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 1934for the fiscal year ended December 31, 2020
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 ☐	Accelerated filer ☐
Non-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 has filed a report on and attestation to its management's assessment of the effectiveness of its internal control over financial reporting under Section 404(b) of the Sarbanes-Oxley Act (15 USC. 7262(b)) by the registered public accounting firm that prepared or issued its audit report. ☐

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, 2020 was approximately $86,525,913, based on the last reported sale of the registrant's common stock on The Nasdaq Capital Market on June 30, 2020 of $4.60 per share.

As of March 12, 2021, there were 22,797,930 shares of the registrant's common stock, par value $0.001 per share, issued and outstanding.

DOCUMENTS INCORPORATED BY REFERENCE

Part III of this Annual Report on Form 10-K incorporates information by reference from the definitive proxy statement for the registrant's 2021 Annual Meeting of Stockholders.

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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. References to "Capricor" in this Annual Report on Form 10-K refer to our wholly owned subsidiary, Capricor, Inc., 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 and vaccine 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 and vaccine 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 preclinical 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 preclinical 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, 2020 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 biotechnology company focused on the development oftransformative cell- and exosome-based therapeutics for the treatment and prevention of a broad spectrum of diseases.

Cell Therapy (CAP-1002) Program

CAP-1002 - Duchenne Muscular Dystrophy Program

We have completed HOPE-2, a Phase II clinical trial in the United States with our product candidate, CAP-1002, a cardiac cell derived therapy which was used to treat patients with late-stage Duchenne muscular dystrophy, or DMD. The 12-month final top-line data showed improvements in multiple measures of upper limb, cardiac and respiratory functions. Following receipt of the 12-month data, we discussed this program with the FDA in a Type B meeting focusing on the data, next steps and a pathway to approval of a Biologics License Application, or BLA, for CAP-1002 in DMD. The FDA has continued to encourage us to conduct a Phase III study; at this time, however, we are still discussing the pathway forward for this program with the FDA and have not initiated a Phase III study. Additionally, we are actively seeking partners for this program.

CAP-1002 - COVID-19 Program

In 2020, under an Expanded Access (or Compassionate Use) program, seven patients hospitalized with severe COVID-19 (also referred to sometimes as SARS-CoV-2) symptoms, six of whom were ventilated, were treated with CAP-1002. Four of the seven patients were fully discharged and three died between one- and two-months post-treatment. Previously published data has shown that COVID-19 patients on ventilators experience higher mortality rates. While we are unable to definitively ascertain whether CAP-1002 improved patient outcomes, by analyzing blood samples and other tests, it was determined that CAP-1002 was associated with identifiable improvements in certain patients such as a decrease in white blood cell count, a decrease in IL-6, a decrease in C-reactive protein, and/or reduced reliance on supplemental oxygen. However, the efficacy of CAP-1002 in treating COVID-19 was not demonstrated due to the small sample size, the fact that seven patients were contemporaneously on other experimental medications, and the lack of an established control group, among other factors.

In August 2020, we received FDA acceptance of our IND application for a clinical study of CAP-1002 in patients with severe or critical COVID-19. The INSPIRE trial is a Phase II, randomized, double-blind, placebo-controlled study that is enrolling up to 60 patients from several trial sites in the United States. The study is enrolling patients who have a diagnosis of SARS-CoV-2 and require supplemental oxygen. Various outcome measures will be analyzed including, but not limited to, safety, cytokine biomarkers, all-cause mortality, cardiac biomarkers and hospitalization length. We expect to have top-line data available in the third quarter of 2021. Following receipt of this data, we will discuss next steps for the program with FDA. Additionally, we are actively seeking partners for this program.

Exosomes Program

Exosome-Based Vaccines

We are currently engaged in the development of two vaccine candidates for the potential prevention of COVID-19.The first vaccine candidate is a tripartite exosome-mRNA vaccine which is designed to elicit a protective, long-lasting immune response to SARS-CoV-2 by targeting multiple structural proteins of the virus. In December 2020, we announced positive preclinical data from a study using our exosome-mRNA vaccine approach We recently met with the FDA in a pre-IND meeting and are planning on filing an IND by the third quarter of 2021, subject to regulatory approval, for this vaccine for SARS-CoV-2. We have also been investigating an exosomal antigen vaccine which is a vesicle-based, nucleic acid-free formulation carrying multiple structural proteins of SARS-CoV-2.

Exosome-Based Therapeutics

We are also developing our exosomes platform technology as a next-generation therapeutic platform. Our current focus is on the development of exosomes loaded with nucleic acids, including mRNA, to treat a variety of diseases. mRNA medicines are not small molecules, like traditional pharmaceutical drugs and they are not traditional biologics (such as recombinant proteins and monoclonal antibodies) – which were the origins of the biotech industry. Instead, mRNA medicines are sets of instructions. And these instructions direct cells in the body to make all the proteins required for life as well as to prevent or fight disease.

Our platform builds on advances in fundamental RNA science, targeting technology and manufacturing, providing us the opportunity to build a broad pipeline of potential new therapeutic candidates. At this time, we are developing therapeutics and vaccines for infectious diseases, monogenic diseases and other indications.

CDC-Derived Exosomes (CAP-2003)

In April 2020, we filed an IND with the FDA to investigate the use of CAP-2003 in patients with DMD. At this time, the FDA has requested more information related to manufacturing and we are evaluating the next steps for this program. We need to submit further information to FDA to support the potential acceptance of this IND.

Additionally, in July 2018, we entered into a Cooperative Research and Development Agreement with the U.S. Army Institute of Surgical Research, or USAISR, pursuant to which we agreed to cooperate in research and development on the evaluation of our CAP-2003 for the treatment of trauma related injuries and conditions.

Aspects of our exosomes pipeline have been supported through collaborations and alliances. We have entered into a Sponsored Research Agreement with Johns Hopkins University, or JHU, pursuant to which researchers in the lab of Dr. Stephen Gould will perform certain research activities in connection with our exosomes program and the further development of the platform. Additional collaborations include the Department of Defense, the National Institutes of Health and Cedars-Sinai Medical Center, or CSMC.

Our executive offices are located at 8840 Wilshire Blvd., 2nd Floor, Beverly Hills, California 90211. Our telephone number is (310) 358-3200 and our Internet address is *www.capricor.com*.

Our Technologies

Cardiosphere-Derived Cells (CAP-1002)

Our core cell therapy 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 over 200 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 DMD and investigating

their effects on skeletal and cardiac function. Preclinical 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 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 and 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

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. Our preclinical data has shown that CDCs mediate most of their therapeutic activities through the secretion of extracellular vesicles.

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, preclinical 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.

The following table summarizes our active product development programs:

Product	Indication/Population	Development Stage
CAP-1002	Duchenne Muscular Dystrophy*	HOPE-3 Phase III – in planning stages HOPE-2 Phase II completed*** HOPE-Duchenne Phase I/II completed**
CAP-1002	SARS-CoV-2	INSPIRE Phase II enrolling
Exosome-mRNA vaccine	SARS-CoV-2	Preclinical
Engineered Exosomes (RNA delivery)	Monogenic Diseases	Discovery
CDC-Exosomes (CAP-2003)	Duchenne Muscular Dystrophy	IND submitted
Exosome-VLP vaccine	SARS-CoV-2	Preclinical
Engineered Exosomes (biologics delivery)	Evaluating	Discovery

***** 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 currently conducting an OLE 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 and degeneration 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 product candidate, CAP-1002.

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 preclinical models of DMD, we believe that CAP-1002 has the potential to decrease inflammation and slow 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 preclinical 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 2019 and we reported final top-line 12-month results in May 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, our ability to partner with another company to advance the development of CAP-1002 for DMD, and/or our ability to manufacture the product through a contract manufacturer, as well as other factors, some of which are not known at this time. Further, we have submitted a proposed Phase III protocol to the FDA. The size of the proposed Phase III trial is estimated to be approximately 60 patients and in our continuing discussions, FDA has indicated its acceptance of this potential study design.

Phase II HOPE-2 Clinical Trial

HOPE-2 is a randomized, double-blind, placebo-controlled clinical trial which was conducted at multiple sites located in the United States. We randomized 20 patients in our HOPE-2 clinical trial. Approximately 80% of the patients were non-ambulant and all patients were on a stable regimen of steroids. Demographic and baseline characteristics were similar between the two treatment groups. 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 were measured through the Performance of the Upper Limb, or PUL, test. In the HOPE-2 study we have evaluated these through both the PUL 1.2 and 2.0 versions. Although the PUL 1.2 version for the mid-level was the primary endpoint established for the trial, we also conducted an analysis using the PUL 2.0 version as the FDA suggested the use of the updated PUL 2.0 version as the primary efficacy endpoint in support of a Biologics License Application, or BLA. HOPE-2 assessed the mid-level dimension of the PUL which evaluates one's ability to use muscles extending from the elbow to the hand, which muscles 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 were included.

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

In May 2020, we reported final top-line 12-month results. The data showed improvements in upper limb, cardiac and respiratory functions with p-values of less than p=0.05 in multiple measures. The 12-month data showed statistically meaningful improvements in the PUL 2.0 in CAP-1002 treated patients (p=0.05) with a mean change of 2.4 points over placebo patients. We also came very close to significance with the PUL 1.2 mid-level with all the data (p=0.08) with a mean change of 2.8 points over placebo patients. With the exception of steroids, preservation of function in DMD is uncommon. The placebo patients declined consistent with natural history, but in the treated group, most patients were stable or improved throughout the one-year treatment period.

The data also showed global improvements in cardiac function as measured by ejection fraction (p=0.004) and indexed volumes (LVESV, p=0.01, LVEDV p=0.07). These are surrogate measures of cardiac function and are considered significant in terms of relevance to long term outcomes. Additionally, there was also a reduction in the biomarker CK-MB, an enzyme that is only released when there is cardiac muscle cell damage. In normal human subjects, there is typically no CK-MB measurable in the blood. It is well accepted that continuous muscle cell damage in DMD leads to pathologically high enzyme levels associated with cardiac muscle cell loss. In HOPE-2 treatment with CAP-1002 was associated with a reduction in CK-MB levels as compared to placebo (p=0.006). This is the first ever study in DMD that correlates cardiac functional stabilization with reduction of a biomarker of cell damage.

Study Results

12-month Top-Line Efficacy Data:

	12-month Time-point		
	CAP-1002 n=8	**Placebo n=12**	**p-value**
Upper Limb Function			
Mid-level PUL (version 1.2)	-2.1 (3.63)	-4.9 (2.57)	p=0.08
Shoulder + Mid + Distal PUL (version 1.2)	-2.3 (3.86)	-6.4 (3.84)	p=0.03
Shoulder + Mid + Distal PUL (version 2.0)	-1.3 (2.14)	-3.7 (1.50)	p=0.05
Cardiac			
LV Ejection Fraction %	-0.33 (2.01)	-1.89 (2.23)	p=0.004
LV End-Diastolic Volume, Indexed mL/m^2	-7.35 (6.10)	0.00 (7.34)	p=0.07
LV End-Systolic Volume, Indexed mL/m^2	-3.10 (1.68)	1.70 (5.02)	p=0.01
Creatine Kinase-MB (% of total CK)	-0.50 (0.55)	2.00 (1.00)	p=0.006

Mean Change from baseline to 12 months (standard deviation) shown.
ITT (intent to treat) population shown
P-values are nominal values unadjusted for multiple testing
Mixed model repeated measures analysis

Additionally, we are conducting an open-label extension available to all patients who participated in the HOPE-2 study which includes those patients who received

placebo.

Safety

CAP-1002 was generally safe and well tolerated throughout the study. With the exception of hypersensitivity reactions which were mitigated with a common pre-medication regimen, no safety signals were identified in the HOPE-2 trial.

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 the 6-month data from the HOPE-2 trial did not provide substantial evidence of effectiveness to support a future 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.

In a Type B meeting with the FDA in 2020, we focused on the 12-month results from the HOPE-2 trial and discussed next steps and a pathway to approval of a BLA for CAP-1002 in DMD. The FDA has continued to encourage us to conduct a Phase III study; at this time, however, we are still discussing the pathway forward for this program with the FDA and have not initiated a Phase III study.

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-Duchenne 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 incidences 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 in which the serious or life-threatening manifestations primarily affect individuals aged from birth to 18 years and that affects fewer than 200,000 individuals 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. 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, modify, reverse, or cure a serious or life-threatening disease or 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 fast track or 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 SARS-CoV-2

Within the framework of SARS-CoV-2 pathogenesis, multiple pathways known to be CAP-1002 sensitive may serve as therapeutic targets. These targets include pro-inflammatory pathways (TNF-α, interferon γ, IL-1, and IL-6) and anti-inflammatory pathways (regulatory T cells and IL-10) that have been explored with CAP-1002 in preclinical models of myocardial ischemia, myocarditis, heart failure, Duchenne muscular dystrophy and pulmonary hypertension. Given that CAP-1002 polarizes macrophages to an anti-inflammatory (healing) immunomodulatory phenotype, CAP-1002 may subsequently attenuate cytokine storm associated with SARS-CoV-2. Furthermore, as CAP-1002 directly targets cardiac dysfunction, CAP-1002 potentially may also be an important tool in the treatment of the cardiac complications of SARS-CoV-2. We are currently conducting the INSPIRE Phase II clinical trial in patients with a diagnosis of SARS-CoV-2.

