide the necessary number of doses and will receive a negotiated amount of monetary compensation therefor.

10. SUBSEQUENT EVENTS

Stock Option Grants

In January 2017, the Company granted a total of 566,131 stock options to its employees and directors.

Termination of Mayo License Agreement

On February 13, 2017, the Company provided Mayo with a notice of termination of the Amended Mayo Agreement pursuant to Section 7.03 of the Amended Mayo Agreement, thereby relinquishing all rights previously licensed by Mayo to Capricor with respect to CD-NP and CU-NP. The Company provided 90 days' notice of the effectiveness of termination, but Mayo has indicated to the Company that it considers the Amended Mayo Agreement to be terminated as of February 14, 2017 due to an ongoing dispute with Mayo regarding the payment of certain fees incurred in the prosecution of the intellectual property rights licensed by Mayo to the Company, which fees the Company does not deem to be material in amount. The Company elected to terminate the Amended Mayo Agreement so we may focus our resources and efforts on our CAP-1002 and CAP-2003 programs.

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, 2016, 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, 2016 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, 2016.

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, 2016 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 2017 Annual Meeting of Stockholders, or our 2017 Proxy Statement, to be filed with the SEC within 120 days after the end of the fiscal year ended December 31, 2016, and is incorporated herein by reference.

ITEM 11. EXECUTIVE COMPENSATION.

The information required by this item will be set forth in the section entitled “2016 Executive Compensation” and “Compensation of Directors” in our 2017 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 2017 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 2017 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 2017 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 63.

(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	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).
4.2	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	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). †
10.5	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). †
10.6	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). †
10.7	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). †
10.8	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). †
10.9	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). †
10.10	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). †
10.11	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). †
10.12	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). †
10.13	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). †
10.14	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). †
10.15	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). †
10.16	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). †
10.17	

	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).
10.18	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).
10.19	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).

10.20	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).
10.21	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).
10.22	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). +
10.23	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). +
10.24	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) . +
10.25	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). +
10.26	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). +
10.27	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) . +
10.28	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). +
10.29	Loan Agreement, dated February 1, 2013, between Capricor, Inc. and the California Institute for Regenerative Medicine (incorporated by reference to Exhibit 10.38 to the Company's Annual Report on Form 10-K, filed with the Commission on March 31, 2014) . +
10.30	Notice of Loan Award, dated February 1, 2013, between Capricor, Inc. and the California Institute for Regenerative Medicine (incorporated by reference to Exhibit 10.39 to the Company's Annual Report on Form 10-K, filed with the Commission on March 31, 2014) . +
10.31	Facilities Lease, dated January 1, 2008, between Capricor, Inc. and Cedars-Sinai Medical Center (incorporated by reference to Exhibit 10.40 to the Company's Annual Report on Form 10-K, filed with the Commission on March 31, 2014).

10.32	Lease Agreement, dated March 29, 2012, between Capricor, Inc. and The Bubble Real Estate Company, LLC (incorporated by reference to Exhibit 10.2 to the Company's Quarterly Report on Form 10-Q, filed with the Commission on August 14, 2015).
10.33	First Amendment to the Lease Agreement, dated June 13, 2013, between Capricor, Inc. and The Bubble Real Estate Company, LLC (incorporated by reference to Exhibit 10.3 to the Company's Quarterly Report on Form 10-Q, filed with the Commission on August 14, 2015). +
10.34	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).

