UNITED STATES
SECURITIES AND EXCHANGE COMMISSION
WASHINGTON, D.C. 20549

FORM 10-K

☑ **Annual Report Pursuant to Section 13 or 15(d) of the Securities Exchange Act of 1934 for the fiscal year ended December 31, 2019**

or

☐ **Transition Report Pursuant to Section 13 or 15(d) of the Securities Exchange Act of 1934 for the transition period from to**

Commission File Number: 001-34058

CAPRICOR THERAPEUTICS, INC.
(Exact Name Of Registrant As Specified In Its Charter)

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

8840 Wilshire Blvd., 2nd Floor, Beverly Hills, California 90211
(Address of principal executive offices including zip code)

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

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

Title of Each Class	**Trading Symbol(s)**	**Name of Each Exchange on Which Registered**
Common Stock, par value $0.001 per share	CAPR	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 ☒ 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 ☒ 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. ☒ Yes ☐ No

Indicate by check mark whether the registrant has submitted electronically every Interactive Data File required to be submitted 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 such files). Yes ☒ No ☐

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

Large accelerated filer ☐
Non-accelerated filer ☒

Accelerated filer ☐
Smaller reporting company ☒
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 ☒ No

The aggregate market value of the registrant's common stock held by non-affiliates of the registrant as of June 30, 2019 was approximately $8,768,243, based on the last reported sale of the registrant's common stock on The Nasdaq Capital Market on June 28, 2019 of $3.32 per share.

As of March 27, 2020, there were 8,908,506 shares of the registrant's common stock, par value $0.001 per share, issued and outstanding.

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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; our ability to continue as a going concern; 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, 2019 are not necessarily indicative of results that may be attained in the future.

PART I

ITEM 1. BUSINESS

Company 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 rare disorders.

We are currently conducting HOPE-2, a Phase II clinical trial in the United States with our product candidate, CAP-1002, a cardiac cell derived therapy which is being used to treat patients with late-stage DMD. We plan to report final 12-month data from HOPE-2 in the second quarter of 2020. Following the receipt of this data, if positive, we plan to continue with the next stages of development towards potential registration which may include seeking approval from the FDA and, whether or not that approval is obtained following HOPE-2, pursuing a partnership to conduct a Phase III trial.

Additionally, we have begun work on developing our exosomes platform technology as a next-generation vaccine and therapeutic investigating a variety of disorders.

Our Technologies

Cardiosphere-Derived Cells (CAP-1002)

Our core therapeutic technology is based on cardiosphere-derived cells, or CDCs, a cardiac-derived cell therapy that was first identified in the academic laboratory of Capricor's scientific founder, Dr. Eduardo Marbán. Since the initial publication in 2007, CDCs have been the subject of over 100 peer-reviewed scientific publications and have been administered to approximately 150 human subjects across several clinical trials. CDCs have been shown to exert potent immunomodulatory activity and to alter the immune system's activity to encourage cellular regeneration. We have been developing allogeneic CDCs (CAP-1002) as a product candidate for the treatment of Duchenne muscular dystrophy, or DMD, 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 preclinical experimental models of heart injury, CDCs have been shown to stimulate cell proliferation and blood vessel growth and to inhibit programmed cell death and scar formation. 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 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-adherent multicellular clusters derived from the heart. 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.

While CDCs 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 manufacturing methods are focused on producing therapeutic doses of CDCs to boost the regenerative capacity of the heart and skeletal muscles, 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 CDCs as a product candidate.

Exosomes

Our preclinical data has shown that cardiosphere-derived cells mediate most of their therapeutic activities through the secretion of extracellular vesicles. Extracellular vesicles, including exosomes and microvesicles, are nano-scale, membrane-enclosed vesicles which are secreted by most cells and contain characteristic lipids, proteins and nucleic acids such as mRNA and microRNAs. They can signal through the binding and activation of membrane receptors or through the delivery of their cargo into the cytosol of target cells.

Exosomes act as messengers to regulate the functions of neighboring or distant cells and have been shown to regulate functions such as cell survival, proliferation, inflammation and tissue regeneration. Furthermore, pre-clinical research has shown that exogenously-administered exosomes can modify cellular activities, thereby supporting their therapeutic potential. Their size, low or null immunogenicity and ability to communicate in native cellular language potentially makes them an exciting new class of therapeutic agents with the potential to expand our ability to address complex biological responses. Because exosomes are a cell-free substance, they can be stored, handled, reconstituted and administered in similar fashion to common biopharmaceutical products such as antibodies.

Our Strategy

Our strategy is to discover, develop and commercialize first-in-class cell-derived therapies for the treatment of diseases. Our drug candidates in active development consist of CAP-1002 (allogeneic CDCs) and our exosome technologies. We believe that CDC-exosomes are primarily responsible for the mechanism of action of our cell therapy product. We are now positioning ourselves to advance our exosome product candidates into a platform technology for clinical development. Additionally, we are also exploring potential strategic alternatives with respect to the Company as well as our product candidates.

Our Product Candidates

Our drug candidates which are in various stages of active development, consist of CAP-1002, our CDC-derived cells, and our exosome technologies. In 2018 we commenced enrollment of patients with DMD in a Phase II clinical trial of CAP-1002 called HOPE-2. CAP-1002 was also the subject of three previous clinical trials conducted by us. 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 two trials, we are providing the investigational product for use in the trials. We are also evaluating our exosomes in pre-clinical studies for the treatment of various indications, with a view to making an IND filing for Duchenne muscular dystrophy in exosomes during the second quarter of 2020.

The following table summarizes our active product development programs:

Product	**Indication/Population**	**Development Stage**	**Commercial Rights**
CAP-1002	Duchenne Muscular Dystrophy*	HOPE-3 Phase III – in planning stages HOPE-2*** Phase II · 6-month interim analysis completed · Final 12-month data expected in Q2-2020 HOPE-Duchenne Phase I/II completed**	Capricor
Exosome Technologies	Immune-inflammatory conditions · Neuromuscular, including DMD	Pre-clinical	Capricor

***** The U.S. Food and Drug Administration, or 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 completed an Open Label Extension, or OLE, for the usual care only comparator arm of the HOPE-Duchenne trial.

***We are planning an OLE for the usual care only comparator arm of the HOPE-2 trial.

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, a loss of ambulation occurs after the first decade of life and eventually the patients suffer 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.

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.

We are currently developing CAP-1002 for the treatment of DMD. We completed the positive HOPE-Duchenne Phase I/II trial in 2017 and then subsequently began the HOPE-2 Phase II trial in 2018. We reported positive interim 6-month results from HOPE-2 in the third quarter of 2019 and we plan to report final 12-month results in the second quarter of 2020. Our further plans with respect to the clinical development of CAP-1002 in DMD, including our decision to conduct a Phase III trial, will be based on the final guidance received from the FDA, our ability to secure funding necessary to conduct the trial should we decide to pursue that path and/or our ability to partner with another company to advance the development of CAP-1002 for DMD, as well as other factors, some of which are not known at this time. After the receipt of our final 12-month data from HOPE-2, we plan to request another meeting with the FDA to discuss the next stages of development which may include seeking approval from the FDA.

Phase II HOPE-2 Clinical Trial

HOPE-2 is a randomized, double-blind, placebo-controlled clinical trial which is being conducted at multiple sites located in the United States. To date, we have randomized 20 patients in our HOPE-2 clinical trial. The clinical trial was designed to 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 who are on a stable regimen of systemic glucocorticoids. 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.

The primary efficacy endpoint of the HOPE-2 trial is 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 the Performance of the Upper Limb, or PUL, test. In the HOPE-2 study we are evaluating these through both the PUL 1.2 and 2.0 versions. HOPE-2 is focusing on the mid-level dimension of the PUL which assesses the ability to use muscles from the elbow to the hand, which are essential for operating wheelchairs and performing other daily functions. In HOPE-2, additional secondary and exploratory endpoints such as cardiac function, pulmonary function, quality of life and additional measures are included.

In July 2019, we reported interim top-line results from the HOPE-2 trial which showed that a pre-specified interim analysis performed on 6-month data showed meaningful results across several independent clinical measures.

In October 2019, we reported additional data from the interim analysis at the 24th Annual International Congress of the World Muscle Society. Data from a total of 20 patients was analyzed (12 placebo and 8 treated) at the 3- and 6-month time-point in the intent to treat (ITT) population. The late breaking podium presentation presented the top-line, 6-month results from the HOPE-2 clinical trial which showed meaningful results across several independent clinical measures which is summarized below.

Skeletal Assessments

To assess skeletal muscle function, investigators used the PUL, versions 1.2 and 2.0. The FDA has suggested the use of the updated PUL 2.0 version as the primary efficacy endpoint in support of a Biologics License Application, or BLA. Additional independent tests assessing grip strength showed improvements at 6 months and tests assessing tip to tip pinch strength showed positive results. We also expanded the skeletal assessment beyond the mid-level and evaluated patients' PUL "scores" to include the upper and distal dimensions.

Skeletal Assessments at 3 and 6-month time-points (PUL 2.0) presented at World Muscle Society

Time-point	3 months			6 months		
Treatment	CAP-1002 n=8	Placebo n=10	p-value	CAP-1002 n=6	Placebo n=8	p-value
Shoulder + Mid + Distal Level	0.5 (1.69)	-1.2 (1.69)	0.0549	-0.3 (0.52)	-2.3 (1.49)	0.0299
Mid + Distal Level	0.4 (1.30)	-0.4 (0.70)	0.1035	0.2 (1.47)	-1.4 (0.92)	0.0177
Mid-level	0.1 (0.99)	-0.4 (0.52)	0.2202	-0.2 (1.17)	-1.1 (0.99)	0.0612

Mean Change from baseline (standard deviation) shown.
ITT (intent to treat) population shown
Comparisons treated vs. placebo using mixed model repeated ANOVA with covariates

Pulmonary Assessments

To assess pulmonary function, investigators measured several clinically relevant parameters. At 3 months, inspiratory flow reserve (absolute), a reflection of diaphragmatic strength, showed an improvement. Additionally, an improvement was observed at 3 months in peak expiratory flow (% predicted), another measure of diaphragmatic strength.

Cardiac Assessments

As reported from our July interim analysis, magnetic resonance imaging, or MRI, was used to assess cardiac structure and function at 6 months. Positive trends were found in cardiac muscle function including systolic wall thickening and cardiac mass among those treated with CAP-1002 compared to placebo. The hearts of DMD patients atrophy progressively and have impaired systolic function. Improved mass and wall thickening suggest possible cardiac regeneration and functional improvement. These trends were consistent with the cardiac findings seen in the previously published HOPE-Duchenne study.

Safety

In late December 2018, Capricor put a voluntary hold on dosing after two patients in the HOPE trials had a serious adverse event in the form of an immediate immune reaction. The investigation suggested the patients may have developed hypersensitivity to something contained in the investigational product, including possibly an excipient or inactive ingredient in the formulation. To reduce the risk of future adverse events, Capricor initiated a commonly used pre-medication strategy including oral steroids and antihistamines to prevent or mitigate potential immune reactions during the administration. Since the initiation of the pre-treatment regimen, approximately 40 infusions of investigational drug (CAP-1002 or placebo) have been administered to HOPE-2 patients with only one serious adverse event reported that required an overnight observation of the patient.

Regulatory Developments

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 BLA. The PUL test is an outcome instrument that was specifically designed to assess upper limb function in ambulant and non-ambulant patients with DMD.

In December 2018, we met with the FDA as part of the expedited review afforded under the RMAT designation. The agency stated that the trial would need to provide evidence of clinically meaningful changes in the PUL, as well as other evidence supportive of CAP-1002 efficacy for patients with advanced Duchenne muscular dystrophy, in order to potentially serve as a registration trial.

In October 2019, we had a meeting with the FDA to discuss, among other things, the results of the 6-month interim analysis of the HOPE-2 trial and our path forward with our DMD program. During the meeting, we proposed the possibility of accelerated approval. The FDA was not supportive of an accelerated approval pathway at that time and noted that the HOPE-2 trial was designed as an exploratory trial and that data from the HOPE-2 trial did not provide substantial evidence of effectiveness to support a future biologics license application, or BLA. The FDA did, however, indicate its support for conducting a Phase III trial of CAP-1002 for the treatment of DMD. In addition, the FDA reiterated that as part of our RMAT designation, they are willing to work with us to further the clinical development of the therapy.

In a follow-up to the October 2019 meeting, Capricor requested an additional meeting to clarify endpoints for a Phase III clinical trial. In a written response, FDA supported the use of the full PUL 2.0 from baseline to twelve months as a primary efficacy endpoint as long as clinical meaningfulness can be demonstrated. They suggested that a 1.0 point change appears suitable from a clinical perspective for a Phase III intended to provide primary evidence of effectiveness to support a BLA.

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 was funded in part through a grant award from the California Institute for Regenerative Medicine, or CIRM. In January 2019, this study was published in the online issue of *Neurology*, the medical journal of the American Academy of Neurology.

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 from the HOPE-Duchenne trial 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 analysis. 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.

Additionally, in 2018 we conducted an open-label extension of the Hope-Duchenne trial, or HOPE-OLE, where 8 patients who were randomized into the control group of the HOPE-Duchenne trial were given two doses of CAP-1002. We have completed enrollment and treatment of the patients in the HOPE-OLE trial. In January 2019, we entered into an Amendment to the CIRM Notice of Award pursuant to which CIRM allowed us to use excess funds from our grant award to fund, in part, certain activities associated with HOPE-OLE.

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 DMD. To receive the RMAT designation, we submitted data from the HOPE-Duchenne Trial.

CAP-1002 for the Treatment of Cardiac Conditions:

In previous years, we completed several trials investigating the use of CAP-1002 for the treatment of various cardiac conditions, including heart failure (the DYNAMIC Trial) and post myocardial infarction (MI) with cardiac dysfunction (ALLSTAR). Because of our decision to focus our efforts on DMD, we have decided not to pursue those indications at this time, nor do we have any plans to continue with the development of these programs although we are continuing to evaluate certain cardiac measures in our HOPE-2 trial. We expect no further material expenses in connection with these programs.

CAP-1002 - 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. We were recently informed that the REGRESS study was put on clinical hold by the FDA. This is an investigator sponsored trial for which Capricor is providing CAP-1002, the investigational product. The preliminary information we have received suggests that the issue may be related to inadequate patient monitoring at the study site to assess safety for certain patients who were experiencing adverse events after receiving an intracoronary infusion of CAP-1002. It is currently not known whether the clinical hold is related to the investigational product or the procedure. Capricor did not use intracoronary infusions in its HOPE-2 trial.

The second trial is known as "Pulmonary Arterial Hypertension treated with Cardiosphere-derived Allogeneic Stem Cells." In this trial, the investigational product is infused into the venous system via catheter into the right atrium. This trial is currently ongoing. In both studies, Capricor is providing 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.

Exosomes Program

Our exosomes program consists of exosomes derived from CDCs (CAP-2003) and engineered exosomes, both of which are in various stages of preclinical development. We have explored the use of our CDC-exosomes in pre-clinical studies of inflammation and intense immune activation such as DMD, sepsis, Graft versus-host disease (GVHD) and trauma. While CDC-exosomes are the initial technology used in preclinical development, we have expanded Capricor's pipeline to include additional exosome technologies. We are now focused on developing a precision-engineered exosome platform technology that can carry defined sets of effector molecules which exert their effects through defined mechanisms of action. We have announced our planned expansion of our exosome platform technology that potentially may be used for vaccine development, vesicle mediated protein therapies and treatment of inherited diseases.

Bioactivity

Capricor has been working to harness the natural therapeutic capability of exosomes by isolating them to develop a new class of therapeutic agents capable of recapitulating the activities mediated by the CDCs. Isolated and purified exosomes appear to be preclinically less immunogenic and demonstrate superior stability than isolated CDCs. To date, we have performed an extensive phenotypic analysis of CDC-exosomes and identified a biomolecular profile that differentiates our CDC-exosomes from exosomes obtained from mesenchymal stem cells (MSC-exosomes). Additionally, we have also developed an *in vitro* bioactivity assay to evaluate the potency of the CDC-exosomes compared to exosomes obtained from different cellular sources. In several preclinical studies, CDC exosomes performed better than MSC exosomes. These assays represent an extremely useful tool for our product development.

Immunomodulation

In pre-clinical studies, Capricor's exosomes have shown strong immunomodulatory activity by their ability to reduce the expression of pro-inflammatory genes and concurrently increase the expression of genes related to tissue regeneration. These activities have been confirmed *in vivo* in different animal models and open the possibility of using our exosomes technologies therapeutically for the treatment of disease.

We have used RNA sequencing analysis to identify miRNAs contained in our exosomes which are not seen in exosomes obtained from other cell types. The levels of these miRNAs in our exosomes correlate with their immunomodulatory capabilities on macrophages. Multiple scientific publications support the role of these miRNAs in macrophage polarization.

Biodistribution

During pre-clinical development, we analyzed the biodistribution of our exosomes using different administration routes (intravenous, intrathecal, intranasal or subconjunctival) in healthy and diseased animal models. After intravenous administration of our exosomes into these models, we observed an accumulation of exosomes in the liver, spleen and lungs as well as in the heart. In disease models we also found exosomes in damaged tissues suggesting a preferential uptake by cells involved in tissue repair.

Ex vivo experiments have shown a strong uptake of our exosomes by skeletal muscle stem cells (or satellite cells), which opens the possibility that our exosome technologies target this population of cells that play a critical role in muscle regeneration and which, to date, have been difficult to reach.

Manufacturing

We have also made significant progress planning the next steps for the manufacturing process for our exosome product candidates. We believe these developments will enable us to scale up our manufacturing capabilities and potentially allow us to manufacture enough material for clinical development.

In order to expand the stability profile of our exosome technologies, we have also established a collaboration to further develop lyophilization of the exosomes. Much of this work has been funded in part through a grant from the Department of Defense (DoD) awarded for the development and characterization of the exosomes for product development.