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 (the ALLSTAR trial). 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, or the REGRESS trial. Dr. Eduardo Marbán is the named principal investigator under the study. The second trial is known as "Pulmonary Arterial Hypertension treated with Cardiosphere-derived Allogeneic Stem Cells, or the ALPHA trial. 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 was estimated to be approximately $2.1 million over several years. Due to the current COVID-19 pandemic, additional testing in each of the ALPHA and REGRESS trials has been delayed and as a result, purchases of additional doses of CAP-1002 have been delayed.

Exosomes Program

Our exosomes program consists of exosome-based vaccines, engineered exosomes and exosomes derived from CDCs (CAP-2003), all of which are in various stages of development. We have explored the use of our CDC-exosomes in preclinical 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 we have 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 has the ability to deliver defined sets of effector molecules which exert their effects through defined mechanisms of action. We have begun work on our planned expansion of our exosome platform technology that potentially may be used for vaccine development, vesicle mediated protein therapies and treatment of monogenic diseases.

In conjunction with these expansion efforts, we have entered into a Sponsored Research Agreement with JHU pursuant to which researchers in the lab of Dr. Stephen Gould will perform certain research activities in connection with our exosomes program and the further development of the platform.

Exosome-Based Vaccine Platform

We are now working on developing exosome-based vaccines for COVID-19. The 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 are currently designing exosome-based vaccines to elicit strong humoral and cellular immune responses due to the simultaneous expression of antigens.

We are developing two exosome vaccine candidates. The first vaccine candidate is a tripartite exosome-mRNA vaccine which is designed to elicit a protective, long-lasting immune response to SARS-CoV-2 by targeting multiple structural proteins of the virus. Recently, in collaboration with researchers at JHU, we announced positive data from a preclinical study in mice using our exosome-based mRNA vaccine. The key findings of the data include the development of a safe exosome formulation capable of delivering functional mRNA *in vitro* and *in vivo.* Furthermore, the potential vaccine induced both antibody responses and cellular immunity to multiple proteins of SARS-CoV-2.

We recently met with the FDA in a pre-IND meeting and are planning on filing an IND by the third quarter of 2021, subject to regulatory approval, for this vaccine for SARS-CoV-2.

The second candidate is an exosomal antigen vaccine which is a vesicle-based, nucleic acid-free formulation carrying multiple structural proteins of SARS-CoV-2. We continue to assess this technology for potential uses within infectious diseases and potentially other uses.

Furthermore, we recently entered into a non-exclusive license to intellectual property, know-how and data with JHU related to a new imaging-based serology test platform for COVID-19. This platform, which is amenable to a vast array of serology applications, has been applied to the analysis of patient antibodies to multiple SARS-CoV-2 proteins, including spike, nucleocapsid, and membrane. The development of this companion diagnostic allows us to accurately evaluate the effects of our vaccines and therapeutics and we intend to explore the potential for partnership opportunities for this technology.

Engineered Exosomes Platform

Building upon the natural ability of exosomes for intercellular communication, we are focused on engineering exosomes to load them with different macromolecules. We are actively developing an engineered exosomes platform for the delivery of nucleic acids (including mRNA) for a variety of different diseases. In collaboration with researchers at JHU, we recently published data demonstrating exosome-mediated delivery of mRNAs with enhanced expression and lower toxicity compared to lipid nanoparticles. Additionally, we showed functional enzyme expression and real-time imaging of mRNA expression in live animals. Building on this platform, we have promising data for enhanced targeting of exosomes. Our plan is to actively develop this platform for a broad spectrum of diseases.

CDC-Exosomes (CAP-2003)

We have promising preclinical 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 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 one of the leading causes of death in the U.S.

In April 2020, we filed an IND with the FDA to investigate the use of CAP-2003 in patients with DMD. At this time, the FDA has requested more information related to manufacturing and we are evaluating the next steps for this program. We need to submit further information to FDA to support the potential acceptance of this IND.

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, formulations, 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, or patent applications, if issued and upon payment of patent maintenance fees, would expire as early as 2024 and as late as 2041. There are also limited opportunities to obtain extensions of patent terms in certain countries.

Capricor's Technology - CAP-1002 and Exosomes

Capricor has entered into exclusive license agreements for intellectual property rights related to certain cardiac-derived cells with Università Degli Studi Di Roma La Sapienza, or the University of Rome, JHU and CSMC. Capricor has also entered into an exclusive license agreement for intellectual property rights related to exosomes with CSMC and a non-exclusive license agreement with JHU related to the imaging-based serology technology for COVID-19. 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 Agreements

License Agreement for CDCs

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 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, or 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. At this time, it is uncertain as to whether the $250,000 milestone payment will become 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.

License Agreement for Serology Diagnostic

Capricor and JHU entered into a Nonexclusive License Agreement, effective January 6, 2021, or the JHU Serology License Agreement, which provides for the grant of a non-exclusive, world-wide, non-royalty-bearing license by JHU to Capricor to develop and commercialize licensed products under the licensed patent rights for COVID-19.

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.

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, August 5, 2016, December 26, 2017, and June 20, 2018, Capricor and CSMC entered into a number of amendments to the Amended CSMC License Agreement, pursuant to which the parties agreed to add and delete certain patent applications from the list of scheduled patents. Capricor reimbursed CSMC for certain attorneys' fees and filing fees incurred in connection with the 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, June 10, 2015, August 5, 2016, December 26, 2017, June 20, 2018, September 25, 2018, August 19, 2020, and August 28, 2020 Capricor and

CSMC entered into a number of amendments to the Exosomes License Agreement. These amendments added additional patent applications and patent families to the Exosomes License Agreement, added certain defined product development milestone payments, modified certain milestone deadlines, and added certain performance milestones with respect to product candidates covered by certain future patent rights in order to maintain an exclusive license to those future patent rights; failure to meet those milestones would cause CSMC to have the right to convert the license from exclusive to non-exclusive or co-exclusive, or to terminate the license, subject to Capricor's right to license such patent rights for internal research purposes on a non-exclusive basis. These amendments also obligated Capricor to reimburse CSMC for certain attorneys' fees and filing fees in connection with the additional patent applications and patent families.

Sponsored Research Agreement with Johns Hopkins University

On April 1, 2020 we entered into a Sponsored Research Agreement, or the SRA, with JHU pursuant to which researchers in the lab of Dr. Stephen Gould will perform certain research activities in connection with our exosomes program. Pursuant to the SRA, we have agreed to fund certain research activities and will have the right to negotiate for exclusive or non-exclusive rights to intellectual property that may result from such research activities.

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 our exosome products, including our exosome-mRNA vaccine for potential clinical use, 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.

In addition to manufacturing CAP-1002 and our exosome technologies for its own clinical trials, Capricor has agreed to provide CAP-1002 for investigational purposes in two clinical trials sponsored by CSMC. If we are unable to 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 of our exosome products.

We have initiated a technology transfer with Lonza Houston, Inc., a leading global contract manufacturing organization to prepare for commercial or possibly for late-stage clinical manufacturing of CAP-1002. The current activities are focused on process development services for the manufacturing processes and related other activities necessary for potential cGMP readiness.

Manufacturing Process for 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.

Manufacturing Process for CDC-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.

Manufacturing Processes for Other Exosome Technologies

We have also made significant progress planning the next steps for the manufacturing process for our exosome product candidates, including our exosome-mRNA vaccine. We believe these developments will enable us to scale up our manufacturing capabilities and allow us to manufacture enough material for early-stage clinical development. We are exploring the use of various cell sources to generate our exosomes for preclinical and potential clinical use.

Research and Development

Capricor's research and development program has been advanced in part through federal and state grants and loan awards totaling approximately $28 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.

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. This competition is particularly intense and advanced with respect to the development of vaccines for SARS-CoV-2. 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, quality control, approval, labeling, packaging, storage, recordkeeping, serialization and tracking, promotion, advertising, distribution and marketing, post-approval monitoring and reporting, and export and import, 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.

FDA Approval Process for Drugs and Biologics

Pharmaceutical products, including biological 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:

- preclinical 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;
- approval by an IRB at each clinical site before each trial may be initiated;
- 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, for a drug, or BLA, for a biological product;
- satisfactory completion of an FDA advisory committee review, if applicable;
- satisfactory completion of an FDA inspection of the manufacturing facility or facilities at which the drug is produced to assesscompliance 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;
- FDA review and approval of the NDA or BLA prior to any commercial marketing or sale of the drug in the United States; and
- compliance with any post-approval requirements, including the potential requirement to implement a REMS, and the potential requirement to conduct post-approval studies.

Sponsors submit NDAs in order to obtain marketing approval for drugs. Sponsors submit BLAs in order to obtain marketing approval for biologics, which include, among other product classes, vaccines.

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 preclinical testing, which include laboratory evaluation of product chemistry, formulation, toxicity and carcinogenicity 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 a clinical trial can begin. In addition, the FDA or IRB may impose a clinical hold on ongoing clinical trials if, among other things, it believes that a clinical trial either is not being conducted in accordance with FDA requirements or presents an unacceptable and significant risk to clinical trial patients. If the FDA imposes a clinical hold, clinical trials can only proceed under terms authorized by the FDA. If applicable, our preclinical 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, the pattern of drug absorption, distribution and metabolism, the mechanism of action in humans, and may include studies where investigational drugs are used as research to explore biological phenomena or disease processes;
- 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 labeling of the drug.

A therapeutic product candidate being studied in clinical trials may be made available for treatment of individual patients, intermediate-size patient populations, or for widespread treatment use under an expanded access protocol, under certain circumstances. Pursuant to the 21st Century Cures Act (Cures Act), which was signed into law in December 2016, the manufacturer of one or more investigational products for the diagnosis, monitoring, or treatment of one or more serious diseases or conditions 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.

Additionally, on May 30, 2018, the Trickett Wendler, Frank Mongiello, Jordan McLinn, and Matthew Bellina Right to Try Act of 2017 was signed into law. The law, among other things, provides a federal framework for certain patients to access certain investigational new drug products that have completed a Phase 1 clinical trial and that are undergoing investigation for FDA approval. Under certain circumstances, eligible patients can seek treatment without enrolling in clinical trials and without obtaining FDA authorization under an FDA expanded access program; however, manufacturers are not obligated to provide investigational new drug products under the current federal right to try law.

The results of the preclinical 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, or issue a Complete Response Letter, or CRL. 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 substantial additional testing or information. 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.

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 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 candidate 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. Among the other benefits of orphan drug designation are tax credits for certain research and an exemption from the NDA or BLA application fee. 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 such drug 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, for seven years, unless the sponsor of the subsequent application demonstrates clinical superiority, in the form of a greater efficacy, greater safety, or a major contribution to patient care. Orphan drug exclusivity, however, could also block the approval of one of our therapeutic candidates for seven years if a competitor obtains orphan drug designation and FDA approval of the same therapeutic candidate for the same condition or disease as our orphan-designated drug. For macromolecules, FDA considers a drug to be the same drug as an orphan-designated macromolecule if it contains the same principal molecular structural features, but not necessarily all of the same structural features.

In addition, as the FDA has interpreted the Orphan Drug Act, even if a previously approved same drug does not have unexpired orphan exclusivity, a demonstration of clinical superiority is required for a subsequent marketing application for the same orphan-designated drug for the same disease or condition 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 an orphan-designated drug that is otherwise the same as an already approved drug for the same rare disease or condition is seeking orphan exclusivity, FDA shall require such sponsor to demonstrate that such drug is clinically superior to any already approved or licensed drug that is the same drug in order to obtain orphan drug exclusivity. 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 FDA may revoke the Fast Track designation if it believes that the designation is no longer supported by data emerging in the clinical trial process.

Products may also be eligible for other types of FDA programs intended to expedite development and review, such as Breakthrough Therapy designation, 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.

A product is eligible for priority review if it is intended to treat a serious condition and, if approved, it would provide a significant improvement in safety or effectiveness. FDA intends to take action on a priority review marketing application within 6 months of receipt, compared to 10 months of receipt for regular review submissions.

Additionally, a product may be eligible for accelerated approval if it is intended to treat a serious or life-threatening disease or condition and would provide meaningful therapeutic benefit over existing treatments. Eligible products may receive accelerated approval 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 a clinical endpoint that can be measured earlier than irreversible morbidity or mortality and is reasonably likely to predict an effect on irreversible morbidity, mortality, or other clinical benefit. As a condition of approval, the FDA may require that a sponsor of a drug or biological product receiving accelerated approval diligently perform adequate and well-controlled post-marketing clinical studies demonstrating clinical benefit. In addition, the FDA requires as a condition for accelerated approval the submission 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 full 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 December 18, 2020, and approved by December 18, 2022, may receive a voucher.

FDA Emergency Use Authorization

Section 564 of the FDCA allows the FDA to authorize the shipment of drugs, biological products (including vaccines), or medical devices that either lack required approval, licensure, or clearance (unapproved products), or are approved but are to be used for unapproved ways to diagnose, treat, or prevent serious diseases or conditions in the event of an emergency declaration by the HHS Secretary.

On February 4, 2020, HHS Secretary Alex M. Azar II declared a public health emergency for COVID-19, under 21 U.S.C. § 360bbb-3(b)(1), justifying the authorization of emergency use of IVDs for detection and/or diagnosis of COVID-19. This determination was published in the Federal Register on February 7, 2020.