10.35	Sublease Agreement, dated April 1, 2013, between Capricor, Inc. and Reprise Technologies, LLC(incorporated by reference to Exhibit 10.44 to the Company's Annual Report on Form 10-K, filed with the Commission on March 31, 2014).
10.36	Exclusive License Agreement, dated May 5, 2014 between Capricor, Inc. and Cedars-Sinai Medical Center (incorporated by reference to Exhibit 10.46 to the Company's Amendment No. 1 to Registration Statement on Form S-1, filed with the Commission on May 23, 2014). +
10.37	Facilities Lease, dated June 1, 2014, between Capricor, Inc. and Cedars-Sinai Medical Center (incorporated by reference to Exhibit 10.1 to the Company's Quarterly Report on Form 10-Q, filed with the Commission on May 15, 2014).
10.38	Transfer Agreement, dated October 8, 2014, by and between Capricor Therapeutics, Inc. and Medtronic, Inc. (incorporated by reference to Exhibit 10.47 to the Company's Registration Statement on Form S-1, filed with the Commission on March 6, 2015). +
10.39	Share Purchase Agreement, dated as of January 9, 2015, by and among Capricor Therapeutics, Inc. and the Investors (incorporated by reference to Exhibit 10.1 to the Company's Amendment No. 1 to Current Report on Form 8-K/A, filed with the Commission on January 22, 2015).
10.40	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).
10.41	Share Purchase Agreement, dated as of February 3, 2015, by and among Capricor Therapeutics, Inc. and the Investors (incorporated by reference to Exhibit 10.1 to the Company's Amendment No. 1 to Current Report on Form 8-K/A, filed with the Commission on February 6, 2015).
10.42	Registration Rights Agreement, dated as of February 3, 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 February 6, 2015).
10.43	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).
10.44	Employment Agreement by and between Capricor, Inc. and Andrew Hamer, dated November 11, 2013 (incorporated by reference to Exhibit 10.53 to the Company's Registration Statement on Form S-1, filed with the Commission on March 6, 2015).†
10.45	First Amendment to Exclusive License Agreement, dated as of February 27, 2015, by and between Capricor, Inc. and Cedars-Sinai Medical Center (incorporated by reference to Exhibit 10.54 to the Company's Registration Statement on Form S-1, filed with the Commission on March 6, 2015). +
10.46	Second Amendment to Lease Agreement, dated March 3, 2015, by and between Capricor, Inc. and The Bubble Real Estate Company, LLC (incorporated by reference to Exhibit 10.55 to the Company's Registration

Statement on Form S-1, filed with the Commission on March 6, 2015).

10.47 Second Amendment to Exclusive License Agreement, dated as of June 10, 2015, by and between Capricor, Inc. and Cedars-Sinai Medical Center (incorporated by reference to Exhibit 10.1 to the Company's Quarterly Report on Form 10-Q, filed with the Commission on August 14, 2015). +

10.48 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).

10.49	Employment Agreement, dated as of August 3, 2015, by and between Capricor, Inc. and Deborah Ascheim, M.D. (incorporated by reference to Exhibit 10.2 to the Company's Quarterly Report on Form 10-Q, filed with the Commission on November 13, 2015). †
10.50	Employment Agreement, dated as of February 22, 2016, by and between Capricor, Inc. and Leland Gershell (incorporated by reference to Exhibit 10.59 to the Company's Annual Report on Form 10-K, filed with the Commission on March 30, 2016). †
10.51	Registration Rights Agreement, dated as of March 14, 2016, by and among the Company and the Investors (incorporated by reference to Exhibit 4.1 to the Company's Amendment No. 1 to Current Report on Form 8-K/A, filed with the Commission on March 16, 2016).
10.52	Subscription Agreement, dated as of March 14, 2016, by and among the Company and the Investors (incorporated by reference to Exhibit 10.1 to the Company's Amendment No. 1 to Current Report on Form 8-K/A, filed with the Commission on March 16, 2016).
10.53	Amendment to Notice of Loan Award, dated as of May 12, 2016 by and between 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 August 15, 2016). +
10.54	Third Amendment to Lease, dated as of May 25, 2016, by and between Capricor, Inc. and The Bubble Real Estate Company, LLC (incorporated by reference to Exhibit 10.2 to the Company's Quarterly Report on Form 10-Q, filed with the Commission on August 15, 2016).
10.55	Notice of Award, dated as of June 16, 2016, by and between Capricor, Inc. and the California Institute for Regenerative Medicine (incorporated by reference to Exhibit 10.3 to the Company's Quarterly Report on Form 10-Q, filed with the Commission on August 15, 2016). +
10.56	Loan Election Agreement, dated as of June 16, 2016, by and between Capricor, Inc. and the California Institute for Regenerative Medicine (incorporated by reference to Exhibit 10.4 to the Company's Quarterly Report on Form 10-Q, filed with the Commission on August 15, 2016).
10.57	Underwriting Agreement, dated as of September 16, 2016, by and among Capricor Therapeutics, Inc., Roth Capital Partners, LLC and National Securities Corporation (incorporated by reference to Exhibit 1.1 to the Company's Current Report on Form 8-K, filed with the Commission on September 16, 2016).
10.58	Subscription Agreement, dated as of September 16, 2016, by and between Capricor Therapeutics, Inc. and Cedars-Sinai Medical Center (incorporated by reference to Exhibit 1.2 to the Company's Current Report on Form 8-K, filed with the Commission on September 16, 2016).
10.59	Second Amendment to Amended and Restated Exclusive License Agreement, dated as of August 5, 2016, by and between Capricor, Inc. and Cedars-Sinai Medical Center (incorporated by reference to Exhibit 10.1 to the Company's Quarterly Report on Form 10-Q, filed with the Commission on November 14, 2016). +
10.60	