Engineered Exosomes Platform

To build upon the natural ability of exosomes for intercellular communication, we have initiated a program to engineer exosomes and load them with different macromolecules. Our preliminary results demonstrated that it is possible to load exosomes with specific miRNAs which pave the way to use our exosomes to potentially deliver miRNAs to specific target tissue. We are now working on developing exosome-based vaccines for COVID-19. While these efforts are still in their early-stages, our exosome-based vaccine platform technology will aim to combine the improved protection that comes from immunizing individuals with multiple antigens in a manner that mimics the advantages of conventional virus vaccines, with the superior safety profile of virus-free vaccines. We plan to design exosome-based vaccines to elicit strong humoral and cellular immune responses due to the simultaneous expression of antigens.

Investigation of Potential Indications for our Exosomes Technologies

Capricor has exclusively licensed intellectual property relating to CDC-exosomes from Cedars-Sinai Medical Center and is also pursuing its own intellectual property rights relating to exosome technologies.

We have promising pre-clinical data in several indications from studies done in our labs as well as in collaboration with other companies and academic institutions. Additionally, in July 2018, we entered into a Cooperative Research and Development Agreement with the U.S. Army Institute of Surgical Research (USAISR) pursuant to which we agreed to cooperate in research and development on the evaluation of our CDC-exosomes for the treatment of trauma related injuries and conditions which are now the third leading cause of death in the U.S.

We plan to file an IND for DMD with the FDA in advance of the filing deadline under our license agreement with CSMC, which is April 19, 2020, unless we negotiate for an extension of this date with CSMC. We have also begun work on developing an exosome-based vaccine platform for COVID-19.

These programs represent our core technology and products.

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 patents, if issued and upon payment of patent maintenance fees, would expire as early as 2024 and as late as 2039. There are also limited opportunities to obtain extensions of patent terms in certain countries.

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

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 next milestone is triggered upon successful completion of a full Phase II study for which a payment of $250,000 will be due.

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 the Amended CSMC License Agreement 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.

On June 20, 2018, Capricor and CSMC entered into a Fourth Amendment to the Amended CSMC License Agreement, or the Fourth License Amendment. Under the Fourth License Amendment, the description of scheduled patent rights has been replaced by a revised schedule that includes two additional patent applications.

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 Exosomes 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.

On June 20, 2018, Capricor and CSMC entered into a Fifth Amendment to the Exosomes License Agreement, or the Fifth License Amendment. Under the Fifth License Amendment, (i) the description of scheduled patent rights has been replaced by a revised schedule that includes four additional patent applications; and (ii) Capricor is required to reimburse CSMC approximately $27,000 for attorneys' fees and filing fees that were incurred in connection with the additional patent rights.

On September 25, 2018, Capricor and CSMC entered into a Sixth Amendment to the Exosomes License Agreement, or the Sixth License Amendment. Under the Sixth License Amendment, the milestone deadline for filing an IND for at least one product has been extended to December 31, 2019. If the Company does not file an IND by December 31, 2019, or negotiate an additional extension of the milestone deadline, CSMC would have the option to convert the exclusive license to a non-exclusive license or to a co-exclusive license or terminate the license under Title 35, Section 203 of the United States Code. Prior to exercising such option, Capricor has the opportunity to cure the failure to file an IND for a period of 90 days after its receipt of written notice from CSMC of its intent to exercise its option. In the first quarter of 2020, Capricor received a notice from CSMC indicating that Capricor was in default of this milestone and further that unless such default is cured by April 19, 2020, the Exosomes License Agreement will automatically terminate. Capricor intends to file an IND in advance of the April 19, 2020 deadline in order to avoid the termination of the license, or alternatively negotiate an extension of the deadline with CSMC. Such intent has been communicated to CSMC.

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 our previous studies as well as for the 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 we elect to not extend the term of our Facilities Lease, 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 potentially for a Phase III trial.

We are currently evaluating a proposed contract manufacturing agreement with a contract manufacturing organization, or CMO, for continued expansion focused on potential commercialization and scale-up of our cell therapy program for the treatment of DMD.

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 participating in clinical trials. CAP-1002 is cryo-preserved, enabling us to produce large lots that can be frozen and then administered to patients as needed.

Exosomes (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 clinical investigation. We believe that the allogeneic, acellular nature of exosomes would potentially enable us to create a 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 $28.0 million to date. Our ongoing research and development activities primarily concern CDCs and 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 $5.1 million and $12.1 million on research and development activities for the years ended December 31, 2019 and 2018, 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 and future 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 patients for clinical trials, 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 NDA or a pending 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 for 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, packaging, 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 certain members of the 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. 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 were 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. For example, the California Consumer Privacy Act of 2018, or CCPA, which took effect on January 1, 2020, gives California residents expanded rights to access and require deletion of their personal information, opt out of certain personal information sharing, and receive detailed information about how their personal information is used. In addition, the CCPA authorizes private lawsuits to recover statutory damages for certain data breaches. While it exempts some data regulated by HIPAA and certain clinical trials data, the CCPA may increase our compliance costs and potential liability with respect to other personal information we collect about California residents.

We expect our product, if and when approved, 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 16 full-time employees. 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. Capricor subsequently entered into several amendments extending the term of the lease and modifying its terms. Effective January 1, 2020, we entered into an amendment with the Bubble Real Estate Company, LLC pursuant to which we extended our lease for an additional year ending December 31, 2020 and reduced the square footage. The monthly rental payment is $16,229 for this annual period.

Capricor leases facilities from CSMC pursuant to a lease, or the Facilities Lease, that was originally effective for a three-year period beginning June 1, 2014. Capricor has subsequently entered into several amendments extending the term of the lease and modifying its terms. From August 1, 2017 through March 1, 2019, total monthly rent was $19,756. Effective March 1, 2019, the square footage of the leased premises was reduced, resulting in a rent reduction of approximately $4,000 per month. In July 2019, Capricor exercised an option to extend the term of the Facilities Lease for an additional 12-month period through July 31, 2020 with a monthly lease payment of $15,805. The Company has a further option to extend the Facilities Lease through July 31, 2021. The premises leased from CSMC are located at 8700 Beverly Blvd., Los Angeles, California 90048.

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, 2019, we had cash, cash equivalents and marketable securities totaling approximately $9.9 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 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 ongoing clinical trials and plans for new clinical trials and product development.

In 2019, we implemented certain cost cutting measures including a reduction in the size of our workforce in order to conserve cash resources. Other than our cash on hand and the funds expected to be received from our supplying product for clinical trials sponsored by CSMC and the DoD grant award which funds ongoing pre-clinical work for our exosomes, as well as potential sales under our August 2019 ATM Program, we currently have no commitments or arrangements for any additional financing to fund the research and clinical development of CAP-1002 or our exosomes.

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. 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 and our ongoing exosomes program;

- the next steps in the development of our Duchenne muscular dystrophy, or DMD, program, which may potentially include a Phase III clinical trial for our CAP-1002 product candidate in DMD;
- the availability of funding from government programs including the NIH, and DoD;
- 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 in the U.S. and 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 technology transfer for, and 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 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 approval for any of our product candidates. 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:

- our need for substantial additional capital to fund our trials and development programs;
- delays in the commencement, enrollment, and timing of clinical testing;
- the viability of CAP-1002 as a potential product candidate for the treatment of DMD and its development through all stages of clinical development;
- the viability of our exosome technologies as potential product candidates and the advancement of our exosome technologies through 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;
- 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, including strategic partnerships for CAP-1002 in DMD;
- our ability and third parties' abilities to obtain and 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 implement additional internal systems and infrastructure;
- our ability to adequately support future growth;
- if our products are approved for commercial sale, the ability to secure reimbursement for our products;
- 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 still in clinical or pre-clinical development.

Each of the Company's two active product candidates, CAP-1002 and our exosome technologies, are in development and each requires further and, in some cases, 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 Company's failure to establish the efficacy of its technologies 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 trial or any potential Phase III trial of our CAP-1002 product candidate in DMD. Additionally, we cannot predict with any certainty if, or when, we might commence any additional clinical trials of our product candidates, whether we will be able to secure a partner to fund and/or conduct a potential Phase III trial, 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.

Business disruptions such as natural disasters, widespread infectious diseases or pandemics 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 being susceptible to drought and fires. A significant natural disaster, such as an earthquake, flood or fire, occurring at our headquarters or manufacturing facilities, or at the facilities of any third-party manufacturer or vendor, could have a material adverse effect on our business, financial condition and results of operations. In addition, outbreaks of viruses, infectious diseases or pandemics (including, for example, recent outbreak of the novel coronavirus (COVID-19)), 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, contractors and collaborators, which could have a material adverse effect on our business, financial condition and results of operations.

The coronavirus outbreak could adversely impact our business.

In December 2019, it was first reported that there had been an outbreak of a novel strain of coronavirus (COVID-19), in China. COVID-19 has since spread globally, and the number of cases is increasing daily. Governments in the United States and elsewhere are taking severe measures to slow the spread of COVID-19, including requiring that certain business close or conduct only the minimum necessary operations.

As COVID-19 continues to spread, we may experience disruptions that could severely impact our business, including:

- delays or difficulties in enrolling patients in our clinical trials;
- diversion of healthcare resources to address COVID-19, which could limit the availability of medical facilities for our clinical trials;
- forced closures, or reductions in operations, at our facilities or the facilities of third parties with whom we do business; and
- disruptions to our workforce, or the workforces of third parties with whom we do business, caused by sickness, travel restrictions or quarantines, including but not limited to the announcement on March 19, 2020 by the Governor of the State of California ordering all individuals living in the State of California to stay at home or at their place of residence.

The global outbreak of COVID-19 continues to evolve and its ultimate impact on our business will depend on future developments, which are highly uncertain and cannot be predicted. Any of the disruptions listed above, or other disruptions caused by new developments associated with the COVID-19 outbreak could severely impact our business.

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 if 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 clinical research organizations, or 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.

If we achieve our near-term product development milestones, we may not be able to manage any subsequent growth

Should we achieve our near-term product development 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 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, if any, 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, 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. Results of our interim analysis of the HOPE-2 trial conducted at 6 months may not be predictive of the 12-month results. Because we partially unblinded the results in order to conduct the interim analysis, our ability to use the data from the HOPE-2 trial has been impacted.

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

Despite the results reported in earlier clinical trials for our product candidates, we do not know whether any Phase II, Phase III or other clinical trial which we may conduct will demonstrate adequate efficacy and safety to result in regulatory approval to market our product candidates. 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 exosome technologies are based on a novel therapeutic approach which makes it difficult to predict the time and cost of development and of subsequently obtaining regulatory approval, if at all.

Our exosome technologies involve a relatively new therapeutic approach which will face both clinical and regulatory challenges. To date, no products based on exosomes have been approved in the United States or the European Union. It is therefore difficult to accurately predict the developmental challenges we may face for our exosome technologies as they proceed through preclinical studies and clinical trials. In addition, because we have only conducted preclinical studies with our exosome technologies, we have not yet been able to assess their safety in humans, and there may be short-term or long-term effects from treatment with our exosomes that we cannot predict at this time. Also, animal models for the indications we may explore may not exist or may be difficult to obtain for our preclinical studies. As a result of these factors, we are unable to predict the time and cost of development of the exosome technologies and we cannot predict whether the application of the exosome technologies, or any similar or competitive exosome technologies, will result in regulatory approval of any products. There can be no assurance that any development problems we experience in the future related to our exosomes or any of our research programs will not cause significant delays or unanticipated costs, or that such development problems can be solved. Any of these factors may prevent us from completing our preclinical studies or any clinical trials that we may initiate or commercializing any product candidates we may develop on a timely or profitable basis, if at all.

The clinical trial requirements of the FDA, the European Medicines Agency, or EMA, and other regulatory authorities and the criteria these regulators use to determine the safety and efficacy of a product candidate vary substantially according to the type, complexity and intended use and market of the product candidate. As a result, the regulatory approval process for our exosomes is uncertain and may be more expensive and take longer than the approval process for other product candidates. It is difficult to determine how long it will take or how much it will cost to obtain regulatory approvals for our exosomes in either the United States or the European Union or other regions of the world or how long it will take to commercialize our product candidates, if at all. Delay or failure to obtain, or unexpected costs in obtaining, the regulatory approval necessary to bring a potential product candidate to market could decrease our ability to generate sufficient product revenue, and our business, financial condition, results of operations and prospects may be harmed.

Negative developments in the field of exosomes could damage public perception of any product candidates that we develop, which could adversely affect our ability to conduct our business or obtain regulatory approvals for such product candidates.

Exosome therapeutics are novel and unproven therapies which may not gain the acceptance of the public, patients or the medical community. To date, other efforts to leverage natural exosomes have generally demonstrated an inability to generate exosomes with predictable biologically active properties or to manufacture exosomes at suitable scale to treat more than a small number of patients. Our success will depend on our ability to demonstrate that our exosome technologies can overcome these challenges.

Additionally, our success will depend upon physicians who specialize in the treatment of diseases targeted by our exosomes prescribing treatments that involve the use of our product candidates in lieu of, or in addition to, existing treatments with which they are more familiar and for which greater clinical data may be available. Adverse events in clinical trials of our exosomes or in clinical trials of others developing similar products and the resulting publicity, as well as any other adverse events in the field of exosome therapeutics, could result in a decrease in demand for any products that we may develop. These events could also result in the suspension, discontinuation, or clinical hold of, or modification to, our clinical trials. Any future negative developments in the field of exosomes and their use as therapies could also result in greater governmental regulation, stricter labeling requirements and potential regulatory delays in the testing or approvals of our exosomes or other future product candidates. Any increased scrutiny could delay or increase the costs of obtaining marketing approval for our exosomes or any other product candidates which we may develop in the future.

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 additional investigational new drug applications, or INDs, over the next several years, including with respect to our exosome technologies in one or more indications. However, the timing of our filing of these INDs is primarily dependent on receiving further data from our pre-clinical studies. As discussed below, we need to file an IND with respect to one therapeutic indication on or before April 19, 2020, in order to retain our exclusive license with CSMC for exosomes.

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 of 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 trial 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, which are complex and subject to strict regulatory oversight.

The Company has limited 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 clinical trials successfully or our failure to capitalize on the results of 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 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. Furthermore, negative, delayed or inconclusive results may result in:

- the withdrawal of clinical trial participants;
- the termination of clinical trial sites or entire trial programs;
- costly litigation arising out of the trials;
- substantial monetary awards to patients or other claimants;
- the requirement that additional trials be conducted;
- 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 or may otherwise be resource constrained. 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 CROs, vendors and trial sites, the terms of which can be subject to extensive negotiation and may vary significantly among different CROs, vendors and trial sites;
- obtaining regulatory clearance 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 inability of the sites to devote their resources to the trial, 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;
- demonstrating the bioequivalence of products we manufacture to prior products manufactured on our behalf;
- 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;
- requirements to conduct additional trials and studies, and increased expenses associated with the services of the Company's CROs and other third parties; and
- meeting logistical requirements for the delivery of investigational product.

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 or will not be realized. 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.

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. 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 may be able to rely upon data obtained from a meaningful number of sites, including through expansion to additional sites. 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 for the treatment of DMD 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. 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. 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.

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 is providing the necessary number of doses and will receive a negotiated amount of monetary compensation in exchange for doing so.

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 commercially reasonable 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 the studies in accordance with the protocol, the manuals provided by Capricor or the sponsor’s instructions, or otherwise act in accordance with applicable law. There is no assurance that if research injuries are sustained, any insurance carrier will compensate Capricor for any liabilities or other losses sustained by Capricor arising out of these injuries. Since we cannot predict when the trials will be completed, there is a risk that product designated for the trials will have expired at the time they are required. Additionally, there is a risk that our product may encounter some kind of contamination internally in our leased facility, at our contracted shipping facility or in transit which may have an adverse effect on our business or operations. While the Company expects to continue to receive payment for the product that it supplies for the REGRESS and ALPHA trials, we cannot predict the rate at which such payments will be made, if at all, due to delays in enrollment or other problems that may arise at the trial sites.

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 which could have a negative impact on the regulatory pathway for our product as well as the viability for other potential indications. After a patient in the HOPE-2 trial had a serious adverse event in the form of anaphylaxis, we put a voluntary hold on dosing in December 2018 to develop a plan to manage potential allergic reactions. The investigation suggests that the patient may have been allergic to something contained in the investigational product, including possibly an excipient, or inactive ingredient, in the formulation. To reduce the risk of future events, we initiated a pre-medication strategy commonly used by physicians to prevent and treat allergic reactions. Although at the time of filing this Annual Report on Form 10-K, all infusions in the HOPE-2 trial have been completed and we are not aware of the occurrence of any additional allergic reactions or further severe safety issues, we cannot provide any assurances that this will not happen again in any future studies. If these or other reactions continue to occur, it could have a material adverse impact on the effectiveness of the product, our ability to receive approval of our product candidates, and could result in substantial delays, increased costs and potentially termination of the trial.

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, clinical trials, and 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, and as further provided 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 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 will be required to manufacture or retain the services of a commercial manufacturer to develop product suitable for commercial sale;
- we may have limitations on how we promote our products; and
- we may be subject to litigation or product liability claims.

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, time delays, and increased risk and may impact the progress of our clinical trials and regulatory approvals.

To the extent we conduct business in the European Union, or EU, or receive information about EU residents, we will also have to comply with the EU General Data Protection Regulation, or the GDPR, which was officially adopted in April 2016 and went into effect in May 2018. The GDPR introduces new data protection requirements in the EU, as well as substantial fines for breaches of data protections rules. The GDPR enhances data protection obligations for processors and controllers of personal data, including, for example, expanded disclosures about how personal information is to be used, limitations on retention of information, mandatory data breach notification requirements and onerous new obligations on services providers. Non-compliance with the GDPR may result in monetary penalties of up to €20 million or 4% of worldwide revenue, whichever is higher. The GDPR and other changes in laws or regulations associated with the enhanced protection of certain types of personal data, such as healthcare data or other sensitive information, could greatly increase our cost of providing our products and services or even prevent us from offering certain services in jurisdictions in which we operate.

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. As we expand our business outside of the United States, ensuring compliance with the FCPA and the laws of other countries will involve additional monetary and time commitments on behalf of the Company.

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, the 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 any of the following were to occur: 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 have 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 trial. 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.

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.

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, if our therapeutic candidates or clinical trials become 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 False Claims Act, or 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;
- the Health Insurance Portability and Accountability Act, or 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 the Health Information Technology for Economic and Clinical Health Act, or 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 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, 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 future business prospects.

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 early 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 healthcare 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.