While this emergency declaration is effective, the FDA may authorize the use of an unapproved product or an unapproved use of an approved product if it concludes that:

- an agent referred to in the emergency declaration could cause a serious or life-threatening disease or condition;
- it is reasonable to believe that the authorized product may be effective in diagnosing, treating, or preventing that disease or condition or a serious or life-threatening disease or condition caused by an approved product or a product marketed under an EUA;
- the known and potential benefits of the authorized product, when used for that disease or condition, outweigh known and potential risks, taking into consideration the material threat of agents identified in the emergency declaration;
- there is no adequate, approved, and available alternative to the authorized product for diagnosing, preventing, or treating the relevant disease or condition; or
- any other criteria prescribed by the FDA is satisfied.

To date, FDA has submitted all EUAs it has received for vaccine candidates to treat COVID-19 for advisory committee review prior to issuing an EUA.

Medical products that are granted an EUA are only permitted to commercialize their products under the terms and conditions provided in the authorization. The FDCA authorizes FDA to impose such conditions on an EUA as may be necessary to protect the public health. Consequently, postmarketing requirements will vary across EUAs. In addition, FDA has, on occasion, waived requirements for drugs marketed under an EUA.

Generally, EUAs for unapproved products or unapproved uses of approved products require that manufacturers distribute factsheets for healthcare providers, addressing significant known and potential benefits and risk, and the extent to which benefits and risks are unknown, and the fact that FDA has authorized emergency use; and, distribution of factsheets for recipients of the product, addressing significant known and potential benefits and risk, and the extent to which benefits and risks are unknown, the option to accept or refuse the product, the consequences of refusing, available alternatives, and the fact that FDA has authorized emergency use.

Generally, EUAs for unapproved products and, per FDA’s discretion, EUAs for unapproved uses of approved products, include requirements for adverse event monitoring and reporting, and other recordkeeping and reporting requirements. Note, however, that approved products are already subject to equivalent requirements.

In addition, FDA may include various requirements in an EUA as a matter of discretion as deemed necessary to protect the public health, including restrictions on which entities may distribute the product, and how to perform distribution (including requiring that distribution be limited to government entities), restrictions on who may administer the product, requirements for collection and analysis of safety and effectiveness data, waivers of cGMP, and restrictions applicable to prescription drugs or restricted devices (including advertising and promotion restrictions).

The FDA may revoke an EUA where it is determined that the underlying health emergency no longer exists or warrants such authorization, if the conditions for the issuance of the EUA are no longer met, or if other circumstances make revocation appropriate to protect the public health or safety.

FDA Approval and Regulation of Companion Diagnostics

A therapeutic product may rely upon an *in vitro* companion diagnostic for use in selecting the patients that will be more likely to respond to that therapy. If safe and effective use of a therapeutic depends on an *in vitro* diagnostic, then the FDA generally will require approval or clearance of that diagnostic, known as a companion diagnostic, at the same time that the FDA approves the therapeutic product. In August 2014, the FDA issued final guidance clarifying the requirements that will apply to approval of therapeutic products and *in vitro* companion diagnostics. According to the guidance, for novel drugs, a companion diagnostic device and its corresponding therapeutic should be approved or cleared contemporaneously by the FDA for the use indicated in the therapeutic product’s labeling. In July 2016, the FDA issued a draft guidance intended to assist sponsors of the drug therapeutic and *in vitro* companion diagnostic device on issues related to co-development of the products.

If FDA determines that a companion diagnostic device is essential to the safe and effective use of a novel therapeutic product or indication, FDA generally will not approve the therapeutic product or new therapeutic product indication if the companion diagnostic device is not approved or cleared for that indication. Approval or clearance of the companion diagnostic device will ensure that the device has been adequately evaluated and has adequate performance characteristics in the intended population. The review of any *in vitro* companion diagnostics developed for use with any of our therapeutic products will, therefore, likely involve coordination of review by the FDA’s Center for Drug Evaluation and Research or Center for Biologics Evaluation and Research, as applicable, and the FDA’s Center for Devices and Radiological Health Office of In Vitro Diagnostics Device Evaluation and Safety.

Under the FDCA, *in vitro* diagnostics, including companion diagnostics, are regulated as medical devices. In the United States, the FDCA and its implementing regulations, and other federal and state statutes and regulations govern, among other things, medical device design and development, preclinical and clinical testing, premarket clearance or approval, registration and listing, manufacturing, labeling, storage, advertising and promotion, sales and distribution, export and import, and post-market surveillance. Unless an exemption applies, diagnostic tests require marketing clearance or approval from the FDA prior to commercial distribution. The two primary types of FDA marketing authorization applicable to a medical device are premarket notification, also called 510(k) clearance, and premarket approval, or PMA. The FDA has generally required PMAs for *in vitro* companion diagnostics.

The PMA process, including the gathering of clinical and preclinical data and the submission to and review by the FDA, can take several years or longer. It involves a rigorous premarket review during which the applicant must prepare and provide the FDA with reasonable assurance of the device's safety and effectiveness and information about the device and its components regarding, among other things, device design, manufacturing and labeling. PMA applications are subject to an application fee of $365,657 for most PMAs for fiscal year 2021. In addition, PMAs for certain devices must generally include the results from extensive preclinical and adequate and well-controlled clinical trials to establish the safety and effectiveness of the device for each indication for which FDA approval is sought. In particular, for a diagnostic, a PMA application typically requires data regarding analytical and clinical validation studies. As part of the PMA review, the FDA will typically inspect the manufacturer's facilities for compliance with the Quality System Regulation, or QSR, which imposes elaborate testing, control, documentation and other quality assurance requirements.

PMA approval is not guaranteed, and the FDA may ultimately respond to a PMA submission with a not approvable determination based on deficiencies in the application and require additional clinical trial or other data that may be expensive and time-consuming to generate and that can substantially delay approval. If the FDA's evaluation of the PMA application is favorable, the FDA typically issues an approvable letter requiring the applicant's agreement to specific conditions, such as changes in labeling, or specific additional information, such as submission of final labeling, in order to secure final approval of the PMA. If the FDA's evaluation of the PMA or manufacturing facilities is not favorable, the FDA will deny approval of the PMA or issue a not approvable letter. A not approvable letter will outline the deficiencies in the application and, where practical, will identify what is necessary to make the PMA approvable. The FDA may also determine that additional clinical trials are necessary, in which case the PMA approval may be delayed for several months or years while the trials are conducted and then the data submitted in an amendment to the PMA. If the FDA concludes that the applicable criteria have been met, the FDA will issue a PMA for the approved indications, which can be more limited than those originally sought by the applicant. The PMA can include post-approval conditions that the FDA believes necessary to ensure the safety and effectiveness of the device, including, among other things, restrictions on labeling, promotion, sale and distribution. Once granted, PMA approval may be withdrawn by the FDA if compliance with post approval requirements, conditions of approval or other regulatory standards are not maintained or problems are identified following initial marketing.

After a device is placed on the market, it remains subject to significant regulatory requirements. Medical devices may be marketed only for the uses and indications for which they are cleared or approved. Device manufacturers must also establish registration and device listings with the FDA. A medical device manufacturer's manufacturing processes and those of its suppliers are required to comply with the applicable portions of the QSR, which cover the methods and documentation of the design, testing, production, processes, controls, quality assurance, labeling, packaging and shipping of medical devices. Domestic facility records and manufacturing processes are subject to periodic unscheduled inspections by the FDA. The FDA also may inspect foreign facilities that export products to the U.S.

Post-Approval Requirements

FDA Requirements

Drugs manufactured or distributed pursuant to FDA approvals are subject to pervasive and continuing regulation by the FDA, including, among other things, requirements relating to recordkeeping, periodic reporting, product sampling and distribution, advertising and promotion with the product. After approval, most changes to the approved product, such as adding new indications or other labeling claims, are subject to prior FDA review and approval. There also are continuing, annual user fee requirements for any marketed products and the establishments at which such products are manufactured, as well as new application fees for supplemental applications with clinical data.

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. In addition, drug manufacturers and other entities involved in the manufacture and distribution of approved drugs are required to register their establishments with the FDA and state agencies, and are subject to periodic unannounced inspections by the FDA and these state agencies for compliance with cGMP requirements. Changes to the manufacturing process are strictly regulated and often require prior FDA approval before being implemented. FDA regulations also require investigation and correction of any deviations from cGMP and impose reporting and documentation requirements upon the sponsor and any third-party manufacturers that the sponsor may decide to use. Accordingly, manufacturers must continue to expend time, money, and effort in the area of production and quality control to maintain cGMP compliance.

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. 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.

Once an approval is granted, the FDA may withdraw the approval if compliance with regulatory requirements and standards is not maintained or if problems occur after the product reaches the market. Later discovery of previously unknown problems with a product, including adverse events of unanticipated severity or frequency, or with manufacturing processes, or failure to comply with regulatory requirements, may result in revisions to the approved labeling to add new safety information; imposition of post-market studies or clinical trials to assess new safety risks; or imposition of distribution or other restrictions under a REMS program. Other potential consequences include, among other things:

- restrictions on the marketing or manufacturing of the product, including total or partial suspension of production, complete withdrawal of the product from the market or product recalls;
- fines, warning letters or holds on post-approval clinical trials;
- refusal of the FDA to approve pending NDAs or supplements to approved NDAs, or suspension or revocation of product license approvals;
- product seizure or detention, or refusal to permit the import or export of products; or
- injunctions or the imposition of civil or criminal penalties.

The FDA strictly regulates marketing, labeling, advertising and promotion of products that are placed on the market. Drugs may be promoted only for the approved indications and in accordance with the provisions of the approved labeling. The FDA and other agencies actively enforce the laws and regulations prohibiting the promotion of off label uses, and a company that is found to have improperly promoted off label uses may be subject to significant liability.

In addition, the distribution of prescription drug products is subject to the Prescription Drug Marketing Act (the PDMA) which regulates the distribution of drugs and

drug samples at the federal level, and sets minimum standards for the registration and regulation of drug distributors by the states. Both the PDMA and state laws limit the distribution of prescription drug product samples and impose requirements to ensure accountability in distribution.

Pricing, Coverage and Reimbursement

Significant uncertainty exists as to the coverage and reimbursement status of any of our products, if any when approved. Sales of pharmaceutical products depend, in part, on the availability of sufficient coverage and adequate reimbursement from third-party payors, which include government health programs, such as Medicare, Medicaid, TRICARE, and the Veterans Administration, as well as commercial insurance, and managed healthcare organizations. Prices at which we or our customers seek reimbursement for our therapeutic product candidates can be subject to challenge, reduction, or denial by payors. 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 process for determining whether a payor will provide coverage for a product is typically separate from the process for setting the reimbursement rate that the payor will pay for the product. A payor's decision to provide coverage for a product does not imply that an adequate reimbursement rate will be available. Additionally, in the United States there is no uniform policy among payors for determining coverage or reimbursement. Many third-party payors often rely upon Medicare coverage policy and payment limitations in setting their own coverage and reimbursement policies, but also have their own methods and approval processes. Therefore, coverage and reimbursement for products can differ significantly from payor to payor. One third-party payor's decision to cover a particular medical product or service does not ensure that other payors will also provide coverage for the medical product or service, or will provide coverage at an adequate reimbursement rate. As a result, the coverage determination process will require us to provide scientific and clinical support for the use of our products to each payor separately and will likely be a time-consuming process. If coverage and adequate reimbursement are not available, or are available only at limited levels, successful commercialization of, and obtaining a satisfactory financial return on, any product we develop may not be possible.

Third-party payors are increasingly challenging the price and examining the medical necessity and cost-effectiveness of medical products and services, in addition to their safety and efficacy. In order to obtain coverage and reimbursement for any product that might be approved for marketing, we may need to conduct expensive studies in order to demonstrate the medical necessity and cost-effectiveness of any products, which would be in addition to the costs expended to obtain regulatory approvals. Third-party payors may not consider our product candidates to be medically necessary or cost-effective compared to other available therapies, or payor negotiations may not enable us to maintain price levels sufficient to realize an appropriate return on our investment in drug development. If these third-party payors do not consider our products to be cost-effective compared to other therapies, they may not cover our products once approved as a benefit under their plans or, if they do, the level of reimbursement may not be sufficient to allow us to sell our products on a profitable basis. Decreases in third-party reimbursement for our products once approved or a decision by a third-party payor to not cover our products could reduce or eliminate utilization of our products and have an adverse effect on our sales, results of operations, and financial condition.

Additionally, efforts to contain healthcare costs (including drug prices) has become a priority of federal and state governments. 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 by generic products. There has also been heightened governmental scrutiny recently over the manner in which drug manufacturers set prices for their marketed products, which has 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. We anticipate additional state and federal healthcare reform measures will be adopted in the future. These may include price controls and cost-containment measures, or more restrictive policies in jurisdictions with existing controls and measures, any of which could limit the amounts that federal and state governments will pay for healthcare products and services, and potentially could reduce demand for our products once approved, create additional pricing pressures, or ultimately limit our net revenue and results.

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.

