CAPRICOR THERAPEUTICS, INC.
Form 10-K
March 22, 2018

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, 2017

or

o **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 o

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

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

Large accelerated filer ¨	Accelerated filer ¨
Non-accelerated filer ¨ (Do not check if a smaller reporting company)	Smaller reporting company x
	Emerging growth company ¨

If an emerging growth company, indicate by check mark if the registrant has elected not to use the extended transition period for complying with any new or revised financial accounting standards provided pursuant to Section 13(a) of the Exchange Act. ¨

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, 2017: $9,560,482

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 20, 2018, there were 27,712,158 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 2018 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, 2017 are incorporated by reference into Part III of this Annual Report on Form 10-K.

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

FORWARD-LOOKING STATEMENTS

This Annual Report on Form 10-K contains “forward-looking statements” within the meaning of Section 27A of the Securities Act of 1933, or the Securities Act, and Section 21E of the Securities Exchange Act of 1934, or the Exchange Act. The forward-looking statements are only predictions and provide our current expectations or forecasts of future events and financial performance and may be identified by the use of forward-looking terminology, including the terms “believes,” “estimates,” “anticipates,” “expects,” “plans,” “potential,” “projects,” “intends,” “may,” “will” or “should” or, in each case, their negative, or other variations or comparable terminology, though the absence of these words does not necessarily mean that a statement is not forward-looking. Forward-looking statements include all matters that are not historical facts and include, without limitation, statements about the development of our drug candidates, including when we expect to undertake, initiate and complete clinical trials of our product candidates; expectation of or dates for commencement of clinical trials, investigational new drug filings, similar plans or projections; the regulatory approval of our drug candidates; our use of clinical research centers, third party manufacturers and other contractors; our ability to find collaborative partners for research, development and commercialization of potential products; our ability to manufacture products for clinical and commercial use; our ability to protect our patents and other intellectual property; our ability to market any of our products; our projected operating losses; the impact of taxes on our business, including our ability to utilize net operating losses; our ability to utilize 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, either on an accelerated basis or at all, (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, 2017 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 diseases, with a focus on Duchenne muscular dystrophy, or DMD, 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, 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 and manufacturing facilities 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 diseases. Our drug candidates in active development consist of CAP-1002 (allogeneic cardiosphere-derived cells, or

CDCs) and CAP-2003 (CDC extracellular vesicles, including exosomes).

We are currently developing CAP-1002 for the treatment of DMD. To date, we have completed the HOPE-Duchenne Phase I/II clinical trial in subjects with DMD, the DYNAMIC trial, a Phase I clinical trial of CAP-1002 in subjects with advanced heart failure, and the ALLSTAR trial, a Phase I/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 developing CAP-2003 for the treatment of certain cardiac and inflammatory conditions. CAP-2003 is currently in pre-clinical development.

These programs represent our core technology and products.

Background on 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 United States. 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. Additionally, the absence of dystrophin in muscle cells leads to significant cell damage and ultimately causes muscle cell death and fibrotic replacement. 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.

Patients with DMD experience progressive muscle weakness starting at an early age, generally loss of ambulation occurs after the first decade of life, and eventual respiratory and cardiac failure. Their lifespan is abbreviated and averages less than three decades. The annual cost of care for patients with DMD is very high and increases with disease progression. We therefore believe that DMD represents a significant market opportunity for our lead product candidate.

Our Technologies

Cardiosphere-Derived Cells

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 the 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. CDCs have been shown to exert potent immunomodulatory activity and alters the immune system's activity to encourage cellular regeneration. We are currently developing allogeneic CDCs (CAP-1002) as a product candidate for the treatment of Duchenne muscular dystrophy and investigating their effects on skeletal and cardiac function. Pre-clinical and clinical data support the therapeutic concept of administering CDCs as a means to address conditions in which the heart or skeletal muscle has been damaged.

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. Recently published data by Cedars-Sinai Medical Center, or CSMC, which tested the effectiveness of CDCs in a mouse model of DMD, showed for the first time that the skeletal and cardiac improvements seen in Capricor's HOPE-Duchenne Phase I/II trial could be directly attributed to treatment with CDCs. The data also provide further evidence of the potential of CDCs to stimulate tissue repair and regeneration by first reducing inflammation, which then enables new healthy muscle to form, as was shown in the mouse model of DMD.

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. The relatively large size of CSps makes them less suitable than CDCs for intracoronary or intravenous route of administration. CDCs are sufficiently small that, within acceptable dose limits, they can be infused into a coronary artery or into the peripheral vasculature. Capricor has performed clinical studies to establish the range of CDC dose levels that appear to be safe via intracoronary administration or peripheral venous access. Additionally, in pre-clinical studies, it has been shown that intravenous administration of CDCs increases exercise capacity and diaphragmatic function in an animal model of DMD.

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 and skeletal muscle, with the goal of improving cardiac and skeletal muscle 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

Extracellular vesicles, is an all-encompassing term for cell-derived vesicles, including exosomes and microvesicles, as well as the polynucleotides contained therein. 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, pro-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. We are currently engaged in pre-clinical studies investigating the use of CDC extracellular vesicles as a potential product candidate for the treatment of certain cardiac and inflammatory conditions.

Our Product Candidates

We currently 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 three clinical trials, in which the patients are in long-term follow-up. CAP-1002 is also currently being investigated in two additional trials sponsored by CSMC, which are the REGRESS trial investigating heart failure with preserved ejection fraction and the ALPHA trial investigating pulmonary arterial hypertension. Although, we are not the sponsor of these trials, we are providing the CAP-1002 investigational product for use in the trials. We are now in the start-up phase of a new clinical trial of CAP-1002 in patients with DMD called HOPE-2, which we plan to begin enrolling patients in Q2 2018. We are evaluating CAP-2003 in pre-clinical studies for the treatment of various indications. 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 cardiospheres, or CSps, and we do not plan to develop CSps as a therapeutic.

Active Product Candidates

The following table summarizes our active product development programs:

Product	**Indication/Population**	**Development Stage**	**Commercial Rights**
CAP-1002	Duchenne Muscular Dystrophy*	HOPE-2 Phase II initiating	Capricor
		HOPE-Duchenne Phase I/II completed**	
	Post-Myocardial Infarction with Cardiac Dysfunction	ALLSTAR Phase I/II completed	Capricor
	Advanced Heart Failure	DYNAMIC Phase I completed	Capricor
CAP-2003	Inflammatory conditions	Pre-clinical	Capricor
	Hypoplastic Left Heart Syndrome (HLHS)	Pre-clinical	Capricor

* FDA has granted Orphan Drug, Regenerative Medicine Advanced Therapies, or RMAT, and Rare Pediatric Disease designations to CAP-1002 for the treatment of DMD.

**We are planning to initiate an Open Label Extension, or OLE, for the usual care only comparator arm of this trial.

CAP-1002 for the Treatment of Duchenne Muscular Dystrophy

Based on our understanding of the mechanism of action of CAP-1002 which has been seen in pre-clinical models of DMD, we believe that CAP-1002 has the potential to decrease inflammation and muscle degeneration while exerting positive effects on muscle regeneration, all of which may translate into patients retaining muscle function for a longer period of time. Data supporting peripheral intravenous route of administration of CAP-1002 in the DMD setting has been provided by pre-clinical mouse studies where CDCs, the active ingredient in CAP-1002, have been shown to increase exercise capacity and diaphragmatic function.

Phase II HOPE-2 Clinical Trial

We are in the start-up phase of the HOPE-2 clinical trial and plan to begin enrolling patients in Q2 2018. The clinical trial will evaluate the safety and efficacy of repeat, intravenous, or IV, doses of CAP-1002, in boys and young men with evidence of skeletal muscle impairment regardless of ambulatory status and on a stable regiment of systemic glucocorticoids.

HOPE-2 will be a randomized, double-blind, placebo-controlled clinical trial conducted at approximately 10-15 sites located in the United States. It will enroll approximately 84 boys and young men with Duchenne muscular dystrophy. Participants will receive four doses of CAP-1002 or placebo – once every three months – over a one-year period.

While there are many clinical initiatives in DMD, HOPE-2 is one of the very few to focus on non-ambulant patients. These boys and young men are looking to maintain what function they have in their arms and hands, and Capricor's previous study of a single intracoronary dose of CAP-1002 provided preliminary evidence of efficacy that CAP-1002 may be able to help DMD patients retain, or slow the loss of, upper limb function.

In June 2017, we had a meeting with the FDA to discuss potential clinical endpoints that could be used for registration strategies for CAP-1002 in the DMD indication. The minutes of the meeting indicated the FDA's willingness to accept Capricor's proposal to use the PUL test as the basis for the primary efficacy endpoint for clinical studies in support of a Biologics License Application, or BLA.

The primary efficacy endpoint will be the relative change in patients' abilities to perform manual tasks that relate to activities of daily living and are important to their quality of life. These abilities will be measured through a validated test for skeletal muscle function in DMD called the Performance of the Upper Limb, or PUL, test. The PUL test is an outcomes instrument that was specifically designed to assess upper limb function in ambulant and non-ambulant patients with DMD. HOPE-2 will focus on the mid-level dimension of the PUL – or the ability to use muscles from the elbow to the fingers, which are essential for operating wheelchairs and performing other daily functions. HOPE-2 will measure the change from the beginning of the trial, or baseline, to Month 12. In HOPE-2, we also include additional secondary and exploratory endpoints which include cardiac function, pulmonary function testing, quality of life and additional measures. Start-up activities for our HOPE-2 trial commenced in Q1 2018. An interim analysis is planned to assess futility. The 12-month results are anticipated to be available in the first half of 2020. The timing of both analyses will be dependent on enrollment rates and various other factors.

Phase I/II HOPE-Duchenne Clinical Trial

We have completed 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 patients with cardiomyopathy associated with Duchenne muscular dystrophy, or DMD. Twenty-five patients were randomized in a 1:1 ratio to receive either CAP-1002 on top of usual care or usual care only. In patients receiving CAP-1002, 25 million cells were infused into each of their three main coronary arteries for a total dose of 75 million cells. It was a one-time treatment, and the last patient was infused in September 2016. Patients were observed over the course of 12 months. Efficacy was evaluated according to several exploratory outcome measures. This study is being funded in part through a grant award from the California Institute for Regenerative Medicine, or CIRM.

We commenced the HOPE-Duchenne trial in February 2016 and completed enrollment in September 2016. In April 2017, we reported positive top-line results from a pre-specified six-month interim analysis of this study, which showed that CAP-1002 was generally safe and well-tolerated over the initial six-month follow-up period. The six-month results were presented at the 22nd Annual International Congress of the World Muscle Society in October 2017.

In exploratory efficacy analyses, observed changes from baseline to Month 6 significantly differed by treatment group for systolic thickening of the inferior wall of the heart as measured by MRI (p=0.03). In a post-hoc analysis of function of the mid- and distal-level upper limb in which a responder was defined as a patient who demonstrated a 10% improvement from baseline in score on the PUL test, CAP-1002 patients were more likely to be responders than patients in usual care (p=0.045) at Week 6. In addition, numerical results in some other cardiac and skeletal muscle measures, including cardiac scar (p=0.09), were consistent with a treatment effect although differences between treatment groups were not statistically significant. The observed clinical results appear to generally corroborate a large body of pre-clinical data from studies in DMD animal models.

We reported our 12-month data at a Late-Breaking Science session of the American Heart Association Scientific Sessions 2017. As shoulder function had already been lost in most of the HOPE participants, investigators used the combined mid-distal PUL subscales to assess changes in skeletal muscle function and found significant improvement in those treated with CAP-1002 in a (defined post-hoc). Among the lower-functioning patients, defined as patients with a baseline mid-distal PUL score < 55 out of 58, investigators reported sustained or improved motor function at 12 months in 8 of 9 (89%) patients treated with CAP-1002 as compared to none (0%) of the usual care participants (p=0.007).

To assess cardiac structure and function, investigators used magnetic resonance imaging, or MRI. They found significant improvements in systolic thickening of the left ventricular wall among those patients treated with CAP-1002. Systolic wall thickening is the component of myocardial contraction ultimately responsible for ejection of blood from the left ventricle. Preservation or enhancement of systolic wall thickening may potentially be the result of the reversal of fibrosis.

In the inferior wall, they recorded a mean (SD) 31.2% (47.0%) increase in thickening six months after treatment and a mean 25.8% (46.7%) increase in thickening 12 months after treatment. In comparison, the usual care group showed a mean 8.8% (27.7%) decrease at six months and a mean 1.6% (37.9%) increase at 12 months in the systolic thickening of the inferior wall. The difference between the groups in absolute change from baseline to six months achieved statistical significance (p=0.04) and trended in favor of CAP-1002 treatment group (p=0.09) from baseline to 12 months.

Investigators also found that scarring of the heart muscle among those treated with CAP-1002 decreased relative to the control group. Progressive cardiac scarring eventually impairs the heart's pumping ability and is currently the leading cause of death in Duchenne muscular dystrophy. At the 12-month follow-up, those treated with CAP-1002 had a mean (SD) 7.1% (10.3%) reduction in scar size, in contrast to a mean 4.8% (22.3%) increase in scar size in the usual care group, a difference that achieved statistical significance using non-parametric analysis to account for outliers (p=0.03).

CAP-1002 was generally safe and well-tolerated in the HOPE-Duchenne trial. There was no significant difference in the incidence of treatment-emergent adverse events in either group. There were no early study discontinuations due to adverse events. Those patients who did not receive CAP-1002 during the HOPE-Duchenne trial may be eligible to receive CAP-1002 as part of the open label now that all participants have completed the controlled portion of the trial.

Regulatory Designations for CAP-1002 for the treatment of DMD

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 United States or a disease or condition that affects more than 200,000 people in the United States and for which there is no reasonable expectation that the cost of developing and making available in the United States a drug for this type of disease or condition will be recovered from sales in the United States for that drug. 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 United States upon FDA approval.

In July 2017, the FDA granted Rare Pediatric Disease Designation to CAP-1002 for the treatment of DMD. The FDA defines a "rare pediatric disease" as a serious or life-threatening disease affecting individuals primarily aged from birth to 18 years and that affects fewer than 200,000 individuals in the United States. Under the FDA's Rare Pediatric Disease Priority Review Voucher program, upon the approval of a qualifying New Drug Application, or NDA, or BLA for the treatment of a rare pediatric disease, the sponsor of such application would be eligible for a Rare Pediatric Disease Priority Review Voucher that can be used to obtain priority review for a subsequent NDA or BLA. The Priority Review Voucher may be sold or transferred an unlimited number of times.

In February 2018, we were notified by the FDA Office of Tissues and Advanced Therapies, that we were granted the Regenerative Medicine Advanced Therapy, or RMAT, designation for CAP-1002 for the treatment of DMD. The FDA grants the RMAT designation to regenerative medicine therapies intended to treat a serious condition and for which preliminary clinical evidence indicates a potential to address unmet medical needs for that condition. The RMAT designation makes therapies eligible for the same actions to expedite the development and review of a marketing application that are available to drugs that receive breakthrough therapy designation – including increased meeting opportunities, early interactions to discuss any potential surrogate or intermediate endpoints and the potential to support accelerated approval. CAP-1002 is one of the few therapies currently in development to help non-ambulant patients with Duchenne muscular dystrophy. To receive the RMAT designation, we submitted data from the HOPE-Duchenne Trial.

CAP-1002 for the Treatment of Cardiac Conditions

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 in patients who had experienced a large heart attack and who had residual cardiac dysfunction. 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. 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.

This Phase I study was funded in large part by a grant received from the National Institutes of Health, or NIH.

Capricor began enrollment of the Phase II ALLSTAR study in the first quarter of 2014. This randomized, double-blind, placebo-controlled trial was designed to determine if treatment with CAP-1002 can reduce scar size in patients who have suffered an MI and other endpoints. 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 were to be followed for periodic evaluations over the course of one year. 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 was 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 also evaluated CAP-1002 according to a variety of clinical and quality of life endpoints. The Phase II portion of the ALLSTAR trial was funded in large part through the support of CIRM.

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 United States and in Canada.

In May 2017, we announced that a pre-specified administrative interim analysis performed on six-month follow-up data from the ALLSTAR trial demonstrated a low probability (futility) of achieving a statistically-significant

difference in the 12-month primary efficacy endpoint of percent change from baseline infarct size as a percentage of left ventricular mass, measured by cardiac MRI. At six months, a near-statistically-significant (p=0.05) reduction of mean end-diastolic volume, as well as a trend of reduction of mean end-systolic volume, were seen in the CAP-1002 treatment group. There was no notable difference between treatment groups with respect to the change in ejection fraction. There were no safety signals in the CAP-1002 treatment cohort. Based on the results of the interim analysis, we elected to forego further MRI analyses and transition all patients in ALLSTAR to long-term follow-up.

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 no plans to conduct the Phase II portion of the DYNAMIC trial.

Investigator Sponsored Clinical Trials

Capricor has agreed to provide cells for investigational purposes in two clinical trials sponsored by CSMC. These cells were developed as part of the Company's past research and development efforts. 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 of cells and will receive a negotiated amount of monetary compensation which is estimated to be approximately $2.1 million over several years.

CAP-2003:

Exosomes, a form of extracellular vesicles, are nano-scale, membrane-enclosed extracellular 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.

CAP-2003 is comprised of exosomes secreted by CDCs which are believed to mediate many of the effects that are observed with the CDCs, including anti-inflammatory, pro-angiogenic, anti-apoptotic, and anti-fibrotic effects. We are currently conducting studies in pre-clinical models of cardiac, inflammatory and other conditions to explore the possible therapeutic benefits that CAP-2003 may possess. We are evaluating CAP-2003 in pre-clinical studies that

would potentially enable an IND for the treatment of various indications, including hypoplastic left heart syndrome, or HLHS. It is unknown at this time when an IND will be submitted for any particular indication.

Inactive or Discontinued Product Candidates

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. 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:

In February 2017, we elected to terminate our former natriuretic peptide development program, consisting of Cenderitide (CD-NP) and CU-NP, so as to more efficiently focus our resources and efforts on our CAP-1002 and CAP-2003 programs.

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 2033 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 certain cardiac-derived cells with Università Degli Studi Di Roma La Sapienza, or the University of Rome, The Johns Hopkins University, or JHU, and CSMC. In addition, Capricor has filed patent applications related to 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. Capricor has a right of first negotiation, for a certain period of time, to obtain a license to any new and separate patent applications owned by the University of Rome utilizing cardiac stem cells in cardiac care.

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 may terminate the agreement upon the other party’s material breach, provided that the breaching party will have up to 90 days to cure its material breach. Capricor may also terminate for any reason upon 90 days’ written notice to the University of Rome.

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. Under the JHU License Agreement, Capricor is required to exercise commercially reasonable and diligent efforts to develop and commercialize licensed products covered by the licenses from JHU.

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 related to its CDC technology. 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, which amended, restated, and superseded the Original 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 for any future rights, 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 ranged 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) after 90 days' notice from CSMC 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. If Capricor fails to undertake commercially reasonable efforts to exploit the patent rights or future patent rights, and fails to cure that breach after 90 days' notice from CSMC, instead of terminating the license, CSMC has the option to convert any exclusive license to Capricor to a non-exclusive or co-exclusive license. 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 applications to the schedule of patent rights set forth in the agreement. Under the Second License Amendment, (i) the description of scheduled patent rights has been replaced by a revised schedule that includes six additional patent 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 applications.

On December 26, 2017, Capricor entered into a Third Amendment to Exclusive License Agreement with CSMC thereby amending the CDCs License, or the Third License Amendment. Under the Third License Amendment, (i) the description of scheduled patent rights has been replaced by a revised schedule that includes seven additional patent applications; and (ii) Capricor is required to reimburse CSMC approximately $50,000 for attorneys' fees and filing fees that were incurred in connection with the additional patent rights.