Recently, the Trump Administration and certain members of U.S. Congress have expressed a desire to modify, repeal, or otherwise invalidate all or certain provisions of the ACA, which contributes 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, a recently enacted federal income tax law effective January 1, 2019 repealed what is commonly referred to as the "individual mandate," a tax-based shared responsibility payment imposed by the ACA on certain individuals who fail to maintain qualifying health coverage.

Separately, pursuant to the health reform legislation and related initiatives, the Centers for Medicare and Medicaid Services, or CMS, is working with various healthcare providers to develop, refine, and implement Accountable Care Organizations, or 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 biotechnology 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 our 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 FCA), 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 other entities subject to the Open Payments regulations. 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 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. Any of these 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.

Our ability to obtain reimbursement or funding for our programs 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 Bipartisan Budget Act of 2015 extended sequestration for Medicare through fiscal year 2027. The U.S. federal budget remains in flux, however, which could, among other things, result in a cut to Medicare payments to providers and otherwise affect federal spending on clinical and pre-clinical research and development. 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 which the actions of President Trump's administration and the U.S. Congress may have on the federal budget. Following the most recent federal elections, Congress has again focused on reducing the cost of drugs and other medical treatments. 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.

Vaccines carry unique risks and uncertainties, which could have a negative impact on future results of operations.

We are in the process of initiating development of vaccine candidates using our exosome technologies. The successful development, testing, manufacturing and commercialization of vaccines is a long, complex, expensive and uncertain process. There are unique risks and uncertainties associated with vaccines, including:

- There may be limited access to, and supply of, normal and diseased tissue samples, cell lines, media pathogens, bacteria, viral strains, synthesized nucleic acids and other biological materials. In addition, government regulations in multiple jurisdictions, such as the United States and the EU, could result in restricted access to, or transport or use of, such materials. If the Company in unable to access sufficient sources of such materials, or if tighter restrictions are imposed on the use of such materials, the Company may not be able to conduct research or product development activities as planned and may incur additional costs.

- The development, manufacturing and marketing of vaccines are subject to regulation by the FDA, the EMA and other regulatory bodies that are often more complex and extensive than the regulations applicable to other pharmaceutical products. For example, in the United States, a BLA, including both preclinical and clinical trial data and extensive data regarding the manufacturing procedures, is required for human vaccine candidates, and FDA approval is generally required for the release of each manufactured commercial lot.

- Vaccines are frequently costly to manufacture because production ingredients are inactive biological materials derived from virus, animals, or plants and most biologics and vaccines cannot be made synthetically. In particular, keeping up with the demand for vaccines may be difficult due to the complexity of producing vaccines.

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 our exosomes, we believe that we follow good manufacturing practices sufficient for an investigational stage product, but it is not a cGMP approved facility and would not be adequate for manufacturing product for commercial use. Capricor manufactured CAP-1002 in this facility for our previous clinical studies as well as our 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.

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 our exosomes. Currently, our Facilities Lease is scheduled to expire on July 31, 2020 although we have an additional 1-year option enabling us to extend the term of our Facilities Lease to July 31, 2021. There can be no assurance that the Facilities Lease will be continued beyond July 31, 2021. 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.

If we were to initiate a Phase III study, we are unsure at this time if the FDA would allow us to produce doses in our current facility or whether the FDA would require us to use a cGMP facility. If we were required to use a cGMP facility to produce product for a Phase III study, this would result in delays and significant expenses which would have a negative impact on our business and product development. Furthermore, given our workforce reductions in our manufacturing group in early 2019, and the scale required for the manufacturing of products for commercial sale, we will have to establish a collaboration agreement with a third party or build out our own manufacturing facility for any commercial scale manufacturing which would also involve significant expenses and cause delays.

We are currently evaluating a proposed contract manufacturing agreement with a contract manufacturing organization, or CMO, for continued expansion focused on potential commercialization and scale-up of our cell therapy program for the treatment of DMD. Concurrently, Capricor is internally developing additional process development improvements in anticipation of potential commercial scale and/or later stage clinical trials which may affect the timing of our technology transfer.

We are required to obtain and maintain certain licenses in connection with our manufacturing facilities and activities. We have been issued a Manufacturing License and a Tissue Bank License from the State of California. There is no guarantee that any licenses issued to us will not be revoked or forfeited by operation of law or otherwise. If we were denied any required license or if any of our licenses were to be revoked or forfeited, we would suffer significant harm. Additionally, 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 or exosomes and the development of our lead product candidates 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.

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 current HOPE-2 clinical trial. Our experience in the manufacturing of exosomes is limited to producing product for pre-clinical use. 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 supply chain issues, equipment failures, labor shortages, natural disasters, power failures and numerous other factors.

If we continue with the development of CAP-1002 or our exosomes, we may need to rely exclusively on third parties to formulate and manufacture these product candidates and provide us with the devices and other products necessary to administer such a product.

We have not established our own manufacturing facilities sufficient for the production of CAP-1002 or our exosomes for commercial purposes. While we plan to utilize our currently manufactured product for a potential Phase III trial, there is no assurance that the FDA will not require that the product used in the Phase III trial be manufactured under cGMP conditions. Also, our resources and expertise to formulate or manufacture this product candidate are limited. If we were to conduct such a trial or reach the commercialization stage, we may have to engage one or more manufacturers to manufacture, supply, store, and distribute drug supplies for such purposes. If CAP-1002 or any of our exosome technologies receives FDA approval, we may need to rely on one or more third-party contractors to manufacture supplies of these drug products which may cause delays in 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 may not be able 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 may not be able 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 practices 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.

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 product candidates, 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 product candidates.

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/or 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, non-transferable, irrevocable, paid-up, worldwide license to practice or have practiced for or on behalf of the government(s) such inventions. In addition, the government(s) has the right to "march in" and require us to grant third parties licenses to such technology, in certain circumstances, such as if we fail to take effective steps to achieve practical application of such inventions.

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 and trade secrets. There can be no assurance that we can adequately protect our rights in such non-patented proprietary know-how and trade secrets, or that others will not independently develop substantially equivalent proprietary information or techniques or gain access to our proprietary know-how and trade secrets. 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 derivation, post-grant review, or *inter partes* review, 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.

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 cardiospheres (CSps), and cardiosphere-derived cells (CDCs), (including our CAP-1002 product candidate) 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 from CSMC that cover extracellular vesicles, such as exosomes and microvesicles derived from CDCs. 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, as the same have been amended, we have assumed, in coordination with CSMC, financial responsibility for the prosecution and maintenance of all patents and patent applications thereunder. Our enforcement of certain of these licensed patents or defense of any claims asserting the invalidity and/or unenforceability of these patents would also be subject to the cooperation of the University of Rome, JHU, and/or CSMC.

Additionally, in 2018, Capricor and CSMC entered into a Sixth Amendment to the Exosomes License Agreement. Under the Sixth License Amendment, the milestone deadline for filing an IND for at least one product has been extended to December 31, 2019. If the Company does not file an IND by December 31, 2019, or negotiate an additional extension of the milestone deadline, CSMC would have the option to convert the exclusive license to a non-exclusive license or to a co-exclusive license or terminate the license under Title 35, Section 203 of the United States Code. Prior to exercising such option, Capricor has the opportunity to cure the failure to file an IND for a period of 90 days after its receipt of written notice from CSMC of its intent to exercise its option. In the first quarter of 2020, CSMC notified Capricor that it was in breach of the Exosomes License Agreement because it failed to file an IND by December 31, 2019 and that if not done so by April 19, 2020, that the Exosomes License Agreement shall immediately terminate. Subsequently, Capricor informed CSMC that it intends to file an IND prior to that date.

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 laws 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 that are in-licensed. Further, if any of our owned or in-licensed patents are determined by legal authority to be invalid or 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 advantage, 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; and
- 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 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.

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 adversarial 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 covered by 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 determine 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 modified certain legal tests so as to make it harder to obtain patents from the USPTO, and to defend issued patents against invalidity challenges. As a consequence, issued patents may be found to contain invalid claims according to the revised legal standards. Some of our own or in-licensed patents may be subject to challenge and subsequent invalidation in a variety of post-grant proceedings, before the Patent Trial and Appeal Board (the PTAB) of the USPTO or in litigation under the revised legal standards, 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 the results of our operations and divert the attention of managerial and technical personnel. There is a risk that a court could determine 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 claim construction by the courts, which is not always predictable or reasonable. 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 proof by 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 licenses to these issued patents covering such technologies. For patent applications filed before the Leahy-Smith Act, 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 we or 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, trade secrets, know-how and proprietary technology, both our own and that 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 take certain developmental actions, fail to pay certain minimum royalties, or fail to maintain the licensed intellectual property. For example, CSMC has indicated that our exclusive license with CSMC for exosomes requires us to file an IND by April 19, 2020 or it will automatically terminate for breach. 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 contract 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, the latter of which is also a stockholder 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. For example, CSMC has indicated that our exclusive license with CSMC for exosomes requires us to file an IND by April 19, 2020 or it will automatically terminate for breach. 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 or 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. Further, the failure of any third-party licensor to comply with its licensing obligations under its respective agreement with us 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 the proprietary technology.

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

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

Commencing in 2009, we received several grants from the NIH and DoD to fund various projects. Some of these awards remain subject to annual and quarterly reporting requirements and require us to allocate expenses to the applicable project.

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 our exosomes. Under the terms of the award, disbursements will be made to Capricor over a period of approximately three years, subject to annual and quarterly reporting requirements. We were subsequently granted a no-cost extension until September 29, 2020 in order to be able to continue to utilize these funds.

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 was forgiven by CIRM thereby terminating Capricor's 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. Additionally, on June 16, 2016, Capricor entered into the CIRM Award with CIRM in the amount of approximately $3.4 million to fund, in part, the HOPE-Duchenne trial. Pursuant to terms of the CIRM Award, disbursements were tied to the achievement of specified operational milestones. 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.

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.

We are actively looking into potential strategic partnerships for our product candidates, particularly for our CAP-1002 product candidate. If we do not establish strategic partnerships, we potentially will have to undertake development and commercialization efforts with respect to our product candidates 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, vendors and strategic partners to conduct our pre-clinical and clinical trials under agreements with us. We negotiate budgets and contracts with CROs, vendors and trial 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. 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 and regulations.

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 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. For example, Dr. Frank Litvack, our Executive Chairman, is only a part-time consultant to the Company and provides services to other non-competing enterprises.

We have experienced employee turnover from time to time, including involving some of our key employees. The loss of any of our current 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, both to enable the Company to grow, and to allow the Company to replace any employees or consultants whose relationships with the Company have been terminated. The market for employees with experience in the cell therapy and exosome industries 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. In early 2019, in an effort to reduce costs and preserve our capital, we reduced our workforce by 21 employees, most of whom were engaged in manufacturing and product development.

There has been 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 can sometimes be 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, delay, or terminate 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 secure sufficient funds, we will not be able to complete our trials or bring our product candidates to market and generate product revenue. We have announced that our goal is pursue a partnership for the continued development of CAP-1002 in DMD.

We have no experience selling, marketing, or distributing products and no current 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. If any of our product candidates are cleared for commercialization, 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 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 the levels of coverage may not be sufficient to reimburse it for 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 and human health and safety 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, as well as laws and regulations designed to protect employees and others who handle hazardous materials. 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 environmental 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 continue to fluctuate significantly.

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 impact of any terms imposed on our business and operations by the providers of 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 and regulatory developments;
- 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;
- failure to satisfy licensing obligations, including our ability to file an IND to meet the milestone requirements under our Exosomes License Agreement;
- 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;
- potential delisting of our stock from the Nasdaq Stock Market; 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.

We may issue shares of blank check preferred stock without stockholder approval 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, and 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, many of which are beyond our control.

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 prospectus 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
- 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, 2019, our executive officers, directors and holders of five percent or more of our outstanding common stock (based upon our review of filings made with the SEC by such holders), together with their respective affiliates, owned approximately 25% 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 warrants, and we expect to issue additional stock awards and shares of common stock in the future. Exercise of these awards and warrants, 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, 2019, there were approximately 5.2 million shares of common stock outstanding, approximately 3.2 million pre-funded common warrants outstanding, and approximately 4.3 million common warrants outstanding, as well as outstanding awards to purchase approximately 0.8 million shares of common stock under various incentive stock plans of the Company. Additionally, as of December 31, 2019, there were approximately 0.1 million shares of common stock available for future issuance under various incentive plans. We may issue additional common stock, warrants and other convertible securities 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, warrants or other convertible securities 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 further be 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 stockholders 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. In addition, these rules and regulations make it more difficult and more expensive for us to obtain director and officer liability insurance. 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.

You may experience future dilution as a result of future equity offerings.

In order to raise additional capital, we may in the future offer additional shares of our common stock or other securities convertible into or exchangeable for our common stock at prices that may not be the same as the price per share paid by any investor. We may sell shares or other securities in any other offering at a price per share that is less than the price per share paid by any investor, and investors purchasing shares or other securities in the future could have rights superior to you. The price per share at which we sell additional shares of our common stock, or securities convertible or exchangeable into common stock, in future transactions may be higher or lower than the price per share paid by any investor.

If our business plans are not successful, we may not be able to continue operations as a going concern and our stockholders may lose their entire investment in us.

We have historically incurred substantial losses to fund our business operations including our research and development activities. We will, in all likelihood, sustain operating expenses without corresponding revenues for the foreseeable future. This may result in our incurring net operating losses that will increase continuously until we are able to obtain regulatory approval for, and commercialize, our product candidates, the occurrence of which cannot be assured. If we cannot continue as a going concern, our stockholders may lose their entire investment in us.

We may be at risk of securities class action litigation.

We may be at risk of securities class action litigation. This risk is especially relevant due to our dependence on positive clinical trial outcomes and regulatory approvals. In the past, biotechnology and pharmaceutical companies have experienced significant stock price volatility, particularly when associated with binary events such as clinical trials and product approvals. If we face such litigation, it could result in substantial costs and a diversion of management's attention and resources, which could harm our business and result in a decline in the market price of our common stock.

In the event we fail to satisfy any of the listing requirements of The NASDAQ Capital Market, our common stock may be delisted, which could affect our market price and liquidity.

Our common stock is listed on The NASDAQ Capital Market. For continued listing on The NASDAQ Capital Market, we will be required to comply with the continued listing requirements, including the minimum market capitalization standard, the minimum stockholders' equity requirement, the corporate governance requirements and the minimum closing bid price requirement, among other requirements. In the event that we fail to satisfy any of the listing requirements of The NASDAQ Capital Market, our common stock may be delisted. For example, we recently received a letter from the NASDAQ Listings Qualification Department indicating that it had determined that we failed to comply with Listing Rule 5550(b)(1) based on the Company's Form 10-Q for the period ended June 30, 2019, evidencing stockholders' equity below the required threshold of $2.5 million. This failure to comply with Rule 5550(b)(1) was remedied in our subsequent Form 10-Q filing for the period ended September 30, 2019, but there is no guarantee that we will be able to resolve any NASDAQ listing deficiencies which may occur in the future. If our securities are delisted from trading on The NASDAQ Stock Market, however, and we are not able to list our securities on another exchange or to have them quoted on The NASDAQ Stock Market, our securities could be quoted on the OTC Markets or on the "pink sheets." As a result, we could face significant adverse consequences including:

- a limited availability of market quotations for our securities;
- a determination that our common stock is a "penny stock," which would require brokers trading in our common stock to adhere to more stringent rules and possibly result in a reduced level of trading activity in the secondary trading market for our securities;
- a limited amount of news and analyst coverage; and
- a decreased ability to issue additional securities (including pursuant to short-form registration statements on Form S-3) or obtain additional financing in the future.

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 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. Capricor subsequently entered into several amendments extending the term of the lease and modifying its terms. Effective January 1, 2020, we entered into an amendment with the Bubble Real Estate Company, LLC pursuant to which we extended our lease for an additional year ending December 31, 2020 and reduced the square footage. The monthly rental payment is $16,229 for this annual period.

Capricor leases facilities from CSMC pursuant to a lease, or the Facilities Lease, that was originally effective for a three-year period beginning June 1, 2014. Capricor has subsequently entered into several amendments extending the term of the lease and modifying its terms. From August 1, 2017 through March 1, 2019, total monthly rent was $19,756. Effective March 1, 2019, the square footage of the leased premises was reduced, resulting in a rent reduction of approximately $4,000 per month. In July 2019, Capricor exercised an option to extend the term of the Facilities Lease for an additional 12-month period through July 31, 2020 with a monthly lease payment of $15,805. The Company has a further option to extend the Facilities Lease through July 31, 2021. The premises leased from CSMC are located at 8700 Beverly Blvd., Los Angeles, California 90048.

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 for the periods indicated. The per share prices reflect a 1-for-10 reverse stock split effected on June 4, 2019. 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, 2018		
First Quarter	$ 20.90	$ 12.80
Second Quarter	15.80	12.60
Third Quarter	14.90	10.20
Fourth Quarter	10.80	3.20
Year ended December 31, 2019		
First Quarter	$ 6.80	$ 4.10
Second Quarter	6.40	2.75
Third Quarter	6.23	2.38
Fourth Quarter	3.55	1.04

Holders

According to the records of our transfer agent, American Stock Transfer & Trust Company, as of March 26, 2020, we had 109 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.

Securities Authorized for Issuance Under Equity Compensation Plans

The information required by this item is set forth in the section entitled "Securities Authorized for Issuance Under Equity Compensation Plans" irour Definitive Proxy Statement for our 2020 Annual Meeting of Stockholders, to be filed with the SEC within 120 days after the end of the fiscal year ended December 31, 2019, and is incorporated herein by reference.

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

As consideration for the services provided to us by H.C. Wainwright & Co., LLC, or Wainwright as placement agent for our December 2019 public offering of our common stock and warrants, or the December 2019 Offering, on December 19, 2019, we issued to designees of Wainwright, warrants, or the Placement Agent Warrants, to purchase an aggregate of 203,915 shares of our common stock. The Placement Agent Warrants have an exercise price of $1.5325 per share, are immediately exercisable and expire in December 2024. Our agreement to issue the Placement Agent Warrants was made, and the Placement Agent Warrants were issued, in reliance on the exemption provided by Section 4(a)(2) of the Securities Act of 1933, as amended, relative to transactions by an issuer not involving any public offering, to the extent an exemption from such registration was required. No underwriters were involved in such transaction.