Coverage and reimbursement of our COVID-19 vaccine candidate, which has not yet been granted EUA status, may be subject to unique regulatory policies. Under the ACA preventive care mandate, non-grandfathered group health plans and health insurance coverage offered in the individual or group market typically have at least one year before it must provide first-dollar coverage for a newly issued preventive care requirement or guideline. However, pursuant to the CARES Act, non-grandfathered group health plans and health insurance coverage offered in the individual or group market must cover any qualifying coronavirus preventive service 15 business days after the United States Preventive Services Task Force, or Advisory Committee on Immunization Practices (ACIP) designates such service as preventive. Third-party reimbursement for providers administering any approved COVID-19 vaccine may affect market acceptance of the product. Currently, the CARES Act and its implementing regulations state (i) providers that participate in the CDC COVID-19 Vaccination Program must administer a COVID-19 immunization regardless of an individual's ability to pay or health insurance coverage status, (ii) providers may not seek any reimbursement, including through balance billing, from an immunization recipient, (iii) that coverage is required, without cost-sharing, for the administration of the immunization even if a third party, such as the federal government, pays for the cost of the immunization, and (iv) that private health insurance plans must cover COVID-19 immunizations and their administration even when provided by out-of-network providers for the duration of the public health emergency for COVID-19. There is no guarantee payors will provide coverage and reimbursement for our COVID-19 vaccine, if approved, during or after the termination of the public health emergency, nor can we guarantee that even if coverage is provided, the approved reimbursement amount will be high enough to allow us to establish or maintain pricing sufficient to realize a sufficient return on our investment.

Under the CARES Act and an accompanying interim final rule, Medicare beneficiaries are expected to have coverage for COVID-19 vaccines through Medicare Part B with no cost sharing. Coverage is further expected to apply whether the vaccine receives FDA authorization through an EUA or is licensed under a BLA and will likely extend to employer-sponsored and individual health plans subject to the ACA's preventive services standards. The outcome of current and future clinical trials, as well as the market demand for COVID-19 vaccines may impact patient eligibility and future coverage determinations. It is unclear whether the FDA will approve the administration of our COVID-19 vaccine, and if so if approval will extend to children and adolescents, or if the vaccine will be required to be administered once (i.e. one-time, double dose), annually, or if future booster shots will be required. We cannot predict continued prevalence of COVID-19, whether herd immunity will be achieved which would affect the need for future administration of the vaccine, or whether the vaccine would be effective against future mutations or variants of the SARS-CoV-2 virus. Such factors may impact whether our vaccine, if approved, would be reimbursable under Medicare Part D rather than Part B and if our vaccine, if approved would be excluded from participating in certain federal entitlement programs such as the Vaccines for Children Program.

Other Healthcare Fraud and Abuse Laws

Although we currently do not have any products on the market, our activities, including current and future arrangements with investigators, healthcare professionals, consultants, third-party payors and customers, may be subject to additional healthcare laws, regulations and enforcement by the federal government and by authorities in the states and foreign jurisdictions in which we conduct our business. Such laws include, without limitation, state and federal anti-kickback, fraud and abuse, false claims, privacy and security, price reporting, and physician sunshine laws. Some of our pre-commercial activities also may be subject to some of these laws.

The federal Anti-Kickback Statute prohibits, among other things, any person or entity, including a prescription drug manufacturer or a party acting on its behalf, 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. Several courts have interpreted the statute's intent requirement to mean that if any one purpose of an arrangement involving remuneration is to induce referrals of federal healthcare covered business, the Anti-Kickback Statute has been violated. 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. Violations of the federal Anti-Kickback Statute may result in civil monetary penalties up to $100,000 for each violation, plus up to three times the remuneration involved. Civil penalties for such conduct can further be assessed under the federal False Claims Act. Violations can also result in criminal penalties, including criminal fines of up to $100,000 and imprisonment of up to 10 years. Similarly, violations can result in exclusion from participation in federal and state healthcare programs, including Medicare and Medicaid.

On November 20, 2020, OIG issued two final regulations implementing significant modifications to regulatory safe harbors to the federal Anti-Kickback Statute. The first rule finalized new safe harbors and modified existing safe harbors to promote certain value-based and coordinated care arrangements and reduce regulatory burden, which are scheduled to become effective January 19, 2021. The second rule (the Rebate Rule) created new safe harbor protection, scheduled to become effective January 29, 2021, for certain (i) point-of-sale discounts from pharmaceutical manufacturers to Medicare Part D plans, Medicaid managed care organizations, and their contracted pharmacy benefit managers (PBMs), and (ii) fees for certain services that PBMs provide to pharmaceutical manufacturers. In addition, the Rebate Rule revised the discount safe harbor to exclude from protection price reductions (e.g., rebates) for pharmaceutical products from manufacturers to Part D plans when made directly or indirectly through a PBM, a change that is scheduled to become effective January 1, 2022. The Rebate Rule is intended to create incentives for manufacturers, covered plans, and PBMs to shift from retrospective rebates to point-of-sale discounts, potentially lowering list prices of, and reducing consumers' out-of-pocket costs for, prescription drugs. In a court order filed on January 30, 2021, the Biden Administration agreed to delay the implementation of provisions of the rule that were scheduled to take effect on January 1, 2022 by one year until January 1, 2023 in response to a suit brought by the Pharmaceutical Care Management Association (PCMA) challenging the rule. The postponement does not affect provisions of the rule that were scheduled to take effect prior to January 1, 2022. PMCA's case will be held in abeyance pending the duration of HHS's review of the rule, subject to the continued consent of the parties. We cannot predict the outcome of the Biden Administration's review of the Rebate Rule or the outcome of any subsequent litigation by PMCA. The federal civil False Claims Act, prohibits, among other things, any person or entity from knowingly presenting, or causing to be presented, for payment to, or approval by, federal programs, including Medicare and Medicaid, claims for items or services, including drugs, that are false or fraudulent or not provided as claimed. Persons and entities can be held liable under these laws if they are deemed to "cause" the submission of false or fraudulent claims by, for example, providing inaccurate billing or coding information to customers or promoting a product off-label. In addition, certain of our future activities relating to the reporting of wholesaler or estimated retail prices for our products, the reporting of prices used to calculate Medicaid rebate information, and other information affecting federal, state, and third-party reimbursement for our products, and the sale and marketing of our products, are subject to scrutiny under this law. Penalties for federal civil False Claims Act violations may include up to three times the actual damages sustained by the government, plus mandatory civil penalties of between $11,665 and $23,331 for each separate false claim per false claim or statement for penalties assessed after June 19, 2020 with respect to violations occurring after November 2, 2015 (and penalties of between $5,500 and $11,000 per claim or statement with respect to violations occurring before that date). Other penalties include the potential for exclusion from participation in federal healthcare programs. Additionally, although the federal False Claims Act is a civil statute, False Claims Act violations may also implicate various federal criminal statutes.

There is also the federal criminal False Claims Act, which is similar to the federal civil False Claims Act and imposes criminal liability on those that make or present a false, fictitious or fraudulent claim to the federal government. The Federal Criminal Statute on False Statements Relating to Health Care Matters makes it a crime to knowingly and willfully falsify, conceal, or cover up a material fact, make any materially false, fictitious, or fraudulent statements or representations, or make or use any materially false writing or document knowing the same to contain any materially false, fictitious, or fraudulent statement or entry in connection with the delivery of or payment for healthcare benefits, items, or services.

The Federal Civil Monetary Penalties Law, or the CMPL, authorizes the imposition of substantial monetary penalties against an entity, such as a pharmaceutical manufacturer, that engaged in activities including, among others (1) knowingly presenting, or causing to be presented, a claim for services not provided as claimed or that is otherwise false or fraudulent in any way; (2) arranging for or contracting with an individual or entity that is excluded from participation in federal health care programs to provide items or services reimbursable by a federal health care program; (3) violations of the federal Anti-Kickback Statute; or (4) failing to report and return a known overpayment.

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.

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. Regulatory guidance and obligations continue to evolve. For example, on December 10, 2020, the Office for Civil Rights issued a proposed rule aimed at reducing regulatory burdens that may exist in discouraging coordination of care, among other changes. As HIPAA requirements evolve, we may be required to update our compliance strategies or modify our business processes to comply.

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 instance, the California Consumer Privacy Act (CCPA) became effective on January 1, 2020, giving California residents expanded privacy rights, and requiring businesses provide detailed information about their data practices. The CCPA provides for civil penalties for violations, as well as a private right of action for data breaches that is expected to increase data breach litigation. Although there are limited exemptions for PHI and certain clinical trial data, the CCPA's implementation standards and enforcement practices may increase our compliance costs and legal risks. Additionally, the California Privacy Rights Act (CPRA) was passed in November 2020, and will amend the CCPA beginning in 2023. The CPRA will impose additional data protection obligations on companies doing business in California, including additional consumer rights processes, limitations on data uses, new audit requirements for higher risk data, and opt outs for certain uses of sensitive data. It will also create a new California data protection agency authorized to issue substantive regulations and could result in increased privacy and information security enforcement. Additional state laws are being proposed, and new obligations may continue to arise. Additional compliance investment and potential business process changes may be required to respond to these rapidly changing privacy law landscape. If we fail to comply with existing or new privacy laws and regulations, we could face legal liability from regulatory actions or litigation, as well as reputational damage.

Additionally, the federal Physician Payments Sunshine Act, or the Sunshine Act, created under 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 submit timely, accurately and completely the required information for all payments, transfers of value and ownership or investment interests may result in civil monetary penalties of up to an aggregate of $176,495 per year and up to an aggregate of $1,176,638 per year for "knowing failures." Covered manufacturers are required to submit reports on aggregate payment data to the Secretary of the U.S. Department of Health and Human Services on an annual basis. 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. Many states have similar statutes or regulations to the above federal laws that may be broader in scope and may apply regardless of payor. We may also be subject to state laws that require pharmaceutical companies to comply with the pharmaceutical industry's voluntary compliance guidelines and the relevant compliance guidance promulgated by the federal government, and/or state laws that require drug manufacturers to report information related to payments and other transfers of value to physicians and other healthcare providers, drug pricing or marketing expenditures. These laws may differ from each other in significant ways and may not have the same effect, further complicating compliance efforts. Additionally, to the extent that we have business operations in foreign countries or sell any of our products in foreign countries and jurisdictions, including Japan or the European Union, we may be subject to additional regulation.

Although we do not currently have any products on the market, once our product candidates or clinical trials are covered by federal health care programs, we will be subject to additional healthcare statutory and regulatory requirements and enforcement by the federal and state governments of the jurisdictions in which we conduct our business. Because we intend to commercialize products that could be reimbursed under a federal healthcare program and other governmental healthcare programs, we intend to develop a comprehensive compliance program that establishes internal controls to facilitate adherence to the rules and program requirements to which we will or may become subject. Although the development and implementation of compliance programs designed to establish internal control and facilitate compliance can mitigate the risk of violating these laws, and the subsequent investigation, prosecution, and penalties assessed for violations of these laws, the risks cannot be entirely eliminated.

If our operations are found to be in violation of any of such laws or any other governmental regulations that apply to us, we may be subject, without limitation, to significant civil, criminal and administrative penalties, damages, fines, individual imprisonment, disgorgement, exclusion from participation in federal and state healthcare programs, reputational harm, diminished profits and future earnings, additional oversight and reporting obligations pursuant to a corporate integrity agreement or similar agreement to resolve allegations of non-compliance with applicable laws and regulations, and the curtailment or restructuring of our operations, any of which could adversely affect our ability to operate our business and our financial results.

Additionally, we expect our products, 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, our products 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.

Healthcare Reform

In the United States and foreign jurisdictions, there have been, and we expect there will continue to be, a number of legislative and regulatory changes to healthcare systems that could affect our future results of operations. There have been, and we expect there will continue to be, a number of initiatives at the United States federal and state levels that seek to promote changes in the healthcare system with the stated goals of reducing healthcare costs, improving quality of care, and expanding access.

In the United States, the pharmaceutical industry has been a particular focus of healthcare reform efforts and has been significantly affected by major legislative and regulatory initiatives, including the ACA, which has had, and is expected to continue to have, a significant impact on the healthcare industry. This law was designed to expand access to health insurance coverage for uninsured and underinsured individuals while at the same time containing overall healthcare costs. With regard to pharmaceutical products, among other things, the ACA contains provisions that may potentially affect the profitability of our products, including, for example, increased rebates for products sold to Medicaid programs, extension of Medicaid rebates to Medicaid managed care plans, mandatory discounts for certain products under Medicare Part D, expansion of entities eligible for discounts under the Public Health Service's pharmaceutical pricing program, and a significant annual fee on companies that manufacture or import certain branded prescription drug products. Substantial new provisions affecting compliance have also been enacted, which may affect our business practices with healthcare providers and entities. The framework of the ACA and other healthcare reforms continues to evolve as a result of executive, legislative, regulatory, and administrative developments; in addition, healthcare-related litigation and judicial proceedings contribute to regulatory uncertainty. While Congress has not passed legislation to comprehensively repeal the ACA, the Tax Cuts and Jobs Act included a provision that, effective January 1, 2019, changed to $0 the tax-based shared responsibility payment imposed by ACA on certain individuals who fail to maintain qualifying health coverage for all or part of a year, which is commonly referred to as the "individual mandate." In December 2018, a federal district court in Texas ruled that the individual mandate, with the penalty that was changed to $0 effective January 1, 2019, was unconstitutional and, further, could not be severed from the other provisions of the ACA. As a result, the court ruled that all of the provisions of the ACA were invalid. The Fifth Circuit Court of Appeals affirmed the district court's ruling that the individual mandate was unconstitutional as a result of the amendment changing the penalty amount to $0, but it remanded the case back to the district court for further analysis of whether the individual mandate could be severed from the ACA. The Fifth Circuit's decision was appealed to the Supreme Court of the United States, which granted certiorari on these issues and conducted oral argument in November 2020. The U.S. Supreme Court is expected to issue its decision in 2021. We cannot predict the full impact of this forthcoming decision or other efforts to challenge, repeal, replace, or alter the implementation of the ACA or other healthcare laws, regulations, or reforms.