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 preparation and prosecution of certain patent applications. 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) after 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. If Capricor fails to undertake commercially reasonable efforts to exploit the patent rights or future patent rights, and fails to cure that breach after 90 days' notice from CSMC, instead of terminating the license, CSMC has the option to convert any exclusive license to Capricor to a non-exclusive or co-exclusive license. 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 scheduled patent rights has been replaced by a revised schedule that includes four additional patent applications; (ii) Capricor was required to pay CSMC an upfront fee of $20,000; (iii) Capricor was 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 applications to the schedule of patent rights under the agreement. Under the Third Exosomes License Amendment, (i) the description of scheduled patent rights has been replaced by a revised schedule that includes three additional patent 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 applications.

On December 26, 2017, Capricor and CSMC entered into a Fourth Amendment to Exclusive License Agreement, thereby amending the Exosomes License, or the Fourth Exosomes License Amendment. Under the Fourth Exosomes License Amendment, (i) the description of scheduled patent rights was replaced by a revised schedule that includes seven additional patent applications; (ii) Capricor is required to reimburse CSMC approximately $50,000 for attorneys' fees and filing fees that were incurred in connection with the additional patent rights; and (iii) a schedule to the Exosomes License was modified to extend the milestone deadline for filing an IND for at least one product to December 31, 2018.

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 had the exclusive right to enter into an exclusive license agreement pursuant to which Janssen would have received a worldwide, exclusive license to exploit CAP-1002 as well as certain CSps and CDCs in the field of cardiology.

On June 30, 2017, Capricor was informed by Janssen that Janssen would not be exercising its exclusive option right to exploit CAP-1002 as well as certain CSps and CDCs in the field of cardiology. Capricor will retain full rights to CAP-1002 in all indications as a result of this decision. Capricor will also have an irrevocable, fully paid-up non-exclusive license under patents controlled by Janssen utilized in the production of the clinical trial materials manufactured pursuant to the CMC development plan between Capricor and Janssen and a non-exclusive perpetual license to publish, disclose and use the information of Janssen that was utilized in the production of the clinical trial materials manufactured pursuant to the CMC development plan.

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. In February 2017, we elected to terminate our former natriuretic peptide development program, consisting of Cenderitide (CD-NP) and CU-NP, so as to more efficiently focus our resources and efforts on our CAP-1002 and CAP-2003 programs.

Medtronic Clinical Trial Funding Agreement

In February 2011, the Company entered into a Clinical Trial Funding Agreement with Medtronic, related to the Company's now discontinued Cenderitide program. Pursuant to its terms, the agreement expired in February 2012. 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 agreement. 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 Company's now discontinued natriuretic peptides program. Pursuant to the Transfer Agreement, Medtronic 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.

In light of the Company's decision to terminate its development program with respect to natriuretic peptides, the Company elected to cease prosecution of all of the Natriuretic Peptide Patents and has offered to reassign to Medtronic rights to certain patent applications obtained through the Transfer Agreement. Medtronic elected not to take a reassignment of the patent rights.

Manufacturing

Capricor presently maintains its laboratory, research and manufacturing facilities in leased premises located at CSMC, or the Facilities Lease. In that portion of the leased premises where we manufacture CAP-1002 and plan to manufacture CAP-2003, we believe that we follow good manufacturing practices to the extent that they are applicable to our clinical programs, but our premises are not approved as a current Good Manufacturing Practices, or cGMP, facility, for the manufacture of commercial product. Capricor manufactured CAP-1002 in this facility for the ALLSTAR and HOPE-Duchenne clinical studies and will continue to do so for our upcoming HOPE-2 clinical trial.

In addition to manufacturing CAP-1002 for its own clinical trials, Capricor has agreed to provide CAP-1002 for investigational purposes in two clinical trials sponsored by CSMC. If the term of the Facilities Lease is not extended, 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 commercial scale manufacturing or a Phase III trial.

In November 2017, Capricor entered into a Master Services Agreement with WuXi AppTech, Inc., or WuXi, for the development, manufacturing and testing of our CAP-1002 product candidate. WuXi owns and operates a cGMP compliant manufacturing facility with space and resources necessary to manufacture our products. The Agreement allows us to begin our technology transfer process in anticipation of potential commercial scale manufacturing and/or later stage clinical trials.

CAP-1002:

The manufacturing process for CAP-1002 begins with material from an entire heart received from a donor that was collected from an organ procurement organization, or OPO. This tissue is then taken to the lab where the cells are isolated, expanded, and processed through a series of proprietary unit operations. 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 $10.8 million and $16.0 million on research and development activities for the years ended December 31, 2017 and 2016, 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 U.S. 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

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 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 cGMP;

- a potential FDA audit of the preclinical and clinical trial sites that generated the data in support of the NDA or BLA;
- the ability to obtain clearance or approval of companion diagnostic tests, if required, on a timely basis, or at all; and
- FDA review and approval of the NDA or BLA.

Regulation by U.S. 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.

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 pre-clinical and clinical studies must conform to the FDA's Good Laboratory Practice, or GLP, and Good Clinical Practice, or GCP, requirements, respectively, which are designed to ensure the quality and integrity of submitted data and protect the rights and well-being of study patients. Information for certain clinical trials also must be publicly disclosed within certain time limits on the clinical trial registry and results databank maintained by the NIH.

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

- Phase I clinical trials typically are conducted in a small number of volunteers or patients to assess the early tolerability and safety profile, and the pattern of drug absorption, distribution and metabolism;
- Phase II clinical trials typically are conducted in a limited patient population with a specific disease in order to assess appropriate dosages and dose regimens, expand evidence of the safety profile and evaluate preliminary efficacy; and
- Phase III clinical trials typically are larger scale, multicenter, well-controlled trials conducted on patients with a specific disease to generate enough data to statistically evaluate the efficacy and safety of the product, to establish the overall benefit-risk relationship of the drug and to provide adequate information for the registration of the drug.

A therapeutic product candidate being studied in clinical trials may be made available for treatment of individual patients, in certain circumstances. Pursuant to the 21st Century Cures Act (Cures Act), which was signed into law in December 2016. The manufacturer of an investigational product for a serious disease or condition is required to make available, such as by posting on its website, its policy on evaluating and responding to requests for individual patient access to such investigational product.

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 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.

Disclosure of Clinical Trial Information

Sponsors of certain clinical trials of FDA-regulated products are required to register and disclose certain clinical trial information. Information related to the product, patient population, phase of investigation, trial sites and investigators, and other aspects of the clinical trial are then made public as part of the registration. Sponsors are also obligated to disclose the results of their clinical trials after completion. Disclosure of the results of these trials can be delayed in certain circumstances for up to two years after the date of completion of the trial. Competitors may use this publicly available information to gain knowledge regarding the progress of development programs.

Orphan Drugs

Under the Orphan Drug Act, the FDA may grant orphan drug designation to therapeutic candidates intended to treat a rare disease or condition, which is generally a disease or condition that affects fewer than 200,000 individuals in the U.S. or more than 200,000 individuals in the U.S. and for which there is no reasonable expectation that the cost of developing and making available in the U.S. a therapeutic candidate for this type of disease or condition will be recovered from sales in the U.S. for that therapeutic candidate. Orphan drug designation must be requested before submitting a marketing application for the therapeutic for that particular disease or condition. After the FDA grants orphan drug designation, the identity of the therapeutic agent and its potential orphan use are disclosed publicly by the FDA. Orphan drug designation does not convey any advantage in or shorten the duration of the regulatory review and approval process. The FDA may revoke orphan drug designation, and if it does, it will publicize that the drug is no longer designated as an orphan drug.

If a therapeutic candidate with orphan drug designation subsequently receives the first FDA approval for the disease for which it has such designation, the therapeutic candidate is entitled to orphan product exclusivity, which means that the FDA may not approve any other applications to market the same therapeutic candidate for the same indication, except in very limited circumstances, for seven years. Orphan drug exclusivity, however, could also block the approval of one of our therapeutic candidates for seven years if a competitor obtains approval of the same therapeutic candidate as defined by the FDA or if our therapeutic candidate is determined to be contained within the competitor’s therapeutic candidate for the same indication or disease.

In addition, as the FDA has interpreted the Orphan Drug Act, even if a previously approved same drug does not have unexpired orphan exclusivity, while a demonstration of clinical superiority is not required for a subsequent orphan-designated drug to obtain marketing approval, a demonstration of clinical superiority is required for the subsequent orphan-designated same drug to be awarded a 7-year period of orphan exclusivity upon marketing approval. In recent years, there have been multiple legal challenges to this FDA interpretation, and in August 2017, Congress amended the orphan drug provisions of the FDCA through enactment of the FDA Reauthorization Act of 2017 to codify FDA's longstanding interpretation. Section 527 of the FDCA now expressly provides that if a sponsor of a drug that is designated as an orphan drug and is otherwise the same as an already approved drug is seeking exclusive approval for the same rare disease or condition as the already approved drug, FDA shall require such sponsor, as a condition of such exclusive approval, to demonstrate that such drug is clinically superior to any already approved or licensed drug that is the same drug. Orphan drug exclusivity does not prevent the FDA from approving a different drug for the same disease or condition, or the same drug for a different disease or condition.

Expedited Development and Review Programs

The FDA has a Fast Track program that is intended to expedite or facilitate the process for reviewing new drugs and biological products that meet certain criteria. Specifically, new drugs and biological products are eligible for Fast Track designation if they are intended to treat a serious or life-threatening condition and demonstrate the potential to address unmet medical needs for the condition. Fast Track designation applies to the combination of the product and the specific indication for which it is being studied. The sponsor of a new drug or biologic may request the FDA to designate the drug or biologic as a Fast Track product at any time during the clinical development of the product. Unique to a Fast Track product, the FDA may consider for review sections of the marketing application on a rolling basis before the complete application is submitted, if the sponsor provides a schedule for the submission of the sections of the application, the FDA agrees to accept sections of the application and determines that the schedule is acceptable, and the sponsor pays any required user fees upon submission of the first section of the application.

Any product submitted to the FDA for marketing, including under a Fast Track program, may be eligible for other types of FDA programs intended to expedite development and review, such as priority review and accelerated approval. Under the Breakthrough Therapy program, products intended to treat a serious or life-threatening disease or condition may be eligible for the benefits of the Fast Track program when preliminary clinical evidence demonstrates that such product may have substantial improvement on one or more clinically significant endpoints over existing therapies. Additionally, FDA will seek to ensure the sponsor of a breakthrough therapy product receives timely advice and interactive communications to help the sponsor design and conduct a development program as efficiently as possible. Any product is eligible for priority review if it has the potential to provide safe and effective therapy where no satisfactory alternative therapy exists or a significant improvement in the treatment, diagnosis or prevention of a disease compared to marketed products. The FDA will attempt to direct additional resources to the evaluation of an application for a new drug or biological product designated for priority review in an effort to facilitate the review. Additionally, a product may be eligible for accelerated approval. Drug or biological products studied for their safety and effectiveness in treating serious or life-threatening illnesses and that provide meaningful therapeutic benefit over existing treatments may receive accelerated approval, which means that they may be approved on the basis of adequate and well-controlled clinical studies establishing that the product has an effect on a surrogate endpoint that is reasonably likely to predict a clinical benefit, or on the basis of an effect on a clinical endpoint other than survival or irreversible morbidity. As a condition of approval, the FDA may require that a sponsor of a drug or biological product receiving accelerated approval perform adequate and well-controlled post-marketing clinical studies. In addition, the FDA currently requires as a condition for accelerated approval the pre-approval of promotional materials, which could adversely impact the timing of the commercial launch of the product. Fast Track designation, Breakthrough Therapy designation, priority review and accelerated approval do not change the standards for approval but may expedite the development or approval process.

Regenerative Medicine Advanced Therapies (RMAT) Designation

The FDA has established a Regenerative Medicine Advanced Therapy (RMAT) designation as part of its implementation of the 21st Century Cures Act, or Cures Act. The RMAT designation program is intended to fulfill the Cures Act requirement that the FDA facilitate an efficient development program for, and expedite review of, any drug that meets the following criteria: (1) it qualifies as a RMAT, which is defined as a cell therapy, therapeutic tissue engineering product, human cell and tissue product, or any combination product using such therapies or products, with limited exceptions; (2) it is intended to treat, modify, reverse, or cure a serious or life-threatening disease or condition; and (3) preliminary clinical evidence indicates that the drug has the potential to address unmet medical needs for such a disease or condition. Like breakthrough therapy designation, RMAT designation provides potential benefits that include more frequent meetings with FDA to discuss the development plan for the product candidate, and eligibility for rolling review and priority review. Products granted RMAT designation may also be eligible for accelerated approval on the basis of a surrogate or intermediate endpoint reasonably likely to predict long-term clinical benefit, or reliance upon data obtained from a meaningful number of sites, including through expansion to additional sites. RMAT-designated products that receive accelerated approval may, as appropriate, fulfill their post-approval requirements through the submission of clinical evidence, clinical studies, patient registries, or other sources of real world evidence (such as electronic health records); through the collection of larger confirmatory data sets; or via post-approval monitoring of all patients treated with such therapy prior to approval of the therapy.

Rare Pediatric Disease Priority Review Voucher

The FDA generally defines a “rare pediatric disease” as a serious or life-threatening disease that affects fewer than 200,000 individuals in the U.S. primarily under the age of 18 years old. Under the FDA's Rare Pediatric Disease Priority Review Voucher (PRV) program, upon the approval of an application for a product for the treatment of a rare pediatric disease, the sponsor of such application is eligible for a Rare Pediatric Disease Priority Review Voucher. Currently, the Priority Review Voucher can be used to obtain priority review for any subsequent application and may be sold or transferred an unlimited number of times. Under the Cures Act, Congress extended the PRV program for rare pediatric diseases through 2020. A drug designated as a drug for a rare pediatric disease by September 30, 2020, and approved by September 30, 2022, may receive a voucher.

Post -Approval Requirements

Oftentimes, 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 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.

Pricing, Coverage and Reimbursement

Sales of pharmaceutical products depend, in part, on the extent to which the costs of products are covered and paid for by third-party payors, such as government health programs, commercial insurance, and managed healthcare organizations. Third-party payors may limit coverage to specific products on an approved list or formulary, which might not include all of the FDA-approved products for a particular indication. Also, third-party payors may refuse to include a particular branded drug on their formularies or otherwise restrict patient access to a branded drug when a less costly generic equivalent or another alternative is available. Third-party payors are increasingly challenging the prices charged for medical products and services. Additionally, the containment of healthcare costs has become a priority of federal and state governments, and the prices of drugs have been a focus in this effort. The U.S. government, state legislatures and foreign governments have shown significant interest in implementing cost-containment programs, including price controls, restrictions on reimbursement and requirements for substitution of generic products. The current U.S. administration has indicated support for possible new measures to regulate drug pricing.

For example, the Patient Protection and Affordable Care Act, as amended by the Health Care and Education Affordability Reconciliation Act of 2010, collectively referred to as the ACA, enacted in March 2010, has had a significant impact on the health care industry by, for example, expanding coverage for the uninsured and seeking to contain overall healthcare costs. With regard to pharmaceutical products, among other things, the ACA contains provisions that may reduce the profitability of drug products such as expanding and increasing industry rebates for drugs covered under Medicaid programs and making changes to the coverage requirements under the Medicare Part D program. Recently, the current U.S. administration and U.S. Congress have expressed a desire to modify, repeal, or otherwise invalidate all, or certain provisions of, the ACA, which has contributed to the uncertainty of the ongoing implementation and impact of the ACA and also underscores the potential for additional health care reform going forward. For example, the newly enacted federal income tax law includes a provision repealing, effective January 1, 2019, the tax-based shared responsibility payment imposed by the ACA on certain individuals who fail to maintain qualifying health coverage for all or part of a year that is commonly referred to as the "individual mandate." Congress

may consider other legislation that would alter other aspects of the ACA. There is still uncertainty with respect to the impact the current U.S. administration and the U.S. Congress may have, if any, and any changes will likely take time to unfold.

Further other legislative changes have been proposed and adopted since the ACA was enacted. For example, in August 2011, President Obama signed into law the Budget Control Act of 2011, which, among other things, created the Joint Select Committee on Deficit Reduction to recommend to Congress proposals in spending reductions. The Joint Select Committee on Deficit Reduction did not achieve a targeted deficit reduction of at least $1.2 trillion for fiscal years 2012 through 2021, triggering the legislation's automatic reduction to several government programs. This includes aggregate reductions to Medicare payments to providers of up to 2% per fiscal year, which went into effect beginning on April 1, 2013 and will stay in effect through 2027 unless additional Congressional action is taken. In addition, on February 9, 2018, Congress passed the Bipartisan Budget Act that made a number of healthcare reforms. For example, the law changes the discounts manufacturers are required to apply to their drugs under the Coverage Gap Discount Program from 50% to 70% of the negotiated price starting in 2019. In addition, the law increases civil and criminal penalties for fraud and abuse laws, including, for example, criminal fines for violations of the Anti-Kickback Statute increase from $25,000 to $100,000 and corresponding prison sentences also increase from no more than five years to no more than ten years.

There has also been heightened governmental scrutiny recently over the manner in which drug manufacturers set prices for their marketed products, which have resulted in several Congressional inquiries and proposed bills designed to, among other things, bring more transparency to product pricing, review the relationship between pricing and manufacturer patient programs, and reform government program reimbursement methodologies for drug products. Individual states in the United States have also become increasingly aggressive in passing legislation and implementing regulations designed to control pharmaceutical and biological product pricing, including price or patient reimbursement constraints, discounts, restrictions on certain product access and marketing cost disclosure and transparency measures. For example, in September 2017, the California State Assembly approved SB17 which requires pharmaceutical companies to notify health insurers and government health plans at least 60 days before any scheduled increases in the prices of their products if they exceed 16% over a two-year period, and further requiring pharmaceutical companies to explain the reasons for such increase.

In addition, in some non-U.S. jurisdictions, the proposed pricing for a product candidate must be approved before it may be lawfully marketed. The requirements governing drug pricing vary widely from country to country. For example, the EU provides options for its member states to restrict the range of medicinal products for which their national health insurance systems provide reimbursement and to control the prices of medicinal products for human use. A member state may approve a specific price for the medicinal product or it may instead adopt a system of direct or indirect controls on the profitability of the company placing the medicinal product on the market. There can be no assurance that any country that has price controls or reimbursement limitations for pharmaceutical products will allow favorable reimbursement and pricing arrangements for any of our product candidates. Historically, product candidates launched in the EU do not follow price structures of the U.S. and generally tend to have price structures that are significantly lower.

Other Healthcare Fraud and Abuse Laws

In the U.S., our activities are potentially subject to regulation by various federal, state and local authorities in addition to the FDA, including but not limited to, the Centers for Medicare and Medicaid Services, or CMS, other divisions of the U.S. Department of Health and Human Services (such as the Office of Inspector General and the Health Resources and Service Administration), the U.S. Department of Justice, or the DOJ, and individual U.S. Attorney offices within the DOJ, and state and local governments. For example, sales, marketing and scientific/educational grant programs may have to comply with the anti-fraud and abuse provisions of the Social Security Act, the false claims laws, the privacy and security provisions of the Health Insurance Portability and Accountability Act, or HIPAA, and similar state laws, each as amended, as applicable.