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 rare disorders. We are currently conducting HOPE-2, a Phase II clinical trial with our product candidate, CAP-1002, and are also actively developing the exosomes platform technology as a next-generation vaccine and therapeutic.

Our Technologies

Cardiosphere-Derived Cells (CAP-1002)

Our core therapeutic technology is based on cardiosphere-derived cells, or CDCs, a cardiac-derived cell therapy that was first identified in the academic laboratory of Capricor's scientific founder, Dr. Eduardo Marbán. Since the initial publication in 2007, CDCs have been the subject of over 100 peer-reviewed scientific publications and have been administered to approximately 150 human subjects across several clinical trials. CDCs have been shown to exert potent immunomodulatory activity and to alter the immune system's activity to encourage cellular regeneration. We have been developing allogeneic CDCs (CAP-1002) as a product candidate for the treatment of Duchenne muscular dystrophy, or DMD, 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 preclinical experimental models of heart injury, CDCs have been shown to stimulate cell proliferation and blood vessel growth and to inhibit programmed cell death and scar formation. 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 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-adherent multicellular clusters derived from the heart. 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.

While CDCs 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 manufacturing methods are focused on producing therapeutic doses of CDCs to boost the regenerative capacity of the heart and skeletal muscles, 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 CDCs as a product candidate.

Exosomes

Our preclinical data has shown that cardiosphere-derived cells mediate most of their therapeutic activities through the secretion of extracellular vesicles. Extracellular vesicles, including exosomes and microvesicles, are nano-scale, membrane-enclosed vesicles which are secreted by most cells and contain characteristic lipids, proteins and nucleic acids such as mRNA and microRNAs. They can signal through the binding and activation of membrane receptors or through the delivery of their cargo into the cytosol of target cells.

Exosomes act as messengers to regulate the functions of neighboring or distant cells and have been shown to regulate functions such as cell survival, proliferation, inflammation and tissue regeneration. Furthermore, pre-clinical research has shown that exogenously-administered exosomes can modify cellular activities, thereby supporting their therapeutic potential. Their size, low or null immunogenicity and ability to communicate in native cellular language potentially makes them an exciting new class of therapeutic agents with the potential to expand our ability to address complex biological responses. Because exosomes are a cell-free substance, they can be stored, handled, reconstituted and administered in similar fashion to common biopharmaceutical products such as antibodies.

Our Product Candidates

Our drug candidates which are in various stages of active development, consist of CAP-1002, our CDC-derived cells, and our exosome technologies. In 2018 we commenced enrollment of patients with DMD in a Phase II clinical trial of CAP-1002 called HOPE-2. CAP-1002 was also the subject of three previous clinical trials conducted by us. 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 two trials, we are providing the investigational product for use in the trials. We are also evaluating our exosomes in pre-clinical studies for the treatment of various indications, with a view to making an IND filing for Duchenne muscular dystrophy in exosomes during the second quarter of 2020.

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.

We are currently developing CAP-1002 for the treatment of DMD. We completed the positive HOPE-Duchenne Phase I/II trial in 2017 and then subsequently began the HOPE-2 Phase II trial in 2018. We reported positive interim 6-month results from HOPE-2 in the third quarter of 2019 and we plan to report final 12-month results in the second quarter of 2020. Our further plans with respect to the clinical development of CAP-1002 in DMD, including our decision to conduct a Phase III trial, will be based on the final guidance received from the FDA, our ability to secure funding necessary to conduct the trial should we decide to pursue that path and/or our ability to partner with another company to advance the development of CAP-1002 for DMD, as well as other factors, some of which are not known at this time. After the receipt of our final 12-month data from HOPE-2, we plan to request another meeting with the FDA to discuss the next stages of development which may include seeking approval from the FDA.

Phase II HOPE-2 Clinical Trial

HOPE-2 is a randomized, double-blind, placebo-controlled clinical trial which is being conducted at multiple sites located in the United States. To date, we have randomized 20 patients in our HOPE-2 clinical trial. The clinical trial was designed to 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 who are on a stable regimen of systemic glucocorticoids. 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.

The primary efficacy endpoint of the HOPE-2 trial is 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 the Performance of the Upper Limb, or PUL, test. In the HOPE-2 study we are evaluating these through both the PUL 1.2 and 2.0 versions. HOPE-2 is focusing on the mid-level dimension of the PUL which assesses the ability to use muscles from the elbow to the hand, which are essential for operating wheelchairs and performing other daily functions. In HOPE-2, additional secondary and exploratory endpoints such as cardiac function, pulmonary function, quality of life and additional measures are included.

In July 2019, we reported interim top-line results from the HOPE-2 trial which showed that a pre-specified interim analysis performed on 6-month data showed meaningful results across several independent clinical measures.

In October 2019, we reported additional data from the interim analysis at the 24th Annual International Congress of the World Muscle Society. Data from a total of 20 patients was analyzed (12 placebo and 8 treated) at the 3- and 6-month time-point in the intent to treat (ITT) population. The late breaking podium presentation presented the top-line, 6-month results from the HOPE-2 clinical trial which showed meaningful results across several independent clinical measures which is summarized below.

Skeletal Assessments

To assess skeletal muscle function, investigators used the PUL, versions 1.2 and 2.0. The FDA has suggested the use of the updated PUL 2.0 version as the primary efficacy endpoint in support of a Biologics License Application, or BLA. Additional independent tests assessing grip strength showed improvements at 6 months and tests assessing tip to tip pinch strength showed positive results. We also expanded the skeletal assessment beyond the mid-level and evaluated patients' PUL "scores" to include the upper and distal dimensions.

Skeletal Assessments at 3 and 6-month time-points (PUL 2.0) presented at World Muscle Society

Time-point	**3 months**			**6 months**		
Treatment	**CAP-1002 n=8**	**Placebo n=10**	**p-value**	**CAP-1002 n=6**	**Placebo n=8**	**p-value**
Shoulder + Mid + Distal Level	0.5 (1.69)	-1.2 (1.69)	0.0549	-0.3 (0.52)	-2.3 (1.49)	0.0299
Mid + Distal Level	0.4 (1.30)	-0.4 (0.70)	0.1035	0.2 (1.47)	-1.4 (0.92)	0.0177
Mid-level	0.1 (0.99)	-0.4 (0.52)	0.2202	-0.2 (1.17)	-1.1 (0.99)	0.0612

Mean Change from baseline (standard deviation) shown.
ITT (intent to treat) population shown
Comparisons treated vs. placebo using mixed model repeated ANOVA with covariates

Pulmonary Assessments

To assess pulmonary function, investigators measured several clinically relevant parameters. At 3 months, inspiratory flow reserve (absolute), a reflection of diaphragmatic strength, showed an improvement. Additionally, an improvement was observed at 3 months in peak expiratory flow (% predicted), another measure of diaphragmatic strength.

Cardiac Assessments

As reported from our July interim analysis, magnetic resonance imaging, or MRI, was used to assess cardiac structure and function at 6 months. Positive trends were found in cardiac muscle function including systolic wall thickening and cardiac mass among those treated with CAP-1002 compared to placebo. The hearts of DMD patients atrophy progressively and have impaired systolic function. Improved mass and wall thickening suggest possible cardiac regeneration and functional improvement. These trends were consistent with the cardiac findings seen in the previously published HOPE-Duchenne study.

Safety

In late December 2018, Capricor put a voluntary hold on dosing after two patients in the HOPE trials had a serious adverse event in the form of an immediate immune reaction. The investigation suggested the patients may have developed hypersensitivity to something contained in the investigational product, including possibly an excipient or inactive ingredient in the formulation. To reduce the risk of future adverse events, Capricor initiated a commonly used pre-medication strategy including oral steroids and antihistamines to prevent or mitigate potential immune reactions during the administration. Since the initiation of the pre-treatment regimen, approximately 40 infusions of investigational drug (CAP-1002 or placebo) have been administered to HOPE-2 patients with only one serious adverse event reported that required an overnight observation of the patient.

Regulatory Developments

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 BLA. The PUL test is an outcome instrument that was specifically designed to assess upper limb function in ambulant and non-ambulant patients with DMD.

In December 2018, we met with the FDA as part of the expedited review afforded under the RMAT designation. The agency stated that the trial would need to provide evidence of clinically meaningful changes in the PUL, as well as other evidence supportive of CAP-1002 efficacy for patients with advanced Duchenne muscular dystrophy, in order to potentially serve as a registration trial.

In October 2019, we had a meeting with the FDA to discuss, among other things, the results of the 6-month interim analysis of the HOPE-2 trial and our path forward with our DMD program. During the meeting, we proposed the possibility of accelerated approval. The FDA was not supportive of an accelerated approval pathway at that time and noted that the HOPE-2 trial was designed as an exploratory trial and that data from the HOPE-2 trial did not provide substantial evidence of effectiveness to support a future biologics license application, or BLA. The FDA did, however, indicate its support for conducting a Phase III trial of CAP-1002 for the treatment of DMD. In addition, the FDA reiterated that as part of our RMAT designation, they are willing to work with us to further the clinical development of the therapy.

In a follow-up to the October 2019 meeting, Capricor requested an additional meeting to clarify endpoints for future clinical trials. In a written response, FDA supported the use of the full PUL 2.0 from baseline to twelve months as a primary efficacy endpoint as long as clinical meaningfulness can be demonstrated. They suggested that a 1.0 point difference appears suitable to demonstrate product efficacy to support a BLA.

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 was funded in part through a grant award from the California Institute for Regenerative Medicine, or CIRM. In January 2019, this study was published in the online issue of *Neurology*, the medical journal of the American Academy of Neurology.

We reported our 12-month data from the HOPE-Duchenne trial 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 analysis. 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). Additionally, we reported significant improvements in systolic thickening of the left ventricular wall as well as reduction in scarring of the heart muscle among those treated with CAP-1002 decreased relative to the control group.

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.

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 DMD. To receive the RMAT designation, we submitted data from the HOPE-Duchenne Trial.

CAP-1002 for the Treatment of Cardiac Conditions:

In previous years, we completed several trials investigating the use of CAP-1002 for the treatment of various cardiac conditions, including heart failure (the DYNAMIC Trial) and post myocardial infarction (MI) with cardiac dysfunction (ALLSTAR). Because of our decision to focus our efforts on DMD, we have decided not to pursue those indications at this time, nor do we have any plans to continue with the development of these programs although we are continuing to evaluate certain cardiac measures in our HOPE-2 trial. We expect no further material expenses in connection with these programs.

CAP-1002 - 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. We were recently informed that the REGRESS study was put on clinical hold by the FDA. This is an investigator sponsored trial for which Capricor is providing CAP-1002, the investigational product. The preliminary information we have received suggests that the issue may be related to inadequate patient monitoring at the study site to assess safety for certain patients who were experiencing adverse events after receiving an intracoronary infusion of CAP-1002. It is currently not known whether the clinical hold is related to the investigational product or the procedure. Capricor did not use intracoronary infusions in its HOPE-2 trial.

The second trial is known as "Pulmonary Arterial Hypertension treated with Cardiosphere-derived Allogeneic Stem Cells." In this trial, the investigational product is infused into the venous system via catheter into the right atrium. This trial is currently ongoing. In both studies, Capricor is providing 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.

Exosomes Program

Our exosomes program consists of exosomes derived from CDCs (CAP-2003) and engineered exosomes, both of which are in various stages of preclinical development. We have explored the use of our CDC-exosomes in pre-clinical studies of inflammation and intense immune activation such as DMD, sepsis, Graft versus-host disease (GVHD) and trauma. While CDC-exosomes are the initial technology used in preclinical development, we have expanded Capricor's pipeline to include additional exosome technologies. We are now focused on developing a precision-engineered exosome platform technology that can carry defined sets of effector molecules which exert their effects through defined mechanisms of action. We have announced our planned expansion of our exosome platform technology that potentially may be used for vaccine development, vesicle mediated protein therapies and treatment of inherited diseases.

Engineered Exosomes Platform

To build upon the natural ability of exosomes for intercellular communication, we have initiated a program to engineer exosomes and load them with different macromolecules. Our preliminary results demonstrated that it is possible to load exosomes with specific miRNAs which pave the way to use our exosomes to potentially deliver miRNAs to specific target tissue. We are now working on developing exosome-based vaccines for COVID-19. While these efforts are still in their early-stages, our exosome-based vaccine platform technology will aim to combine the improved protection that comes from immunizing individuals with multiple antigens in a manner that mimics the advantages of conventional virus vaccines, with the superior safety profile of virus-free, vaccines. We plan to design exosome-based vaccines to elicit strong humoral and cellular immune responses due to the simultaneous expression of antigens.

Investigation of Potential Indications for our Exosomes Technologies

Capricor has exclusively licensed intellectual property relating to CDC-exosomes from Cedars-Sinai Medical Center and is also pursuing its own intellectual property rights relating to exosome technologies.

We have promising pre-clinical data in several indications from studies done in our labs as well as in collaboration with other companies and academic institutions. Additionally, in July 2018, we entered into a Cooperative Research and Development Agreement with the U.S. Army Institute of Surgical Research (USAISR) pursuant to which we agreed to cooperate in research and development on the evaluation of our CDC-exosomes for the treatment of trauma related injuries and conditions which are now the third leading cause of death in the U.S.

We plan to file an IND for DMD with the FDA in advance of the filing deadline under our license agreement with CSMC, which is April 19, 2020, unless we negotiate for an extension of this date with CSMC. We have also begun work on developing an exosome-based vaccine platform for COVID-19.

These programs represent our core technology and products.

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, exosomes and our former product candidate, Cenderitide. As we proceed with the clinical development of CAP-1002, and as we further develop exosomes, our expenses will further 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 our 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 under our now terminated collaboration agreement, and a loan and grant award from CIRM. While we pursue our pre-clinical and clinical programs, we continue to explore financing and other strategic alternatives with respect to the Company as well as one or more of our product candidates.

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, 2019 and 2018

Revenue

Grant Income. Grant income for the years ended December 31, 2019 and 2018 was approximately $0.5 million and $1.0 million, respectively. The decrease in grant income of approximately $0.5 million in 2019 as compared to 2018 is primarily due to the timing of grant activities. The pre-clinical phase of the NIH grant award came to completion during the third quarter of 2018.

Miscellaneous Income. Miscellaneous income for the years ended December 31, 2019 and 2018 was approximately $0.5 million and $0.7 million, respectively. The miscellaneous income was related to providing cells for investigational purposes for clinical trials sponsored by CSMC. The decrease in miscellaneous income of approximately $0.2 million in 2019 as compared to 2018 is primarily due to the associated enrollment of the CSMC clinical trials.

Operating Expenses

General and Administrative Expenses. G&A expenses for the years ended December 31, 2019 and 2018 were approximately $3.6 million and $4.9 million, respectively. The decrease of approximately $1.3 million in G&A expenses in the year ended December 31, 2019 compared to the year ended December 31, 2018 is attributable to approximately $0.6 million decrease in stock-based compensation expense, approximately $0.3 million decrease in salaries due to a decrease in headcount, approximately $0.2 million decrease in investor relations expenses, and a decrease of approximately $0.2 million in general corporate expenses.

Research and Development Expenses. R&D expenses for the years ended December 31, 2019 and 2018 were approximately $5.1 million and $12.1 million, respectively. The decrease of approximately $7.0 million for the year ended December 31, 2019 as compared to the year ended December 31, 2018 is primarily due to the timing of clinical development activities of CAP-1002 (HOPE-Duchenne, HOPE-2 and HOPE-OLE clinical trials). These activities resulted in a decrease of approximately $4.1 million. This reduction included the winding down of clinical activities and operational expenses related to the HOPE-2 trial for the year ended December 31, 2019. Furthermore, for the year ended December 31, 2019, there was a decrease of approximately $0.4 million related to reduced clinical development expenses in connection with the clinical headcount and general clinical expenses. Additionally, there was a decrease of approximately $2.1 million in research and development expenses related to CAP-1002 and exosomes for the year ended December 31, 2019 as compared to the same period in 2018. Lastly, there was a decrease of approximately $0.3 million in stock-based compensation expenses allocable to R&D for the year ended December 31, 2019 as compared to December 31, 2018.

Other Income

Investment Income. Investment income for the years ended December 31, 2019 and 2018 was $94,791 and $135,991, respectively. The decrease in investment income in 2019 as compared to 2018 is due to the reduction in capital from 2018 to 2019.

Products Under Active Development

CAP-1002 – CAP-1002 is in its developmental stages. We expect to spend approximately $2.0 million to $4.0 million during 2020 on the clinical development of CAP-1002 for DMD, which expenses are primarily related to our HOPE-2 clinical trial as well as additional regulatory and manufacturing-related expenses. These figures are largely dependent on the final results of our HOPE-2 trial, our discussions with the FDA, our ability to secure additional funding and various other factors and our ability to secure a partner for the potential future further clinical development of CAP-1002 for DMD, if necessary.

Exosome Technologies – We expect to spend approximately $2.0 million to $3.0 million during 2020 on pre-clinical and other research expenses related to our exosomes program, a portion of which will be offset by our grant award from the DoD. Capricor is currently engaged in pre-clinical testing of exosomes to explore its therapeutic potential, including studies that could enable an IND and which we plan to file by the CSMC deadline. We have received 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. As of December 31, 2019, the Company has approximately $0.2 million available under this grant award, pursuant to the terms of the award.

Our expenditures on current and future clinical development programs, particularly our CAP-1002 and exosomes programs, cannot be predicted with any significant degree of certainty as they are dependent on the results of our current trials and our ability to secure additional funding and a strategic partner. Further, 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.

Liquidity and Capital Resources for the fiscal years ended December 31, 2019 and 2018

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, 2019**	**December 31, 2018**
Cash, cash equivalents and marketable securities	$ 9,885	$ 7,256
Working capital	$ 9,647	$ 7,216
Stockholders' equity	$ 6,839	$ 4,616

	Years ended December 31,	
Cash flow data	**2019**	**2018**
Cash provided by (used in):		
Operating activities	$ (6,822)	$ (13,862)
Investing activities	(3,002)	4,672
Financing activities	9,178	6,853
Net decrease in cash, cash equivalents, and restricted cash	$ (646)	$ (2,337)

Our total cash, cash equivalents and marketable securities as of December 31, 2019 was approximately $9.9 million compared to approximately $7.3 million as of December 31, 2018. The increase in cash, cash equivalents and marketable securities from December 31, 2019 as compared to December 31, 2018 was primarily due to net financing activities of approximately $9.2 million and a net loss of approximately $7.6 million in 2019. As of December 31, 2019, we had approximately $4.3 million in total liabilities. As of December 31, 2019, we had approximately $9.6 million in net working capital. We had a net loss of approximately $7.6 million for the year ended December 31, 2019.