Other legislative changes have been proposed and adopted since the ACA was enacted. For example, the Budget Control Act of 2011 included reductions to Medicare payments to providers of up to 2% per fiscal year, which went into effect on April 1, 2013 and, due to subsequent legislation, will stay in effect through 2030 unless additional Congressional action is taken, with the exception of a temporary suspension of the payment reduction from May 1, 2020 through December 31, 2020 enacted as part of the Coronavirus Aid, Relief, and Economic Security Act, or the CARES Act. Additionally, the American Taxpayer Relief Act of 2012, among other things, further reduced Medicare payments to several providers and increased the statute of limitations period for the government to recover overpayments to providers from three to five years. Further, effective January 1, 2019, the Bipartisan Budget Act of 2018, among other things, further amended portions of the Social Security Act implemented as part of the ACA to increase from 50% to 70% the point-of-sale discount that pharmaceutical manufacturers participating in the Coverage Gap Discount Program must provide to eligible Medicare Part D beneficiaries during the coverage gap phase of the Part D benefit, commonly referred to as the "donut hole," and to reduce standard beneficiary cost sharing in the coverage gap from 30% to 25% in most Medicare Part D plans. In the future, there may be additional challenges and/or amendments to the ACA. It remains to be seen precisely what any new legislation will provide, when or if it will be enacted, and what impact it may have on the availability and cost of healthcare items and services, including drug products.

In addition, in recent years the pricing and costs of prescription pharmaceuticals has been the subject of considerable discussion in the United States. A number of federal reports and inquiries have focused on these issues, and various legislative and regulatory provisions have been proposed and enacted at the federal and state level that seek to, among other things, bring more transparency to drug pricing, review the relationship between pricing and manufacturer patient programs, reduce the out-of-pocket cost of prescription drugs, and reform government program reimbursement methodologies for drugs. Additionally, on December 21, 2020, Congress passed a $900 billion U.S. coronavirus relief and government appropriations legislation, or the Act, which contains several important new drug price reporting and transparency measures that could result in additional transparency with respect to manufacturers' prescription drug prices. Among other things, the Act includes provisions requiring Medicare Part D prescription drug plan, or the PDP, sponsors and Medicare Advantage organizations, or MAOs, to implement tools to display Medicare Part D prescription drug benefit information in real time and provisions requiring group and health insurance issuers offering health insurance coverage to report information on certain pharmacy benefit and drug costs to the Secretaries of HHS, Labor, and the Treasury.

Further, the incoming Biden Administration and the new Congress may pursue additional and potentially significant changes to the current healthcare laws, regulations, and related guidance. The Biden Administration issued a memorandum on January 20, 2021 (President Biden's inauguration day) that, like similar memoranda issued by prior incoming Administrations, directed federal agencies to take steps to halt, delay, or conduct further review of certain regulatory actions taken by the Trump Administration, such as those that had not taken effect by inauguration day. We cannot predict what regulatory actions the Biden Administration will take as a result of its review. We also cannot predict what other healthcare reforms will ultimately be implemented at the federal or state level or the effect of any future legislation or regulation. Accordingly, we face uncertainties that might result from additional reforms.

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 26 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, 2021, 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, 2021. The lease is terminable by either party upon 90 days' written notice to the other party. The monthly rental payment is $13,073 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. In July 2020, Capricor exercised its option to extend the term of the Facilities Lease for an additional 12-month period through July 31, 2021 with a monthly lease payment of $15,805. The Company has a further option to extend the Facilities Lease with respect to a portion of the leased premises through July 31, 2022 and a monthly lease payment of $10,707. The premises leased from CSMC are located at 8700 Beverly Blvd., Los Angeles, California 90048. At this time, we are actively considering new facilities for our research, development and/or manufacturing activities or the possible extension of our current lease.

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.

Summary Risk Factors

Our business is subject to a number of risks, including risks that may prevent us from achieving our business objectives or may adversely affect our business, clinical

and commercialization activities, the manufacturing of our product candidates, intellectual property, third-party relationships, competition factors, product and environmental liability, and common stock. These risks are discussed more fully below and include, but are not limited to, risks related to:

Risks Related to Our Business

- the COVID-19 pandemic, including its impact on our business and operations;
- substantial additional funding is needed to complete the development of our product candidates;
- the Company has incurred significant losses and may never be profitable;
- the occurrence of security breaches, improper access to or disclosure of our data or user data, and other cyber incidents or undesirable cyber activity related to our, or our third party vendor's systems and data;
- we may not have adequate personnel and may not be able to attract or retain personnel needed to develop our products;

Risks Related to Clinical and Commercialization Activities

- our success depends upon the viability of our product candidates, all of which require regulatory approval to commercialize and we cannot be certain any of them will receive regulatory approval to be commercialized;
- delays in 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;
- our exosome technologies are unproven in their ability to achieve sufficient biological activity or scale in development to date;
- product candidates can fail to meet their efficacy endpoints at any time during the clinical development process, which would likely make them ineligible for becoming commercial products;

Risks Related to the Manufacturing of our Product Candidates

- the manufacturing of our product candidates is heavily reliant on supply chain requirements including the availability of raw materials that are critical for the manufacturing of our product candidates;
- we rely upon third party manufacturers for the expansion of our manufacturing capabilities for later-stage clinical trials and for ultimate commercialization;
- we may not have adequate manufacturing facilities required for any scale-up of manufacturing which may be required in the future;

Risks Related to Our Intellectual Property

- our ability to obtain, maintain, protect, and enforce our intellectual property rights;
- potential challenges to the enforceability or scope of our intellectual property;
- potential claims from third parties that we are infringing their patents or other intellectual property rights;

Risks Related to Our Relationships with Third Parties

- we depend on our relationships with our licensors and collaborators and there is no guarantee that such relationships will continue;

Risks Related to Competitive Factors

- our products will likely face intense competition;
- any of our product candidates for which we receive regulatory approval may not achieve broad market acceptance, which could limit the revenue that we will generate from their sales, if any;

Risks Related to Product and Environmental Liability

- our products may expose us to potential product liability;

Risks Related to Our Common Stock

- we expect that our stock price will continue to fluctuate significantly; and
- we have never paid dividends and we do not anticipate paying dividends in the future.

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 preclinical studies and clinical trials and establishing manufacturing capabilities, is expensive. As of December 31, 2020, we had cash and cash equivalents totaling approximately $32.7 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 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. 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.

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.

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. The 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 CAP-1002 and exosomes programs;
- 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, if applicable;
- 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 preclinical 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 COVID-19 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 preclinical 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 and our exosomes technologies;
- 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 preclinical development.

The Company's 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 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 preclinical studies of our exosomes products will result in a viable clinical development program.

Our business depends entirely on the successful development and commercialization of our product candidates. We currently have no products approved for sale and generate no revenues from sales of any products, and we may never be able to develop a marketable product.

Our product candidates will require additional clinical development, evaluation of clinical, preclinical and manufacturing activities, marketing approval in multiple jurisdictions, substantial investment and significant marketing efforts before we generate any revenues from product sales. We are not permitted to market or promote our product candidates, before we receive marketing approval from the FDA and comparable foreign regulatory authorities, and we may never receive such marketing approvals.

The success of our product candidates will depend on several factors, including the following:

- successful and timely completion of our clinical trials;
- initiation and successful patient enrollment and completion of additional clinical trials on a timely basis;
- the impact of COVID-19 on our operations, ability to conduct clinical trials and on the ability of our regulators to review and approve or authorize our products;
- our ability to demonstrate our products' safety, tolerability and efficacy to the FDA or any comparable foreign regulatory authority for emergency use authorization (EUA) or marketing approval;
- timely receipt of an EUA or marketing approval for our products;
- obtaining and maintaining patent protection, trade secret protection and regulatory exclusivity, both in the United States and internationally;
- successfully defending and enforcing our rights in our intellectual property portfolio;
- avoiding and successfully defending against any claims that we have infringed, misappropriated or otherwise violated any intellectual property of any third party;
- the performance of our current and future collaborators, if any;
- the extent of, and our ability to timely complete, any required post-marketing approval commitments imposed by FDA or other applicable regulatory authorities;
- successfully developing a companion diagnostic test on a timely and cost effective basis, if required;
- establishment of supply arrangements with third-party raw materials and drug product suppliers and manufacturers who are able to manufacture clinical trial and commercial quantities of drug substance and drug product and to develop, validate and maintain a commercially viable manufacturing process that is compliant with current good manufacturing practices, or cGMP, at a scale sufficient to meet anticipated demand and over time enable us to reduce our cost of manufacturing;

- establishment of scaled production arrangements with third-party manufacturers to obtain finished products that are compliant with cGMP and appropriately packaged for sale;
- successful launch of commercial sales following any EUA or marketing approval;
- a continued acceptable safety profile following any EUA or marketing approval;
- commercial acceptance by patients, the medical community and third-party payors;
- the availability of coverage and adequate reimbursement and pricing by third-party payors and government authorities;
- the availability, perceived advantages, relative cost, relative safety and relative efficacy of alternative and competing treatments; and
- our ability to compete with other therapies.

We do not have complete control over many of these factors, including certain aspects of clinical development and the regulatory submission process, potential threats to our intellectual property rights and the manufacturing, marketing, distribution and sales efforts of any future collaborator. Accordingly, we cannot assure you that we will ever be able to generate revenue through the sale of our products. If we are not successful in marketing or commercializing our products, or are significantly delayed in doing so, our business will be materially harmed.

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, the 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.

An epidemic or pandemic disease outbreak, including the 2019 novel coronavirus (COVID-19), could severely disrupt our operations or the operations of third parties that we depend on, including our single third-party contract manufacturer, our CROs, clinical data management organizations, medical institutions and clinical investigators, and have a material adverse effect on our business, results of operations, financial condition and prospects. 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 while cases and hospitalization are currently on the decline in the US, there can be no assurances they will not continue at the current rate or increase in the future especially in light of the number of variants that are emerging across the world. Governments in the United States and elsewhere have taken and are continuing to take severe measures to slow the spread of COVID-19, including requiring that certain businesses 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 and having patients complete their assessments in accordance with the clinical protocol;
- restrictions preventing trial investigators, patients or other critical staff from traveling to our trial sites;
- 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;
- supply chain disruptions, which could have a material adverse effect on the availability or cost of materials for our product candidates; 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.

Additionally, disruptions at the at FDA, the EMA and other regulators, caused by global health concerns, including the COVID-19 pandemic, including delays in inspections of clinical trial or manufacturing sites required as part of the application review process, could result in delays of reviews and approvals of our product candidate or

our proposed clinical trials. For example, in response to the COVID-19 pandemic, on March 10, 2020, the FDA announced its intention to postpone most inspections of foreign manufacturing facilities and products inspections of domestic manufacturing facilities through April 2020. On March 18, 2020, the FDA announced its intention to temporarily postpone routine surveillance inspections of domestic manufacturing facilities and provided guidance regarding the conduct of clinical trials. On July 10, 2020, the FDA announced that it is working toward the goal of restarting on-site inspections it deems to be "mission critical." On August 19, 2020, the FDA published guidance clarifying how it intends to conduct inspections during the COVID-19 pandemic, including how it plans to determine which inspections are "mission-critical." It is unclear how FDA's policies and guidance will impact any inspections of our facilities, including our clinical trial sites. Regulatory authorities outside the United States may adopt similar restrictions or other policy measures in response to the COVID-19 pandemic.

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, as well as the information technology systems and data of our third party vendors, especially if we expand our clinical trials and therefore our databases of patient information. Our or our third party vendors' 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, we intend to defend against and respond to data security incidents, and there can be no assurance that our efforts will prevent breakdowns or breaches in our systems, or adequately contain and mitigate risks from a data security incident, 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 and cybersecurity laws, there can be no assurance that such third parties will comply with applicable laws or regulations. Non-compliance by such vendors or weaknesses in their information security programs may result in liability for us which would have a material adverse effect on our business, financial condition 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 testing, which are referred to as preclinical studies, as well as human testing, 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 preclinical 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 preclinical 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 preclinical 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 preclinical 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 preclinical testing.

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 adversely impacted.

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-based vaccines and therapeutics are novel and unproven therapies which may not gain the acceptance of the public, patients or the medical community. To date, efforts by others 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 potential 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.

Advancing vaccine candidates based on our exosome platform as novel products creates significant challenges for us, including:

- obtaining marketing approval, as obtaining an EUA or regulatory approval of such a vaccine candidate from the FDA or comparable foreign regulatory authorities has never been done before;
- educating medical personnel regarding the potential efficacy and safety benefits, as well as the challenges, of incorporating our product candidates, if approved, into treatment regimens; and
- establishing the sales and marketing capabilities to gain market acceptance, if approved.

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 preclinical studies and having sufficient processes in place in connection with the manufacturing of the 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 late-stage clinical trials, which are complex and subject to strict regulatory oversight.