	Third Amendment to Exclusive License Agreement, dated as of August 5, 2016, by and between Capricor, Inc. and Cedars-Sinai Medical Center (incorporated by reference to Exhibit 10.2 to the Company's Quarterly Report on Form 10-Q, filed with the Commission on November 14, 2016). +
10.61	Second Amendment to Capricor Therapeutics, Inc. 2012 Restated Equity Plan (incorporated by reference to Exhibit 4.14 to the Company's Registration Statement on Form S-8, filed with the Commission on January 11, 2017). †
10.62	Third Amendment to Capricor Therapeutics, Inc. 2012 Restated Equity Plan (incorporated by reference to Exhibit 4.15 to the Company's Registration Statement on Form S-8, filed with the Commission on January 11, 2017). †
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.*

32.2 Certification of Principal Financial Officer pursuant to Section 906 of the Sarbanes-Oxley Act of 2002.*

101 The following financial information formatted in eXtensible Business Reporting Language (XBRL): (i) Consolidated Balance Sheets as of December 31, 2016 and 2015, (ii) Consolidated Statements of Operations for the years ended December 31, 2016 and 2015, (iii) Consolidated Statement of Stockholders' Equity (Deficit) for the period from December 31, 2014 through December 31, 2016, (iv) Consolidated Statements of Cash Flows for the years ended December 31, 2016 and 2015, 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.

ITEM 16. Form 10-K Summary

None.

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 14, 2017.

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 14, 2017
/s/ Leland Gershell, M.D., Ph.D. Leland Gershell, M.D., Ph.D.	Chief Financial Officer *(Principal Financial Officer)*	March 14, 2017
/s/ Anthony J. Bergmann Anthony J. Bergmann	Vice President of Finance *(Principal Accounting Officer)*	March 14, 2017
/s/ Frank Litvack, M.D. Frank Litvack, M.D.	Executive Chairman	March 14, 2017

/s/ Joshua A. Kazam Joshua A. Kazam	Director	March 14, 2017
/s/ Earl M. Collier Earl M. Collier	Director	March 14, 2017
/s/ Louis V. Manzo Louis V. Manzo	Director	March 14, 2017
/s/ George W. Dunbar George W. Dunbar	Director	March 14, 2017
/s/ David B. Musket David B. Musket	Director	March 14, 2017

PART IV

ITEM 15. EXHIBITS AND FINANCIAL STATEMENT SCHEDULES

2.1	Agreement and Plan of Merger, dated as of August 15, 2007, by and among SMI Products, Inc., Nile Merger Sub, Inc. and Nile Therapeutics, Inc. (incorporated by reference to Exhibit 2.1 to the Company's Current Report on Form 8-K, filed with the Commission on August 17, 2007).
2.2	Agreement and Plan of Merger and Reorganization, dated as of July 7, 2013, by and among Nile Therapeutics, Inc., Bovet Merger Corp. and Capricor, Inc. (incorporated by reference to Exhibit 2.1 to the Company's Current Report on Form 8-K, filed with the Commission on July 9, 2013).
2.3	First Amendment to Agreement and Plan of Merger and Reorganization, dated as of September 27, 2013, by and between Nile Therapeutics, Inc., Bovet Merger Corp. and Capricor, Inc. (incorporated by reference to Exhibit 2.1 to the Company's Current Report on Form 8-K, filed with the Commission on October 3, 2013).
3.1	Certificate of Incorporation of the Company (incorporated by reference to Exhibit 3.1 to the Company's Current Report on Form 8-K, filed with the Commission on February 9, 2007).
3.2	Certificate of Amendment of Certificate of Incorporation of the Company (incorporated by reference to Exhibit 3.1 to the Company's Current Report on Form 8-K, filed with the Commission on November 26, 2013).
3.3	Bylaws of the Company (incorporated by reference to Exhibit 3.2 to the Company's Current Report on Form 8-K, filed with the Commission on February 9, 2007).
4.1	Form of Warrant issued to Investors in 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).
4.2	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	

	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). †
10.5	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). †
10.6	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). †
10.7	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). †
10.8	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). †
10.9	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). †