Cash used in operating activities was approximately $6.8 million and $13.9 million for the years ended December 31, 2019 and 2018, respectively. The difference of approximately $7.1 million in cash from operating activities is primarily due to a decrease of approximately $7.5 million in net loss for the year ended December 31, 2019 as compared to the same period in 2018. Furthermore, there was a change of approximately $1.0 million in stock-based compensation expense and a change of approximately $0.4 million in prepaid expenses and other current assets for the year ended December 31, 2019 as compared to the same period in 2018. 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 (used in) investing activities of approximately $(3.0) million and $4.7 million for the years ended December 31, 2019 and 2018, respectively. The decrease in cash provided by investing activities for the year ended December 31, 2019 as compared to the same period of 2018 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 $9.2 million and $6.9 million for the years ended December 31, 2019 and 2018, respectively. The increase in cash provided by financing activities for the year ended December 31, 2019 as compared to the same period of 2018 is primarily due to the net proceeds from the sale of common stock. During 2019 we received net proceeds of approximately $9.2 million compared to approximately $6.7 million over the same period of 2018. Furthermore, we received $0.1 million from stock option exercises in 2018 compared to nominal proceeds received in 2019.

From inception through December 31, 2019, we financed our operations primarily 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. 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. 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, complete our clinical trials 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;
- additional costs associated with maintaining licenses and insurance;
- the costs involved in prosecuting and enforcing patent claims and other intellectual property rights; and
- the costs and timing of regulatory approvals.

Financing Activities by the Company

March 2020 Warrant Inducement. On March 25, 2020, the Company entered into a letter agreement (the "Exercise Agreement") with a holder of the Existing Warrants (the "Exercising Holder"). Pursuant to the Exercise Agreement, in connection with exercise by the Exercising Holder of the remaining 4,000,000 Existing Warrants held by the Exercising Holder which had not been previously exercised, the Company agreed to issue 4,000,000 additional warrants (the "New Warrants") to purchase Common Stock. The Existing Warrants had a per share exercise price of $1.10, and pursuant to the Exercise Agreement, the Exercising Holder agreed to pay $1.225 per share to cover both the exercise price of the Existing Warrants and a $0.125 per share purchase price for the New Warrants. The New Warrants have an exercise price of $1.27 per share. The New Warrants and the shares of Common Stock issuable upon the exercise of the New Warrants are not being registered under the Securities Act of 1933, as amended (the "Securities Act"), and are being offered pursuant to the exemption provided in Section 4(a)(2) under the Securities Act or Rule 506(b) promulgated thereunder. Pursuant to the Exercise Agreements, the New Warrants shall be substantially in the form of the Existing Warrants (except for customary legends and other language typical for an unregistered warrant, including the ability for the holder of the New Warrant to make a cashless exercise if no resale registration statement covering the Common Stock underlying the New Warrants is effective after six months), will be exercisable immediately, and will have a term of exercise of 5 1/2 years), and the Company will be required to register for resale the shares of Common Stock underlying the New Warrants. The Company expects to receive aggregate gross proceeds of approximately $4.9 million from the exercise of the Existing Warrants by the Exercising Holder. These gross proceeds will be reduced by fees due and payable to the placement agent for the transactions pursuant to the Exercise Agreement and New Warrants in the amount of $343,000, and further reduced by reimbursements to the placement agent for legal fees and other expenses. In addition, the placement agent will receive a new warrant for shares of Common Stock equal to 5.0% of the New Warrants issued, or 200,000 shares.

December 2019 Public Offering. In December 2019, the Company completed a public offering (the December Offering), pursuant to which the Company issued (i) 531,173 shares of its common stock, (ii) warrants to purchase up to 4,139,477 shares of common stock, and (iii) pre-funded warrants to purchase up to 3,608,304 shares of common stock, at a combined purchase price of $1.226 per share and associated common warrant and $1.225 per pre-funded warrant and associated common warrant for an aggregate purchase price of approximately $5.1 million. The Company issued (a) to each purchaser of shares in the December Offering a common warrant to purchase a number of shares of common stock equal to the number of shares purchased by such purchaser in the December Offering, and (b) to each purchaser of pre-funded warrants in the December Offering a common warrant to purchase a number of shares of common stock equal to the number of pre-funded warrant shares underlying the pre-funded warrants purchased by such purchaser in the December Offering. All shares and warrants issued pursuant to the December Offering, other than the Placement Agent Warrants, were issued pursuant to our registration statement on Form S-1 (File No. 333-235358), which was initially filed with the Securities and Exchange Commission, or the SEC, on December 5, 2019, amended on December 13, 2019 and declared effective by the SEC on December 17, 2019. Fees paid in conjunction with the deal, which included placement agent commissions, management fees, legal costs, and other offering expenses, amount to approximately $0.7 million in the aggregate and were recorded as a reduction to additional paid-in capital, resulting in net proceeds of approximately $4.4 million. Since December 19, 2019 and through March 26, 2020, all 3,608,304 pre-funded warrants and 78,304 common warrants have been exercised.

August 2019 ATM Program. On August 29, 2019, the Company initiated an at-the-market offering under a prospectus supplement for aggregate sales proceeds of up to $1.95 million, or the August 2019 ATM Program, with the common stock to be distributed at the market prices prevailing at the time of sale. The August 2019 ATM Program was established under a Common Stock Sales Agreement, or the July 2019 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. The July 2019 Sales Agreement provides that Wainwright is 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 August 2019 ATM Program have been and will be issued pursuant to our shelf registration statement on Form S-3 (File No. 333-227955), which was initially filed with the SEC, on October 24, 2018, amended on July 17, 2019 and declared effective by the SEC on July 18, 2019. Since August 29, 2019 and through the date of filing, the Company has sold an aggregate of 360,316 shares of common stock under the August 2019 ATM Program at an average price of approximately $3.07 per share for gross proceeds of approximately $1.1 million. The Company paid cash commissions on the gross proceeds, plus reimbursement of expenses of the placement agent and legal fees in the aggregate amount of approximately $0.1 million.

July 2019 ATM Program. On July 22, 2019, the Company initiated an at-the-market offering under a prospectus supplement for aggregate sales proceeds of up to $1.8 million, or the July 2019 ATM Program, with the common stock to be distributed at the market prices prevailing at the time of sale. The July 2019 ATM Program was established under the July 2019 Sales Agreement, which 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. All shares issued pursuant to the July 2019 ATM Program were issued pursuant to our shelf registration statement on Form S-3 (File No. 333-227955), which was initially filed with the SEC on October 24, 2018, amended on July 17, 2019 and declared effective by the SEC on July 18, 2019. As of the expiration of the July 2019 ATM Program, the Company sold an aggregate of 418,450 shares of common stock under the July 2019 ATM Program at an average price of approximately $4.30 per share for gross proceeds of approximately $1.8 million. The Company paid cash commissions on the gross proceeds, plus reimbursement of expenses of the placement agent and legal fees in the aggregate amount of approximately $0.1 million.

October 2017 Common Stock Sales Agreement. On October 19, 2017, the Company entered into a Common Stock Sales Agreement, or the October 2017 Sales Agreement, with Wainwright, under which it 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 $14.0 million, or the October 2017 ATM Program. The common stock was distributed at the market prices prevailing at the time of sale. The October 2017 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 October 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. As of the expiration of the October 2017 ATM Program on April 23, 2019, the Company sold an aggregate of 899,233 shares of common stock at an average price of approximately $13.04 per share for gross proceeds of approximately $11.7 million. The Company paid cash commissions on the gross proceeds, plus reimbursement of expenses of the placement agent and legal fees in the aggregate amount of approximately $0.4 million.

Financing Activities by Capricor, Inc.

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 were tied to the achievement of specified operational milestones. In addition, the terms of the CIRM Award included a co-funding requirement pursuant to which Capricor was required to spend approximately $2.3 million of its own capital to fund the CIRM funded research project. 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 at any time after the award period end date (but no later than the ten-year anniversary of the date of the award), 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 Capricor elects to convert the grant into a loan, the term of the loan could be up to five years from the date of execution of the applicable loan agreement; provided that the maturity date of the loan will not surpass the ten-year anniversary of the grant date of the CIRM Award. Beginning on the date of the loan, the loan shall bear interest on the unpaid principal balance, plus the interest that has 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. If we elect to do so, Capricor would be required to repay some or all of the amounts awarded by CIRM, therefore the Company accounts for this award as a liability rather than income.

As of December 31, 2019, Capricor's liability balance for the CIRM Award was approximately $3.4 million. In June 2019, Capricor completed all milestones associated with the CIRM Award and expended all funds received. In the third quarter of 2019, Capricor completed all final close-out documentation associated with this award.

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 June 30, 2019, approximately $0.7 million has been incurred under the terms of the NIH grant award. In the second quarter of 2019, the award was closed and all filings were completed with no additional expenses expected to be incurred.

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 three years, subject to annual and quarterly reporting requirements. The Company was granted a no-cost extension until September 29, 2020 to be able to continue to utilize these funds. As of December 31, 2019, approximately $2.2 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, 2019.

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.

Revenue Recognition

For contracts completed as of December 31, 2017, revenue was recognized in accordance with ASC 605 and other standards which have been superseded for subsequent fiscal years. The Company applied ASU 606 using the modified retrospective approach for all contracts in process as of January 1, 2018.

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. Grant income is due upon submission of reimbursement request. The transaction price varies for grant income based on the expenses incurred under the awards.

Miscellaneous 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 the Company has satisfied the obligations as identified in the contracts with the customer. Miscellaneous income is due upon billing. Miscellaneous income is based on contracts with fixed transaction prices.

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.

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. In addition, the Board has approved the 2020 Equity Incentive Plan (the "2020 Plan"); however, the 2020 Plan will not become effective unless and until it is approved by the stockholders of the Company. We intend to submit the 2020 Plan for stockholder approval at the 2020 annual meeting.

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, and the risk-free interest rate. We account for forfeitures upon occurrence.

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. The fair value of stock options is determined using the Black-Scholes option-pricing model. Historically, the Company periodically re-measured the fair value for non-qualified option grants recording an expense over the applicable vesting periods. However, in the third quarter of 2018, the Company early adopted ASU 2018-07. The Company calculates the fair value for non-qualified options as of the date of grant and expenses over the applicable vesting periods.

The terms and vesting schedules for share-based awards vary by type of grant and the employment status of the grantee. Generally, the awards vest based upon time-based or performance-based conditions. Performance-based conditions generally include the attainment of goals related to our financial and development performance. Stock-based compensation expense is included in general and administrative expense or research and development expense, as applicable, in the Statements of Operations and Comprehensive Income (Loss). We expect to record additional non-cash compensation expense in the future, which may be significant.

Restricted Cash

Prior to March 31, 2019, restricted cash represented funds received under the CIRM Award. Restricted cash funds were 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 Company fully utilized the CIRM Award in June 2019.

In April 2019, the Company entered into a letter of credit as a security deposit for its lease agreement for corporate office space. The Company delivered to the landlord a letter of credit in the amount of $232,803 to cover payments of rent for the remainder of the 2019 lease term, which was subsequently cancelled and funds returned to Capricor. As such, no restricted cash is recorded as of December 31, 2019.

Clinical Trial Expense

As part of the process of preparing our consolidated financial statements, we are required to estimate our accrued expenses. Our clinical trial accrual process is designed to account for expenses resulting from our obligations under contracts with vendors, consultants, and CROs and clinical site agreements in connection with conducting clinical trials. The financial terms of these contracts are subject to negotiations, which vary from contract to contract and may result in payment flows that do not match the periods over which materials or services are provided to us under such contracts. Our objective is to reflect the appropriate clinical trial expenses in our consolidated financial statements by matching the appropriate expenses with the period in which services are provided and efforts are expended. We account for these expenses according to the progress of the trial as measured by patient progression and the timing of various aspects of the trial. We determine accrual estimates through financial models that take into account discussion with applicable personnel and outside service providers as to the progress or state of completion of trials, or the services completed. During the course of a clinical trial, we adjust our clinical expense recognition if actual results differ from our estimates. We make estimates of our accrued expenses as of each balance sheet date in our consolidated financial statements based on the facts and circumstances known to us at that time. Our clinical trial accrual and prepaid assets are dependent, in part, upon the receipt of timely and accurate reporting from CROs and other third-party vendors. Although we do not expect our estimates to be materially different from amounts actually incurred, our understanding of the status and timing of services performed relative to the actual status and timing of services performed may vary and may result in us reporting amounts that are too high or too low for any particular period.

Recently Issued or Newly Adopted Accounting Pronouncements

In February 2016, the Financial Accounting Standards Board, or 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 issued additional clarification throughout 2018. Under the new guidance, a lessee should recognize assets and liabilities that arise from its leases and disclose qualitative and quantitative information about its leasing arrangements. The Company elected the optional transition method to apply the standard as of January 1, 2019 as the effective date and therefore, did not apply the standard to comparative periods. The Company did not apply the recognition requirements to short-term leases and recognized those lease payments in the Consolidated Statements of Operations and Comprehensive Loss on a straight-line basis over the lease term. The Company also elected the available package of practical expedients in transition which allowed us to not re-assess whether existing or expired arrangements contain a lease, the lease classification of existing or expired leases, or whether previous initial direct costs would qualify for capitalization under the new lease standard. The adoption of this update did not have a material impact on the Company's financial statements.

In June 2018, the FASB issued ASU 2018-07, *Compensation – Stock Compensation (Topic 718): Improvements to Nonemployee Share-Based Payment Accounting*, which simplifies several aspects of the accounting for nonemployee share-based payment transactions resulting from expanding the scope of Topic 718 to include share-based payment transactions for acquiring goods and services from nonemployees. The Company early adopted ASU 2018-07 and all subsequent updates related to this topic on a prospective basis effective July 1, 2018. The adoption of this update did not have a material impact on the Company's financial statements.

In November 2018, the FASB issued ASU 2018-18, *Collaborative Arrangements (Topic 808):* clarifying the interaction between Topic 808 and Topic 606. The amendments in the update clarifies that certain transactions between collaborative arrangement participants should be accounted for as revenue under Topic 606 when the collaborative arrangement participant is a customer in the context of a unit of account; adds unit-of-account guidance in Topic 808 to align with the guidance in Topic 606 when an entity is assessing whether the collaborative arrangement or a party of the arrangement is within the scope of Topic 606; requires that in a transaction with a collaborative arrangement participant that is not directly related to sales to third parties, presenting the transaction together with revenue recognized under Topic 606 is precluded if the collaborative arrangement participant is not a customer. The amendments for this update are effective for fiscal years beginning after December 15, 2019, and interim periods within those fiscal years. Early adoption is permitted. The Company is currently evaluating the impact of the new guidance on our Consolidated financial statements.

Other recent accounting pronouncements issued by the FASB, including its Emerging Issues Task Force, the American Institute of Certified Public Accountants, and the 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, 2019, the fair value of our cash, cash equivalents, and marketable securities was approximately $9.9 million. Additionally, as of December 31, 2019, 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.

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.
INDEX TO FINANCIAL STATEMENTS

REPORT OF INDEPENDENT REGISTERED PUBLIC ACCOUNTING FIRM

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

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, 2019 and 2018, 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, 2019, 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 consolidated financial position of the Company as of December 31, 2019 and 2018, and the consolidated results of its operations and its cash flows for each of the years in the two-year period ended December 31, 2019, 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 26, 2020

CAPRICOR THERAPEUTICS, INC.
CONSOLIDATED BALANCE SHEETS
DECEMBER 31, 2019 AND 2018

ASSETS

	December 31, 2019	December 31, 2018
CURRENT ASSETS		
Cash and cash equivalents	$ 3,899,328	$ 4,259,266
Marketable securities	5,986,050	2,997,150
Restricted cash	-	285,831
Grant receivable	87,968	204,868
Prepaid expenses and other current assets	571,382	724,184
TOTAL CURRENT ASSETS	10,544,728	8,471,299
PROPERTY AND EQUIPMENT, net	442,806	574,206
OTHER ASSETS		
Intangible assets, net of accumulated amortization of $253,187 and $209,910, respectively	6,495	49,772
Other assets	119,608	151,788
TOTAL ASSETS	$ 11,113,637	$ 9,247,065
LIABILITIES AND STOCKHOLDERS' EQUITY		
CURRENT LIABILITIES		
Accounts payable and accrued expenses	$ 875,677	$ 1,148,853
Accounts payable and accrued expenses, related party	22,315	106,366
TOTAL CURRENT LIABILITIES	897,992	1,255,219
LONG-TERM LIABILITIES		
CIRM liability	3,376,259	3,376,259
TOTAL LONG-TERM LIABILITIES	3,376,259	3,376,259
TOTAL LIABILITIES	4,274,251	4,631,478
COMMITMENTS AND CONTINGENCIES (NOTE 6)		
STOCKHOLDERS' EQUITY		
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, 5,227,398 and 3,138,748 shares issued and outstanding, respectively	5,227	3,138
Additional paid-in capital	81,215,647	71,338,970
Accumulated other comprehensive income (loss)	(757)	12,393
Accumulated deficit	(74,380,731)	(66,738,914)
TOTAL STOCKHOLDERS' EQUITY	6,839,386	4,615,587
TOTAL LIABILITIES AND STOCKHOLDERS' EQUITY	$ 11,113,637	$ 9,247,065

See accompanying notes to the audited consolidated financial statements.