The Company has limited late-stage 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. The current pandemic has had an impact on the ability to conduct clinical trials due to inabilities to enroll or even get subjects to complete the trials due to lockdowns, reluctance to travel, limitations set by trial sites and other reasons. We cannot predict how long this will exist and while the hospitalization rates and number of cases seem to be on the decline, no assurance it will not revert to prior critical levels. 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 preclinical 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;
- the impact of COVID-19 on patient screening and patient enrollment;
- developing and validating any companion diagnostic to be used in the trial, to the extent we are required to do so;
- patients failing to comply with the clinical trial protocol or dropping out of a trial;
- clinical trial sites failing to comply with the clinical trial protocol or dropping out of a trial;
- addressing any conflicts with new or existing laws or regulations;
- the need to add new clinical trial sites;
- 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;
- obtaining advice from regulatory authorities regarding the statistical analysis plan to be used to evaluate the clinical trial data or other trial design issues;
- 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.

We may experience numerous unforeseen events during, or as a result of, clinical trials that could delay or prevent our ability to receive marketing approval or commercialize our product candidates, including:

- we may receive feedback from regulatory authorities that requires us to modify the design of our clinical trials;
- clinical trials of our product candidates may produce negative or inconclusive results, and we may decide, or regulators may require us, to conduct additional clinical trials or abandon drug development programs;
- the number of patients required for clinical trials of our product candidates may be larger than we anticipate, enrollment in these clinical trials may be slower than we anticipate or participants may drop out of these clinical trials at a higher rate than we anticipate;
- our third-party contractors, including our CROs, may fail to comply with regulatory requirements or meet their contractual obligations to us in a timely manner, or at all;
- we, our investigators, or any of the overseeing IRBs or ethics committees might decide to suspend or terminate clinical trials of our product candidates for various reasons, including non-compliance with regulatory requirements, a finding that our product candidates have undesirable side effects or other unexpected characteristics, or a finding that the participants are being exposed to unacceptable health risks;
- the cost of clinical trials of our product candidates may be greater than we anticipate;
- the supply or quality of our product candidates or other materials necessary to conduct clinical trials of our product candidates may be insufficient or inadequate;
- regulators may revise the requirements for approving our product candidates, or such requirements may not be as we anticipate; and
- any future collaborators that conduct clinical trials may face any of the above issues, and may conduct clinical trials in ways they view as advantageous to them but that are suboptimal for us.

If we are required to conduct additional clinical trials or other testing of our product candidates beyond those that we currently contemplate, if we are unable to successfully complete clinical trials of our product candidates or other testing, if the results of these trials or tests are not positive or are insufficiently positive to support marketing approval, or if there are safety concerns, we may:

- incur unplanned costs;
- be delayed in obtaining marketing approval for our product candidates or not obtain marketing approval at all;
- obtain marketing approval in some countries and not in others;
- obtain marketing approval for indications or patient populations that are narrower or more limited in scope than intended or desired;
- obtain marketing approval subject to significant use or distribution restrictions or with labeling that includes significant safety warnings, including boxed warnings;
- be subject to additional post-marketing testing requirements; or
- have the drug removed from the market after obtaining marketing approval.

Our drug development costs will also increase if we experience delays in testing or marketing approvals. We do not know whether clinical trials will begin as planned, will need to be restructured or will be completed on schedule, or at all. Furthermore, we rely on third-party CROs and clinical trial sites to ensure the proper and timely conduct of our clinical trials, and while we have agreements governing their committed activities, we have limited influence over their actual performance. Significant clinical trial delays also could shorten any periods during which we may have the exclusive right to commercialize our product candidates or allow our competitors to bring drugs to market before we do and impair our ability to successfully commercialize our product candidates and may harm our business and results of operations.

The outcome of preclinical testing and early clinical trials may not be predictive of the success of later clinical trials, interim results of a clinical trial do not necessarily predict final results, and the results of our clinical trials may not satisfy the requirements of the FDA or comparable foreign regulatory authorities.

We currently have no products approved for sale and we cannot guarantee that we will ever have marketable drugs. Clinical failure can occur at any stage of clinical development. Clinical trials may produce negative or inconclusive results, and we or any future collaborators may decide, or regulators may require us, to conduct additional clinical trials or preclinical studies. We will be required to demonstrate with substantial evidence through adequate and well-controlled clinical trials that our product candidates are safe and effective for use in treating specific conditions in order to obtain marketing approvals for their commercial sale. Success in preclinical studies and early-stage clinical trials does not mean that future larger registration clinical trials will be successful because product candidates in later-stage clinical trials may fail to demonstrate safety and efficacy to the satisfaction of the FDA and non-U.S. regulatory authorities despite having progressed through preclinical studies and early-stage clinical trials. Product candidates that have shown promising results in preclinical studies and early-stage clinical trials may still suffer significant setbacks in subsequent registration clinical trials. Additionally, the outcome of preclinical studies and early-stage clinical trials may not be predictive of the success of later-stage clinical trials.

From time to time, we may publish or report interim or preliminary data from our clinical trials, once initiated. Interim or preliminary data from clinical trials that we may conduct may not be indicative of the final results of the trial and are subject to the risk that one or more of the clinical outcomes may materially change as patient enrollment continues and more patient data become available. Interim or preliminary data also remain subject to audit and verification procedures that may result in the final data being materially different from the interim or preliminary data. As a result, interim or preliminary data should be viewed with caution until the final data are available.

In addition, the design of a clinical trial can determine whether its results will support approval of a drug and flaws in the design of a clinical trial may not become apparent until the clinical trial is well advanced. We have limited experience in designing clinical trials and may be unable to design and conduct a clinical trial to support marketing approval. Further, if our product candidates are found to be unsafe or lack efficacy, we will not be able to obtain marketing approval for them and our business would be harmed. A number of companies in the pharmaceutical industry, including those with greater resources and experience than us, have suffered significant setbacks in advanced clinical trials, even after obtaining promising results in preclinical studies and earlier clinical trials.

In some instances, there can be significant variability in safety and efficacy results between different clinical trials of the same product candidate due to numerous factors, including changes in trial protocols, differences in size and type of the patient populations, differences in and adherence to the dosing regimen and other trial protocols and the rate of dropout among clinical trial participants. We do not know whether any clinical trials we may conduct will demonstrate consistent or adequate efficacy and safety sufficient to obtain marketing approval to market our product candidates.

In the event that an adverse safety issue, clinical hold or other adverse finding occurs in one or more of our clinical trials, once initiated, such event could adversely affect our other clinical trials using the same product candidate. Moreover, there is a relatively limited safety data set for product candidates using an exosome platform. An adverse safety issue or other adverse finding in a clinical trial conducted by a third party with a product candidate similar to ours could adversely affect our clinical trials.

Further, our product candidates may not be approved even if they achieve their primary endpoints in Phase 3 clinical trials or registration trials. The FDA or comparable foreign regulatory authorities may disagree with our trial design and our interpretation of data from preclinical studies and clinical trials. In addition, any of these regulatory authorities may change requirements for the approval of a product candidate even after reviewing and providing comments or advice on a protocol for a pivotal clinical trial that has the potential to result in approval by the FDA or comparable foreign regulatory authorities. In addition, any of these regulatory authorities may also approve a product candidate for fewer or more limited indications than we request or may grant approval contingent on the performance of costly post-marketing clinical trials.

In addition, the FDA or other comparable foreign regulatory authorities may not approve the labeling claims that we believe would be necessary or desirable for the successful commercialization of our product candidates.

Before obtaining marketing approvals for the commercial sale of any product candidate for a target indication, we must demonstrate with substantial evidence gathered in preclinical studies and adequate and well-controlled clinical trials, and, with respect to approval in the United States, to the satisfaction of the FDA and elsewhere to the satisfaction of other comparable foreign regulatory authorities, that the product candidate is safe and effective for use for that target indication. There is no assurance that the FDA or other comparable foreign regulatory authorities will consider our future clinical trials to be sufficient to serve as the basis for approval of one of our product candidates for any indication. The FDA and other comparable foreign regulatory authorities retain broad discretion in evaluating the results of our clinical trials and in determining whether the results demonstrate that a product candidate is safe and effective. If we are required to conduct additional clinical trials of a product candidate than we expect prior to its approval, we will need substantial additional funds and there is no assurance that the results of any such additional clinical trials will be sufficient for approval.

The failure to obtain required regulatory clearances or approvals for any companion diagnostic tests that we may pursue may prevent or delay approval of any of our product candidates. Moreover, the commercial success of any of our product candidates that require a companion diagnostic will be tied to the receipt of any required regulatory clearances or approvals and the continued availability of such tests.

In connection with the clinical development of our product candidates for certain indications, we may work with collaborators to develop or obtain access to companion diagnostic tests to identify appropriate patients for our product candidates. We may rely on third parties for the development, testing and manufacturing of these companion diagnostics, the application for and receipt of any required regulatory clearances or approvals, and the commercial supply of these companion diagnostics. The FDA and foreign regulatory authorities regulate companion diagnostics as medical devices that will likely be subject to clinical trials in conjunction with the clinical trials for product candidates, and which will require separate regulatory clearance or approval prior to commercialization. This process could include additional meetings with health authorities, such as a pre-submission meeting and the requirement to submit an investigational device exemption. In the case of a companion diagnostic that is designated as "significant risk device," approval of an investigational device exemption by the FDA and IRB is required before such diagnostic is used in conjunction with the clinical trials for a corresponding product candidate. We or our third-party collaborators may fail to obtain the required regulatory clearances or approvals, which could prevent or delay approval of our product candidates. In addition, the commercial success of any of our product candidates that require a companion diagnostic will be tied to and dependent upon the receipt of required regulatory clearances or approvals and the continued ability of such third parties to make the companion diagnostic commercially available to us on reasonable terms in the relevant geographies.

If we are required to in the future and if we are unable to successfully develop companion diagnostic tests for our product candidates that require such tests, or experience significant delays in doing so, we may not realize the full commercial potential of these product candidates.

We may be required by the FDA to develop, either by ourselves or with collaborators, companion diagnostic tests for our product candidates for certain indications. To be successful, we or our collaborators will need to address a number of scientific, technical, regulatory and logistical challenges. We have no prior experience with medical device or diagnostic test development. If we choose to develop and seek FDA approval for companion diagnostic tests on our own, we will require additional personnel. We may rely on third parties for the design, development and manufacture of companion diagnostic tests for our therapeutic product candidates that require such tests. If these parties are unable to successfully develop companion diagnostics for these therapeutic product candidates, or experience delays in doing so, we may be unable to enroll enough patients for our current and planned clinical trials, the development of these therapeutic product candidates may be adversely affected, these therapeutic product candidates may not obtain marketing approval, and we may not realize the full commercial potential of any of these therapeutics that obtain marketing approval. Any failure to successfully develop this companion diagnostic may cause or contribute to delayed enrollment of this trial, and may prevent us from initiating or completing further clinical trials to support marketing approval for our product candidates. As a result, our business, results of operations and financial condition could be materially harmed.

We may be unsuccessful in adapting our COVID-19 vaccine or developing future versions of our COVID-19 vaccine to protect against variants of the SARS-CoV-2 virus and a market for vaccines against these variants may not develop.

As the pandemic has continued, the SARS-CoV-2 virus continues to evolve, and new strains of the virus or those that are already in circulation may prove more transmissible or cause more severe forms of COVID-19 disease than the predominant strains to date. There is a risk that any vaccine product candidates we develop will not be as effective in protecting against variant strains of the SARS-CoV-2 virus. The failure to adapt our vaccine product candidate to other variants of the SARS-CoV-2 virus could lead to significant reputational harm, in addition to adversely affecting our financial results. It is also possible that we may expend significant resources adapting our COVID-19 vaccine to protect against variants of the SARS-CoV-2 virus, but that a market for this adapted vaccine does not develop or demand does not align with our projections or cost expenditures.

The regulatory pathway for COVID-19 vaccines is continually evolving, and may result in unexpected or unforeseen challenges.

The speed at which all parties are acting to create and test many therapeutics and vaccines for COVID-19 is atypical, and evolving or changing plans or priorities within the FDA or the regulatory authorities in other jurisdictions, including changes based on new knowledge of COVID-19 and how the disease affects the human body, and new variants of the virus, may significantly affect the regulatory timeline for further authorizations or approvals for our COVID vaccine. We cannot anticipate or predict with certainty the timelines or regulatory processes that may be required for the development of ourCOVID-19 vaccine, or vaccines that may be developed to fight against variants of the SARS-CoV-2 virus.

We may not be successful in our efforts to identify or discover additional potential product candidates.

Our research programs may initially show promise in identifying potential product candidates, yet fail to yield product candidates for clinical development for a number of reasons, including:

- the research methodology used may not be successful in identifying potential product candidates;
- potential product candidates may, on further study, be shown to have harmful side effects or other characteristics that indicate that they are unlikely to be drugs that will receive marketing approval and/or achieve market acceptance; and
- potential product candidates may not be safe or effective in treating their targeted diseases.

Research programs to identify new product candidates require substantial technical, financial and human resources. If we are unable to identify suitable compounds for preclinical and clinical development, our business would be harmed.

Negative perception of the efficacy, safety, or tolerability of any investigational medicines that we develop, or of other products similar to products we are developing, such

as mRNA medicines and COVID-19 vaccines, could adversely affect our ability to conduct our business, advance our investigational medicines, or obtain regulatory approvals.