10.10	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). †
10.11	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). †
10.12	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). †
10.13	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). †
10.14	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). †
10.15	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). †
10.16	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). †
10.17	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).
10.18	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).
10.19	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).
10.20	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).
10.21	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).
10.22	

	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). +
10.23	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). +
10.24	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) . +
10.25	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). +

10.26	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). +
10.27	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) . +
10.28	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). +
10.29	Loan Agreement, dated February 1, 2013, between Capricor, Inc. and the California Institute for Regenerative Medicine (incorporated by reference to Exhibit 10.38 to the Company's Annual Report on Form 10-K, filed with the Commission on March 31, 2014) . +
10.30	Notice of Loan Award, dated February 1, 2013, between Capricor, Inc. and the California Institute for Regenerative Medicine (incorporated by reference to Exhibit 10.39 to the Company's Annual Report on Form 10-K, filed with the Commission on March 31, 2014) . +
10.31	Facilities Lease, dated January 1, 2008, between Capricor, Inc. and Cedars-Sinai Medical Center (incorporated by reference to Exhibit 10.40 to the Company's Annual Report on Form 10-K, filed with the Commission on March 31, 2014).
10.32	Lease Agreement, dated March 29, 2012, between Capricor, Inc. and The Bubble Real Estate Company, LLC (incorporated by reference to Exhibit 10.2 to the Company's Quarterly Report on Form 10-Q, filed with the Commission on August 14, 2015).
10.33	First Amendment to the Lease Agreement, dated June 13, 2013, between Capricor, Inc. and The Bubble Real Estate Company, LLC (incorporated by reference to Exhibit 10.3 to the Company's Quarterly Report on Form 10-Q, filed with the Commission on August 14, 2015). +
10.34	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).
10.35	Sublease Agreement, dated April 1, 2013, between Capricor, Inc. and Reprise Technologies, LLC(incorporated by reference to Exhibit 10.44 to the Company's Annual Report on Form 10-K, filed with the Commission on March 31, 2014).
10.36	Exclusive License Agreement, dated May 5, 2014 between Capricor, Inc. and Cedars-Sinai Medical Center (incorporated by reference to Exhibit 10.46 to the Company's Amendment No. 1 to Registration Statement on Form S-1, filed with the Commission on May 23, 2014). +
10.37	Facilities Lease, dated June 1, 2014, between Capricor, Inc. and Cedars-Sinai Medical Center (incorporated by reference to Exhibit 10.1 to the Company's Quarterly Report on Form 10-Q, filed with the Commission on May 15, 2014).

10.38	Transfer Agreement, dated October 8, 2014, by and between Capricor Therapeutics, Inc. and Medtronic, Inc. (incorporated by reference to Exhibit 10.47 to the Company's Registration Statement on Form S-1, filed with the Commission on March 6, 2015). +
10.39	Share Purchase Agreement, dated as of January 9, 2015, by and among Capricor Therapeutics, Inc. and the Investors (incorporated by reference to Exhibit 10.1 to the Company's Amendment No. 1 to Current Report on Form 8-K/A, filed with the Commission on January 22, 2015).
10.40	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).
10.41	Share Purchase Agreement, dated as of February 3, 2015, by and among Capricor Therapeutics, Inc. and the Investors (incorporated by reference to Exhibit 10.1 to the Company's Amendment No. 1 to Current Report on Form 8-K/A, filed with the Commission on February 6, 2015).