The federal Anti-Kickback Statute prohibits, among other things, any person or entity from knowingly and willfully offering, paying, soliciting or receiving any remuneration, directly or indirectly, overtly or covertly, in cash or in kind, to induce or in return for purchasing, leasing, ordering or arranging for the purchase, lease or order of any item or service reimbursable, in whole or in part, under Medicare, Medicaid or other federal healthcare programs. The term remuneration has been interpreted broadly to include anything of value. The Anti-Kickback Statute has been

interpreted to apply to arrangements between therapeutic product manufacturers on one hand and prescribers, purchasers, and formulary managers on the other. There are a number of statutory exceptions and regulatory safe harbors protecting some common activities from prosecution. The exceptions and safe harbors are drawn narrowly and practices that involve remuneration that may be alleged to be intended to induce prescribing, purchasing or recommending may be subject to scrutiny if they do not qualify for an exception or safe harbor. Failure to meet all of the requirements of a particular applicable statutory exception or regulatory safe harbor does not make the conduct per se illegal under the Anti-Kickback Statute. Instead, the legality of the arrangement will be evaluated on a case-by-case basis based on a cumulative review of all of its facts and circumstances. Additionally, the intent standard under the Anti-Kickback Statute was amended by the ACA to a stricter standard such that a person or entity no longer needs to have actual knowledge of the statute or specific intent to violate it in order to have committed a violation. In addition, the ACA codified case law that a claim including items or services resulting from a violation of the federal Anti-Kickback Statute constitutes a false or fraudulent claim for purposes of the federal False Claims Act, or FCA.

The federal false claims and civil monetary penalty laws, including the FCA, which imposes significant penalties and can be enforced by private citizens through civil qui tam actions, prohibit any person or entity from, among other things, knowingly presenting, or causing to be presented, a false or fraudulent claim for payment to, or approval by, the federal healthcare programs, including Medicare and Medicaid, or knowingly making, using, or causing to be made or used a false record or statement material to a false or fraudulent claim to the federal government. A claim includes “any request or demand” for money or property presented to the U.S. government. For instance, historically, pharmaceutical and other healthcare companies have been prosecuted under these laws for allegedly providing free product to customers with the expectation that the customers would bill federal programs for the product. Other companies have been prosecuted for causing false claims to be submitted because of the companies’ marketing of the product for unapproved, off-label, and thus generally non-reimbursable, uses.

HIPAA created additional federal criminal statutes that prohibit, among other things, knowingly and willfully executing, or attempting to execute, a scheme to defraud or to obtain, by means of false or fraudulent pretenses, representations or promises, any money or property owned by, or under the control or custody of, any healthcare benefit program, including private third-party payors, willfully obstructing a criminal investigation of a healthcare offense, and knowingly and willfully falsifying, concealing or covering up by trick, scheme or device, a material fact or making any materially false, fictitious or fraudulent statement in connection with the delivery of or payment for healthcare benefits, items or services. Like the Anti-Kickback Statute, the ACA amended the intent standard for certain healthcare fraud statutes under HIPAA such that a person or entity no longer needs to have actual knowledge of the statute or specific intent to violate it in order to have committed a violation.

Many states have similar, and typically more prohibitive, fraud and abuse statutes or regulations that apply to items and services reimbursed under Medicaid and other state programs, or, in several states, apply regardless of the payor. Additionally, to the extent that our product candidates may in the future be sold in a foreign country, we may be subject to similar foreign laws.

We may be subject to data privacy and security regulations by both the federal government and the states in which we conduct our business. HIPAA, as amended by the Health Information Technology for Economic and Clinical Health Act, or HITECH, and its implementing regulations, imposes requirements relating to the privacy, security and transmission of individually identifiable health information. Among other things, HITECH makes HIPAA's privacy and security standards directly applicable to business associates, independent contractors, or agents of covered entities that receive or obtain protected health information in connection with providing a service on behalf of a covered entity. HITECH also created four new tiers of civil monetary penalties, amended HIPAA to make civil and criminal penalties directly applicable to business associates, and gave state attorneys general new authority to file civil actions for damages or injunctions in federal courts to enforce HIPAA and seek attorneys' fees and costs associated with pursuing federal civil actions. In addition, many state laws govern the privacy and security of health information in specified circumstances, many of which differ from each other in significant ways, are often not pre-empted by HIPAA, and may have a more prohibitive effect than HIPAA, thus complicating compliance efforts.

We expect our product, after approval, may be eligible for coverage under Medicare, the federal health care program that provides health care benefits to the aged and disabled, and covers outpatient services and supplies, including certain pharmaceutical products, that are medically necessary to treat a beneficiary's health condition. In addition, the product may be covered and reimbursed under other government programs, such as Medicaid and the 340B Drug Pricing Program. The Medicaid Drug Rebate Program requires pharmaceutical manufacturers to enter into and have in effect a national rebate agreement with the Secretary of the Department of Health and Human Services as a condition for states to receive federal matching funds for the manufacturer's outpatient drugs furnished to Medicaid patients. Under the 340B Drug Pricing Program, the manufacturer must extend discounts to entities that participate in the program. As part of the requirements to participate in certain government programs, many pharmaceutical manufacturers must calculate and report certain price reporting metrics to the government, such as average manufacturer price, or AMP, and best price. Penalties may apply in some cases when such metrics are not submitted accurately and timely.

Additionally, the federal Physician Payments Sunshine Act, or the Sunshine Act, within the ACA, and its implementing regulations, require that certain manufacturers of drugs, devices, biological and medical supplies for which payment is available under Medicare, Medicaid or the Children's Health Insurance Program (with certain exceptions) report annually to CMS information related to certain payments or other transfers of value made or distributed to physicians and teaching hospitals, or to entities or individuals at the request of, or designated on behalf of, the physicians and teaching hospitals and to report annually certain ownership and investment interests held by physicians and their immediate family members. Failure to report accurately could result in penalties. In addition, many states also govern the reporting of payments or other transfers of value, many of which differ from each other in significant ways, are often not pre-empted, and may have a more prohibitive effect than the Sunshine Act, thus further complicating compliance efforts.

New Legislation and Regulations

From time to time, legislation is drafted, introduced and passed in Congress that could significantly change the statutory provisions governing the testing, approval, manufacturing and marketing of products regulated by the FDA. In addition to new legislation, FDA regulations and policies are often revised or interpreted by the agency in ways that may significantly affect our business and our products. It is impossible to predict whether further legislative changes will be enacted or whether FDA regulations, guidance, policies or interpretations will be changed or what the effect of such changes, if any, may be.

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 39 full-time employees and one part-time employee, although several of our full-time employees also perform part-time services for CSMC. Our Chief Medical Officer, Deborah Ascheim, M.D serves as a visiting faculty member to CSMC but does not provide services. 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 perform various operational and administrative functions. 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 from The Bubble Real Estate Company, LLC 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, 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. Under the terms of the Third Lease Amendment, the lease term commenced on July 1, 2016 and will terminate 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, increased 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.

The Facilities Lease which Capricor entered into with CSMC is for a term of three years commencing June 1, 2014 and replaced 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. The Facilities Lease expired on May 31, 2017 and transitioned to a month-to-month tenancy. On August 10, 2017, the Company and CSMC entered into the First Amendment to the Facilities Lease effective August 1, 2017, or the First Amendment, pursuant to which the term of the Facilities Lease was extended for an additional 12-month period, and the Company was granted an option to further extend the term for an additional 12-month period thereafter through July 31, 2019. Under the First Amendment, the total monthly rent increased from approximately $19,350 to $19,756. In addition, pursuant to the First Amendment, the premises covered by the Facilities Lease now also include the manufacturing facility currently being utilized by Capricor. In lieu of further increasing the monthly rental payment set forth in the First Amendment, the Company has also agreed to provide doses of CAP-1002 for use in CSMC’s clinical trials for a negotiated amount of monetary compensation. The premises leased from CSMC 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 and clinical 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, 2017, we had cash and cash resources, including marketable securities and restricted cash, totaling approximately $14.9 million. We have not generated any revenues from the commercial sale of products. 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 commercial sales 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 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 Cedars-Sinai Medical Center, or CSMC, and the DoD and NIH grant awards which fund ongoing pre-clinical work, 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 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 HOPE-2 clinical trial, the HOPE-OLE, and our ongoing exosomes program;
- the continued availability of funding from government programs including the NIH, DoD and CIRM;
- the costs of developing adequate manufacturing processes and facilities;
- the costs associated with 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 DMD program 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 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 in sufficient quantities and on a timely basis to meet clinical trial and potential commercial demand;
- our dependency on third parties to formulate and manufacture our product candidates;
- our ability to maintain our current manufacturing facility, including our ability to achieve and maintain current Good Manufacturing Practices, or cGMP, certification, and to 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, is in an early stage of development and requires extensive clinical testing before it may be approved by the FDA, or another regulatory authority in a jurisdiction outside the United States, which could take several years to complete, if ever. The effectiveness of the Company's technology has not been definitively proven in completed human clinical trials or pre-clinical 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 HOPE-2 and HOPE-OLE trials. 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 product candidates and may not have products to sell commercially for several years, if at all. Our product candidates will require substantial additional research and development time and expense, as well as extensive clinical trials and perhaps additional pre-clinical testing, prior to commercialization, which may never occur. There can be no assurance that product candidates 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 hope to file a number of investigational new drug applications, or INDs, over the next several years. However, the timing of our filing of these INDs is primarily dependent on receiving further data from our pre-clinical 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 result in the suspension or termination 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 require 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 pre-clinical 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; and
- requirements to conduct additional trials and studies, and increased expenses associated with the services of the Company's CROs and other third parties.

If we are required to conduct additional clinical trials or other testing of our product candidates beyond those that we currently contemplate, we or our development partners, if any, may be delayed in obtaining, or may not be able to obtain 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 pre-clinical studies or 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 pre-clinical studies and clinical trials are completed as planned, including our HOPE-2 and HOPE-OLE 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, tThe 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.

The FDA has granted orphan drug status and a Regenerative Medicine Advanced Therapy (RMAT) designation to CAP-1002 for the treatment of DMD, but we may be unable to maintain or receive the benefits associated with orphan drug status, including market exclusivity, or an RMAT designation.

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.

We have also obtained an RMAT designation for CAP-1002 for the treatment of DMD. RMAT designation does not change the standards for product approval, and there is no assurance that such designation will result in expedited review or approval or that the approved indication will not be narrower than the indication covered by the RMAT designation. Additionally, RMAT designation can be revoked if the criteria for eligibility cease to be met as clinical data emerges.

Even if we were to obtain approval for CAP-1002 with the rare pediatric disease designation, the Rare Pediatric Disease Priority Review Voucher Program may no longer be in effect at the time of such approval.

CAP-1002 has received rare pediatric disease designation from the FDA for the treatment of DMD. The FDA generally defines a "rare pediatric disease" as a serious or life-threatening disease that affects fewer than 200,000 individuals in the U.S. primarily under the age of 18 years old. Under the FDA's Rare Pediatric Disease Priority Review Voucher program, upon the approval of a NDA or BLA for the treatment of a rare pediatric disease, the sponsor of such application would be eligible for a Rare Pediatric Disease Priority Review Voucher that can be used to obtain priority review for a subsequent NDA or BLA. The Priority Review Voucher may be sold or transferred an unlimited number of times. Congress has extended the Priority Review Voucher Program until September 30, 2020. This program has been subject to criticism, including by the FDA, and it is possible that even if we obtain approval for CAP-1002 and qualify for such a Priority Review Voucher, the program may no longer be in effect at the time of approval.

Certain of our product candidates may require companion diagnostics in certain indications. Failure to successfully develop, validate and obtain regulatory clearance or approval for such tests could harm our product development strategy or prevent us from realizing the full commercial potential of our product candidates.

Certain of our product candidates may require companion diagnostics to identify appropriate patients for those product candidates in certain indications. Companion diagnostics are subject to regulation by the FDA and comparable foreign regulatory authorities as a medical device and may require separate regulatory authorization prior to commercialization. We may rely on third parties for the design, development, testing and manufacturing of these companion diagnostics, the application for and receipt of any required regulatory authorization, and the commercial supply of these companion diagnostics. If these parties are unable to successfully develop companion diagnostics for these product candidates, or experience delays in doing so, the development of our product candidates may be adversely affected and we may not be able to obtain marketing authorization for these product candidates. Furthermore, our ability to market and sell, as well as the commercial success, of any of our product candidates that require a companion diagnostic will be tied to, and dependent upon, the receipt of required regulatory authorization and the continued ability of such third parties to make the companion diagnostic commercially available on reasonable terms in the relevant geographies. Any failure to develop, validate, obtain and maintain marketing authorization for a companion diagnostic and supply such companion diagnostic will harm our business, results of operations and financial condition.

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 has agreed 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." 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 and efficacy 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, pre-clinical 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 U.S. 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. If any of our products were granted accelerated approval, FDA could require post-marketing confirmatory trials to verify and describe the anticipated effect on irreversible morbidity or mortality or other clinical benefit. FDA may withdraw approval of a drug or indication approved under the accelerated approval pathway if a trial required to verify the predicted clinical benefit of the product fails to verify such benefit; other evidence demonstrates that the product is not shown to be safe or effective under the conditions of use; the applicant fails to conduct any required post-approval trial of the drug with due diligence; or the applicant disseminates false or misleading promotional materials relating to the product. In addition, the FDA currently requires as a condition for accelerated approval the pre-approval of promotional materials, which could adversely impact the timing of the commercial launch of the product.

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.

If we or current or future collaborators, manufacturers, or service providers fail to comply with healthcare laws and regulations, we or they could be subject to enforcement actions and substantial penalties, which could affect

our ability to develop, market and sell our products and may harm our reputation.

Although we do not currently have any products on the market, once our therapeutic candidates or clinical trials are covered by federal health care programs, we will be subject to additional healthcare statutory and regulatory requirements and enforcement by the federal, state and foreign governments of the jurisdictions in which we conduct our business. Healthcare providers, physicians and third party payors play a primary role in the recommendation and prescription of any therapeutic candidates for which we obtain marketing approval. Our future arrangements with third party payors and customers may expose us to broadly applicable fraud and abuse, transparency, and other healthcare laws and regulations that may constrain the business or financial arrangements and relationships through which we market, sell and distribute our therapeutic candidates for which we obtain marketing approval. Restrictions under applicable federal and state healthcare laws and regulations include, but are not limited to, the following:

- the U.S. federal Anti-Kickback Statute, which prohibits, among other things, persons from soliciting, receiving, offering or providing remuneration, directly or indirectly, to induce either the referral of an individual for a healthcare item or service, or the purchasing or ordering of an item or service, for which payment may be made, in whole or in part, under a federal healthcare program such as Medicare or Medicaid;

- federal civil and criminal false claims laws and civil monetary penalty laws, such as the U.S. federal FCA, which imposes criminal and civil penalties, including through civil whistleblower or *qui tam* actions, against, individuals or entities for knowingly presenting or causing to be presented, to the federal government, claims for payment that are false or fraudulent or making a false statement to avoid, decrease or conceal an obligation to pay money to the federal government. In addition, the government may assert that a claim including items and services resulting from a violation of the federal Anti-Kickback Statute constitutes a false or fraudulent claim for purposes of the FCA;

- HIPAA includes a fraud and abuse provision referred to as the HIPAA All-Payor Fraud Law, which imposes criminal and civil liability for executing a scheme to defraud any healthcare benefit program, or knowingly and willfully falsifying, concealing or covering up a material fact or making any materially false statement in connection with the delivery of or payment for healthcare benefits, items or services. Similar to the federal Anti-Kickback Statute, a person or entity does not need to have actual knowledge of the statute or specific intent to violate it in order to have committed a violation;

- HIPAA, as amended by HITECH, and its implementing regulations, which impose obligations on certain covered entity healthcare providers, health plans, and healthcare clearinghouses as well as their business associates that perform certain services involving the use or disclosure of individually identifiable health information, including mandatory contractual terms, with respect to safeguarding, the privacy, security, and transmission of individually identifiable health information, and require notification to affected individuals and regulatory authorities of certain breaches of security of individually identifiable health information;

- federal and state consumer protection and unfair competition laws, which broadly regulate marketplace activities and activities that potentially harm consumers;

- the federal Physician Payment Sunshine Act and the implementing regulations, also referred to as "Open Payments," issued under the ACA, which require that manufacturers of pharmaceutical and biological drugs reimbursable under Medicare, Medicaid, and Children's Health Insurance Programs report to the Department of Health and Human Services all consulting fees, travel reimbursements, research grants, and other payments, transfers of value or gifts made to physicians and teaching hospitals with limited exceptions; and

- analogous state laws and regulations, such as, state anti-kickback and false claims laws potentially applicable to sales or marketing arrangements and claims involving healthcare items or services reimbursed by nongovernmental third party payors, including private insurers; and some state laws require pharmaceutical companies to comply with the pharmaceutical industry's voluntary compliance guidelines and the relevant compliance guidance promulgated by the federal government in addition to requiring drug manufacturers to report information related to payments to physicians and other healthcare providers or marketing expenditures, and state laws governing the privacy and security of health information in certain circumstances, many of which differ from each other in significant ways and often are not preempted by HIPAA, thus complicating compliance efforts.

The scope and enforcement of each of these laws is uncertain and subject to rapid change in the current environment of healthcare reform, especially in light of the lack of applicable precedent and regulations. Federal and state enforcement bodies have recently increased their scrutiny of interactions between healthcare companies and healthcare providers, which has led to a number of investigations, prosecutions, convictions and settlements in the healthcare industry. Responding to investigations can be time-and resource-consuming and can divert management's attention from the business. Any such investigation or settlement could increase our costs or otherwise have an adverse effect on our business.

Ensuring that our business arrangements with third-parties comply with applicable healthcare laws and regulations could involve substantial costs. If our operations are found to be in violation of any such requirements, we may be subject to penalties, including civil or criminal penalties, monetary damages, the curtailment or restructuring of our operations, or exclusion from participation in government contracting, healthcare reimbursement or other government

programs, including Medicare and Medicaid, any of which could adversely affect our financial results. Although effective compliance programs can mitigate the risk of investigation and prosecution for violations of these laws, these risks cannot be entirely eliminated. Any action against us for an alleged or suspected violation could cause us to incur significant legal expenses and could divert our management's attention from the operation of our business, even if our defense is successful. In addition, achieving and sustaining compliance with applicable laws and regulations may be costly to us in terms of money, time and resources.

Any drugs we develop may become subject to unfavorable pricing regulations, third party coverage and reimbursement practices or healthcare reform initiatives, thereby harming our business.

The regulations that govern marketing approvals, pricing, coverage and reimbursement for new drugs vary widely from country to country. Some countries require approval of the sale price of a drug before it can be marketed. In many countries, the pricing review period begins after marketing or product licensing approval is granted. In some foreign markets, prescription pharmaceutical pricing remains subject to continuing governmental control even after initial approval is granted. Although we intend to monitor these regulations, our programs are currently in earlier stages of development and we will not be able to assess the impact of price regulations for a number of years. As a result, we might obtain regulatory approval for a product in a particular country, but then be subject to price regulations that delay our commercial launch of the product and negatively impact the revenues we are able to generate from the sale of the product in that country.

Our ability to commercialize any products successfully also will depend in part on the extent to which coverage and reimbursement for these products and related treatments will be available from government health administration authorities, private health insurers and other organizations. However, there may be significant delays in obtaining coverage for newly-approved drugs. Moreover, eligibility for coverage does not necessarily signify that a drug will be reimbursed in all cases or at a rate that covers our costs, including research, development, manufacture, sale and distribution costs. Also, interim payments for new drugs, if applicable, may be insufficient to cover our costs and may not be made permanent. Thus, even if we succeed in bringing one or more products to the market, these products may not be considered medically necessary or cost-effective, and the amount reimbursed for any products may be insufficient to allow us to sell our products on a competitive basis. Because our programs are in earlier stages of development, we are unable at this time to determine their cost effectiveness, or the likely level or method of reimbursement. In addition, obtaining coverage and reimbursement approval of a product from a government or other third-party payor is a time-consuming and costly process that could require us to provide to each payor supporting scientific, clinical and cost-effectiveness data for the use of our product on a payor-by-payor basis, with no assurance that coverage and adequate reimbursement will be obtained. A payor's decision to provide coverage for a product does not imply that an adequate reimbursement rate will be approved. Further, one payor's determination to provide coverage for a product does not assure that other payors will also provide coverage for the product. Adequate third-party reimbursement may not be available to enable us to maintain price levels sufficient to realize an appropriate return on our investment in product development. If reimbursement is not available or is available only at limited levels, we may not be able to successfully commercialize any product candidate that we successfully develop.