To date, COVID-19 vaccines have only received EUAs in the United States, and FDA has not granted full approval of a BLA for any COVID-19 vaccine. Other than these EUAs, no other mRNA medicines have been granted EUA or have been approved to date by the FDA or any other regulatory agency. Adverse events in clinical trials of our investigational medicines or in clinical trials of others developing similar products, including other mRNA COVID-19 vaccine, and the resulting publicity, as well as any other adverse events in the field of mRNA medicine, or other products that are perceived to be similar to mRNA medicines, such as those related to gene therapy or gene editing, could result in a decrease in the perceived benefit of one or more of our programs, increased regulatory scrutiny, decreased confidence by patients and clinical trial collaborators in our investigational medicines, and less demand for any product that we may develop. If and when they are used in clinical trials, our developmental candidates and investigational medicines could result in a greater quantity of reportable adverse events, including suspected unexpected serious adverse reactions, other reportable negative clinical outcomes, manufacturing reportable events or material clinical events that could lead to clinical delay or hold by the FDA or applicable regulatory authority or other clinical delays, any of which could negatively impact the perception of one or more of our programs, as well as our business as a whole. In addition, responses by U.S., state, or foreign governments to negative public perception may result in new legislation or regulations that could limit our ability to develop any investigational medicines or commercialize any approved products, obtain or maintain regulatory approval, or otherwise achieve profitability. More restrictive statutory regimes, government regulations, or negative public opinion would have an adverse effect on our business, financial condition, results of operations, and prospects and may delay or impair the development of our investigational medicines and commercialization of any approved products or demand for any products we may develop.

If any of our product candidates receives marketing approval or an EUA and we, or others, later discover that the drug is less effective than previously believed or causes undesirable side effects that were not previously identified, our ability, or that of any future collaborators, to market the drug could be compromised.

Clinical trials of our product candidates must be conducted in carefully defined subsets of patients who have agreed to enter into clinical trials. Consequently, it is possible that our clinical trials, or those of any future collaborator, may indicate an apparent positive effect of a product candidate that is greater than the actual positive effect, if any, or alternatively fail to identify undesirable side effects. If one or more of our product candidates receives marketing approval and we, or others, discover that the drug is less effective than previously believed or causes undesirable side effects that were not previously identified, a number of potentially significant negative consequences could result, including:

- regulatory authorities may withdraw their approval of the drug or seize the drug;
- we, or any future collaborators, may be required to recall the drug, change the way the drug is administered or conduct additional clinical trials;
- additional restrictions may be imposed on the marketing of, or the manufacturing processes for, the particular drug;
- we may be subject to fines, injunctions or the imposition of civil or criminal penalties;
- regulatory authorities may require the addition of labeling statements, such as a “black box” warning or a contraindication;
- we, or any future collaborators, may be required to create a Medication Guide outlining the risks of the previously unidentified side effects for distribution to patients;
- we, or any future collaborators, could be sued and held liable for harm caused to patients;
- the drug may become less competitive in the marketplace; and
- our reputation may suffer.

Any of these events could have a material and adverse effect on our operations and business and could adversely impact our stock price.

Even if any of our product candidates receive marketing approval, they may fail to achieve the degree of market acceptance by physicians, patients, healthcare payors and others in the medical community necessary for commercial success.

If any of our product candidates receive marketing approval, they may nonetheless fail to gain sufficient market acceptance by physicians, patients, healthcare payors and others in the medical community. If our product candidates do not achieve an adequate level of acceptance, we may not generate significant revenues from sales of drugs and we may not become profitable. The degree of market acceptance of our product candidates, if approved for commercial sale, will depend on a number of factors, including:

- the efficacy and safety of the product;
- the potential advantages of the product compared to alternative therapies;
- the prevalence and severity of any side effects;
- whether the product is designated under physician and other provider treatment guidelines as a first-, second- or third-line therapy;
- our ability, or the ability of any future collaborators, to offer the product for sale at competitive prices;
- the product’s convenience and ease of administration for patients and healthcare practitioners compared to alternative treatments;
- the willingness of the target patient population to try, and of physicians to prescribe, the product;
- limitations or warnings, including distribution or use restrictions and safety information contained in the product’s approved labeling;
- the strength of sales, marketing and distribution support;
- changes in the standard of care for the targeted indications for the product; and
- the availability of coverage by, and the amount of reimbursement from, government payors, managed care plans and other third-party payors.

We face substantial competition, which may result in others discovering, developing or commercializing products before or more successfully than we do.

The pharmaceutical and biotechnology industries are highly competitive and characterized by rapidly advancing technologies, evolving understanding of disease etiology and a strong emphasis on proprietary drugs. We face competition with respect to any product candidates that we may seek to discover and develop or commercialize in the future, from major pharmaceutical, specialty pharmaceutical and biotechnology companies. Potential competitors also include academic institutions and governmental agencies and public and private research institutions.

Many of the companies that we compete or may compete against in the future have significantly greater financial resources and expertise in research and development, manufacturing, preclinical testing, conducting clinical trials, obtaining regulatory approvals and marketing approved drugs than we do. Small or early-stage companies may also prove to be significant competitors, particularly through collaborative arrangements with large and established companies. These competitors also compete with us in recruiting and retaining qualified scientific and management personnel and establishing clinical trial sites and patient registration for clinical trials, as well as in acquiring technologies complementary to, or that may be necessary for, our programs.

Our commercial opportunity could be reduced or eliminated if our competitors develop and commercialize drugs that are safer, more effective, have fewer or less severe side effects, are more convenient or are less expensive than any drugs that we may develop. Our competitors also may obtain FDA or other comparable foreign regulatory approval for their drugs more rapidly than we may obtain approval for ours, which could result in our competitors establishing a strong market position before we are able to enter the market. The key competitive factors affecting the success of all of our product candidates, if approved, are likely to be their efficacy, safety, convenience, price, the effectiveness of companion diagnostics in guiding the use of related therapeutics, the level of generic competition and the availability of reimbursement from government and other third-party payors.

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 define “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 December 18, 2020, and approved by December 18, 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.

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. 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, preclinical 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 FDA 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. The term remuneration has been broadly interpreted to include anything of value. The Patient Protection and Affordable Care Act, as amended by the Health Care and Education Reconciliation Act of 2010, or collectively the Affordable Care Act, or the ACA, among other things, amended the intent requirement of the federal Anti-Kickback Statute to clarify that a person or entity need not have actual knowledge of this statute or specific intent to violate it. The Anti-Kickback Statute applies to arrangements between pharmaceutical manufacturers on the one hand and individuals, such as healthcare providers and prescribers, patients, purchasers, pharmacy benefit managers, group purchasing organizations, third-party payors, wholesalers and distributors on the other hand, including, for example, consulting/speaking arrangements, discount and rebate offers, certain pricing arrangements, grants, charitable contributions, and patient support offerings, among others. Although 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. Practices that involve remuneration that may be alleged to be intended to induce prescribing, purchases or recommendations may be subject to scrutiny if they do not qualify for an exception or safe harbor. Violations of the federal Anti-Kickback Statute may result in significant civil monetary penalties for each violation, plus up to three times the remuneration involved. Civil penalties for such conduct can further be assessed under the federal False Claims Act. Violations can also result in criminal penalties, including criminal fines and imprisonment. Similarly, violations can result in exclusion from participation in government healthcare programs, including Medicare and Medicaid;

- the federal False Claims Act imposes 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, knowingly making, using or causing to be made or used, a false record or statement material to a false or fraudulent claim, or knowingly making or causing to be made, 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 or services resulting from a violation of the federal Anti-Kickback Statute constitutes a false or fraudulent claim for purposes of the False Claims Act. When an entity is determined to have violated the federal civil False Claims Act, the government may impose significant civil fines and penalties for each false claim, plus treble damages, and exclude the entity from participation in Medicare, Medicaid and other federal healthcare programs. As a result of a modification made by the Fraud Enforcement and Recovery Act of 2009, a claim includes “any request or demand” for money or property presented to the U.S. government. In addition, manufacturers can be held liable under the federal False Claims Act even when they do not submit claims directly to government payors if they are deemed to “cause” the submission of false or fraudulent claims

- the Federal Criminal Statute on False Statements Relating to Health Care Matters makes it a crime to knowingly and willfully falsify, conceal, or cover up a material fact, make any materially false, fictitious, or fraudulent statements or representations, or make or use any materially false writing or document knowing the same to contain any materially false, fictitious, or fraudulent statement or entry in connection with the delivery of or payment for healthcare benefits, items, or services;

- the Federal Civil Monetary Penalties Law authorizes the imposition of substantial civil monetary penalties against an entity, such as a pharmaceutical manufacturer, that engages in activities including, among others (1) knowingly presenting, or causing to be presented, a claim for services not provided as claimed or that is otherwise false or fraudulent in any way; (2) arranging for or contracting with an individual or entity that is excluded from participation in federal health care programs to provide items or services reimbursable by a federal health care program; (3) violations of the federal Anti-Kickback Statute; or (4) failing to report and return a known overpayment;

- 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 Payments Sunshine Act, which requires certain manufacturers of drugs, devices, biologics, and medical supplies for which payment is available under Medicare, Medicaid or the Children's Health Insurance Program (with certain exceptions) to report annually to the government information related to payments or other "transfers of value" made to, at the request of, or on behalf of "covered recipients," which include physicians, certain other healthcare providers, and teaching hospitals, and requires applicable manufacturers and group purchasing organizations to report annually to the government ownership and investment interests held by physicians and their immediate family members; 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.

Efforts to ensure that our current and future 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 significant penalties, including the imposition of civil, criminal or administrative penalties, monetary fines, damages, disgorgement, individual imprisonment, 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. If our operations are found to be in violation of any of these or any other health regulatory laws that may apply to us, we may be subject to significant penalties, including the imposition of significant civil, criminal and administrative penalties, damages, monetary fines, disgorgement, individual imprisonment, possible exclusion from participation in Medicare, Medicaid and other federal healthcare programs or similar programs in other countries or jurisdictions, contractual damages, reputational harm, diminished profits and future earnings, additional reporting requirements and oversight if we become subject to a corporate integrity agreement or similar agreement and curtailment or restructuring of our operations, any of which could adversely impact our ability to operate our business and our results of operations.

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, even the mere issuance of a subpoena or the fact of an investigation alone, regardless of the merit, could result in negative publicity, a drop in our share price, or other harm to our business, financial condition and results of operations. Defending against any such actions 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.

There have been, and continue to be, several legislative and regulatory changes and proposed changes regarding the healthcare system that could prevent or delay marketing approval of product candidates, restrict or regulate post approval activities and affect our ability to profitably sell any product candidates for which we obtain marketing approval. Among policy makers and payors in the United States there is significant interest in promoting changes in healthcare systems with the stated goals of containing healthcare costs, improving quality and/or expanding access and the pharmaceutical industry has been a particular focus of these efforts and has been significantly affected by major legislative initiatives. 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.

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.

The ACA substantially changed the way healthcare is financed by both the government and private insurers, and significantly impacts the U.S. pharmaceutical industry. The ACA, among other things: (1) introduced a new average manufacturer price definition for drugs and biologics that are inhaled, infused, instilled, implanted or injected and not generally dispensed through retail community pharmacies; (2) increased the minimum Medicaid rebates owed by manufacturers under the Medicaid Drug Rebate Program, or MDRP; (3) established a branded prescription drug fee that pharmaceutical manufacturers of branded prescription drugs must pay to the federal government; (4) expanded the list of covered entities eligible to participate in the 340B drug pricing program by adding new entities to the program; (5) established a new Medicare Part D coverage gap discount program, in which manufacturers must agree to offer point-of-sale discounts (which through subsequent legislative amendments, was increased to 70% from 50% starting in 2019) off negotiated prices of applicable branded drugs to eligible beneficiaries during their coverage gap period, as a condition for the manufacturer's outpatient drugs to be covered under Medicare Part D; (6) extended manufacturers' MDRP rebate liability to covered drugs dispensed to individuals who are enrolled in Medicaid managed care organizations; (7) expanded eligibility criteria for Medicaid programs by, among other things, allowing states to offer Medicaid coverage to additional individuals, including individuals with income at or below 133% of the federal poverty level, thereby potentially increasing manufacturers' Medicaid rebate liabilities; (8) created a licensure framework for follow-on biologic products; and (9) established a Center for Medicare and Medicaid Innovation at the Centers for Medicare and Medicaid Services to test innovative payment and service delivery models to improve patient care and lower costs.

The framework of the ACA and other healthcare reforms continues to evolve as a result of executive, legislative, regulatory, and administrative developments; in addition, healthcare-related litigation and judicial proceedings contribute to regulatory uncertainty. While Congress has not passed legislation to comprehensively repeal the ACA, the Tax Cuts and Jobs Act of 2017, included a provision that, effective January 1, 2019, changed to $0 the tax-based shared responsibility payment imposed by the ACA on certain individuals who fail to maintain qualifying health coverage for all or part of a year, which is commonly referred to as the "individual mandate." In December 2018, a federal district court in Texas ruled that the individual mandate, with the penalty that was changed to $0 effective January 1, 2019, was unconstitutional and, further, could not be severed from the other provisions of the ACA. As a result, the court ruled that all of the provisions of the ACA were invalid. The Fifth Circuit Court of Appeals affirmed the district court's ruling that the individual mandate was unconstitutional as a result of the amendment changing the penalty amount to $0, but it remanded the case back to the district court for further analysis of whether the individual mandate could be severed from the ACA. The Fifth Circuit's decision was appealed to the Supreme Court of the United States, which granted certiorari on these issues and conducted oral argument in November 2020. The U.S. Supreme Court is expected to issue its decision in 2021. We cannot predict the full impact of this forthcoming decision or other efforts to challenge, repeal, replace, or alter the implementation of the ACA or other healthcare laws, regulations, or reforms.