CAPRICOR THERAPEUTICS, INC.
CONSOLIDATED STATEMENTS OF OPERATIONS AND COMPREHENSIVE LOSS
FOR THE YEARS ENDED DECEMBER 31, 2019 AND 2018

	Years ended December 31,	
	2019	2018
REVENUE		
Revenue	$ 1,005,028	$ 1,671,356
TOTAL REVENUE	1,005,028	1,671,356
OPERATING EXPENSES		
Research and development	5,141,805	12,066,800
General and administrative	3,597,111	4,931,642
TOTAL OPERATING EXPENSES	8,738,916	16,998,442
LOSS FROM OPERATIONS	(7,733,888)	(15,327,086)
OTHER INCOME (EXPENSE)		
Investment income	94,791	135,991
Loss on disposal of fixed asset	(2,720)	-
TOTAL OTHER INCOME (EXPENSE)	92,071	135,991
NET LOSS	(7,641,817)	(15,191,095)
OTHER COMPREHENSIVE INCOME (LOSS)		
Net unrealized gain (loss) on marketable securities	(13,150)	773
COMPREHENSIVE LOSS	$ (7,654,967)	$ (15,190,322)
Net loss per share, basic and diluted	$ (2.06)	$ (5.17)
Weighted average number of shares, basic and diluted	3,711,333	2,941,084

See accompanying notes to the audited consolidated financial statements.

CAPRICOR THERAPEUTICS, INC.
CONSOLIDATED STATEMENTS OF CHANGES IN STOCKHOLDERS' EQUITY
FOR THE PERIOD FROM DECEMBER 31, 2017 THROUGH DECEMBER 31, 2019

	COMMON STOCK					
	SHARES	AMOUNT	ADDITIONAL PAID-IN CAPITAL	OTHER COMPREHENSIVE INCOME (LOSS)	ACCUMULATED DEFICIT	TOTAL STOCKHOLDERS' EQUITY
Balance at December 31, 2017	2,627,049	$ 2,626	$ 62,760,428	$ 11,620	$ (51,547,819)	$ 11,226,855
Issuance of common stock, net of fees	468,679	469	6,713,855	-	-	6,714,324
Stock-based compensation	5,415	5	1,725,585	-	-	1,725,590
Unrealized gain on marketable securities	-	-	-	773	-	773
Stock options exercised	37,605	38	139,102	-	-	139,140
Net loss	-	-	-	-	(15,191,095)	$ (15,191,095)
Balance at December 31, 2018	3,138,748	$ 3,138	$ 71,338,970	$ 12,393	$ (66,738,914)	$ 4,615,587
Issuance of common stock, net of fees	1,637,849	1,638	9,173,115	-	-	9,174,753
Exercise of pre-funded common stock warrants	450,000	450	-	-	-	450
Stock-based compensation	-	-	700,984	-	-	700,984
Fractional shares eliminated pursuant to reverse stock split	(27)	-	(193)	-	-	(193)
Unrealized loss on marketable securities	-	-	-	(13,150)	-	(13,150)
Stock options exercised	828	1	2,771	-	-	2,772
Net loss	-	-	-	-	(7,641,817)	(7,641,817)
Balance at December 31, 2019	5,227,398	$ 5,227	$ 81,215,647	$ (757)	$ (74,380,731)	$ 6,839,386

See accompanying notes to the audited consolidated financial statements.

CAPRICOR THERAPEUTICS, INC.
CONSOLIDATED STATEMENTS OF CASH FLOWS
FOR THE YEARS ENDED DECEMBER 31, 2019 AND 2018

	Years ended December 31,	
	2019	2018
CASH FLOWS FROM OPERATING ACTIVITIES:		
Net loss	$ (7,641,817)	$ (15,191,095)
Adjustments to reconcile net loss to net cash used in operating activities:		
Loss on disposal of fixed asset	2,720	-
Depreciation and amortization	171,956	157,652
Stock-based compensation	700,984	1,725,590
Change in assets - (increase) decrease:		
Receivables	116,900	139,707
Prepaid expenses and other current assets	152,802	(223,020)
Other assets	32,180	(55,819)
Change in liabilities - increase (decrease):		
Accounts payable and accrued expenses	(273,175)	(347,398)
Accounts payable and accrued expenses, related party	(84,051)	(68,058)
NET CASH USED IN OPERATING ACTIVITIES	(6,821,501)	(13,862,441)
CASH FLOWS FROM INVESTING ACTIVITIES:		
Purchase of marketable securities	(6,002,050)	(18,011,577)
Proceeds from sales and maturities of marketable securities	3,000,000	23,000,000
Purchases of property and equipment	-	(316,486)
NET CASH PROVIDED BY (USED IN) INVESTING ACTIVITIES	(3,002,050)	4,671,937
CASH FLOWS FROM FINANCING ACTIVITIES:		
Net proceeds from sale of common stock	9,174,753	6,714,324
Proceeds from exercise of pre-funded common stock warrants	450	-
Repurchase of fractional shares pursuant to reverse stock split	(193)	-
Proceeds from stock options	2,772	139,140
NET CASH PROVIDED BY FINANCING ACTIVITIES	9,177,782	6,853,464
NET DECREASE IN CASH, CASH EQUIVALENTS, AND RESTRICTED CASH	(645,769)	(2,337,040)
Cash, cash equivalents, and restricted cash balance at beginning of period	4,545,097	6,882,137
Cash, cash equivalents, and restricted cash balance at end of period	$ 3,899,328	$ 4,545,097
SUPPLEMENTAL DISCLOSURES:		
Interest paid in cash	$ -	$ -
Income taxes paid in cash	$ -	$ -

See accompanying notes to the audited consolidated financial statements.

1. ORGANIZATION AND SUMMARY OF SIGNIFICANT ACCOUNTING POLICIES

Description of Business

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 innovative cell and exosome-based therapies for the treatment of diseases, with a focus on Duchenne muscular dystrophy ("DMD") and other rare disorders. 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, has two active drug candidates in various stages of development.

Basis of Consolidation

Our consolidated financial statements include the accounts of the Company and our wholly-owned subsidiary, Capricor. 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, 2019 were approximately $9.9 million, compared to approximately $7.3 million as of December 31, 2018. In December 2019, the Company closed an offering for gross proceeds of approximately $5.1 million comprised of common stock and warrants. The Company issued 531,173 shares of common stock, pre-funded warrants to purchase 3,608,304 shares of common stock, and common warrants to purchase up to 4,139,477 shares of common stock (see Note 2 – "Stockholders' Equity"). The Company has entered into various Common Stock Sales Agreements with H.C. Wainwright & Co. LLC ("Wainwright") to create at-the-market equity programs under which the Company from time to time offered and sold shares of its common stock, par value $0.001 per share. From October 19, 2017 to December 31, 2019, through the use of these programs, the Company has raised gross proceeds of approximately $14.6 million (see Note 2 – "Stockholders' Equity").

Additionally, the Company has been awarded various grant and loan awards, which fund, in part, various pre-clinical and clinical activities (see Note 5 – "Government Grant Awards"). As of December 31, 2019, the Company has approximately $0.2 million remaining available under its grants and awards for disbursement, pursuant to the terms of the 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.

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.

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

Based on the Company's current estimates, recent warrant exercise (see Note 9 – "Subsequent Events") and largely dependent on our decision with respect to our DMD program, the Company believes it has sufficient cash to fund operations through at least the end of the year 2021.

The Company's options to address its financial position include potentially seeking 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 other assets, and from government grants.

The Company will require substantial additional capital to fund its operations. 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. 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. The Company would likely need to delay, curtail or terminate all or portions of its clinical trial programs. To the extent the Company issues additional equity securities, its existing stockholders would experience substantial dilution.

Reverse Stock Split

On June 4, 2019, the Company effected a reverse stock split of its outstanding shares of common stock at a ratio of one-for-ten pursuant to a Certificate of Amendment to the Company's Certificate of Incorporation filed with the Secretary of State of the State of Delaware. The reverse stock split was reflected on the Nasdaq Capital Market ("Nasdaq") beginning with the opening of trading on June 5, 2019. The primary purpose of the reverse stock split, which was approved by the Company's stockholders at the Company's Annual Stockholders Meeting on May 29, 2019, was to enable the Company to regain compliance with the $1.00 minimum bid price requirement for continued listing on Nasdaq. Pursuant to the reverse stock split, every ten shares of the Company's issued and outstanding shares of common stock were automatically combined into one issued and outstanding share of common stock, without any change in the par value per share of the common stock. Unless otherwise indicated, all share and per share amounts of the common stock included in the accompanying consolidated financial statements have been retrospectively adjusted to give effect to the reverse stock split for all periods presented, including reclassifying an amount equal to the reduction in par value to additional paid-in capital. Amounts of common stock resulting from the reverse stock split were rounded down to the nearest whole share and any resulting fractional shares were cancelled for cash. The number of authorized shares of the Company's common stock remained unchanged. The reverse stock split affected all issued and outstanding shares of the Company's common stock, and the respective numbers of shares of common stock underlying outstanding stock options, outstanding warrants and the Company's equity incentive plans were proportionately adjusted.

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 less than 30 days at the date of purchase to be cash equivalents.

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

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, 2019	December 31, 2018
Cash and cash equivalents	$ 3,899,328	$ 4,259,266
Restricted cash	-	285,831
Total cash, cash equivalents, and restricted cash shown in the statements of cash flows	$ 3,899,328	$ 4,545,097

For the year ended December 31, 2018, restricted cash represents funds received under a CIRM award (the "CIRM Award") (See Note 5 – "Government Grant Awards"). Restricted cash funds 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. As of December 31, 2019, the Company had no restricted funds.

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 (loss) 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 $128,680 and $114,376 for the years ended December 31, 2019 and 2018, respectively.

Property and equipment, net consisted of the following at December 31:

	2019	2018
Furniture and fixtures	$ 43,617	$ 46,709
Laboratory equipment	931,166	936,480
Leasehold improvements	47,043	47,043
	1,021,826	1,030,232
Less accumulated depreciation	(579,020)	(456,026)
Property and equipment, net	$ 442,806	$ 574,206

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

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 approximately $43,276 for both the years ended December 31, 2019 and 2018. A summary of future amortization expense as of December 31, 2019 is as follows:

Years ended	Amortization Expense
2020	4,330
2021	2,165

The Company reviews goodwill and intangible assets at least annually for possible impairment. Goodwill and 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. No impairment was recorded for the years ended December 31, 2019 and 2018.

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, 2019 and 2018.

Revenue Recognition

For contracts completed as of December 31, 2017, revenue was recognized in accordance with ASC 605 and other superseded standards. The company applied ASU 606 using the modified retrospective approach for all contracts in process as of January 1, 2018.

Grant Income

Generally, government research grants that provide funding for research and development activities are recognized as income when the related expenses are incurred, as applicable. Because the terms of the CIRM Award allow Capricor to elect to convert the grant into a loan after the end of the project period, the CIRM Award is being classified as a liability rather than income (see Note 5 - “Government Grant Awards”). Grant income is due upon submission of reimbursement request. The transaction price varies for grant income based on the expenses incurred under the awards.

Miscellaneous 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 the Company has satisfied the obligations as identified in the contracts with the customer (see Note 8 – “Related Party Transactions”). Miscellaneous income is due upon billing. Miscellaneous income is based on contracts with fixed transaction prices.

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.

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

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

As of December 31, 2019, the Company had federal net operating loss carryforwards of approximately $96.7 million, available to reduce future taxable income, of which $76.1 million will begin to expire in 2026. The post December 31, 2017 net operating losses generated of $20.6 million will carryforward indefinitely, but may be subject to an 80% limitation upon utilization. As of December 31, 2019, the Company had state net operating loss carryforwards of approximately $92.5 million, available to reduce future taxable income, which will begin to expire in 2028. 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 $2.7 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, 2019 and 2018. The Company files income tax returns with the IRS and the California Franchise Tax Board.

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 $5.1 million and $12.1 million for the years ended December 31, 2019 and 2018, respectively.

Comprehensive Income (Loss)

Comprehensive income (loss) generally represents all changes in stockholders' equity during the period except those resulting from investments by, or distributions to, stockholders. The Company's comprehensive loss was approximately $7.7 million and $15.2 million for the years ended December 31, 2019 and 2018, 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, 2019 and 2018, the Company's other comprehensive gain (loss) was $(13,150) and $773, respectively.

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

Clinical Trial Expense

As part of the process of preparing our consolidated financial statements, we are required to estimate our accrued expenses. Our clinical trial accrual process is designed to account for expenses resulting from our obligations under contracts with vendors, consultants, and contract research organizations, or CROs, and clinical site agreements in connection with conducting clinical trials. The financial terms of these contracts are subject to negotiations, which vary from contract to contract and may result in payment flows that do not match the periods over which materials or services are provided to us under such contracts. Our objective is to reflect the appropriate clinical trial expenses in our consolidated financial statements by matching the appropriate expenses with the period in which services are provided and efforts are expended. We account for these expenses according to the progress of the trial as measured by patient progression and the timing of various aspects of the trial. We determine accrual estimates through financial models that take into account discussion with applicable personnel and outside service providers as to the progress or state of completion of trials, or the services completed. During the course of a clinical trial, we adjust our clinical expense recognition if actual results differ from our estimates. We make estimates of our accrued expenses as of each balance sheet date in our consolidated financial statements based on the facts and circumstances known to us at that time. Our clinical trial accrual and prepaid assets are dependent, in part, upon the receipt of timely and accurate reporting from CROs and other third-party vendors. Although we do not expect our estimates to be materially different from amounts actually incurred, our understanding of the status and timing of services performed relative to the actual status and timing of services performed may vary and may result in us reporting amounts that are too high or too low for any particular period.

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.

Basic and Diluted 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 stockholders by the weighted-average number of shares of common stock 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 shares of common stock that would have been outstanding if the potential shares of common stock had been issued and if the additional shares of common stock were dilutive. The components of basic and diluted earnings (loss) per share for the years ended December 31, 2019 and 2018 were as follows:

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

	December 31, 2019	December 31, 2018
Numerator		
Net loss	**$ (7,641,817)**	**$ (15,191,095)**
Denominator		
Weighted-average number of shares of common stock outstanding	3,711,333	2,941,084
Dilutive effect of stock options	-	-
Common stock and common stock equivalents used for diluted loss per share	**3,711,333**	**2,941,084**

For the years ended December 31, 2019 and 2018, warrants and options to purchase 8,256,609 and 785,894 shares, respectively, have been excluded from the computation of potentially dilutive securities. Because the impact of these items is anti-dilutive during periods of net loss, there was no difference between basic and diluted loss per share for the years ended December 31, 2019 and 2018.

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, 2019			
	Level I	Level II	Level III	Total
Marketable Securities	$ 5,986,050	$ -	$ -	$ 5,986,050

	December 31, 2018			
	Level I	Level II	Level III	Total
Marketable Securities	$ 2,997,150	$ -	$ -	$ 2,997,150

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.

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

Recent Accounting Pronouncements

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 issued additional clarification throughout 2018. Under the new guidance, a lessee should recognize assets and liabilities that arise from its leases and disclose qualitative and quantitative information about its leasing arrangements. The Company elected the optional transition method to apply the standard as of January 1, 2019 as the effective date and therefore, did not apply the standard to comparative periods. The Company did not apply the recognition requirements to short-term leases and recognized those lease payments in the Consolidated Statements of Operations and Comprehensive Loss on a straight-line basis over the lease term. The Company also elected the available package of practical expedients in transition which allowed us to not re-assess whether existing or expired arrangements contain a lease, the lease classification of existing or expired leases, or whether previous initial direct costs would qualify for capitalization under the new lease standard. The adoption of this update did not have a material impact on the Company's financial statements.

In June 2018, the FASB issued ASU 2018-07, *Compensation – Stock Compensation (Topic 718): Improvements to Nonemployee Share-Based Payment Accounting*, which simplifies several aspects of the accounting for nonemployee share-based payment transactions resulting from expanding the scope of Topic 718 to include share-based payment transactions for acquiring goods and services from nonemployees. The Company early adopted ASU 2018-07 and all subsequent updates related to this topic on a prospective basis effective July 1, 2018. The adoption of this update did not have a material impact on the Company's financial statements.

In November 2018, the FASB issued ASU 2018-18, *Collaborative Arrangements (Topic 808):* clarifying the interaction between Topic 808 and Topic 606. The amendments in the update clarifies that certain transactions between collaborative arrangement participants should be accounted for as revenue under Topic 606 when the collaborative arrangement participant is a customer in the context of a unit of account; adds unit-of-account guidance in Topic 808 to align with the guidance in Topic 606 when an entity is assessing whether the collaborative arrangement or a party of the arrangement is within the scope of Topic 606; requires that in a transaction with a collaborative arrangement participant that is not directly related to sales to third parties, presenting the transaction together with revenue recognized under Topic 606 is precluded if the collaborative arrangement participant is not a customer. The amendments for this update are effective for fiscal years beginning after December 15, 2019, and interim periods within those fiscal years. Early adoption is permitted. The Company is currently evaluating the impact of the new guidance on our Consolidated financial statements.

Other recent accounting pronouncements issued by the FASB, including its Emerging Issues Task Force, the American Institute of Certified Public Accountants, and the 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. STOCKHOLDER'S EQUITY

Common Stock Sales Agreements

Since October 2017, the Company has entered into multiple Common Stock Sales Agreements with Wainwright establishing ATM programs by which Wainwright sold and may continue to sell common stock at the market prices prevailing at the time of sale. Wainwright is 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. These programs are referred to below as the "October 2017 ATM Program," the "July 2019 ATM Program," and the "August 2019 ATM Program" based on when each program was initiated. In addition, the Company completed a public offering of its common stock in December 2019.

October 2017 ATM Program

From October 19, 2017 through expiration of the October 2017 ATM Program on April 23, 2019, the Company sold an aggregate of 899,233 shares of common stock at an average price of approximately $13.04 per share for gross proceeds of approximately $11.7 million. The Company paid 3.0% cash commission on the gross proceeds, plus reimbursement of expenses of Wainwright and legal fees in the aggregate amount of approximately $0.4 million.

2. STOCKHOLDER'S EQUITY (Continued)

July 2019 ATM Program

From July 22, 2019 through expiration of the July 2019 ATM Program on August 23, 2019, the Company sold an aggregate of 418,450 shares of common stock under the July 2019 ATM Program at an average price of approximately $4.30 per share for gross proceeds of approximately $1.8 million. The Company paid cash commissions on the gross proceeds, plus reimbursement of expenses of Wainwright and legal fees in the aggregate amount of approximately $0.1 million.