Increasingly, the third party payors who reimburse patients or healthcare providers, such as government and private insurance plans, are seeking greater upfront discounts, additional rebates and other concessions to reduce the prices for pharmaceutical products. If the price we are able to charge for any products we develop, or the reimbursement provided for such products, is inadequate in light of our development and other costs, our return on investment could be adversely affected.

We currently expect that certain drugs we develop may need to be administered under the supervision of a physician on an outpatient basis. Under currently applicable U.S. law, certain drugs that are not usually self-administered (including injectable drugs) may be eligible for coverage under Medicare through Medicare Part B. Specifically, Medicare Part B coverage may be available for eligible beneficiaries when the following, among other requirements have been satisfied:

- the product is reasonable and necessary for the diagnosis or treatment of the illness or injury for which the product is administered according to accepted standards of medical practice;
- the product is typically furnished incident to a physician's services;
- the indication for which the product will be used is included or approved for inclusion in certain Medicare-designated pharmaceutical compendia (when used for an off-label use); and
- the product has been approved by the FDA.

Average prices for drugs may be reduced by mandatory discounts or rebates required by government healthcare programs or private payors and by any future relaxation of laws that presently restrict imports of drugs from countries where they may be sold at lower prices than in the U.S. Reimbursement rates under Medicare Part B would depend in part on whether the newly approved product would be eligible for a unique billing code. Self-administered, outpatient drugs are typically reimbursed under Medicare Part D, and drugs that are administered in an inpatient hospital setting are typically reimbursed under Medicare Part A under a bundled payment. It is difficult for us to predict how Medicare coverage and reimbursement policies will be applied to our products in the future and coverage and reimbursement under different federal healthcare programs are not always consistent. Medicare reimbursement rates may also reflect budgetary constraints placed on the Medicare program.

Third party payors often rely upon Medicare coverage policies and payment limitations in setting their own reimbursement rates. These coverage policies and limitations may rely, in part, on compendia listings for approved therapeutics. Our inability to promptly obtain relevant compendia listings, coverage, and adequate reimbursement from both government-funded and private payors for new drugs that we develop and for which we obtain regulatory approval could have a material adverse effect on our operating results, our ability to raise capital needed to commercialize products and our financial condition.

We expect that these and other healthcare reform measures that may be adopted in the future, may result in more rigorous coverage criteria and lower reimbursement, and in additional downward pressure on the price that we receive for any approved product. Any reduction in reimbursement from Medicare or other government-funded programs may result in a similar reduction in payments from private payors. The implementation of cost containment measures or other healthcare reforms may prevent us from being able to generate revenue, attain profitability or commercialize our drugs, once marketing approval is obtained.

We believe that the efforts of governments and third party payors to contain or reduce the cost of healthcare and legislative and regulatory proposals to broaden the availability of healthcare will continue to affect the business and financial condition of pharmaceutical and biopharmaceutical companies. A number of legislative and regulatory changes in the healthcare system in the U.S. and other major healthcare markets have been proposed, and such efforts have expanded substantially in recent years. These developments could, directly or indirectly, affect our ability to sell our products, if approved, at a favorable price. For example, in the U.S., in 2010, the U.S. Congress passed the ACA, a sweeping law intended to broaden access to health insurance, reduce or constrain the growth of health spending, enhance remedies against fraud and abuse, add new transparency requirements for the healthcare and health insurance industries, impose new taxes and fees on the health industry and impose additional policy reforms. Among the provisions of the ACA addressing coverage and reimbursement of pharmaceutical products, of importance to our potential therapeutic candidates are the following:

- increases to pharmaceutical manufacturer rebate liability under the Medicaid Drug Rebate Program due to an increase in the minimum basic Medicaid rebate on most branded prescription drugs and the application of Medicaid rebate liability to drugs used in risk-based Medicaid managed care plans;

- the expansion of the 340B Drug Pricing Program to require discounts for “covered outpatient drugs” sold to certain children’s hospitals, critical access hospitals, freestanding cancer hospitals, rural referral centers, and sole community hospitals;

- requirements imposed on pharmaceutical companies are required to offer discounts on brand-name drugs to patients who fall within the Medicare Part D coverage gap, commonly referred to as the “Donut Hole”;

- requirements imposed on pharmaceutical companies to pay an annual non-tax-deductible fee to the federal government based on each company’s market share of prior year total sales of branded drugs to certain federal healthcare programs, such as Medicare, Medicaid, Department of Veterans Affairs and Department of Defense; and

- for products classified as biologics, marketing approval for a follow-on biologic product may not become effective until 12 years after the date on which the reference innovator biologic product was first licensed by the FDA, with a possible six-month extension for pediatric products. After this exclusivity ends, it may be possible for biosimilar manufacturers to enter the market, which is likely to reduce the pricing for the innovator product and could affect our profitability if our products are classified as biologics.

Separately, pursuant to the health reform legislation and related initiatives, the Centers for Medicare and Medicaid Services ("CMS") is working with various healthcare providers to develop, refine, and implement Accountable Care Organizations ("ACOs"), and other innovative models of care for Medicare and Medicaid beneficiaries, including the Bundled Payments for Care Improvement Initiative, the Comprehensive Primary Care Initiative, the Duals Demonstration, and other models. The continued development and expansion of ACOs and other innovative models of care will have an uncertain impact on any future reimbursement we may receive for approved therapeutics administered by these organizations.

The healthcare industry is heavily regulated in the U.S. at the federal, state, and local levels, and our failure to comply with applicable requirements may subject us to penalties and negatively affect our financial condition.

As a healthcare company, our operations, clinical trial activities and interactions with healthcare providers may be subject to extensive regulation in the U.S., particularly if we receive FDA approval for any of its products in the future. For example, if we receive FDA approval for a product for which reimbursement is available under a federal healthcare program (e.g., Medicare, Medicaid), it would be subject to a variety of federal laws and regulations, including those that prohibit the filing of false or improper claims for payment by federal healthcare programs (e.g. the federal False Claims Act), prohibit unlawful inducements for the referral of business reimbursable by federal healthcare programs (e.g. the federal Anti-Kickback Statute), and require disclosure of certain payments or other transfers of value made to U.S.-licensed physicians and teaching hospitals or Open Payments. We are not able to predict how third parties will interpret these laws and apply applicable governmental guidance and may challenge our practices and activities under one or more of these laws. If our past or present operations are found to be in violation of any of these laws, we could be subject to civil and criminal penalties, which could hurt our business, our operations and financial condition.

The federal Anti-Kickback Statute prohibits, among other things, any person or entity, from knowingly and willfully offering, paying, soliciting or receiving any remuneration, directly or indirectly, overtly or covertly, in cash or in kind, to induce or in return for purchasing, leasing, ordering or arranging for the purchase, lease or order of any item or service reimbursable under Medicare, Medicaid or other federal healthcare programs. The term remuneration has been interpreted broadly to include anything of value. The Anti-Kickback Statute has been interpreted to apply to arrangements between pharmaceutical manufacturers on one hand and prescribers, purchasers, and formulary managers on the other. There are a number of statutory exceptions and regulatory safe harbors protecting some common activities from prosecution. The exceptions and safe harbors are drawn narrowly and practices that involve remuneration that may be alleged to be intended to induce prescribing, purchasing or recommending may be subject to scrutiny if they do not qualify for an exception or safe harbor. Failure to meet all of the requirements of a particular applicable statutory exception or regulatory safe harbor does not make the conduct per se illegal under the Anti-Kickback Statute. Instead, the legality of the arrangement will be evaluated on a case-by-case basis based on a cumulative review of all of its facts and circumstances. Our practices may not in all cases meet all of the criteria for protection under a statutory exception or regulatory safe harbor.

Additionally, the intent standard under the Anti-Kickback Statute was amended by the ACA, to a stricter standard such that a person or entity no longer needs to have actual knowledge of the statute or specific intent to violate it in order to have committed a violation. In addition, the ACA codified case law that a claim including items or services resulting from a violation of the federal Anti- Kickback Statute constitutes a false or fraudulent claim for purposes of the federal FCA.

The civil monetary penalties statute imposes penalties against any person or entity that, among other things, is determined to have presented or caused to be presented a claim to a federal healthcare program that the person knows or should know is for an item or service that was not provided as claimed or is false or fraudulent.

Federal false claims and false statement laws, including the federal FCA, prohibit, among other things, any person or entity from knowingly presenting, or causing to be presented, a false or fraudulent claim for payment to, or approval by, the federal healthcare programs, including Medicare and Medicaid, or knowingly making, using, or causing to be made or used a false record or statement material to a false or fraudulent claim to the federal government. A claim includes “any request or demand” for money or property presented to the U.S. government. For instance, historically, pharmaceutical and other healthcare companies have been prosecuted under these laws for allegedly providing free product to customers with the expectation that the customers would bill federal programs for the product. Other companies have been prosecuted for causing false claims to be submitted because of the companies’ marketing of the product for unapproved, off-label, and thus generally non-reimbursable, uses.

HIPAA prohibits, among other offenses, knowingly and willfully executing a scheme to defraud any health care benefit program, including private payors, or falsifying, concealing or covering up a material fact or making any materially false, fictitious or fraudulent statement in connection with the delivery of or payment for items or services under a health care benefit program. To the extent that we act as a business associate to a healthcare provider engaging

in electronic transactions, we may also be subject to the privacy and security provisions of HIPAA, as amended by HITECH, which restricts the use and disclosure of patient-identifiable health information, mandates the adoption of standards relating to the privacy and security of patient-identifiable health information, and requires the reporting of certain security breaches to healthcare provider customers with respect to such information. Additionally, many states have enacted similar laws that may impose more stringent requirements on entities like ours. Failure to comply with applicable laws and regulations could result in substantial penalties and adversely affect our financial condition and results of operations.

Many states also have similar fraud and abuse statutes or regulations that apply to items and services reimbursed under Medicaid and other state programs, or, in several states, apply regardless of the payor. Additionally, to the extent that our product is sold in a foreign country, we may be subject to similar foreign laws.

Our products, once approved, may be eligible for coverage under Medicare and Medicaid, among other government healthcare programs. Accordingly, we may be subject to a number of obligations based on their participation in these programs, such as a requirement to calculate and report certain price reporting metrics to the government, such as average sales price (ASP) and best price. Penalties may apply in some cases when such metrics are not submitted accurately and timely. Further, these prices for drugs may be reduced by mandatory discounts or rebates required by government healthcare programs or private payors and by any future relaxation of laws that presently restrict imports of drugs from countries where they may be sold at lower prices than in the United States. It is difficult to predict how Medicare coverage and reimbursement policies will be applied to our products in the future and coverage and reimbursement under different federal healthcare programs are not always consistent. Medicare reimbursement rates may also reflect budgetary constraints placed on the Medicare program.

In order to distribute products commercially, we must comply with state laws that require the registration of manufacturers and wholesale distributors of drug and biological products in a state, including, in certain states, manufacturers and distributors who ship products into the state even if such manufacturers or distributors have no place of business within the state. Some states also impose requirements on manufacturers and distributors to establish the pedigree of product in the chain of distribution, including some states that require manufacturers and others to adopt new technology capable of tracking and tracing product as it moves through the distribution chain. Several states have enacted legislation requiring pharmaceutical and biotechnology companies to establish marketing compliance programs, file periodic reports with the state, make periodic public disclosures on sales, marketing, pricing, clinical trials and other activities, and/or register their sales representatives, as well as to prohibit pharmacies and other healthcare entities from providing certain physician prescribing data to pharmaceutical and biotechnology companies for use in sales and marketing, and to prohibit certain other sales and marketing practices. All of our activities are potentially subject to federal and state consumer protection and unfair competition laws.

If our operations are found to be in violation of any of the federal and state healthcare laws described above or any other governmental regulations that apply to us, we may be subject to penalties, including without limitation, civil, criminal and/or administrative penalties, damages, fines, disgorgement, exclusion from participation in government programs, such as Medicare and Medicaid, injunctions, private “qui tam” actions brought by individual whistleblowers in the name of the government, or refusal to allow us to enter into government contracts, contractual damages, reputational harm, administrative burdens, diminished profits and future earnings, and the curtailment or restructuring of our operations, any of which could adversely affect our ability to operate our business and our results of operations.

Our ability to obtain reimbursement or funding from the federal government may be impacted by possible reductions in federal spending.

U.S. federal government agencies currently face potentially significant spending reductions. The Budget Control Act of 2011, or the BCA, established a Joint Select Committee on Deficit Reduction, which was tasked with achieving a reduction in the federal debt level of at least $1.2 trillion. That committee did not draft a proposal by the BCA’s deadline. As a result, automatic cuts, referred to as sequestration, in various federal programs were scheduled to take

place, beginning in January 2013, although the American Taxpayer Relief Act of 2012 delayed the BCA's automatic cuts until March 1, 2013. While the Medicare program's eligibility and scope of benefits are generally exempt from these cuts, Medicare payments to providers and Part D health plans are not exempt. The BCA did, however, provide that the Medicare cuts to providers and Part D health plans would not exceed two percent. President Obama issued the sequestration order on March 1, 2013, and cuts went into effect on April 1, 2013. Additionally, the Bipartisan Budget Act of 2015 extended sequestration for Medicare through fiscal year 2027.

The U.S. federal budget remains in flux, which could, among other things, cut Medicare payments to providers. The Medicare program is frequently mentioned as a target for spending cuts. The full impact on our business of any future cuts in Medicare or other programs is uncertain. In addition, we cannot predict any impact President Trump's administration and the U.S. Congress may have on the federal budget. If federal spending is reduced, anticipated budgetary shortfalls may also impact the ability of relevant agencies, such as the FDA or the National Institutes of Health, to continue to function at current levels. Amounts allocated to federal grants and contracts may be reduced or eliminated. These reductions may also impact the ability of relevant agencies to timely review and approve drug research and development, manufacturing, and marketing activities, which may delay our ability to develop, market and sell any products we may develop.

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, research and manufacturing facilities in leased premises at CSMC in Los Angeles, California. In that portion of the leased premises where we manufacture CAP-1002 and plan to manufacture CAP-2003, we believe we follow good manufacturing practices, but it is not a cGMP approved facility. Capricor manufactured CAP-1002 in this facility for the ALLSTAR and HOPE-Duchenne clinical studies and will continue to do so for our HOPE-2 clinical trial and HOPE-OLE trials. In addition to manufacturing CAP-1002 for its own clinical trials, Capricor has agreed to provide CAP-1002 for investigational purposes in two clinical trials sponsored by CSMC.

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. Currently, our facilities lease is scheduled to expire on July 31, 2018 and we have an option to extend the term of the facilities lease for an additional twelve months through July 31, 2019. We have not yet exercised our option to extend the lease, and even if we do, there can be no assurance that the facilities lease will be continued beyond July 31, 2019. If the facilities lease with CSMC is terminated or expires, we would have to secure alternative facilities in which to operate our research and development activities and/or manufacture our products, which would involve a significant monetary investment and would negatively impact the progress of our clinical trials and regulatory approvals. In addition, we will have to establish a collaboration agreement with a third party or build out our own manufacturing facility for any commercial scale manufacturing or a Phase III trial.

In November 2017, Capricor entered into a Master Services Agreement with WuXi AppTech, Inc., or WuXi, for the development, manufacturing and testing of our CAP-1002 product candidate. WuXi owns and operates a cGMP compliant manufacturing facility with space and resources necessary to manufacture Customer's products. The Agreement allows us to begin our technology transfer process in anticipation of potential commercial scale an and/or later stage clinical trials.

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 clinical 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 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, the ongoing CSMC trials and our upcoming HOPE-2 and HOPE-OLE 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 other 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, 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 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. For example, we have recently entered into a Master Services Agreement with WuXi for the development, manufacturing and testing of our CAP-1002 product candidate. WuXi, which owns and operates a cGMP compliant manufacturing facility, has experience manufacturing pharmaceutical and biopharmaceutical products but does not have any experience manufacturing our product candidates and there can be no assurance that it will be able to manufacture our product candidates of the quality required to meet our clinical and commercial needs, or in a timely manner 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 which may cause delays to our ability to sell commercially. 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, as well as susceptible to drought and fires. 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 United States, 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.

We utilize and rely on services of third parties to perform services in connection with our clinical trials, which services involve the collection, use, storage and analysis of personal health information. While we receive assurances from these vendors that their services are compliant with the Health Insurance Portability and Accountability Act, or HIPAA, and other applicable privacy laws, there can be no assurance that such third parties will comply with applicable laws or regulations. Non-compliance by such vendors may result in liability for us which would have a material adverse effect on our business, financial conditions and results of operations.

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 have 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 upon 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 U.S. government and the State of California. As a result of such funding, the U.S. 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, or misappropriated, 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 United States 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 U.S. Patent and Trademark Office, or USPTO, and may become involved in opposition, derivation, post-grant and *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. The Leahy-Smith Act and its implementation could increase the uncertainties and costs surrounding the prosecution of our patent applications and the enforcement or defense of our issued patents and those licensed to us.

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

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

We have licensed certain patent and other intellectual property rights that cover our CAP-1002, CAP-1001, and CSps product candidates from Università Degli Studi Di Roma La Sapienza, or the 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 the 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. Under the Transfer Agreement, we had 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 early 2017, we decided to terminate our development program with respect to natriuretic peptides and to cease prosecution of all of the natriuretic peptide patents and patent applications assigned to the Company and have offered to reassign to Medtronic rights to certain patent applications obtained through the Transfer Agreement. Medtronic has elected not to accept a reassignment of those patent rights.

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 products 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 protectable under trade secrets law; 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 unauthorized disclosure and use of confidential information and, where applicable, require disclosure and assignment to us of the ideas, developments, discoveries and inventions important to our business. 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 improperly 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 U.S. 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 variety of post-grant proceedings, particularly *inter partes* review, before the USPTO or during litigation under the revised criteria, which make it more difficult to defend the validity of claims in already issued 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, manufacturing processes 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, manufacturing processes 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 U.S. 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 or *inter partes* review proceedings 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 improperly used, misappropriated 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 the University of Rome, JHU and CSMC. These licenses may be terminated upon certain conditions, including in some cases, if we fail to meet certain minimum funding or spending requirements, fail to pay certain minimum royalties, or fail to maintain the licensed intellectual property. 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 Smidt 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, including meeting defined milestones, 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 and DoD to fund various projects. Some of these awards remain 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 were required to repay the CIRM loan with interest at maturity. So long as we were not in default, the Loan Agreement had provisions allowing for forgiveness of the debt after the end of the project period, if we elected to abandon the project under certain circumstances. On November 17, 2017, we gave notice to CIRM that we were electing to abandon the CIRM-funded project pursuant to the Loan Agreement and on December 11, 2017, Capricor and CIRM entered into Amendment No. 3 to the CIRM Notice of Loan Award whereby the total loan balance under the CIRM Loan Agreement has been forgiven by CIRM thereby terminating Capricor and the Company's obligation to repay the loan balance. The Company classified the forgiveness of the loan payable, consisting of principal and accrued interest, of approximately $15.7 million as "other income" in our Consolidated Statement of Operations and Comprehensive Income (Loss). The decision to terminate the Loan Award and forgive the loan balance was due to the abandonment of the ALLSTAR project at the end of the project period in accordance with Section 4.10 of the Loan Agreement and Article VII, Section I of the CIRM Loan Administration Policy.