10.42	Registration Rights Agreement, dated as of February 3, 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 February 6, 2015).
10.43	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).
10.44	Employment Agreement by and between Capricor, Inc. and Andrew Hamer, dated November 11, 2013 (incorporated by reference to Exhibit 10.53 to the Company's Registration Statement on Form S-1, filed with the Commission on March 6, 2015).†
10.45	First Amendment to Exclusive License Agreement, dated as of February 27, 2015, by and between Capricor, Inc. and Cedars-Sinai Medical Center (incorporated by reference to Exhibit 10.54 to the Company's Registration Statement on Form S-1, filed with the Commission on March 6, 2015). +
10.46	Second Amendment to Lease Agreement, dated March 3, 2015, by and between Capricor, Inc. and The Bubble Real Estate Company, LLC (incorporated by reference to Exhibit 10.55 to the Company's Registration Statement on Form S-1, filed with the Commission on March 6, 2015).
10.47	Second Amendment to Exclusive License Agreement, dated as of June 10, 2015, by and between Capricor, Inc. and Cedars-Sinai Medical Center (incorporated by reference to Exhibit 10.1 to the Company's Quarterly Report on Form 10-Q, filed with the Commission on August 14, 2015). +
10.48	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).
10.49	Employment Agreement, dated as of August 3, 2015, by and between Capricor, Inc. and Deborah Ascheim, M.D. (incorporated by reference to Exhibit 10.2 to the Company's Quarterly Report on Form 10-Q, filed with the Commission on November 13, 2015). †
10.50	Employment Agreement, dated as of February 22, 2016, by and between Capricor, Inc. and Leland Gershell (incorporated by reference to Exhibit 10.59 to the Company's Annual Report on Form 10-K, filed with the Commission on March 30, 2016). †
10.51	Registration Rights Agreement, dated as of March 14, 2016, by and among the Company and the Investors (incorporated by reference to Exhibit 4.1 to the Company's Amendment No. 1 to Current Report on Form 8-K/A, filed with the Commission on March 16, 2016).
10.52	Subscription Agreement, dated as of March 14, 2016, by and among the Company and the Investors (incorporated by reference to Exhibit 10.1 to the Company's Amendment No. 1 to Current Report on Form 8-K/A, filed with the Commission on March 16, 2016).
10.53	Amendment to Notice of Loan Award, dated as of May 12, 2016 by and between 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 August 15, 2016). +

10.54 Third Amendment to Lease, dated as of May 25, 2016, by and between Capricor, Inc. and The Bubble Real Estate Company, LLC (incorporated by reference to Exhibit 10.2 to the Company's Quarterly Report on Form 10-Q, filed with the Commission on August 15, 2016).

10.55 Notice of Award, dated as of June 16, 2016, by and between Capricor, Inc. and the California Institute for Regenerative Medicine (incorporated by reference to Exhibit 10.3 to the Company's Quarterly Report on Form 10-Q, filed with the Commission on August 15, 2016). +

10.56 Loan Election Agreement, dated as of June 16, 2016, by and between Capricor, Inc. and the California Institute for Regenerative Medicine (incorporated by reference to Exhibit 10.4 to the Company's Quarterly Report on Form 10-Q, filed with the Commission on August 15, 2016).

10.57	Underwriting Agreement, dated as of September 16, 2016, by and among Capricor Therapeutics, Inc., Roth Capital Partners, LLC and National Securities Corporation (incorporated by reference to Exhibit 1.1 to the Company's Current Report on Form 8-K, filed with the Commission on September 16, 2016).
10.58	Subscription Agreement, dated as of September 16, 2016, by and between Capricor Therapeutics, Inc. and Cedars-Sinai Medical Center (incorporated by reference to Exhibit 1.2 to the Company's Current Report on Form 8-K, filed with the Commission on September 16, 2016).
10.59	Second Amendment to Amended and Restated Exclusive License Agreement, dated as of August 5, 2016, by and between Capricor, Inc. and Cedars-Sinai Medical Center (incorporated by reference to Exhibit 10.1 to the Company's Quarterly Report on Form 10-Q, filed with the Commission on November 14, 2016). +
10.60	Third Amendment to Exclusive License Agreement, dated as of August 5, 2016, by and between Capricor, Inc. and Cedars-Sinai Medical Center (incorporated by reference to Exhibit 10.2 to the Company's Quarterly Report on Form 10-Q, filed with the Commission on November 14, 2016). +
10.61	Second Amendment to Capricor Therapeutics, Inc. 2012 Restated Equity Plan (incorporated by reference to Exhibit 4.14 to the Company's Registration Statement on Form S-8, filed with the Commission on January 11, 2017). †
10.62	Third Amendment to Capricor Therapeutics, Inc. 2012 Restated Equity Plan (incorporated by reference to Exhibit 4.15 to the Company's Registration Statement on Form S-8, filed with the Commission on January 11, 2017). †
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.*
32.2	Certification of Principal Financial Officer pursuant to Section 906 of the Sarbanes-Oxley Act of 2002.*
101	The following financial information formatted in eXtensible Business Reporting Language (XBRL): (i) Consolidated Balance Sheets as of December 31, 2016 and 2015, (ii) Consolidated Statements of Operations for the years ended December 31, 2016 and 2015, (iii) Consolidated Statement of Stockholders' Equity (Deficit) for the period from December 31, 2014 through December 31, 2016, (iv) Consolidated Statements of Cash Flows for the years ended December 31, 2016 and 2015, 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.