August 2019 ATM Program

On August 29, 2019, the Company initiated the August 2019 ATM Program. Since August 29, 2019 and through the date of this filing, the Company has sold an aggregate of 360,316 shares of common stock under the August 2019 ATM Program at an average price of approximately $3.07 per share for gross proceeds of approximately $1.1 million. The Company paid cash commissions on the gross proceeds, plus reimbursement of expenses of Wainwright and legal fees in the aggregate amount of approximately $0.1 million.

December 2019 Financing

In December 2019, the Company completed a public offering pursuant to which the Company issued (i) 531,173 shares of its common stock, (ii) warrants to purchase up to 4,139,477 shares of common stock, and (iii) pre-funded warrants to purchase up to 3,608,304 shares of common stock, at a combined purchase price of $1.226 per share and associated common warrant and $1.225 per pre-funded warrant and associated common warrant for an aggregate purchase price of approximately $5.1 million. The Company issued (a) to each purchaser of shares in the offering a common warrant to purchase a number of shares of common stock equal to the number of shares purchased by such purchaser in the offering, and (b) to each purchaser of pre-funded warrants in the offering a common warrant to purchase a number of shares of common stock equal to the number of pre-funded warrant shares underlying the pre-funded warrants purchased by such purchaser in the offering. In connection with the offering, the Company issued to designees of Wainwright, the placement agent for the offering, warrants (the "Placement Agent Warrants") to purchase an aggregate of 203,915 shares of common stock. The Placement Agent Warrants have an exercise price of $1.5325 per share, are immediately exercisable and expire in December 2024. Fees paid in conjunction with the deal, which included placement agent commissions, management fees, legal costs, and other offering expenses, amount to approximately $0.7 million in the aggregate and were recorded as a reduction to additional paid-in capital, resulting in net proceeds of approximately $4.4 million. Since December 19, 2019 and through March 26, 2020, all 3,608,304 pre-funded warrants and 78,304 common warrants have been exercised (see Note 9 - "Subsequent Events").

Outstanding Shares

At December 31, 2019, the Company had 5,227,398 shares of common stock issued and outstanding.

3. STOCK AWARDS, WARRANTS AND OPTIONS

Warrants

The following table summarizes all warrant activity for the years ended December 31, 2019 and 2018:

	Warrants	Weighted Average Exercise Price
Outstanding at January 1, 2018	108,171	$ 40.14
Expired	(23,564)	22.70
Outstanding at December 31, 2018	84,607	$ 45.00
Expired	(84,607)	45.00
Granted	7,951,696	0.61
Exercised	(450,000)	0.001
Outstanding at December 31, 2019	7,501,696	$ 0.65

3. STOCK AWARDS, WARRANTS AND OPTIONS (Continued)

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

Type	Grant Date	December 31, 2019	December 31, 2018	Exercise Price per Share	Expiration Date
Common Warrants	3/16/2016	-	84,607	$ 45.00	3/16/2019
Common Warrants	12/19/2019	4,139,477	-	$ 1.10	12/19/2024
Common Warrants	12/19/2019	203,915	-	$ 1.5325	12/17/2024
Pre-Funded Warrants	12/19/2019	3,158,304	-	$ 0.001	N/A
		7,501,696	**84,607**		

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"). In addition, subsequent to December 31, 2019, the Board has approved the 2020 Equity Incentive Plan (the "2020 Plan"), however the 2020 Plan will not become effective unless and until it is approved by the stockholders of the Company. The Company intends to seek stockholder approval for the 2020 Plan at its 2020 annual stockholders' meeting.

At the time the merger between Capricor and Nile became effective, 414,971 shares of common stock were reserved under the 2012 Plan for the issuance of stock options, stock appreciation rights, restricted stock awards and performance unit/share awards to employees, consultants and other service providers. Included in the 2012 Plan are the shares of common stock that were originally reserved under the 2006 Stock Option Plan. Under the 2012 Plan, each stock option granted will be designated in the award agreement as either an incentive stock option or a nonstatutory stock option. Notwithstanding such designation, however, to the extent that the aggregate fair market value of the shares with respect to which incentive stock options are exercisable for the first time by the participant during any calendar year (under all plans of the Company and any parent or subsidiary) exceeds $100,000, such options will be treated as nonstatutory stock options.

On June 2, 2016, at the Company's annual stockholder meeting, the stockholders approved a proposal to amend the 2012 Plan, to, among other things, increase the number of shares of common stock of the Company that may be issued under the 2012 Plan to equal the sum of 414,971 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). For the fiscal years beginning on January 1, 2020 and 2019, the amount of shares that were added was equal to 104,547 and 62,775 shares, respectively.

At the time the merger between Capricor and Nile became effective, 269,731 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 2019 and 2018 were approximately $2.73 and $13.09 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, 2019 and 2018:

3. STOCK AWARDS, WARRANTS AND OPTIONS (Continued)

	December 31, 2019	December 31, 2018
Expected volatility	106% - 128%	137% - 145%
Expected term	5-6 years	5-6 years
Dividend yield	0%	0%
Risk-free interest rates	1.4% - 1.6%	2.3% - 3.0%

Employee and non-employee stock-based compensation expense for the years ended December 31, 2019 and 2018 was as follows:

	2019	2018
General and administrative	$ 509,212	$ 1,158,904
Research and development	191,772	510,189
Total	$ 700,984	$ 1,669,093

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.

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. The fair value of stock options is determined using the Black-Scholes option-pricing model. Historically, the Company periodically re-measured the fair value for non-qualified option grants recording an expense over the applicable vesting periods. However, in the third quarter of 2018, the Company early adopted ASU 2018-07. The Company calculates the fair value for non-qualified options as of the date of grant and expenses over the applicable vesting periods. We account for forfeitures upon occurrence.

The following table summarizes information about stock options outstanding and exercisable at December 31, 2019:

Options Outstanding

Range of Ex. Prices	Options Outstanding	Weighted Average Term (yrs.)	Weighted Average Exercise Price
$1.90 - $3.25	196,082	7.51	$ 3.12
$3.70	330,241	2.17	$ 3.70
$11.40 - $35.80	149,226	7.36	$ 22.34
$43.40 - $57.80	79,364	4.95	$ 55.00
	754,913		

Options Exercisable

Range of Ex. Prices	Options Exercisable	Weighted Average Term (yrs.)	Weighted Average Exercise Price
$1.90 - $3.25	111,898	5.93	$ 3.06
$3.70	330,241	2.17	$ 3.70
$11.40 - $35.80	107,750	7.18	$ 23.95
$43.40 - $57.80	79,364	4.95	$ 55.00
	629,253		

3. STOCK AWARDS, WARRANTS AND OPTIONS (Continued)

As of December 31, 2019, the total unrecognized fair value compensation cost related to non-vested stock options was approximately $0.8 million, which is expected to be recognized over a weighted average period of approximately 1.1 years.

The following is a schedule summarizing employee and non-employee stock option activity for the years ended December 31, 2019 and 2018:

	Number of Options	Weighted Average Exercise Price	Aggregate Intrinsic Value
Outstanding at January 1, 2018	687,367	$ 16.25	
Granted	99,460	14.21	
Exercised	(37,604)	3.70	$ 521,678
Expired/Cancelled	(47,936)	22.82	
Outstanding at December 31, 2018	701,287	$ 16.18	
Granted	130,000	3.20	
Exercised	(828)	3.35	$ 1,987
Expired/Cancelled	(75,546)	29.48	
Outstanding at December 31, 2019	754,913	$ 12.63	$ -
Exercisable at December 31, 2019	629,253	$ 13.52	$ -

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.

In February 2020, the board of directors of the Company approved an option repricing program (see Note 9 – "Subsequent Events").

4. 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, 2019, the Company maintained approximately $9.4 million of uninsured deposits.

5. 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 were tied to the achievement of specified operational milestones. In addition, the terms of the CIRM Award included a co-funding requirement pursuant to which Capricor was required to spend approximately $2.3 million of its own capital to fund the CIRM funded research project. 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.

5. GOVERNMENT GRANT AWARDS (Continued)

After completing the CIRM funded research project and at any time after the award period end date (but no later than the ten-year anniversary of the date of the award), 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 Capricor elects to convert the grant into a loan, the term of the loan could be up to five years from the date of execution of the applicable loan agreement; provided that the maturity date of the loan will not surpass the ten-year anniversary of the grant date of the CIRM Award. Beginning on the date of the loan, the loan shall bear interest on the unpaid principal balance, plus the interest that has 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. If we elect to do so, Capricor would be required to repay some or all of the amounts awarded by CIRM; therefore, the Company accounts for this award as a liability rather than income.

As of December 31, 2019, Capricor's liability balance for the CIRM Award was approximately $3.4 million. In June 2019, Capricor completed all milestones associated with the CIRM Award and expended all funds received. In the third quarter of 2019, Capricor completed all final close-out documentation associated with this award.

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, Capricor is eligible to receive disbursements 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 June 30, 2019, approximately $0.7 million had been incurred under the terms of the NIH grant award. In the second quarter of 2019, the award was closed, and all filings were completed with no additional expenses expected to be incurred.

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 three years, subject to annual and quarterly reporting requirements. The Company was granted a no-cost extension until September 29, 2020 to be able to utilize these funds. As of December 31, 2019, approximately $2.2 million has been incurred under the terms of the award.

6. COMMITMENTS AND CONTINGENCIES

Leases

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. Capricor subsequently entered into several amendments extending the term of the lease and modifying its terms. On January 11, 2019, Capricor entered into a Fourth Amendment to Lease (the "Fourth Lease Amendment") with The Bubble Real Estate Company, LLC. Under the terms of the Fourth Lease Amendment, the lease term extension commenced on January 1, 2019 and ended on December 31, 2019 with a base rent of $25,867 per month. The Company delivered to the landlord a letter of credit in the amount of $232,803 to cover payments of rent for the remainder of the 2019 lease term, which was subsequently cancelled and funds returned to Capricor. Effective January 1, 2020, the Company entered into an amendment with the Bubble Real Estate Company, LLC pursuant to which Capricor extended the lease for an additional year ending December 31, 2020 and reduced the square footage. The monthly rental payment is $16,229 for this annual period (see Note 9 – "Subsequent Events").

6. COMMITMENTS AND CONTINGENCIES (Continued)

Capricor leases facilities from Cedars-Sinai Medical Center ("CSMC") pursuant to a lease (the "Facilities Lease") that was originally effective for a three-year period beginning June 1, 2014. Capricor has subsequently entered into several amendments extending the term of the lease and modifying its terms. From August 1, 2017 through March 1, 2019, total monthly rent was $19,756. Effective March 1, 2019, the square footage of the leased premises was reduced, resulting in a rent reduction of approximately $4,000 per month. In July 2019, Capricor exercised an option to extend the term of the Facilities Lease for an additional 12-month period through July 31, 2020 with a monthly lease payment of $15,805. The Company has a further option to extend the Facilities Lease through July 31, 2021.

Included within the table below, future minimum rental payments to related parties totaled approximately $110,635. A summary of future minimum rental payments required under operating leases as of December 31, 2019 is as follows:

Years ended	Operating Leases
2020	$ 110,635

Expenses incurred under operating leases to unrelated parties for the years ended December 31, 2019 and 2018 were approximately $317,404 and $332,640, respectively. Expenses incurred under operating leases to related parties for each of the years ended December 31, 2019 and 2018 were approximately $197,562 and $237,072, 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 or otherwise.

Accounts Payable

Over the normal course of business, disputes with vendors may arise. If a vendor dispute payment is probable and able to be estimated, we will record an estimated liability.

Employee Severances

In the event of a termination, subject to certain conditions, the Board of Directors approved severance packages for specific full-time employees based on their length of service and position ranging up to six months of their base salaries. No liability has been recorded as of December 31, 2019.

7. LICENSE AGREEMENTS

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

Capricor has entered into exclusive license agreements for intellectual property rights related to 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 (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.

7. LICENSE AGREEMENTS (Continued)

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 (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 U.S. Food and Drug Administration (the "FDA"). The development milestones range from $100,000 upon successful completion of a full Phase I clinical study to $1,000,000 upon full FDA market approval and are fully creditable against payments owed by Capricor to JHU on account of sublicense consideration attributable to milestone payments received from a sublicensee. The maximum aggregate amount of milestone payments payable under the JHU License Agreement, as amended, is $1,850,000. 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 next milestone is triggered upon successful completion of a full Phase II study for which a payment of $250,000 will be due.

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.

7. LICENSE AGREEMENTS (Continued)

Cedars-Sinai Medical Center License Agreements

License Agreement for CDCs

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

7. LICENSE AGREEMENTS (Continued)

On December 26, 2017, Capricor entered into a Third Amendment to the Amended CSMC License Agreement thereby amending the CDCs License (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.

On June 20, 2018, Capricor and CSMC entered into a Fourth Amendment to the Amended CSMC License Agreement (the "Fourth License Amendment"). Under the Fourth License Amendment, the description of scheduled patent rights has been replaced by a revised schedule that includes two additional patent applications.

License Agreement for Exosomes

On May 5, 2014, Capricor entered into an Exclusive License Agreement with CSMC (the "Exosomes License Agreement"), for certain intellectual property rights related to exosomes technology. The Exosomes License Agreement provides for the grant of an exclusive, world-wide, royalty-bearing license by CSMC to Capricor (with the right to sublicense) in order to conduct research using the patent rights and know-how and to develop and commercialize products in the field using the patent rights and know-how. In addition, Capricor has the exclusive right to negotiate for an exclusive license to any future rights arising from related work conducted by or under the direction of Dr. Eduardo Marbán on behalf of CSMC. In the event the parties fail to agree upon the terms of an exclusive license, Capricor shall have a non-exclusive license to such future rights, subject to royalty obligations.

Pursuant to the Exosomes License Agreement, CSMC was paid a license fee and Capricor reimbursed CSMC for certain fees and costs incurred in connection with the 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 (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.

7. LICENSE AGREEMENTS (Continued)

On August 5, 2016, Capricor and CSMC entered into a Third Amendment to the Exosomes License Agreement (the "Third Exosomes License Amendment"), pursuant to which the parties agreed to add certain patent 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 applica

On December 26, 2017, Capricor and CSMC entered into a Fourth Amendment to Exosomes License Agreement, thereby amending the Exosomes License (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.

On June 20, 2018, Capricor and CSMC entered into a Fifth Amendment to the Exosomes License Agreement (the "Fifth License Amendment"). Under the Fifth License Amendment, (i) the description of scheduled patent rights has been replaced by a revised schedule that includes four additional patent applications; and (ii) Capricor is required to reimburse CSMC approximately $27,000 for attorneys' fees and filing fees that were incurred in connection with the additional patent rights.

On September 25, 2018, Capricor and CSMC entered into a Sixth Amendment to the Exosomes License Agreement (the "Sixth License Amendment"). Under the Sixth License Amendment, the milestone deadline for filing an IND for at least one product has been extended to December 31, 2019. If the Company does not file an IND by December 31, 2019, or negotiate an additional extension of the milestone deadline, CSMC would have the option to convert the exclusive license to a non-exclusive license or to a co-exclusive license or terminate the license under Title 35, Section 203 of the United States Code. Prior to exercising such option, Capricor has the opportunity to cure the failure to file an IND for a period of 90 days after its receipt of written notice from CSMC of its intent to exercise its option. In the first quarter of 2020, Capricor received a notice from CSMC indicating that Capricor was in default of this milestone and further that unless such default is cured by April 19, 2020, the Exosomes License Agreement will automatically terminate. Capricor intends to file an IND in advance of the April 19, 2020 deadline in order to avoid the termination of the license, or alternatively negotiate an extension of the deadline with CSMC. Such intent has been communicated to CSMC.

8. RELATED PARTY TRANSACTIONS

Lease and Sub-Lease Agreement

As noted above, Capricor is a party to lease agreements with CSMC, which holds more than 5% of the outstanding capital stock of Capricor Therapeutics (see Note 6 – "Commitments and Contingencies"), and CSMC has served as an investigative site in Capricor's clinical trials. Additionally, Dr. Eduardo Marbán, who is a stockholder of Capricor Therapeutics and participates from time to time as an observer at the Company's meetings of the Board of Directors, is the Director of the Cedars-Sinai Smidt Heart Institute, and co-founder of Capricor.

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, 2019 and 2018, 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

In 2013, Capricor entered into a Consulting Agreement with Dr. Frank Litvack, the Company's Executive Chairman and a member of its Board of Directors, whereby Capricor agreed to pay Dr. Litvack $10,000 per month for consulting services. The agreement is terminable upon 30 days' notice.

8. RELATED PARTY TRANSACTIONS (Continued)

Payables to Related Party

At December 31, 2019 and 2018, the Company had accounts payable and accrued expenses to related parties totaling $22,315 and $106,366, respectively. CSMC accounts for $12,315 and $100,191 of the total accounts payable and accrued expenses to related parties as of December 31, 2019 and 2018, respectively. CSMC expenses relate to research and development costs. During the years ended December 31, 2019 and 2018, the Company paid CSMC approximately $140,000 and $400,000, 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. We were recently informed that the REGRESS study was put on clinical hold by the FDA. The preliminary information we have received suggests that the issue may be related to inadequate patient monitoring at the study site to assess safety for certain patients who were experiencing adverse events after receiving an intracoronary infusion of CAP-1002. It is currently not known whether the clinical hold is related to the investigational product or the procedure. 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. While the Company expects to continue to receive payment for the product that it supplies for the REGRESS and ALPHA trials, we cannot predict the rate at which such payments will be made, if at all, due to delays in enrollment or other problems that may arise at the trial sites. For the years ended December 31, 2019 and 2018, the Company recognized approximately $460,000 and $700,000, respectively, as revenue. As of December 31, 2019, and 2018, approximately $58,000 and $269,000, respectively, is outstanding and recorded in prepaid expenses and other current assets. As of December 31, 2019, the Company has approximately $0.7 million to be received, subject to enrollment and certain conditions under the agreements.

Related Party Agreement

On May 10, 2018, Capricor and TrialTech Medical, Inc., a corporation in which Dr. Frank Litvack, our Executive Chairman and a director, is a co-founder, stockholder and chairman, entered into an agreement whereby TrialTech Medical, Inc. would provide clinical trial services to Capricor for its HOPE-2 clinical trial. In December 2018, Capricor ceased the use of these services and subsequently terminated the contract. Total costs incurred under the agreement were approximately $42,600.