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 pre-clinical 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, any Phase III clinical trials which we may conduct must be conducted with biologic product produced under cGMP and may require a large number of test patients. Biologic products for commercial purposes must also be produced under cGMP. 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, which in some instances may be limited, we cannot control whether or not they devote sufficient time and resources to our ongoing pre-clinical, 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. Existing or future therapies developed by others may 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 other entities which may result in the creation of intellectual property rights in favor of those entities.

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. Several of our full-time employees also perform part-time services for CSMC. Dr. Deborah Ascheim, our Chief Medical Officer, serves as a visiting faculty member to CSMC, but does not provide services. 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 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. The market for employees with experience in the cell therapy industry is especially competitive, and we may not be able to recruit employees needed to develop and manufacture our products, or be able to retain the employees whom we do recruit.

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. As a result, it is unclear whether intellectual property developed out of these services for CSMC would be owned by CSMC or by the Company, although if owned by CSMC, the Company may have rights to that intellectual property under the terms of its license agreements with CSMC. 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 complete our trials or 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 may 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, 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, if approved, 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. Orphan drugs in particular have received recent negative publicity for the perceived high prices charged for them by their manufacturers, and as a result other orphan drug developers such as us may be negatively impacted by such publicity and any U.S. or other government regulatory response.

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 U.S. 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 U.S. 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.

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

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

There may be 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, the price of our stock could also decline. If one or more of these analysts cease to cover our stock altogether, 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.

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
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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.

As of December 31, 2017, our executive officers, directors and holders of five percent or more of our outstanding common stock, together with their respective affiliates, beneficially owned over 40% of our outstanding common stock. The interests of these stockholders may not be the same as, or may even conflict with the interests of our other stockholders. These 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, 2017, there were approximately 26.3 million shares of common stock outstanding and outstanding awards to purchase approximately 6.9 million shares of common stock under various incentive stock plans of the Company. Additionally, as of December 31, 2017, there were approximately 0.6 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.

The merger between Nile Therapeutics, Inc., or 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, or Nasdaq. 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 in order 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.

The Facilities Lease which Capricor entered into with CSMC is for a term of three years commencing June 1, 2014 and replaced 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. The Facilities Lease expired on May 31, 2017 and transitioned to a month-to-month tenancy. On August 10, 2017, the Company and CSMC entered into the First Amendment to the Facilities Lease effective August 1, 2017, or the First Amendment, pursuant to which the term of the Facilities Lease was extended for an additional 12-month period, and the Company was granted an option to further extend the term for an additional 12-month period thereafter through July 31, 2019. Under the First Amendment, the total monthly rent increased from approximately $19,350 to $19,756. In addition, pursuant to the First Amendment, the premises covered by the Facilities Lease now also include the manufacturing facility currently being utilized by Capricor. In lieu of further increasing the monthly rental payment set forth in the First Amendment, the Company has also agreed to provide doses of CAP-1002 for use in CSMC's clinical trials for a negotiated amount of monetary compensation. The premises leased from CSMC are located at 8700 Beverly Blvd., Los Angeles, California 90048. As our operations expand, we expect our space requirements and related expenses to increase.

Our laboratories and manufacturing facility are located at 8700 Beverly Blvd., Los Angeles, California 90048. As our operations expand, we expect our space requirements and related expenses to increase.

ITEM 3. LEGAL PROCEEDINGS

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

ITEM 4. MINE SAFETY DISCLOSURES

Not applicable.

PART II

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

Market for Common Stock

Our common stock is traded 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, 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, 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
Year ended December 31, 2017		
First Quarter	$3.40	$2.18
Second Quarter	3.29	0.63
Third Quarter	3.03	0.67
Fourth Quarter	3.45	1.46

Holders

According to the records of our transfer agent, American Stock Transfer & Trust Company, as of March 20, 2018, we had 126 holders of record of common stock, not including holders who 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.

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 develop first-in-class biological therapies for the treatment of diseases, with a focus on Duchenne muscular dystrophy, or DMD, and other medical conditions. 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

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, 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 and manufacturing facilities are located in space that Capricor leases from CSMC.

Drug Candidates

Our Product Candidates

We currently 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 three clinical trials, in which the patients are in long-term follow-up. CAP-1002 is also currently being investigated in two additional trials sponsored by CSMC, which are the REGRESS trial investigating heart failure with preserved ejection fraction and the ALPHA trial investigating pulmonary arterial hypertension. Although, we are not the sponsor of these trials, we are providing the CAP-1002 investigational product for use in the trials. We are now in the start-up phase of a new clinical trial of CAP-1002 in patients with DMD called HOPE-2, which we plan to begin enrolling patients in Q2 2018. We are evaluating CAP-2003 in pre-clinical studies for the treatment of various indications. 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 cardiospheres, or CSps, and we do not plan to develop CSps as a therapeutic.

CAP-1002 for the Treatment of Duchenne Muscular Dystrophy

Based on our understanding of the mechanism of action of CAP-1002 which has been seen in pre-clinical models of DMD, we believe that CAP-1002 has the potential to decrease inflammation and muscle degeneration while exerting positive effects on muscle regeneration, all of which may translate into patients to retaining muscle function for a longer period of time. Data supporting peripheral intravenous route of administration of CAP-1002 in the DMD setting has been provided by pre-clinical mouse studies where CDCs, the active ingredient in CAP-1002, has been shown to increase exercise capacity and diaphragmatic function.

Phase II HOPE-2 Clinical Trial

We are in the start-up phase of the HOPE-2 clinical trial and plan to begin enrolling patients in Q2 2018. The clinical trial will evaluate the safety and efficacy of repeat, intravenous, or IV, doses of CAP-1002, in boys and young men with evidence of skeletal muscle impairment regardless of ambulatory status and on a stable regiment of systemic glucocorticoids.

HOPE-2 will be a randomized, double-blind, placebo-controlled clinical trial conducted at approximately 10-15 sites located in the United States. It will enroll approximately 84 boys and young men with Duchenne muscular dystrophy. Participants will receive four doses of CAP-1002 or placebo – once every three months – over a one-year period.

While there are many clinical initiatives in DMD, HOPE-2 is one of the very few to focus on non-ambulant patients. These boys and young men are looking to maintain what function they have in their arms and hands, and Capricor’s previous study of a single intracoronary dose of CAP-1002 provided preliminary evidence of efficacy that CAP-1002 may be able to help DMD patients retain, or slow the loss of, upper limb function.

In June 2017, we had a meeting with the FDA to discuss potential clinical endpoints that could be used for registration strategies for CAP-1002 in the DMD indication. The minutes of the meeting indicated the FDA's willingness to accept Capricor's proposal to use the PUL test as the basis for the primary efficacy endpoint for clinical studies in support of a Biologics License Application, or BLA.

The primary efficacy endpoint will be the relative change in patients’ abilities to perform manual tasks that relate to activities of daily living and are important to their quality of life. These abilities will be measured through a validated test for skeletal muscle function in DMD called the Performance of the Upper Limb, or PUL, test. The PUL test is an outcomes instrument that was specifically designed to assess upper limb function in ambulant and non-ambulant patients with DMD. HOPE-2 will focus on the mid-level dimension of the PUL – or the ability to use muscles from the elbow to the fingers, which are essential for operating wheelchairs and performing other daily functions. HOPE-2 will measure the change from the beginning of the trial, or baseline, to Month 12. In HOPE-2, we also include additional secondary and exploratory endpoints which include cardiac function, pulmonary function testing, quality of life and additional measures. Start-up activities for our HOPE-2 trial commenced in Q1 2018. An interim analysis is planned to assess futility. The 12-month results are anticipated to be available in the first half of 2020. The timing of both analyses will be dependent on enrollment rates and various other factors.

Phase I/II HOPE-Duchenne Clinical Trial

We have completed 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 patients with cardiomyopathy associated with Duchenne muscular dystrophy, or DMD. Twenty-five patients were randomized in a 1:1 ratio to receive either CAP-1002 on top of usual care or usual care only. In patients receiving CAP-1002, 25 million cells were infused into each of their three main coronary arteries for a total dose of 75 million cells. It was a one-time treatment, and the last patient was infused in September 2016. Patients were observed over the course of 12 months. Efficacy was evaluated according to several exploratory outcome measures. This study is being funded in part through a grant award from the California Institute for Regenerative Medicine, or CIRM.

We commenced the HOPE-Duchenne trial in February 2016 and completed enrollment in September 2016. In April 2017, we reported positive top-line results from a pre-specified six-month interim analysis of this study, which showed that CAP-1002 was generally safe and well-tolerated over the initial six-month follow-up period. The six-month results were presented at the 22nd Annual International Congress of the World Muscle Society in October 2017.

In exploratory efficacy analyses, observed changes from baseline to Month 6 significantly differed by treatment group for systolic thickening of the inferior wall of the heart as measured by MRI (p=0.03). In a post-hoc analysis of function of the mid- and distal-level upper limb in which a responder was defined as a patient who demonstrated a 10% improvement from baseline in score on the PUL test, CAP-1002 patients were more likely to be responders than patients in usual care (p=0.045) at Week 6. In addition, numerical results in some other cardiac and skeletal muscle measures, including cardiac scar (p=0.09), were consistent with a treatment effect although differences between treatment groups were not statistically significant. The observed clinical results appear to generally corroborate a large body of pre-clinical data from studies in DMD animal models.

We reported our 12-month data at a Late-Breaking Science session of the American Heart Association Scientific Sessions 2017. As shoulder function had already been lost in most of the HOPE participants, investigators used the combined mid-distal PUL subscales to assess changes in skeletal muscle function and found significant improvement in those treated with CAP-1002 in a (defined post-hoc). Among the lower-functioning patients, defined as patients with a baseline mid-distal PUL score < 55 out of 58, investigators reported sustained or improved motor function at 12 months in 8 of 9 (89%) patients treated with CAP-1002 as compared to none (0%) of the usual care participants (p=0.007).

To assess cardiac structure and function, investigators used magnetic resonance imaging, or MRI. They found significant improvements in systolic thickening of the left ventricular wall among those patients treated with CAP-1002. Systolic wall thickening is the component of myocardial contraction ultimately responsible for ejection of blood from the left ventricle. Preservation or enhancement of systolic wall thickening may potentially be the result of the reversal of fibrosis.

In the inferior wall, they recorded a mean (SD) 31.2% (47.0%) increase in thickening six months after treatment and a mean 25.8% (46.7%) increase in thickening 12 months after treatment. In comparison, the usual care group showed a mean 8.8% (27.7%) decrease at six months and a mean 1.6% (37.9%) increase at 12 months in the systolic thickening of the inferior wall. The difference between the groups in absolute change from baseline to six months achieved statistical significance (p=0.04) and trended in favor of CAP-1002 treatment group (p=0.09) from baseline to 12 months.

Investigators also found that scarring of the heart muscle among those treated with CAP-1002 decreased relative to the control group. Progressive cardiac scarring eventually impairs the heart's pumping ability and is currently the leading cause of death in Duchenne muscular dystrophy. At the 12-month follow-up, those treated with CAP-1002 had a mean (SD) 7.1% (10.3%) reduction in scar size, in contrast to a mean 4.8% (22.3%) increase in scar size in the usual care group, a difference that achieved statistical significance using non-parametric analysis to account for outliers (p=0.03).

CAP-1002 was generally safe and well-tolerated in the HOPE-Duchenne trial. There was no significant difference in the incidence of treatment-emergent adverse events in either group. There were no early study discontinuations due to adverse events. Those patients who did not receive CAP-1002 during the HOPE-Duchenne trial may be eligible to receive CAP-1002 as part of the open label now that all participants have completed the controlled portion of the trial.

Regulatory Designations for CAP-1002 for the treatment of DMD

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 United States or a disease or condition that affects more than 200,000 people in the United States and for which there is no reasonable expectation that the cost of developing and making available in the United States a drug for this type of disease or condition will be recovered from sales in the United States for that drug. 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 United States upon FDA approval.

In July 2017, the FDA granted Rare Pediatric Disease Designation to CAP-1002 for the treatment of DMD. The FDA defines a "rare pediatric disease" as a serious or life-threatening disease affecting individuals primarily aged from birth to 18 years and that affects fewer than 200,000 individuals in the United States. Under the FDA's Rare Pediatric Disease Priority Review Voucher program, upon the approval of a qualifying New Drug Application, or NDA, or BLA for the treatment of a rare pediatric disease, the sponsor of such application would be eligible for a Rare Pediatric Disease Priority Review Voucher that can be used to obtain priority review for a subsequent NDA or BLA. The Priority Review Voucher may be sold or transferred an unlimited number of times.

In February 2018, we were notified by the FDA Office of Tissues and Advanced Therapies, that we were granted the Regenerative Medicine Advanced Therapy, or RMAT, designation for CAP-1002 for the treatment of DMD. The FDA grants the RMAT designation to regenerative medicine therapies intended to treat a serious condition and for which preliminary clinical evidence indicates a potential to address unmet medical needs for that condition. The RMAT designation makes therapies eligible for the same actions to expedite the development and review of a marketing application that are available to drugs that receive breakthrough therapy designation – including increased meeting opportunities, early interactions to discuss any potential surrogate or intermediate endpoints and the potential to support accelerated approval. CAP-1002 is one of the few therapies currently in development to help non-ambulant patients with Duchenne muscular dystrophy. To receive the RMAT designation, we submitted data from the HOPE-Duchenne Trial.

CAP-1002 for the Treatment of Cardiac Conditions

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 in patients who had experienced a large heart attack and who had residual cardiac dysfunction. 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. 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.

This Phase I study was funded in large part by a grant received from the National Institutes of Health, or NIH.

Capricor began enrollment of the Phase II ALLSTAR study in the first quarter of 2014. This randomized, double-blind, placebo-controlled trial was designed to determine if treatment with CAP-1002 can reduce scar size in patients who have suffered an MI and other endpoints. 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 were to be followed for periodic evaluations over the course of one year. 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 was 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 also evaluated CAP-1002 according to a variety of clinical and quality of life endpoints. The Phase II portion of the ALLSTAR trial was funded in large part through the support of CIRM.

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 United States and in Canada.

In May 2017, we announced that a pre-specified administrative interim analysis performed on six-month follow-up data from the ALLSTAR trial demonstrated a low probability (futility) of achieving a statistically-significant

difference in the 12-month primary efficacy endpoint of percent change from baseline infarct size as a percentage of left ventricular mass, measured by cardiac MRI. At six months, a near-statistically-significant (p=0.05) reduction of mean end-diastolic volume, as well as a trend of reduction of mean end-systolic volume, were seen in the CAP-1002 treatment group. There was no notable difference between treatment groups with respect to the change in ejection fraction. There were no safety signals in the CAP-1002 treatment cohort. Based on the results of the interim analysis, we elected to forego further MRI analyses and transition all patients in ALLSTAR to long-term follow-up.

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 no plans to conduct the Phase II portion of the DYNAMIC trial.

Investigator Sponsored Clinical Trials

Capricor has agreed to provide cells for investigational purposes in two clinical trials sponsored by CSMC. These cells were developed as part of the Company's past research and development efforts. 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 of cells and will receive a negotiated amount of monetary compensation which is estimated to be approximately $2.1 million over several years.

CAP-2003:

Exosomes, a form of extracellular vesicles, are nano-scale, membrane-enclosed extracellular 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.

CAP-2003 is comprised of exosomes secreted by CDCs which are believed to mediate many of the effects that are observed with the CDCs, including anti-inflammatory, pro-angiogenic, anti-apoptotic, and anti-fibrotic effects. We are currently conducting studies in pre-clinical models of cardiac, inflammatory and other conditions to explore the possible therapeutic benefits that CAP-2003 may possess. We are evaluating CAP-2003 in pre-clinical studies that

would potentially enable an IND for the treatment of various indications, including hypoplastic left heart syndrome, or HLHS. It is unknown at this time when an IND will be submitted for any particular indication.

Inactive or Discontinued Product Candidates

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. 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:

In February 2017, we elected to terminate our former natriuretic peptide development program, consisting of Cenderitide (CD-NP) and CU-NP, so as to more efficiently focus our resources and efforts on our CAP-1002 and CAP-2003 programs.

Financial Operations Overview

We have no commercial product sales to date and will not have the ability to generate any commercial 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 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 to increase. 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 and our clinical programs. 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, rent for laboratories and manufacturing facilities, 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, 2017 and 2016

General and Administrative Expenses. G&A expenses for the years ended December 31, 2017 and 2016 were approximately $4.8 million and $4.9 million, respectively. The decrease of approximately $0.1 million in G&A expenses in the year ended December 31, 2017 compared to the year ended December 31, 2016 is primarily attributable to an increase of approximately $0.2 million related to compensation and recruiting costs along with an increase of $0.1 million in legal expenses. Furthermore, there was a decrease of approximately $0.2 million in stock-based compensation expense and a decrease of $0.2 million in investor relation expenses.

Research and Development Expenses. R&D expenses for the years ended December 31, 2017 and 2016 were approximately $10.8 million and $16.0 million, respectively. The decrease of approximately $5.2 million for the year ended December 31, 2017 as compared to the year ended December 31, 2016 is primarily due to the timing of clinical development activities of CAP-1002 (ALLSTAR and HOPE-Duchenne clinical trials). These activities resulted in a decrease of approximately $3.9 million. Additionally, reduced activity under the DYNAMIC and Cenderitide clinical trials resulted in a decrease of approximately $1.3 million.

Products Under Active Development

CAP-1002 – The development of CAP-1002 is in its developmental stages. We expect to spend approximately $8.0 million to $12.0 million during 2018 on the clinical development and manufacturing of CAP-1002, which expenses are primarily related to our planned HOPE-2 clinical trial and manufacturing of CAP-1002. We have transitioned the ALLSTAR study to long-term follow-up. We have entered into a Master Services Agreement with WuXi AppTech, Inc., or WuXi, for the development, manufacturing and testing of our CAP-1002 product candidate. WuXi owns and operates a cGMP compliant manufacturing facility with space and resources necessary to manufacture Customer's products. The Agreement allows us to begin our technology transfer process in anticipation of potential commercial scale manufacturing and/or later stage clinical trials. Our strategy for further development of CAP-1002 will depend to a large degree on the outcome of our upcoming HOPE-2 trial.

CAP-2003 – We expect to spend approximately $2.0 million to $4.0 million during 2018 on pre-clinical and other research expenses related to the CAP-2003 program, a portion of which will be offset by our grant awards from the NIH and DoD. Capricor is currently engaged in pre-clinical testing of CAP-2003 to explore its therapeutic potential, including studies that would potentially enable an IND. We have received a grant for up to approximately $4.2 million from the NIH to study CAP-2003 for HLHS as well as a grant from the DoD for up to approximately $2.4 million to be used towards the development of a scalable, commercially-ready process to manufacture CAP-2003.

Products Not Under Active Development

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. At present, there is no plan for a 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.

Cenderitide – We acquired the rights to Cenderitide in 2006. 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. We do not anticipate having any further material expenses with respect to this product candidate.

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.

Collaboration Income. As a result of the Janssen Agreement, collaboration income for the years ended December 31, 2017 and 2016 was approximately $1.4 million and $3.2 million, respectively. A ratable portion of the payment to Capricor under the Janssen Agreement was recognized in both the years ended December 31, 2017 and 2016. On June 30, 2017, Capricor was informed by Janssen that Janssen would not be exercising its exclusive license option under the Janssen Agreement. Additionally, there are no further activities ongoing in connection with the Collaboration with Janssen and all revenue has been recognized as of June 30, 2017.

Grant Income. Grant income for the years ended December 31, 2017 and 2016 was approximately $1.1 million and $0.8 million, respectively. The increase in grant income of approximately $0.3 million in 2017 as compared to 2016 is primarily due to the timing of grant activities. At the end of 2016, the DYNAMIC clinical trial was undergoing completion. Additionally, during 2017 the DoD Award and NIH Grant Award were commencing and ongoing.