9. SUBSEQUENT EVENTS

Corporate Offices Lease Amendment

Effective January 1, 2020, the Company entered into a Fifth Amendment with the Bubble Real Estate Company, LLC pursuant to which we extended our lease for an additional year ending December 31, 2020 and reduced the square footage. The monthly rental payment is $16,229 for this annual period.

Repricing of Stock Option Grants

On February 12, 2020, pursuant to the authority granted to it under the 2012 Restated Equity Incentive Plan and the 2012 Non-Employee Director Stock Option Plan, the board of directors of the Company approved a program under which outstanding options and other awards granted under the 2012 Plan and the 2012 Director Plan to employees, officers and directors of the Company, and designated service providers shall be repriced to their then current fair market value. There were 662,968 outstanding options which were repriced to $1.39 per share, which was the market price of our common stock on the date of the approval of the repricing. The effect of the modification generated a total incremental cost of approximately $178,000, of which $171,000 will be recognized in the first quarter of 2020 with the remainder to be expensed over the remaining unvested period terms.

Economic Uncertainty Related to the Coronavirus

As a result of the spread of the COVID-19 coronavirus, economic uncertainties have arisen that could potentially impact enrollment of clinical trials, deliverables related to contract performance, payments from vendors, supply chain disruptions or delays, timing of grant disbursements as well as other potential business operations. While the disruption is currently expected to be temporary, there is considerable uncertainty around the duration. Other financial impact could occur though such potential impact is unknown at this time.

Warrant Inducement

On March 25, 2020, the Company entered into a letter agreement (the "Exercise Agreement") with a holder of the Existing Warrants (the "Exercising Holder"). Pursuant to the Exercise Agreement, in connection with exercise by the Exercising Holder of the remaining 4,000,000 Existing Warrants held by the Exercising Holder which had not been previously exercised, the Company agreed to issue 4,000,000 additional warrants (the "New Warrants") to purchase Common Stock. The Existing Warrants had a per share exercise price of $1.10, and pursuant to the Exercise Agreement, the Exercising Holder agreed to pay $1.225 per share to cover both the exercise price of the Existing Warrants and a $0.125 per share purchase price for the New Warrants. The New Warrants have an exercise price of $1.27 per share.

The New Warrants and the shares of Common Stock issuable upon the exercise of the New Warrants are not being registered under the Securities Act of 1933, as amended (the "Securities Act"), and are being offered pursuant to the exemption provided in Section 4(a)(2) under the Securities Act or Rule 506(b) promulgated thereunder. Pursuant to the Exercise Agreements, the New Warrants shall be substantially in the form of the Existing Warrants (except for customary legends and other language typical for an unregistered warrant, including the ability for the holder of the New Warrant to make a cashless exercise if no resale registration statement covering the Common Stock underlying the New Warrants is effective after six months), will be exercisable immediately, and will have a term of exercise of 5 1/2 years), and the Company will be required to register for resale the shares of Common Stock underlying the New Warrants.

The Company expects to receive aggregate gross proceeds of approximately $4.9 million from the exercise of the Existing Warrants by the Exercising Holder. These gross proceeds will be reduced by fees due and payable to the placement agent for the transactions pursuant to the Exercise Agreement and New Warrants in the amount of $343,000, and further reduced by reimbursements to the placement agent for legal fees and other expenses. In addition, the placement agent will receive a new warrant for shares of Common Stock equal to 5.0% of the New Warrants issued, or 200,000 shares.

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, 2019, 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, 2019 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, 2019.

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, 2019 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 2020 Annual Meeting of Stockholders, or our 2020 Proxy Statement, to be filed with the SEC within 120 days after the end of the fiscal year ended December 31, 2019, and is incorporated herein by reference.

ITEM 11. EXECUTIVE COMPENSATION.

The information required by this item will be set forth in the section entitled "2019 Executive Compensation" and "Compensation of Directors" in our 2020 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 2020 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 2020 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 2020 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 76.

(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 SEC 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 SEC 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 SEC 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 SEC 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 SEC on November 26, 2013).
3.3	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 SEC on June 4, 2019).
3.4	Bylaws of the Company (incorporated by reference to Exhibit 3.2 to the Company's Current Report on Form 8-K, filed with the SEC on February 9, 2007).
4.1	Description of the Company's Common Stock, par value $0.001 per share.*
4.2	Form of Common Warrant (incorporated by reference to Exhibit 4.4 to the Company's Amendment No. 1 to Registration Statement on Form S-1/A, filed with the Commission on December 13, 2019).
4.3	Form of Pre-Funded Warrant (incorporated by reference to Exhibit 4.5 to the Company's Amendment No. 1 to Registration Statement on Form S-1/A, filed with the Commission on December 13, 2019).
4.4	Form of Placement Agent Warrant (incorporated by reference to Exhibit 4.6 to the Company's Amendment No. 1 to Registration Statement on Form S-1/A, filed with the Commission on December 13, 2019).
10.1	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). †

10.2	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). †
10.3	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). †
10.4	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). †
10.5	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). †
10.6	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). †
10.7	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). †
10.8	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). †
10.9	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). †
10.10	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). †
10.11	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). †
10.12	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). †
10.13	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). +
10.14	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). +
10.15	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). +
10.16	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). +
10.17	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). +

10.18	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). +
10.19	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). +
10.20	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).
10.21	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). +
10.22	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).
10.23	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).
10.24	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). +
10.25	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).
10.26	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). +
10.27	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).
10.28	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). +
10.29	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).
10.30	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). +
10.31	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).
10.32	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). +

10.33	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).
10.34	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). +
10.35	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). +
10.36	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). †
10.37	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). †
10.38	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).
10.39	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 11, 2017).
10.40	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 11, 2017).
10.41	Fourth Amendment to Exclusive License Agreement, dated as of December 26, 2017, by and between Capricor, Inc. and Cedars-Sinai Medical Center (incorporated by reference to Exhibit 10.58 to the Company's Annual Report on Form 10-K, filed with the Commission on March 22, 2018). +
10.42	Third Amendment to Exclusive License Agreement, dated as of December 26, 2017, by and between Capricor, Inc. and Cedars-Sinai Medical Center (incorporated by reference to Exhibit 10.59 to the Company's Annual Report on Form 10-K, filed with the Commission on March 22, 2018). +
10.43	Fourth Amendment to Amended and Restated Exclusive License Agreement, dated as of June 20, 2018, 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 13, 2018). +
10.44	Fifth Amendment to Exclusive License Agreement, dated as of June 20, 2018, 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 August 13, 2018). +
10.45	Restated and Amended Employment Agreement by and among Capricor Therapeutics, Inc., Capricor, Inc. and Linda Marbán, dated June 5, 2019 (incorporated by reference to Exhibit 10.1 to the Company's Quarterly Report on Form 10-Q, filed with the Commission on August 8, 2019).†
10.46	Employment Agreement by and among Capricor Therapeutics, Inc., Capricor, Inc. and Anthony J. Bergmann, dated May 14, 2019 (incorporated by reference to Exhibit 10.2 to the Company's Quarterly Report on Form 10-Q, filed with the Commission on August 8, 2019).†
10.47	Employment Agreement by and among Capricor Therapeutics, Inc., Capricor, Inc. and Karen G. Krasney, dated May 14, 2019 (incorporated by reference to Exhibit 10.3 to the Company's Quarterly Report on Form 10-Q, filed with the Commission on August 8, 2019).†

10.48	Common Stock Sales Agreement, dated July 22, 2019, 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 July 22, 2019).
10.49	Form of Placement Agency Agreement (incorporated by reference to Exhibit 1.1 to the Company's Amendment No. 1 to Registration Statement on Form S-1/A, filed with the Commission on December 13, 2019).
10.50	Form of Securities Purchase Agreement (incorporated by reference to Exhibit 1.1 to the Company's Current Report on Form 8-K, filed with the Commission on December 18, 2019).
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, 2019 and 2018, (ii) Consolidated Statements of Operations and Comprehensive Loss for the years ended December 31, 2019 and 2018, (iii) Consolidated Statement of Stockholders' Equity for the period from December 31, 2017 through December 31, 2019, (iv) Consolidated Statements of Cash Flows for the years ended December 31, 2019 and 2018, 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 26, 2020.

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 26, 2020
/s/ Anthony J. Bergmann Anthony J. Bergmann	Chief Financial Officer *(Principal Financial and Accounting Officer)*	March 26, 2020
/s/ Frank Litvack, M.D. Frank Litvack, M.D.	Executive Chairman and Director	March 26, 2020
/s/ Earl M. Collier Earl M. Collier	Director	March 26, 2020
/s/ Louis V. Manzo Louis V. Manzo	Director	March 26, 2020
/s/ George W. Dunbar George W. Dunbar	Director	March 26, 2020
/s/ David B. Musket David B. Musket	Director	March 26, 2020

Exhibit 4.1

DESCRIPTION OF REGISTRANT'S SECURITIES

REGISTERED PURSUANT TO SECTION 12 OF THE

SECURITIES EXCHANGE ACT OF 1934

The authorized capital stock of Capricor Therapeutics, Inc. consists of 55,000,000 shares, consisting of 50,000,000 shares of common stock, $0.001 par value per share (the "common stock") and 5,000,000 shares of preferred stock, $0.001 par value per share (the "preferred stock"). We have one class of securities registered under Section 12 of the Securities Exchange Act of 1934, our common stock, which is listed on the Nasdaq Capital Market under the symbol "CAPR." For purposes of this exhibit, unless the context otherwise requires, the words "we," "our," "us" and "the company" refer to Capricor Therapeutics, Inc., a Delaware corporation.

DESCRIPTION OF COMMON STOCK

General

The following summary sets forth some of the general terms of our common stock. Because this is a summary, it does not contain all of the information that may be important to you. For a more detailed description of our common stock, you should read our certificate of incorporation, as amended, and our bylaws, each of which is an exhibit to our Annual Report on Form 10-K to which this summary is also an exhibit, and the applicable provisions of the General Corporation Law of the State of Delaware (the "DGCL").

Voting Rights

Holders of our common stock are entitled to one vote for each share held of record on all matters submitted to a vote of the stockholders, and do not have cumulative voting rights in the election of directors.

Dividend Rights

Subject to rights that may be applicable to any outstanding shares of preferred stock and the requirements, if any, with respect to the setting aside of sums as sinking funds or redemption or purchase accounts for the benefit of the holders of preferred stock, the holders of our common stock are entitled to receive dividends, if any, as may be declared from time to time by our board of directors out of assets legally available for dividend payments. Any such dividends shall be divided among the holders of our common stock on a pro rata basis.

Liquidation Rights

In the event of any liquidation of the Company, the holders of our common stock will be entitled to share ratably in the assets that are remaining after payment or provision for payment of all of our debts and obligations and after liquidation payments to holders of outstanding shares of preferred stock are made, if any.

No Preemptive or Similar Rights

The holders of our common stock have no preferences or rights of conversion, exchange, pre-emption or other subscription rights, and our common stock is not subject to any sinking fund provisions.

Fully Paid and Nonassessable

All outstanding shares of our common stock are fully paid and nonassessable.

Preferred Stock

Our board of directors has been authorized to designate and issue up to an aggregate of 5,000,000 shares of preferred stock in one or more series without action by the stockholders. Our board of directors can fix the rights, preferences and privileges of the shares of each series and any of its qualifications, limitations or restrictions. Our board of directors may authorize the issuance of preferred stock with voting or conversion rights that could adversely affect the voting power or other rights of the holders of common stock. The issuance of preferred stock, while providing flexibility in connection with possible future financings and acquisitions and other corporate purposes could, under certain circumstances, have the effect of delaying or preventing a change in control of our company and might harm the market price of our common stock. As of December 31, 2019, there were no shares of preferred stock issued and outstanding.

Anti-Takeover Effects of Certain Provisions of the DGCL and Our Certificate of Incorporation and Bylaws

The provisions of the DGCL, our certificate of incorporation, as amended, and our bylaws may be deemed to have an anti-takeover effect and may delay, deter or prevent a tender offer or takeover attempt that a stockholder might consider to be in its best interests, including attempts that might result in a premium being paid over the market price for the shares held by stockholders. These provisions are intended to enhance the likelihood of continuity and stability in the composition of our board of directors and in the policies formulated by the board of directors and to discourage certain types of transactions that may involve an actual or threatened change of control. These provisions, summarized below, are designed to reduce our vulnerability to an unsolicited acquisition proposal and are intended to discourage certain tactics that may be used in proxy fights. Such provisions may also have the effect of preventing changes in our management.

Section 203 of the DGCL

As a Delaware corporation, we are subject to Section 203 of the DGCL. In general, Section 203 prohibits a publicly held Delaware corporation from engaging in a "business combination" with an "interested stockholder" for a period of three years after the date of the transaction in which the person became an interested stockholder, unless the business combination is, or the transaction in which the person became an interested stockholder was, approved in a prescribed manner or another prescribed exception applies. For purposes of Section 203, a "business combination" is defined broadly to include, among other things, a merger, asset or stock sale or other transaction resulting in a financial benefit to the interested stockholder. Subject to certain exceptions, an "interested stockholder" is a person who, together with affiliates and associates, owns (or, within three years prior, did own) 15% or more of the corporation's voting stock.

Issuance of Additional Shares

Our board of directors has authority, without further action by the stockholders, to issue up to 5,000,000 shares of preferred stock, in one or more series, and to designate the rights, preferences, privileges and restrictions of each series. The issuance of preferred stock could have the effect of delaying or preventing a change in control of the Company without further action by the stockholders.

In addition, our board of directors has authority to issue the authorized but unissued shares of our common stock, without further action by the stockholders, subject to any applicable stock exchange rules. Under certain circumstances, we could use the additional shares to create voting impediments or to frustrate persons seeking to effect a takeover or otherwise gain control by, for example, issuing those shares in private placement transactions to purchasers who are likely to side with our board of directors in opposing a hostile takeover bid.

Special Meetings of Stockholders

Our bylaws provide that special meetings of stockholders may be called by the Chairman of the Board, the President or our board of directors. A special meeting shall be called by the President or Secretary upon one or more written demands (which must state the purpose or purposes therefor) signed and dated by the holders of shares representing not less than 10% of all votes entitled to be cast on any issue(s) that may be properly proposed to be considered at the special meeting. These provisions may delay or impede the ability of a stockholder or group of stockholders to force consideration of a proposal or stockholders holding a majority of our outstanding capital stock to take a certain desired action.

Advance Notice Provisions for Stockholder Proposals

Our bylaws provide that the nomination of persons to stand for election to the board of directors at any annual or special meeting of stockholders may be made by the holders of our common stock only if written notice of such stockholder's intent to make such nomination has been given to the Secretary of the Company not later than 30 days prior to the meeting.

Furthermore, our bylaws require that any stockholder who gives notice of any stockholder proposal shall deliver therewith the text of the proposal to be presented and a brief written statement of the reasons why such stockholder favors the proposal and setting forth such stockholder's name and address, the number and class of all shares of each class of stock of the Company beneficially owned by such stockholder and any financial interest of such stockholder in the proposal (other than as a stockholder).

The foregoing provisions may preclude our stockholders from bringing matters or from making nominations for directors at our annual meeting of stockholders if the proposals are not in compliance with the required procedures. Additionally, the requisite procedures may deter a potential acquirer from conducting a solicitation of proxies to elect its own nominees to our board of directors or otherwise attempting to gain control of the Company.

Filling of Vacancies on the Board of Directors

Our bylaws provide that a vacancy on our board of directors caused by the removal of a director or by an increase in the authorized number of directors between annual meetings may be filled only by a majority of the remaining directors. In addition, the number of directors constituting our board of directors may only be set from time to time by resolution of our board of directors. These provisions would prevent a stockholder from increasing the size of our board of directors and then gaining control of our board of directors by filling any resulting vacancies with its own nominees; thereby making it more difficult to change the composition of our board of directors.

Amendment of Bylaws

Our board of directors is expressly authorized to adopt, amend or repeal our bylaws.

Transfer Agent and Registrar

The transfer agent and registrar for our common stock is American Stock Transfer & Trust Company, LLC. Its address is 6201 15th Avenue, Brooklyn, New York 11219, and its telephone number is 800-937-5449.

Exhibit 21.1

SUBSIDIARIES OF THE REGISTRANT

Legal Name	**Jurisdiction of Organization**
Capricor, Inc.	Delaware

Exhibit 23.1

CONSENT OF INDEPENDENT REGISTERED PUBLIC ACCOUNTING FIRM

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

We consent to the incorporation by reference in the Registration Statements of Capricor Therapeutics, Inc. on Form S-8 (File Nos. 333-152283, 333-175727, 333-194317, and 333-215510), Form S-3 (File Nos. 333-161339, 333-165167, 333- 207149, 333-212017, 333-219188, and 333-227955), and Form S-1 (File No. 333-235358) of our report dated March 26, 2020, relating to the consolidated financial statements, appearing in this Annual Report on Form 10-K.

/s/ Rose, Snyder & Jacobs LLP

Rose, Snyder & Jacobs LLP
Encino, California

March 26, 2020

Exhibit 31.1

CERTIFICATION OF PRINCIPAL EXECUTIVE OFFICER

I, Linda Marbán, Ph.D., certify that:

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

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

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

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

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

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

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

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

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

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

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

Date: March 26, 2020

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

Exhibit 31.2

CERTIFICATION OF PRINCIPAL FINANCIAL OFFICER

I, Anthony J. Bergmann, certify that:

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

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

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

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

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

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

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

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

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

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

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

Date: March 26, 2020

/s/ Anthony J. Bergmann
Name: Anthony J. Bergmann
Title: Chief Financial Officer and Principal Financial Officer

Exhibit 32.1

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

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

(1) the Annual Report on Form 10-K of the Company for the period ended December 31, 2019 (the "**Report**") fully complies with the requirements of Section 13(a) or Section 15(d), as applicable, of the Securities Exchange Act of 1934, as amended; and

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

Date: March 26, 2020

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

Exhibit 32.2

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

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

(1) the Annual Report on Form 10-K of the Company for the period ended December 31, 2019 (the "**Report**") fully complies with the requirements of Section 13(a) or Section 15(d), as applicable, of the Securities Exchange Act of 1934, as amended; and

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

Date: March 26, 2020

/s/ Anthony J. Bergmann
Name: Anthony J. Bergmann
Title: Chief Financial Officer and Principal Financial Officer