Other Income. Other income for the years ended December 31, 2017 and 2016 was approximately $0.2 million and zero, respectively. The other income was related to providing cells for investigational purposes for clinical trials sponsored by CSMC.

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 assessed the fair value of this indefinite-lived intangible asset to be $0 at December 31, 2016. No impairment expense was recorded for the year ended December 31, 2017.

Interest Expense. Interest expense for the years ended December 31, 2017 and 2016 was $398,807 and $344,665, respectively. The increase in interest expense in 2017 as compared to 2016 is due to accrued interest on the CIRM Loan Award.

Forgiveness of Loan Payable. Forgiveness of loan payable, a non-cash income, was approximately $15.7 million for the year ended December 31, 2017. Forgiveness of loan payable included $14,405,857 in principal and $1,248,276 in accrued interest. No forgiveness of loan payable was recorded for the year ended December 31, 2016.

Liquidity and Capital Resources for the fiscal years ended December 31, 2017 and 2016

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, 2017	December 31, 2016
Cash and cash equivalents	$ 6,140	$ 3,204
Working capital	$ 14,042	$ 13,213

Stockholders' equity (deficit)	$ 11,227	$ (4,003)

	Years ended December 31,	
Cash flow data	2017	2016
Cash provided by (used in):		
Operating activities	$ (14,231)	$ (14,455)
Investing activities	4,982	(5,191)
Financing activities	11,580	18,629
Net increase (decrease) in cash and cash equivalents	$ 2,331	$ (1,017)

Our total cash and cash equivalents, not including restricted cash, as of December 31, 2017 was approximately $6.1 million compared to approximately $3.2 million as of December 31, 2016. The increase in cash and cash equivalents from December 31, 2016 as compared to December 31, 2017 is due to the approximately $3.7 million received as a result of our May 2017 private placement, $5.0 million received as a result of our March 2017 ATM Program, and approximately $2.7 million received as a result of our October 2017 ATM Program, along with an allocation of marketable securities to cash and cash equivalents. Furthermore, we received $776,259 from CIRM, which included $500,000 in relation to CIRM Loan Agreement operational milestones and $276,259 in relation to the final CIRM Grant Award operational milestone, all which were reached during 2017. Total marketable securities, consisting primarily of U.S. treasuries, were approximately $8.0 million as of December 31, 2017, as compared to approximately $13.0 million as of December 31, 2016. As of December 31, 2017, we had approximately $5.0 million in total liabilities. As of December 31, 2017, we had approximately $14.0 million in net working capital. We had a net income of approximately $2.4 million for the year ended December 31, 2017 primarily due to the forgiveness of the CIRM Loan balance of approximately $15.7 million.

Cash used in operating activities was approximately $14.2 million and $14.5 million for the years ended December 31, 2017 and 2016, respectively. The difference of approximately $0.3 million in cash from operating activities is primarily due to a decrease of approximately $2.1 million from a change in accounts payable and accrued liabilities and an increase of approximately $1.8 million in the change in deferred revenue for the year ended December 31, 2017 as compared to the same period in 2016. Furthermore, there was a net decrease in the change in CIRM liability of approximately $2.8 million. 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 losses, which will generate negative net cash flows from operating activities.

We had cash flow provided by investing activities of approximately $5.0 million and cash flow used in of approximately $5.2 million for the years ended December 31, 2017 and 2016, respectively. The increase in cash provided by investing activities for the year ended December 31, 2017 as compared to the same period of 2016 is primarily due to the net effect from purchases, sales, and maturities of marketable securities.

We had cash flow provided by financing activities of approximately $11.6 million and $18.6 million for the years ended December 31, 2017 and 2016, respectively. The decrease in cash provided by financing activities for the year ended December 31, 2017 as compared to the same period of 2016 is primarily due to the net proceeds from the sale of common stock. During 2016 we received net proceeds of approximately $13.9 million compared to approximately $11.1 million over the same period of 2017. Furthermore, we received approximately $4.8 million in loan proceeds under our CIRM Loan Agreement in 2016 compared to $0.5 million in the same period of 2017.

Phase II of Capricor’s ALLSTAR trial was funded in large part through a loan award from CIRM. On November 17, 2017, we gave notice to CIRM that we were electing to abandon the CIRM-funded project pursuant to the Loan Agreement and on December 11, 2017, Capricor and CIRM entered into Amendment No. 3 whereby the total loan balance under the CIRM Loan Agreement has been forgiven by CIRM thereby terminating Capricor and the Company’s obligation to repay the loan balance.

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.

From inception through December 31, 2017, 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 second quarter of 2017, we completed a private placement to purchase shares of our common stock, securing approximately $3.7 million in additional capital through the issuance of securities. Additionally, we received gross proceeds of approximately $5.0 million in connection with our March 2017 ATM Program. As we have not generated any revenue from the commercial 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. For example, in October 2017 we entered into a Common Stock Sales Agreement with H.C. Wainwright & Co., LLC, or Wainwright, to create an additional at-the-market equity program. 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

October 2017 Common Stock Sales Agreement. On October 19, 2017, the Company entered into a Common Stock Sales Agreement, or the October Sales Agreement, with Wainwright under which we may, from time to time, issue and sell shares of our common stock through Wainwright as sales agent in an at-the-market offering under a prospectus supplement for aggregate sales proceeds of up to $14.0 million, or the October 2017 ATM Program. The common stock will be distributed at the market prices prevailing at the time of sale. The October Sales Agreement provides that Wainwright will be entitled to compensation for its services at a commission rate of 3.0% of the gross sales price per share of common stock sold. Any shares issued pursuant to the October 2017 ATM Program will be 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 October 2017 ATM Program was filed with the SEC on October 19, 2017.

As of March 20, 2018, the Company has sold an aggregate of 2,079,215 common shares under the October 2017 ATM Program at an average price of approximately $2.30 per common share for gross proceeds of approximately $4.8 million.

May 2017 Financing. On May 5, 2017, the Company entered into subscription agreements with certain accredited investors, or the 2017 Investors, pursuant to which the Company agreed to issue and sell to the investors, in a private placement, or the 2017 Private Placement, an aggregate of 1,196,291 shares of its common stock, par value $0.001 per share, at a price per share of $3.10 for an aggregate purchase price of approximately $3.7 million.

In connection with the 2017 Private Placement, the Company also entered into a Registration Rights Agreement with the 2017 Investors. Pursuant to the terms of the Registration Rights Agreement, the Company was obligated (i) to prepare and file with the SEC a registration statement to register for resale the shares issued in the 2017 Private Placement, and (ii) to use its reasonable best efforts to cause the registration statement to be declared effective by the SEC as soon as practicable, in each case subject to certain deadlines. The Company will be required to pay to each 2017 Investor liquidated damages equal to 1.0% of the aggregate purchase price paid by such 2017 Investor pursuant to the Subscription Agreements for the shares per month (up to a cap of 10.0%) if it does not meet certain obligations

with respect to the registration of the shares, subject to certain conditions. Pursuant to its obligations under the Registration Rights Agreement, the Company registered for resale the shares issued in the 2017 Private Placement pursuant to a registration statement on Form S-3 (File No. 333-219188), which was filed with the SEC on July 7, 2017 and declared effective on July 17, 2017. The 2017 Private Placement included participation from certain of the Company's directors.

March 2017 Common Stock Sales Agreement. On March 31, 2017, the Company entered into a Common Stock Sales Agreement, or the March Sales Agreement with Wainwright under which we could, from time to time, issue and sell shares of our common stock through Wainwright as sales agent in an at-the-market offering under a prospectus supplement for aggregate sales proceeds of up to $5.0 million, or the March 2017 ATM Program. The common stock was distributed at the market prices prevailing at the time of sale. The March Sales Agreement provided that Wainwright would be entitled to compensation for its services at a commission rate of 3.0% of the gross sales price per share of common stock sold. All shares issued pursuant to the March 2017 ATM Program 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 March 2017 ATM Program was filed with the SEC on April 3, 2017.

The Company sold an aggregate of 2,589,078 common shares under the March 2017 ATM Program at an average price of approximately $1.93 per common share for gross proceeds of approximately $5.0 million. The March 2017 ATM Program became fully utilized in October 2017.

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 approximately $10.9 million. 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 was 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 2016 Investors, pursuant to which, on March 16, 2016, we issued and sold to the 2016 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 2016 Investors, and the 2016 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 2016 Investors, in a concurrent private placement, or the 2016 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 became 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 2016 Private Placement, we entered into a Registration Rights Agreement with the 2016 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 2016 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 of the 2016 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 in the Offerings. Each of our officers and directors who purchased Warrants in the 2016 Private Placement paid a purchase price of $0.125 per share of common stock issuable upon exercise of such Warrants.

Financing Activities by Capricor, Inc.

CIRM Loan Agreement

Pursuant to the terms of the CIRM Loan Agreement, 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. So long as we were not in default, the Loan Agreement had provisions allowing for forgiveness of the debt after the end of the project period, if we elected to abandon the project under certain circumstances.

On November 17, 2017, we gave notice to CIRM that we were electing to abandon the CIRM-funded project pursuant to the Loan Agreement and on December 11, 2017, Capricor and CIRM entered into Amendment No. 3 to the CIRM Notice of Loan Award whereby the total loan balance under the CIRM Loan Agreement has been forgiven by CIRM thereby terminating Capricor and the Company's obligation to repay the loan balance. The Company classified the forgiveness of the loan payable, consisting of principal and accrued interest, of approximately $15.7 million as "other income" in our Consolidated Statement of Operations and Comprehensive Income (Loss) for the period ending December 31, 2017. The decision to terminate the Loan Award and forgive the loan balance was due to the abandonment of the ALLSTAR project at the end of the project period in accordance with Section 4.10 of the Loan Agreement and Article VII, Section I of the CIRM Loan Administration Policy.

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 are 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, California Code of Regulations (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 the 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 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 has not yet made its decision as to whether it will elect to convert the CIRM Award into a loan at this time. 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. In July 2016, Capricor received the first disbursement of $2.0 million under the terms of the CIRM Award.

In September 2016, the Company 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. Additionally, in September 2017, the Company completed the second operational milestone tied to the last patient completing one year of follow-up, for which approximately $0.3 million was received by Capricor in November 2017.

On August 8, 2017, we entered into an Amendment to the CIRM Notice of Award pursuant to which CIRM approved the Company’s request to use the remaining estimated project funds of the CIRM Award for technology transfer activities in support of the manufacture of CAP-1002 to a designated contract manufacturing organization, or CMO, which will enable Capricor to offer access to CAP-1002 to patients from the control arm of the HOPE-Duchenne trial via an open-label extension protocol.

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 September 30, 2016, the full award of $2.9 million had been disbursed.

NIH Grant Award (HLHS)

In September 2016, Capricor was approved for a grant from the NIH to study CAP-2003 for 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, 2017, approximately $0.5 million has been incurred 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, 2017, approximately $0.9 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, 2017.

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.

Other Income

Revenue is recognized in connection with the delivery of doses which were developed as part of our past R&D efforts. Income is recorded when evidence of an arrangement exists, delivery has occurred and collection is reasonably assured.

CIRM Grant Award

Capricor accounts for the disbursements under its CIRM Award as long-term liabilities. Capricor recognizes 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.

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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 the Janssen Agreement 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, were recorded as deferred revenue and were classified as a short-term or long-term liability on the consolidated balance sheets and amortized over the estimated period of performance. We periodically reviewed the estimated performance period of our contract based on the progress of our project. As of June 30, 2017, the full amount of income had been recognized under the Janssen Agreement.

Research and Development Expenses and Accruals

R&D expenses consist primarily of salaries and related personnel costs, supplies, clinical trial costs, patient treatment costs, rent for laboratories and manufacturing facilities, 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 three stock option plans: (i) the 2006 Stock Option Plan, (ii) the 2012 Restated Equity Incentive Plan (which superseded the 2006 Stock Option Plan), and (iii) 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 award issued to non-employees is recorded as expense over the vesting period.

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 and Comprehensive Income (Loss). 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. At December 31, 2017, there are no warrants outstanding which require classification as a liability in accordance with the guidance.

Long-Term Debt

Capricor historically accounted for the loan proceeds under its CIRM Loan Agreement as long-term liabilities. On November 17, 2017, we gave notice to CIRM that we were electing to abandon the CIRM-funded project pursuant to the Loan Agreement and on December 11, 2017, Capricor and CIRM entered into Amendment No. 3 to the CIRM Notice of Loan Award whereby the total loan balance under the CIRM Loan Agreement was forgiven by CIRM thereby terminating Capricor and the Company’s obligation to repay the loan balance. The Company has classified the forgiveness of the loan payable consisting of principal and accrued interest of approximately $15.7 million as “other income” in our Consolidated Statement of Operations and Comprehensive Income (Loss) for the period ending December 31, 2017.

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. No impairment expense was noted for the year ended December 31, 2017.

Restricted Cash

We had 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 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*, 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 Company adopted this provision in the first quarter of 2017. The adoption of this update did not have a material effect on the Company's financial statements.

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. 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. The Company adopted this standard on January 1, 2017. The adoption of these provisions did not have a material effect on the Company's 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. 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. The Company elected to early adopt this provision in the first quarter of 2017. This update was applied on a retrospective basis, wherein the statement of cash flow of each period presented was adjusted to reflect the effects of applying the new guidance.

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, 2017, the fair value of our cash, cash equivalents, including restricted cash, and marketable securities was approximately $14.9 million. Additionally, as of December 31, 2017, 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 U.S. 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 U.S. 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.

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REPORT OF INDEPENDENT REGISTERED PUBLIC ACCOUNTING FIRM

To the Board of Directors and Stockholders of

Capricor Therapeutics, Inc.

Opinion on the Consolidated Financial Statements

We have audited the accompanying consolidated balance sheets of Capricor Therapeutics, Inc. and Subsidiary (the Company) as of December 31, 2017 and 2016, and the related consolidated statements of operations and comprehensive income (loss), stockholders' equity (deficit), and cash flows for each of the years in the two-year period ended December 31, 2017, and the related notes (collectively referred to as the consolidated financial statements). In our opinion, the consolidated financial statements present fairly, in all material respects, the financial position of the Company as of December 31, 2017 and 2016, and the results of its operations and its cash flows for each of the years in the two-year period ended December 31, 2017, in conformity with accounting principles generally accepted in the United States of America.

Basis for Opinion

These consolidated financial statements are the responsibility of the Company's management. Our responsibility is to express an opinion on the Company's consolidated financial statements based on our audits. We are a public accounting firm registered with the Public Company Accounting Oversight Board (United States) (PCAOB) and are required to be independent with respect to the Company in accordance with the U.S. federal securities laws and the applicable rules and regulations of the Securities and Exchange Commission and the PCAOB.

We conducted our audits in accordance with the standards of the PCAOB. 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, whether due to error or fraud. The Company is not required to have, nor were we engaged to perform, an audit of its internal control over financial reporting. As part of our audits, we are required to obtain an understanding of internal control over financial reporting, 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.

Our audits included performing procedures to assess the risks of material misstatement of the consolidated financial statements, whether due to error or fraud, and performing procedures that respond to those risks. Such procedures included examining, on a test basis, evidence regarding the amounts and disclosures in the consolidated financial statements. Our audits also included evaluating the accounting principles used and significant estimates made by management, as well as evaluating the overall presentation of the consolidated financial statements. We believe that our audits provide a reasonable basis for our opinion.

/s/ Rose, Snyder & Jacobs LLP

Rose, Snyder & Jacobs LLP

We have served as the Company’s auditor since 2011.

Encino, California
March 20, 2018

CAPRICOR THERAPEUTICS, INC.

CONSOLIDATED BALANCE SHEETS

DECEMBER 31, 2017 AND 2016

	December 31, 2017	December 31, 2016
ASSETS		
CURRENT ASSETS		
Cash and cash equivalents	$ 6,140,135	$ 3,204,378
Marketable securities	7,984,800	12,990,510
Restricted cash	742,002	1,347,225
Grant receivable	344,575	223,335
Prepaid expenses and other current assets	501,164	342,892
TOTAL CURRENT ASSETS	15,712,676	18,108,340
PROPERTY AND EQUIPMENT, net	372,096	435,336
OTHER ASSETS		
Intangible assets, net of accumulated amortization of $166,634 and $147,429, respectively	93,048	142,253
Other assets	95,969	61,426
TOTAL ASSETS	$ 16,273,789	$ 18,747,355
LIABILITIES AND STOCKHOLDERS' EQUITY (DEFICIT)		
CURRENT LIABILITIES		
Accounts payable and accrued expenses	$ 1,496,251	$ 3,038,780
Accounts payable and accrued expenses, related party	174,424	489,217
Deferred revenue	-	1,367,186
TOTAL CURRENT LIABILITIES	1,670,675	4,895,183
LONG-TERM LIABILITIES		
Loan payable	-	13,905,857
CIRM liability	3,376,259	3,100,000
Accrued interest	-	849,469
TOTAL LONG-TERM LIABILITIES	3,376,259	17,855,326
TOTAL LIABILITIES	5,046,934	22,750,509

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, 26,270,491 and 21,399,019 shares issued and outstanding, respectively	26,271	21,399
Additional paid-in capital	62,736,783	49,951,165
Accumulated other comprehensive income	11,620	3,524
Accumulated deficit	(51,547,819)	(53,979,242)
TOTAL STOCKHOLDERS' EQUITY (DEFICIT)	11,226,855	(4,003,154)
TOTAL LIABILITIES AND STOCKHOLDERS' EQUITY (DEFICIT)	$ 16,273,789	$ 18,747,355

See accompanying notes to the audited consolidated financial statements.

CAPRICOR THERAPEUTICS, INC.

CONSOLIDATED STATEMENTS OF OPERATIONS AND COMPREHENSIVE INCOME (LOSS)

FOR THE YEARS ENDED DECEMBER 31, 2017 AND 2016

	Years ended December 31	
	2017	**2016**
INCOME		
Collaboration income	$1,367,186	$3,190,106
Grant income	1,115,430	808,512
Other income	183,724	-
TOTAL INCOME	2,666,340	3,998,618
OPERATING EXPENSES		
Research and development	10,766,095	16,042,082
General and administrative	4,762,642	4,933,054
TOTAL OPERATING EXPENSES	15,528,737	20,975,136
LOSS FROM OPERATIONS	(12,862,397)	(16,976,518)
OTHER INCOME (EXPENSE)		
Investment income	38,494	14,407
Interest expense	(398,807)	(344,665)
Forgiveness of loan payable	15,654,133	-
Impairment of in-process research and development	-	(1,500,000)
TOTAL OTHER INCOME (EXPENSE)	15,293,820	(1,830,258)
NET INCOME (LOSS)	2,431,423	(18,806,776)
OTHER COMPREHENSIVE INCOME (LOSS)		
Net unrealized gain (loss) on marketable securities	8,096	(5,861)
COMPREHENSIVE INCOME (LOSS)	$2,439,519	$(18,812,637)
Net income (loss) per share - basic	$0.10	$(1.01)
Weighted average number of shares - basic	23,193,278	18,551,013
Net income (loss) per share - diluted	$0.09	$(1.01)
Weighted average number of shares - diluted	26,788,076	18,551,013

See accompanying notes to the audited consolidated financial statements.

CAPRICOR THERAPEUTICS, INC.

CONSOLIDATED STATEMENTS OF CHANGES IN STOCKHOLDERS' EQUITY (DEFICIT)

FOR THE PERIOD FROM DECEMBER 31, 2015 THROUGH DECEMBER 31, 2017

	COMMON STOCK		ADDITIONAL PAID-	OTHER COMPREHENSIVE	ACCUMULATED	TOTAL STOCKHOLDERS'
	SHARES	AMOUNT	IN CAPITAL	INCOME	DEFICIT	EQUITY (DEFICIT)
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)
Issuance of common stock, net of fees	4,811,472	4,812	11,068,340	-	-	11,073,152
Stock-based compensation	-	-	1,710,698	-	-	1,710,698
Unrealized gain on marketable securities	-	-	-	8,096	-	8,096
Stock options exercised	60,000	60	6,580	-	-	6,640
Net income	-	-	-	-	2,431,423	2,431,423

Balance at December 31, 2017	26,270,491	$ 26,271	$ 62,736,783	$ 11,620	$ (51,547,819)	$ 11,226,855

See accompanying notes to the audited consolidated financial statements.

CAPRICOR THERAPEUTICS, INC.

CONSOLIDATED STATEMENTS OF CASH FLOWS

FOR THE YEARS ENDED DECEMBER 31, 2017 AND 2016

	Years ended December 31,	
	2017	**2016**
CASH FLOWS FROM OPERATING ACTIVITIES:		
Net income (loss)	$2,431,423	$(18,806,776)
Adjustments to reconcile net income (loss) to net cash used in operating activities:		
Depreciation and amortization	144,174	125,719
Stock-based compensation	1,710,698	1,962,465
Forgiveness of loan payable	(15,654,133)	-
Non-cash impairment	-	1,500,000
Change in assets - (increase) decrease:		
Receivables	(121,240)	(11,397)
Prepaid expenses and other current assets	(158,272)	(132,289)
Other assets	(34,543)	8,720
Change in liabilities - increase (decrease):		
Accounts payable and accrued expenses	(1,542,073)	508,280
Accounts payable and accrued expenses, related party	(314,793)	136,883
Accrued interest	398,807	344,106
CIRM liability	276,259	3,100,000
Deferred revenue	(1,367,186)	(3,190,106)
NET CASH USED IN OPERATING ACTIVITIES	(14,230,879)	(14,454,395)
CASH FLOWS FROM INVESTING ACTIVITIES:		
Purchase of marketable securities	(18,986,194)	(17,997,361)
Proceeds from sales and maturities of marketable securities	24,000,000	13,000,000
Purchases of property and equipment	(32,185)	(191,970)
Payments for leasehold improvements	-	(1,769)
NET CASH PROVIDED BY (USED IN) INVESTING ACTIVITIES	4,981,621	(5,191,100)
CASH FLOWS FROM FINANCING ACTIVITIES:		
Net proceeds from sale of common stock	11,073,152	13,864,817
Proceeds from loan payable	500,000	4,750,000
Proceeds from stock awards, warrants, and options	6,640	13,975
NET CASH PROVIDED BY FINANCING ACTIVITIES	11,579,792	18,628,792
NET INCREASE (DECREASE) IN CASH, CASH EQUIVALENTS, AND RESTRICTED CASH	2,330,534	(1,016,703)

Cash, cash equivalents, and restricted cash balance at beginning of period	4,551,603	5,568,306
Cash, cash equivalents, and restricted cash balance at end of period	$6,882,137	$4,551,603
SUPPLEMENTAL DISCLOSURES:		
Interest paid in cash	$-	$1,343
Income taxes paid in cash	$-	$-

See accompanying notes to the audited consolidated financial statements.

CAPRICOR THERAPEUTICS, INC.

NOTES TO CONSOLIDATED FINANCIAL STATEMENTS

DECEMBER 31, 2017 AND 2016

1. ORGANIZATION AND SUMMARY OF SIGNIFICANT ACCOUNTING POLICIES

Description of Business

Capricor Therapeutics, Inc., a Delaware corporation (referred to herein as "Capricor Therapeutics" or the "Company"), is a clinical-stage biotechnology company focused on the discovery, development and commercialization of first-in-class biological therapies for the treatment of diseases, with a focus on Duchenne muscular dystrophy ("DMD"), and other medical conditions. Capricor, Inc. ("Capricor"), 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, 2017 were approximately $14.1 million, compared to approximately $16.2 million as of December 31, 2016. On March 31, 2017, the Company entered into a Common Stock Sales Agreement (the "March Sales Agreement") with H.C. Wainwright & Co., LLC ("Wainwright") to create an at-the-market equity program providing for the offer and sale, from time to time, by the Company of shares of its common stock, par value $0.001 per share, having an aggregate offering price of up to $5.0 million (the "March 2017 ATM Program") through Wainwright, as sales agent (see Note 3 – "Stockholders' Equity"). In October 2017, the Company fully utilized the March 2017 ATM Program, selling an aggregate of 2,589,078 common shares at an average price of approximately $1.93 per common share for gross proceeds of approximately $5.0 million (see Note 3 – "Stockholders' Equity").

On October 19, 2017, the Company entered into a Common Stock Sales Agreement (the "October Sales Agreement") with Wainwright to create additional at-the-market equity program under which the Company from time to time may offer and sell shares of its common stock, par value $0.001 per share, having an aggregate offering price of up to $14.0 million (the "October 2017 ATM Program") through Wainwright, as sales agent. As of March 20, 2018, the Company has sold an aggregate of 2,079,215 common shares under the October 2017 ATM Program at an average price of approximately $2.30 per common share for gross proceeds of approximately $4.8 million (see Note 3 – "Stockholders' Equity" and Note 10 – "Subsequent Events").

The Company has been awarded various grant and loan awards, which fund, in part, various pre-clinical and clinical activities (see Note 2 – "Loan Payable" and Note 6 – "Government Grant Awards"). As of December 31, 2017, the Company has up to approximately $5.2 million available under these grants and awards for disbursement, pursuant to the terms of each of the respective 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, 2017 AND 2016

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 its clinical trials and pre-clinical studies;
- the timing and costs associated with the manufacturing of its product candidates;
- the timing and costs associated with commercialization of its product candidates;
- 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 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. If necessary, Capricor is able to make certain operational adjustments to further reduce expenses by slowing down certain R&D efforts, decreasing headcount, and implementing further budget restrictions in order for the current cash/investments to last through at least, the first quarter of 2019. 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 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, Cash Equivalents, and Restricted Cash

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

The following table provides a reconciliation of cash, cash equivalents, and restricted cash reported within the consolidated balance sheets that total the same such amounts shown in the statement of cash flows.

	December 31, 2017	December 31, 2016
Cash and cash equivalents	$ 6,140,135	$ 3,204,378
Restricted cash	742,002	1,347,225
Total cash, cash equivalents, and restricted cash shown in the statements of cash flows	$ 6,882,137	$ 4,551,603

For the years ended December 31, 2017 and 2016, the Company had 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 $0.7 million and $1.3 million as of December 31, 2017 and December 31, 2016, respectively, and is entirely related to the CIRM Award.

CAPRICOR THERAPEUTICS, INC.

NOTES TO CONSOLIDATED FINANCIAL STATEMENTS

DECEMBER 31, 2017 AND 2016

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

Marketable Securities

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

Property and Equipment

Property and equipment are stated at cost. Repairs and maintenance costs are expensed in the period incurred. Depreciation is computed using the straight-line method over the related estimated useful life of the asset, which such estimated useful lives range from five to seven years. Leasehold improvements are depreciated on a straight-line basis over the shorter of the useful life of the asset or the lease term. Depreciation was $94,968 and $85,888 for the years ended December 31, 2017 and 2016, respectively.

Property and equipment consisted of the following at December 31:

	2017	2016
Furniture and fixtures	$46,709	$51,161
Laboratory equipment	619,994	587,809
Leasehold improvements	47,043	47,043
	713,746	686,013
Less accumulated depreciation	(341,650)	(250,677)
Property and equipment, net	$372,096	$435,336

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. Total amortization expense was $49,206 and $48,749 for the years ended December 31, 2017 and 2016, respectively. A summary of future amortization expense as of December 31, 2017 is as follows:

Years ended	Amortization Expense
2018	$ 43,277
2019	43,276
2020	4,330
2021	2,165

CAPRICOR THERAPEUTICS, INC.

NOTES TO CONSOLIDATED FINANCIAL STATEMENTS

DECEMBER 31, 2017 AND 2016

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

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. During the year ended December 31, 2016, the Company recognized an impairment expense of $1.5 million shown within the statement of operations and comprehensive loss as another expense. No impairment was recorded for the year ended December 31, 2017.

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, 2017 and 2016.

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 granted in connection with the HOPE trial 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 recognized revenue from non-refundable, upfront fees ratably over the term of its performance under the agreement with Janssen. The upfront payments received, pending recognition as revenue, were recorded as deferred revenue and were 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 reviewed the estimated performance period of its contract based on the estimated progress of its project. As of June 30, 2017, the full amount of income has been recognized under the Janssen Agreement and the Janssen Agreement terminated.

CAPRICOR THERAPEUTICS, INC.

NOTES TO CONSOLIDATED FINANCIAL STATEMENTS

DECEMBER 31, 2017 AND 2016

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

Income Taxes

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

The Company uses guidance issued by the FASB that clarifies the accounting for uncertainty in income taxes recognized in an enterprise's financial statements and prescribes a recognition threshold of more likely than not and a measurement process for financial statement recognition and measurement of a tax position taken or expected to be taken in a tax return. In making this assessment, a company must determine whether it is more likely than not that a tax position will be sustained upon examination, based solely on the technical merits of the position, and must assume that the tax position will be examined by taxing authorities.

As of December 31, 2017, the Company had federal net operating loss carryforwards of approximately $76.0 million, available to reduce future taxable income, which will begin to expire in 2026. As of December 31, 2017, the Company had state net operating loss carryforwards of approximately $70.7 million, available to reduce future taxable income, which will begin to expire in 2018. 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 $1.9 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, 2017 and 2016. The Company files income tax returns with the IRS and the California Franchise Tax Board.

Other Income

Revenue is recognized in connection with the delivery of doses which were developed as part of our past R&D efforts. Income is recorded when evidence of an arrangement exists, delivery has occurred and collection is reasonably assured (see Note 9 – "Related Party Transactions").

Loan Payable

The Company accounted for the funds advanced under the CIRM Loan Agreement as a loan payable as the eventual repayment of the loan proceeds or forgiveness of the loan was contingent upon certain milestones being met and other conditions (see Note 2 – "Loan Payable"). On November 17, 2017, the Company gave notice to CIRM that it was electing to abandon the CIRM-funded project pursuant to the Loan Agreement and on December 11, 2017, Capricor and CIRM entered into Amendment No. 3 to the CIRM Notice of Loan Award whereby the total loan balance under the CIRM Loan Agreement has been forgiven by CIRM thereby terminating Capricor and the Company's obligation to repay the loan balance.

CAPRICOR THERAPEUTICS, INC.

NOTES TO CONSOLIDATED FINANCIAL STATEMENTS

DECEMBER 31, 2017 AND 2016

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

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 under accounts payable and accrued expenses. 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 $10.8 million and $16.0 million for the years ended December 31, 2017 and 2016, respectively.

Comprehensive Income (Loss)

Comprehensive income (loss) generally represents all changes in stockholders' equity during the period except those resulting from investments by, or distributions to, stockholders. The Company's comprehensive income (loss) was approximately $2.4 million and $(18.8) million for the years ended December 31, 2017 and 2016, 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, 2017 and 2016, the Company's other comprehensive gain (loss) was $8,096 and $(5,861), 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. For employees and directors, the expected life was calculated based on the simplified method as described by the SEC Staff Accounting Bulletin No. 110, Share-Based Payment. For other service providers, the expected life was calculated using the contractual term of the award. The Company's estimate of expected volatility was based on the historical stock price of the Company. The Company has selected a risk-free rate based on the implied yield available on U.S. Treasury securities with a maturity equivalent to the expected term of the options.

Earnings (Loss) per Share

The Company reports earnings per share in accordance with FSAB ASC 260-10, *Earnings per Share.* Basic earnings (loss) per share is computed by dividing income (loss) available to common shareholders by the weighted-average number of common shares outstanding during the period. Diluted earnings (loss) per share is computed similarly to basic earnings (loss) per share except that the denominator is increased to include the number of additional common shares that would have been outstanding if the potential common shares had been issued and if the additional common shares were dilutive. The components of basic and diluted earnings (loss) per share for the years ended December 31, 2017 and 2016 were as follows:

CAPRICOR THERAPEUTICS, INC.

NOTES TO CONSOLIDATED FINANCIAL STATEMENTS

DECEMBER 31, 2017 AND 2016

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

	December 31, 2017	December 31, 2016
Numerator		
Net income (loss)	$ 2,431,423	$ (18,806,776)
Denominator		
Weighted-average number of common shares outstanding	23,193,278	18,551,013
Dilutive effect of stock options	3,594,798	-
Common stock and common stock equivalents used for diluted earnings (loss) per share	26,788,076	18,551,013

Fair Value Measurements

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

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

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

	December 31, 2017			
	Level I	Level II	Level III	Total
Marketable Securities	$7,984,800	$ -	$ -	$7,984,800

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

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.

CAPRICOR THERAPEUTICS, INC.

NOTES TO CONSOLIDATED FINANCIAL STATEMENTS

DECEMBER 31, 2017 AND 2016

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

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. At December 31, 2017, there are no warrants outstanding which require classification as a liability in accordance with the guidance.

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 Company adopted this provision in the first quarter of 2017. The adoption of this update did not have a material effect on the Company's financial statements.

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. The Company adopted this standard on January 1, 2017. The adoption of these provisions did not have a material effect on the Company's 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. 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.

CAPRICOR THERAPEUTICS, INC.

NOTES TO CONSOLIDATED FINANCIAL STATEMENTS

DECEMBER 31, 2017 AND 2016

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

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. The Company elected to early adopt this provision in the first quarter of 2017. This update was applied on a retrospective basis, wherein the statement of cash flow of each period presented was adjusted to reflect the effects of applying the new guidance.

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.

2. LOAN PAYABLE

On February 5, 2013, the Company entered into the CIRM Loan Agreement, pursuant to which CIRM agreed to disburse approximately $19.8 million to the Company over a period of approximately three and one-half years to support Phase II of our ALLSTAR clinical trial. Under the CIRM Loan Agreement, the Company was required to repay the CIRM loan with interest at maturity. So long as the Company was not in default, the Loan Agreement had provisions allowing for forgiveness of the debt after the end of the project period, if the Company elected to abandon the project under certain circumstances.

On November 17, 2017, the Company gave notice to CIRM that it was electing to abandon the CIRM-funded project pursuant to the Loan Agreement and on December 11, 2017, Capricor and CIRM entered into Amendment No. 3 to the CIRM Notice of Loan Award whereby the total loan balance under the CIRM Loan Agreement has been forgiven by CIRM thereby terminating Capricor and the Company’s obligation to repay the loan balance. The Company has classified the forgiveness of the loan payable consisting of principal and accrued interest of approximately $15.7 million as “other income” in our Consolidated Statement of Operations and Comprehensive Income (Loss) for the

period ending December 31, 2017. The decision to terminate the Loan Award and forgive the loan balance was due to the abandonment of the ALLSTAR project at the end of the project period in accordance with Section 4.10 of the Loan Agreement and Article VII, Section I of the CIRM Loan Administration Policy.

For the years ended December 31, 2017 and 2016, interest expense under the CIRM loan was $398,807 and $344,106, respectively.

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.

CAPRICOR THERAPEUTICS, INC.

NOTES TO CONSOLIDATED FINANCIAL STATEMENTS

DECEMBER 31, 2017 AND 2016

3.STOCKHOLDER'S EQUITY (Continued)

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.

March 2017 Common Stock Sales Agreement

On March 31, 2017, the Company entered into a Sales Agreement with Wainwright, under which the Company from time to time, issued and sold shares of its common stock through Wainwright as sales agent in an at-the-market offering under a prospectus supplement for aggregate sales proceeds of $5.0 million The common stock was distributed at the market prices prevailing at the time of sale. The Company sold an aggregate of 2,589,078 common shares under the March 2017 ATM Program at an average price of approximately $1.93 per common share for gross proceeds of approximately $5.0 million. The Company paid 3.0% cash commission on the gross proceeds, plus reimbursement of expenses of the placement agent and legal fees in the aggregate amount of approximately $0.2 million. The March 2017 ATM Program became fully utilized in October 2017.

May 2017 Financing

On May 5, 2017, the Company entered into Subscription Agreements with certain accredited investors (the "Investors"), pursuant to which the Company agreed to issue and sell to the investors, in a private placement (the "Private Placement"), an aggregate of 1,196,291 shares of its common stock, par value $0.001 per share, at a price per share of $3.10 for an aggregate purchase price of approximately $3.7 million. This placement included participation from some

of the Company's directors.

In connection with the Private Placement, the Company also entered into a Registration Rights Agreement with the Investors. Pursuant to the terms of the Registration Rights Agreement, the Company was obligated (i) to prepare and file with the SEC a registration statement to register for resale the shares issued in the Private Placement, and (ii) to use its reasonable best efforts to cause the registration statement to be declared effective by the SEC as soon as practicable, in each case subject to certain deadlines. The Company will be required to pay to each Investor liquidated damages equal to 1.0% of the aggregate purchase price paid by such Investor pursuant to the Subscription Agreements for the shares per month (up to a cap of 10.0%) if it does not meet certain obligations with respect to the registration of the shares, subject to certain conditions. Pursuant to its obligations under the Registration Rights Agreement, the Company registered for resale the shares issued in the Private Placement pursuant to a registration statement on Form S-3 (File No. 333-219188), which was filed with the SEC on July 7, 2017 and declared effective on July 17, 2017.

October 2017 Common Stock Sales Agreement

On October 19, 2017, the Company entered into the October Sales Agreement with Wainwright, establishing the October 2017 ATM Program. The common stock sold in the October 2017 ATM Program will be distributed at the market prices prevailing at the time of sale. The October Sales Agreement provides that Wainwright will be entitled to compensation for its services at a commission rate of 3.0% of the gross sales price per share of common stock sold plus reimbursement of certain expenses. As of December 31, 2017, the Company sold an aggregate of 1,026,103 shares under the October 2017 ATM Program at an average price of approximately $2.66 per common share for gross proceeds of approximately $2.7 million. The Company paid 3.0% cash commission on the gross proceeds, plus reimbursement of expenses of the placement agent and legal fees in the aggregate amount of approximately $0.1 million. Subsequent to December 31, 2017, the Company sold additional shares under the October 2017 ATM Program (see Note 10 – "Subsequent Events").

Outstanding Shares

At December 31, 2017, the Company had 26,270,491 shares of common stock issued and outstanding.

CAPRICOR THERAPEUTICS, INC.

NOTES TO CONSOLIDATED FINANCIAL STATEMENTS

DECEMBER 31, 2017 AND 2016

4.STOCK AWARDS, WARRANTS AND OPTIONS

Warrants

The following table summarizes all warrant activity for the years ended December 31, 2017 and 2016:

	Warrants	Weighted Average Exercise Price
Outstanding at January 1, 2016	235,830	$ 2.27
Granted	846,073	4.50
Outstanding at December 31, 2016	1,081,903	$ 4.01
Expired	(187)	2.27
Outstanding at December 31, 2017	1,081,716	$ 4.01

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

Grant Date	Warrants Outstanding December 31, 2017	December 31, 2016	Exercise Price per Share	Expiration Date
4/4/2012	-	187	$ 2.27	4/4/2017
11/20/2013	235,643	235,643	$ 2.27	11/20/2018
3/16/2016	846,073	846,073	$ 4.50	3/16/2019
	1,081,716	1,081,903		

Restricted Stock

In December 2017, the Company entered into an agreement pursuant to which the Company agreed to grant 12,500 shares of restricted stock to one of its consultants in consideration of services to be rendered. The restricted stock will fully vest upon completion of services. No shares were issued as of December 31, 2017. On February 28, 2018, the Company issued 12,500 shares of restricted stock to a consulting firm, which was valued at approximately $22,750.

Stock Options

The Company's Board of Directors (the "Board") has approved three stock option plans: (i) the 2006 Stock Option Plan, (ii) the 2012 Restated Equity Incentive Plan (which superseded the 2006 Stock Option Plan) (the "2012 Plan"), and (iii) 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.

CAPRICOR THERAPEUTICS, INC.

NOTES TO CONSOLIDATED FINANCIAL STATEMENTS

DECEMBER 31, 2017 AND 2016

4.STOCK AWARDS, WARRANTS AND OPTIONS (Continued)

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 years beginning on January 1, 2018 and 2017, the amount of shares that were added was equal to 525,409 and 427,980 shares, respectively.

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 who 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 2017 and 2016 were approximately $1.83 and $2.09 per share, respectively.

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

December 31, 2017 and 2016:

	December 31, 2017	December 31, 2016
Expected volatility	78% - 278%	78% - 82%
Expected term	5-10 years	5-7 years
Dividend yield	0%	0%
Risk-free interest rates	2.0% - 2.3%	0.5% - 2.3%

Employee and non-employee stock-based compensation expense for the years ended December 31, 2017 and 2016 was as follows:

	2017	**2016**
General and administrative	$1,194,065	$1,400,059
Research and development	516,633	562,406
Total	$1,710,698	$1,962,465

The Company does not recognize an income tax benefit as the Company believes that an actual income tax benefit may not be realized. For non-qualified stock options, the loss creates a timing difference, resulting in a deferred tax asset, which is fully reserved by a valuation allowance.

CAPRICOR THERAPEUTICS, INC.

NOTES TO CONSOLIDATED FINANCIAL STATEMENTS

DECEMBER 31, 2017 AND 2016

4.STOCK AWARDS, WARRANTS AND OPTIONS (Continued)

The following table summarizes information about stock options outstanding and exercisable at December 31, 2017:

Shares Outstanding			
Range of Ex. Prices	Shares Outstanding	Weighted Average Term (yrs.)	Weighted Average Exercise Price
$0.19 - $0.87	4,403,688	3.99	$ 0.37
$1.80 - $3.58	1,391,309	7.70	2.79
$4.34 - $5.78	1,074,757	6.98	5.25
$9.14	4,149	7.23	9.14
	6,873,903	5.21	$ 1.62

Shares Exercisable			
Range of Ex. Prices	Shares Exercisable	Weighted Average Term (yrs.)	Weighted Average Exercise Price
$0.19 - $0.87	4,403,688	3.99	$ 0.37
$1.80 - $3.58	661,056	7.78	2.85
$4.34 - $5.78	768,823	6.91	5.27
$9.14	2,767	7.23	9.14
	5,836,334	4.81	$ 1.30

As of December 31, 2017, the total unrecognized fair value compensation cost related to non-vested stock options was approximately $2.4 million, which is expected to be recognized over a weighted average period of approximately 1.1 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. We account for estimated forfeitures at the date of grant.

The following is a schedule summarizing employee and non-employee stock option activity for the years ended December 31, 2017 and 2016:

	Number of Options	Weighted Average Exercise Price	Aggregate Intrinsic Value
Outstanding at January 1, 2016	5,997,323	$ 1.59	
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
Granted	620,131	2.59	
Exercised	(62,244)	0.16	
Expired/Cancelled	(292,366)	3.88	
Outstanding at December 31, 2017	6,873,903	$ 1.62	$ -
Exercisable at December 31, 2017	5,836,334	$ 1.30	$ 1,649,246

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.

CAPRICOR THERAPEUTICS, INC.

NOTES TO CONSOLIDATED FINANCIAL STATEMENTS

DECEMBER 31, 2017 AND 2016

4. STOCK AWARDS, WARRANTS AND OPTIONS (Continued)

The aggregate intrinsic value of options exercised was $117,849 and $142,031 for the years ended December 31, 2017 and 2016, 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, 2017, the Company maintained approximately $14.5 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 for the treatment of Duchenne muscular dystrophy-associated cardiomyopathy. Pursuant to terms of the CIRM Award, the disbursements are 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, California Code of Regulations (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 the 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 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 (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 has not yet made its decision as to whether it will elect to convert the CIRM Award into a loan at this time. 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. In July 2016, Capricor received the first disbursement of $2.0 million under the terms of the CIRM Award.

CAPRICOR THERAPEUTICS, INC.

NOTES TO CONSOLIDATED FINANCIAL STATEMENTS

DECEMBER 31, 2017 AND 2016

6. GOVERNMENT GRANT AWARDS (Continued)

In September 2016, the Company 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. Additionally, in September 2017, the Company completed the second operational milestone tied to the last patient completing one year of follow-up, for which approximately $0.3 million was received by Capricor in November 2017. As of December 31, 2017, the Company's liability balance for the CIRM Award was $3.4 million, of which approximately $0.7 million is recorded as restricted cash, due to the fact that Capricor is required to expend approved project costs in order to use these funds.

On August 8, 2017, we entered into an Amendment to the CIRM Notice of Award pursuant to which CIRM approved the Company's request to use the remaining estimated project funds of the CIRM Award for technology transfer activities in support of the manufacture of CAP-1002 to a designated contract manufacturing organization, or CMO, which will enable Capricor to offer access to CAP-1002 to patients from the control arm of the HOPE-Duchenne trial via an open-label extension protocol.

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. As of September 30, 2016, the full award of $2.9 million had been disbursed under the terms of the NIH grant.

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, 2017, approximately $0.5 million has been incurred 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 Department of Defense 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, 2017, approximately $0.9 million has been incurred under the terms of the award.

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 extension 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 THERAPEUTICS, INC.

NOTES TO CONSOLIDATED FINANCIAL STATEMENTS

DECEMBER 31, 2017 AND 2016

7. COMMITMENTS AND CONTINGENCIES (Continued)

The Facilities Lease which Capricor entered into with CSMC is for a term of three years commencing June 1, 2014 and replaced 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. The Facilities Lease expired on May 31, 2017 and transitioned to a month-to-month tenancy. On August 10, 2017, the Company and CSMC entered into the First Amendment to the Facilities Lease effective August 1, 2017 (the “First Amendment”) pursuant to which the term of the Facilities Lease was extended for an additional 12-month period, and the Company was granted an option to further extend the term for an additional 12-month period thereafter through July 31, 2019. Under the First Amendment, the total monthly rent increased from approximately $19,350 to $19,756. In addition, pursuant to the First Amendment, the premises covered by the Facilities Lease now also include the manufacturing facility currently being utilized by Capricor. In lieu of further increasing the monthly rental payment set forth in the First Amendment, the Company has also agreed to provide doses of CAP-1002 for use in CSMC’s clinical trials for a negotiated amount of monetary compensation.

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 $138,292. A summary of future minimum rental payments required under operating leases as of December 31, 2017 is as follows:

Years ended	Operating Leases
2018	$ 431,014

Expenses incurred under operating leases to unrelated parties for the years ended December 31, 2017 and 2016 were approximately $284,861 and $272,607, respectively. Expenses incurred under operating leases to related parties for each of the years ended December 31, 2017 and 2016 were approximately $230,989 and $224,421, respectively.

Legal Contingencies

The Company is not a party to any material legal proceedings at this time. From time to time, the Company may become involved in various legal proceedings that arise in the ordinary course of its business.

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 certain 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 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. Capricor has a right of first negotiation, for a certain period of time, to obtain a license to any new and separate patent applications owned by the University of Rome utilizing cardiac stem cells in cardiac care.

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.

CAPRICOR THERAPEUTICS, INC.

NOTES TO CONSOLIDATED FINANCIAL STATEMENTS

DECEMBER 31, 2017 AND 2016

8. LICENSE AGREEMENTS (Continued)

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 may terminate the agreement upon the other party's material breach, provided that the breaching party will have up to 90 days to cure its material breach. Capricor may also terminate for any reason upon 90 days' written notice to the University of Rome.

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. Under the JHU License Agreement, Capricor is required to exercise commercially reasonable and diligent efforts to develop and commercialize licensed products covered by the licenses from JHU.

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 related to its CDC technology. 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, which amended, restated, and superseded the Original 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.

CAPRICOR THERAPEUTICS, INC.

NOTES TO CONSOLIDATED FINANCIAL STATEMENTS

DECEMBER 31, 2017 AND 2016

8. LICENSE AGREEMENTS (Continued)

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 for any future rights, 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 ranged 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) after 90 days' notice from CSMC 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. If Capricor fails to undertake commercially reasonable efforts to exploit the patent rights or future patent rights, and fails to cure

that breach after 90 days' notice from CSMC, instead of terminating the license, CSMC has the option to convert any exclusive license to Capricor to a non-exclusive or co-exclusive license. 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 applications to the schedule of patent rights set forth in the agreement. Under the Second License Amendment, (i) the description of scheduled patent rights has been replaced by a revised schedule that includes six additional patent 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 applications.

On December 26, 2017, Capricor entered into a Third Amendment to Exclusive License Agreement with CSMC thereby amending the CDCs License, or the Third License Amendment. Under the Third License Amendment, (i) the description of scheduled patent rights has been replaced by a revised schedule that includes seven additional patent applications; and (ii) Capricor is required to reimburse CSMC approximately $50,000 for attorneys' fees and filing fees that were incurred in connection with the additional patent rights.

CAPRICOR THERAPEUTICS, INC.

NOTES TO CONSOLIDATED FINANCIAL STATEMENTS

DECEMBER 31, 2017 AND 2016

8. LICENSE AGREEMENTS (Continued)

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 preparation and prosecution of certain patent applications. 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) after 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. If Capricor fails to undertake commercially reasonable efforts to exploit the patent rights or future patent rights, and fails to cure that breach after 90 days' notice from CSMC, instead of terminating the license, CSMC has the option to convert any exclusive license to Capricor to a

non-exclusive or co-exclusive license. 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 scheduled patent rights has been replaced by a revised schedule that includes four additional patent applications; (ii) Capricor was required to pay CSMC an upfront fee of $20,000; (iii) Capricor was 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 applications to the schedule of patent rights under the agreement. Under the Third Exosomes License Amendment, (i) the description of scheduled patent rights has been replaced by a revised schedule that includes three additional patent 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 applications.

CAPRICOR THERAPEUTICS, INC.

NOTES TO CONSOLIDATED FINANCIAL STATEMENTS

DECEMBER 31, 2017 AND 2016

8. LICENSE AGREEMENTS (Continued)

On December 26, 2017, Capricor and CSMC entered into a Fourth Amendment to Exclusive License Agreement, thereby amending the Exosomes License, or the Fourth Exosomes License Amendment. Under the Fourth Exosomes License Amendment, (i) the description of scheduled patent rights was replaced by a revised schedule that includes seven additional patent applications; (ii) Capricor is required to reimburse CSMC approximately $50,000 for attorneys' fees and filing fees that were incurred in connection with the additional patent rights; and (iii) a schedule to the Exosomes License was modified to extend the milestone deadline for filing an IND for at least one product to December 31, 2018.

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 had the exclusive right to enter into an exclusive license agreement pursuant to which Janssen would have received a worldwide, exclusive license to exploit CAP-1002 as well as certain CSps and CDCs in the field of cardiology.

On June 30, 2017, Capricor was informed by Janssen that Janssen would not be exercising its exclusive option right to exploit CAP-1002 as well as certain CSps and CDCs in the field of cardiology. Capricor will retain full rights to CAP-1002 in all indications as a result of this decision. Capricor will also have an irrevocable, fully paid-up non-exclusive license under patents controlled by Janssen utilized in the production of the clinical trial materials manufactured pursuant to the CMC development plan between Capricor and Janssen and a non-exclusive perpetual license to publish, disclose and use the information of Janssen that was utilized in the production of the clinical trial materials manufactured pursuant to the CMC development plan.

Company's 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. In February 2017, we elected to terminate our former natriuretic peptide development program, consisting of Cenderitide (CD-NP) and CU-NP, so as to more efficiently focus our resources and efforts on our CAP-1002 and CAP-2003 programs.

Medtronic Clinical Trial Funding Agreement

In February 2011, the Company entered into a Clinical Trial Funding Agreement with Medtronic, related to the Company's now discontinued Cenderitide program. Pursuant to its terms, the agreement expired in February 2012. 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 agreement. 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 Company's now discontinued natriuretic peptides program. Pursuant to the Transfer Agreement, Medtronic 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.

In light of the Company's decision to terminate its development program with respect to natriuretic peptides, the Company elected to cease prosecution of all of the Natriuretic Peptide Patents and has offered to reassign to Medtronic rights to certain patent applications obtained through the Transfer Agreement. Medtronic elected not to take a reassignment of the patent rights.

CAPRICOR THERAPEUTICS, INC.

NOTES TO CONSOLIDATED FINANCIAL STATEMENTS

DECEMBER 31, 2017 AND 2016

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 Smidt 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, 2017 and 2016, Capricor recognized $30,000 in sublease income from the related party. Sublease income is recorded as a reduction to general and administrative expenses.

Consulting Agreements

Effective January 1, 2013, Frank Litvack, the Company's Executive Chairman and a member of its Board of Directors, entered into an oral Consulting Agreement with Capricor whereby Capricor agreed to pay Dr. Litvack fees of $10,000 per month for consulting services. On March 24, 2014, Capricor entered into a written Consulting Agreement with Dr. Litvack memorializing the $10,000 per month compensation arrangement described above. The agreement is terminable upon 30 days' notice. Additionally, beginning 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, 2017 and 2016, the Company had accounts payable and accrued expenses to related parties totaling $174,424 and $489,217, respectively. CSMC accounts for $160,566 and $477,907 of the total accounts payable and accrued expenses to related parties as of December 31, 2017 and 2016, respectively. CSMC expenses relate to research and development and clinical trial costs. During the years ended December 31, 2017 and 2016, the Company paid CSMC approximately $900,000 and $500,000, respectively, for such costs.

Related Party Clinical Trials

Capricor has agreed to provide cells for investigational purposes in two clinical trials sponsored by CSMC. These cells were developed as part of the Company's past research and development efforts. 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 of cells and will receive a negotiated amount of monetary compensation which is estimated to be approximately $2.1 million over several years. For the year ended December 31, 2017, the Company recognized approximately $184,000 as other income. As of December 31, 2017, $122,500 is outstanding and recorded in prepaid expenses and other current assets.

10. SUBSEQUENT EVENTS

Stock Option Grants

In January 2018, the Company granted a total of 602,327 stock options to its employees and directors.

October 2017 Common Stock Sales Agreement

Subsequent to December 31, 2017 and through March 20, 2018, the Company has sold an aggregate of 1,053,112 common shares under the October 2017 ATM Program at an average price of approximately $1.95 per common share for gross proceeds of approximately $2.1 million. The Company paid 3.0% cash commission on the gross proceeds, plus reimbursement of expenses of the placement agent in the aggregate amount of approximately $64,000.

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, 2017, 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, 2017 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, 2017.

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, 2017 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 2018 Annual Meeting of Stockholders, or our 2018 Proxy Statement, to be filed with the SEC within 120 days after the end of the fiscal year ended December 31, 2017, and is incorporated herein by reference.

ITEM 11. EXECUTIVE COMPENSATION.

The information required by this item will be set forth in the section entitled “2017 Executive Compensation” and “Compensation of Directors” in our 2018 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 2018 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 2018 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 2018 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 74.

(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	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). †
10.3	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). †

10.4	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). †
10.5	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). †
10.6	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). †
10.7	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). †
10.8	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). †
10.9	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). †
10.10	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). †
10.11	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). †
10.12	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). †
10.13	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). †
10.14	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). †
10.15	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). +
10.16	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) . +
10.17	

	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). +
10.18	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). +
10.19	Amended and Restated Exclusive License Agreement, dated December 30, 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) . +

10.20	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) . +
10.21	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) . +
10.22	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).
10.23	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). +
10.24	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).
10.25	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).
10.26	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). +
10.27	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).
10.28	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).
10.29	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).
10.30	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).
10.31	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).

10.32	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).
10.33	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). +
10.34	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).

10.35	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). +
10.36	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).
10.37	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). †
10.38	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).
10.39	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).
10.40	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). +
10.41	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).
10.42	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). +
10.43	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).
10.44	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).
10.45	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).
10.46	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). +

10.47	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). +
10.48	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). †

10.49	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). †
10.50	Common Stock Sales Agreement, dated as of March 31, 2017, by and between Capricor Therapeutics, Inc. and H.C. Wainwright & Co. LLC (incorporated by reference to Exhibit 10.1 to the Company's Current Report on Form 8-K, filed with the Commission on March 31, 2017).
10.51	Form of Subscription Agreement (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 May 9, 2017).
10.52	Registration Rights Agreement, dated as of May 5, 2017, by and among Capricor Therapeutics, Inc. and the Investors party thereto (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 May 9, 2017).
10.53	Amendment No. 2 to Notice of Loan Award, dated as of June 7, 2017 (incorporated by reference to Exhibit 10.1 to the Company's Current Report on Form 8-K, filed with the Commission on June 13, 2017).
10.54	Common Stock Sales Agreement, dated as of October 19, 2017, by and between Capricor Therapeutics, Inc. and H.C. Wainwright & Co. LLC (incorporated by reference to Exhibit 10.1 to the Company's Current Report on Form 8-K, filed with the Commission on October 19, 2017).
10.55	Common Stock Sales Agreement, dated as of March 31, 2017, by and between Capricor Therapeutics, Inc. and H.C. Wainwright & Co. LLC (incorporated by reference to Exhibit 10.1 to the Company's Current Report on Form 8-K, filed with the Commission on March 31, 2017).
10.56	Amendment No. 1 to Notice of Award, dated as of August 8, 2017 (incorporated by reference to Exhibit 10.1 to the Company's Quarterly Report on Form 10-Q, filed with the Commission on November 14, 2017).
10.57	First Amendment to Facilities Lease, dated as of August 1, 2017, 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, 2017).
10.58	Fourth Amendment to Exclusive License Agreement, dated as of December 26, 2017, by and between Capricor, Inc. and Cedars-Sinai Medical Center.*+
10.59	Third Amendment to Exclusive License Agreement, dated as of December 26, 2017, by and between Capricor, Inc. and Cedars-Sinai Medical Center.*+
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, 2017 and 2016, (ii) Consolidated Statements of Operations and Comprehensive Income (Loss) for the years ended December 31, 2017 and 2016, (iii) Consolidated Statement of Stockholders' Equity (Deficit) for the period from December 31, 2015 through December 31, 2017, (iv) Consolidated Statements of Cash Flows for the years ended December 31, 2017 and 2016, and (v) Notes to Consolidated Financial Statements.*

* Filed herewith.

† Indicates management contract or compensatory plan or arrangement.

+ The Company has requested and/or 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 21, 2018.

CAPRICOR THERAPEUTICS, INC.

By: /s/ Linda Marbán, Ph.D.
Linda Marbán, Ph.D.
Chief Executive Officer

KNOW ALL MEN BY THESE PRESENTS, that we, the undersigned officers and directors of Capricor Therapeutics, Inc., hereby severally constitute Linda Marbán, Ph.D. and Anthony J. Bergmann and each of them singly, our true and lawful attorneys with full power to them, and each of them singly, to sign for us and in our names in the capacities indicated below, any and all amendments to said 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 21, 2018
/s/ Anthony J. Bergmann Anthony J. Bergmann	Chief Financial Officer *(Principal Financial and Accounting Officer)*	March 21, 2018
/s/ Frank Litvack, M.D. Frank Litvack, M.D.	Executive Chairman	March 21, 2018
/s/ Joshua A. Kazam Joshua A. Kazam	Director	March 21, 2018

/s/ Earl M. Collier Earl M. Collier	Director	March 21, 2018
/s/ Louis V. Manzo Louis V. Manzo	Director	March 21, 2018
/s/ George W. Dunbar George W. Dunbar	Director	March 21, 2018
/s/ David B. Musket David B. Musket	Director	March 21, 2018