Other legislative changes have been proposed and adopted since the ACA was enacted. These changes include aggregate reductions to Medicare payments to providers of 2% per fiscal year pursuant to the Budget Control Act of 2011 and subsequent laws, which began in 2013 and will remain in effect through 2030, with the exception of a temporary suspension from May 1, 2020 through March 31, 2021 enacted as part of the Coronavirus Aid, Relief, and Economic Security, or the CARES Act, unless additional Congressional action is taken. Additionally, the American Taxpayer Relief Act of 2012, among other things, further reduced Medicare payments to several types of providers, including hospitals, imaging centers and cancer treatment centers, and increased the statute of limitations period for the government to recover overpayments to providers from three to five years. New laws may result in additional reductions in Medicare and other healthcare funding, which may materially adversely affect customer demand and affordability for our products and, accordingly, the results of our financial operations.

In addition, effective January 1, 2019, the Bipartisan Budget Act of 2018, among other things, further amended portions of the Social Security Act implemented as part of the ACA to increase from 50% to 70% the point-of-sale discount that pharmaceutical manufacturers participating in the Coverage Gap Discount Program must provide to eligible Medicare Part D beneficiaries during the coverage gap phase of the Part D benefit, commonly referred to as the "donut hole," and to reduce standard beneficiary cost sharing in the coverage gap from 30% to 25% in most Medicare Part D plans. In the future, there may be additional challenges and/or amendments to the ACA. It remains to be seen precisely what any new legislation will provide, when or if it will be enacted, and what impact it will have on the availability and cost of healthcare items and services, including drug products.

In addition, in recent years the pricing and costs of prescription pharmaceuticals has been the subject of considerable discussion in the United States. A number of federal reports and inquiries have focused on these issues, and various legislative and regulatory provisions have been proposed and enacted at the federal and state level that

seek to bring more transparency to product pricing, reduce the cost of prescription drugs under Medicare, review the relationship between pricing and manufacturer patient programs, and reform government program reimbursement methodologies for drug products. On December 21, 2020, Congress passed a $900 billion U.S. coronavirus relief and government appropriations legislation, or the Act, which contains several important new drug price reporting and transparency measures that could result in additional transparency with respect to manufacturers' prescription drug prices. Among other things, the Act includes provisions requiring Medicare Part D prescription drug plan, or PDP, sponsors and Medicare Advantage organizations, or MAOs, to implement tools to display Medicare Part D prescription drug benefit information in real time and provisions requiring group and health insurance issuers offering health insurance coverage to report information on certain pharmacy benefit and drug costs to the Secretaries of HHS, Labor, and the Treasury. 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.

Further, the Biden Administration and the new Congress may pursue additional and potentially significant changes to the current healthcare laws, regulations, and related guidance. The Biden Administration issued a memorandum on January 20, 2021 (President Biden's inauguration day) that, like similar memoranda issued by prior incoming Administrations, directed federal agencies to take steps to halt, delay, or conduct further review of certain regulatory actions taken by the Trump Administration, such as those that had not taken effect by inauguration day. The Biden Administration's review is ongoing and we cannot predict which regulatory actions it may or may not affect. We also cannot predict what other healthcare reforms will ultimately be implemented at the federal or state level or the effect of any future legislation or regulation and, accordingly, face uncertainties that might result from additional reforms.

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. For example, as a result of the Budge Control Act of 2011, the Bipartisan Budget Act, or BBA, and the CARES Act, an annual 2% reduction to Medicare payments took effect on April 1, 2013, and has been extended through 2030 (though the reduction was temporarily suspended from May 1, 2020 through March 31, 2021 in connection with COVID-19 relief related legislation). 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 preclinical 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 Biden'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 developing 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, including mRNA 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 exosome technologies, including our exosome-mRNA vaccine, 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 technologies. Currently, our Facilities Lease pertaining to our research and development facility is scheduled to expire on July 31, 2021. We have an additional 1-year option enabling us to extend the term of our Facilities Lease to July 31, 2022. There can be no assurance that the Facilities Lease for the manufacturing space will be continued beyond July 31, 2022. If the Facilities Lease with CSMC is terminated or expires, we would have to secure alternative facilities in which to manufacture our products, which would involve a significant monetary investment and would negatively impact the progress of our clinical trials and regulatory approvals. At this time, we are actively considering new facilities for our research, development and/or manufacturing activities or the possible extension of our current lease.

If we were to initiate a Phase III study for DMD, 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, it may result in delays and significant expenses which would have a negative impact on our business and product development.

In 2020, we initiated a technology transfer with Lonza Houston, Inc., a leading global contract manufacturing organization to prepare for commercial or possibly late-stage clinical manufacturing of CAP-1002.

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, HOPE-Duchenne, HOPE-2, and INSPIRE clinical trials, and the ongoing CSMC trials. Our experience in the manufacturing of exosomes is limited to producing product for preclinical 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 in the early stages of technology transfer of our CAP-1002 product with Lonza Houston, Inc. We can provide no assurances that they will be able to meet product demand for potential late-stage clinical trials or commercial use.

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 exosome technologies, 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 exosome technologies for commercial purposes. While we plan to potentially 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 on a large or commercial scale basis are limited. In 2020, we initiated a technology transfer with Lonza Houston, Inc., to prepare for commercial or possibly late-stage clinical manufacturing of CAP-1002. Additionally, if the field of mRNA and other nucleic acid medicines continues to expand, we may encounter increasing competition for these supplies, materials and services. Demand for third-party manufacturing or testing facilities may grow at a faster rate than their existing capacity, which could disrupt our ability to find and retain third-party manufacturers capable of producing sufficient quantities of such raw materials, components, parts, and consumables required to manufacture our exosome-based RNA products. 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, FDA may also exercise oversight over manufacturing facilities for products authorized under an EUA.
- 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.
- Our contract manufacturers may elect to terminate our agreements with them.
- 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 certain 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.

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. 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. 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) and Dr. Stephen Gould (Johns Hopkins University) 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 or research 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 were made to Capricor, subject to annual and quarterly reporting requirements. The Company utilized approximately $2.3 million of the $2.4 million under the terms of the award. We are currently completing all close-out documentation associated with this award.

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

Risks Related to Competitive Factors

Our products will likely face intense competition.

The Company is engaged in fields that are characterized by extensive worldwide research and competition by pharmaceutical companies, medical device companies, specialized biotechnology companies, hospitals, physicians and academic institutions, both in the United States and abroad. We will experience intense competition with respect

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

Our future success will depend in part on our ability to maintain a competitive position with respect to evolving therapies as well as other novel technologies. 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.

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.

We have also developed a close working relationship between the academic lab of Dr. Stephen Gould at Johns Hopkins University 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 would be owned by JHU or by the Company, although if owned by JHU, the Company may have rights to that intellectual property under the terms of its license and research agreements with JHU.

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 development of a potential vaccine for COVID-19 is at an early stage and is subject to significant risks.

Our development of a COVID-19 vaccine is in early stages, and we may be unable to produce a vaccine that successfully treats the virus in a timely manner, if at all. Even if we are able to successfully develop and obtain regulatory approval for a COVID-19 vaccine, if the outbreak is effectively contained or the risk of coronavirus infection is diminished or eliminated before we can successfully develop and manufacture our vaccine, we may not be able to generate product revenues from the vaccine. Additionally, a number of pharmaceutical companies have already obtained regulatory approval for COVID-19 vaccines, and other companies with significantly more resources than us are developing COVID-19 vaccines. Even if we are able to successfully develop and obtain regulatory approval for a COVID-19 vaccine, vaccines produced by these other companies may be superior to our vaccine. Even if a vaccine that we develop is not inferior to other available vaccines, it could be difficult to obtain market acceptance. We are committing financial resources and personnel to the development of a COVID-19 vaccine which may cause delays in or otherwise negatively impact our other development programs, despite uncertainties surrounding the longevity and extent of coronavirus as a global health concern. Our business could be negatively impacted by our allocation of significant resources to a global health threat that is unpredictable and could rapidly dissipate or against which our vaccine, if developed, may not be partially or fully effective, or for which better vaccine options may be available.

Even if our product candidates are approved, 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 the United States, no uniform policy of coverage and reimbursement for products exists among third-party payors. Many third-party payors often rely upon Medicare coverage policy and payment limitations in setting their own coverage and reimbursement policies, but also have their own methods and approval processes to decide which drugs they will pay for and establish reimbursement levels. Coverage decisions may depend upon clinical and economic standards that disfavor new drug products when more established or lower cost therapeutic alternatives are already available or subsequently become available. If any of our product candidates fail to demonstrate attractive efficacy profiles, they may not qualify for coverage and reimbursement. However, decisions regarding the extent of coverage and amount of reimbursement to be provided for any product candidates that we develop through approval will be made on a plan-by-plan basis. One payor's determination to provide coverage for a product does not assure that other payors will also provide coverage and adequate reimbursement for the product. As a result, the coverage determination process will require us to provide scientific and clinical support for the use of our products to each payor separately and will likely be a time-consuming process. Each plan determines whether or not it will provide coverage for a drug, what amount it will pay for the drug, the applicable formulary tier, and whether to require step therapy or other utilization management controls. Such decisions can strongly influence the adoption of a drug by patients and physicians. Patients who are prescribed treatments for their conditions and treating healthcare providers generally rely on third-party payors to reimburse all or part of the associated healthcare costs. Patients may be unlikely to use and prescribers unlikely to prescribe our products unless adequate coverage is provided and reimbursement are available.

Additionally, a third-party payor's decision to provide coverage for a drug does not imply that an adequate reimbursement rate will be approved. The process for determining whether a third-party payor will provide coverage for a product may be separate from the process for setting the price of a product or for establishing the reimbursement rate that such a payor will pay for the product. Third-party payors, such as government or private healthcare insurers, carefully review and increasingly question the coverage of, and challenge the prices charged for, drug products. A primary trend in the U.S. healthcare industry and elsewhere is cost containment. Government authorities and third-party payors have attempted to control costs by limiting coverage and the amount of reimbursement for particular medications. Increasingly, third-party payors are requiring that pharmaceutical companies provide them with predetermined discounts from list prices and are challenging the prices charged for products. We may also be required to conduct expensive pharmacoeconomic studies to justify the coverage and the amount of reimbursement for particular medications. We cannot be sure that coverage and reimbursement will be available for any product that we commercialize and, if reimbursement is available, what the level of reimbursement will be. Inadequate coverage or reimbursement may impact the demand for, or the price of, any product for which we obtain marketing approval. If coverage and adequate reimbursement are not available, or are available only to limited levels, we may not be able to successfully commercialize any product candidates that we develop.

Further, there have been a number of legislative and regulatory proposals to change the healthcare system that could affect our ability to sell any future drugs

profitably. 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 by generic products. We anticipate additional state and federal healthcare reform measures will be adopted in the future. These may include price controls and cost-containment measures, or more restrictive policies in jurisdictions with existing controls and measures, any of which could limit the amounts that federal and state governments will pay for healthcare products and services, and potentially could reduce demand for our products once approved, create additional pricing pressures, or ultimately limit our net revenue and results. There can be no assurance that any of our product candidates, if approved, will be considered medically reasonable and necessary, that they will be considered cost-effective by third-party payors, that coverage or an adequate level of reimbursement will be available, or that reimbursement policies and practices in the United States and in foreign countries where our products are sold will not harm our ability to sell our product candidates profitably, if they are approved for sale.

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.

In addition, our clinical trial agreements and most agreements with third-party vendors contain indemnification obligations requiring us to indemnify them from any losses and claims that may be brought in connection with their provision of services, testing, manufacture or other activities in connection with the use of our products.

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 and maintaining new strategic alliances or with existing alliances or collaborators;
- failure to satisfy licensing obligations, including our ability to meet milestone requirements under our license agreements;
- 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.

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, 2020, there were approximately 20.6 million shares of common stock outstanding and approximately 0.1 million common warrants outstanding, as well as outstanding awards to purchase approximately 2.4 million shares of common stock under various incentive stock plans of the Company. Additionally, as of December 31, 2020, there were approximately 1.0 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 is 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, 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 our business plans are not successful, our stockholders may lose their entire investment in us.

We may be at risk of securities class action litigation or litigation initiated by individual stockholders.

We may be at risk of securities class action litigation or litigation initiated by individual stockholders. 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, maintaining Board diversity 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. 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.

If we fail to comply with California laws governing the diversity of corporate boards of directors, we could be fined by the California Secretary of State.

In September 2018, California Governor Jerry Brown signed into law Senate Bill 826, or SB 826, which generally requires public companies with principal executive offices in California to have a minimum number of females on the company's board of directors. As of December 31, 2019, each public company with principal executive offices in California was required to have at least one female on its board of directors. By December 31, 2021, each public company will be required to have at least two females on its board of directors if the company has at least five directors, and at least three females on its board of directors if the company has at least six directors.

Additionally, on September 30, 2020, California Governor Gavin Newsom signed into law Assembly Bill 979, or AB 979, which generally requires public companies with principal executive offices in California to include specified numbers of directors from "underrepresented communities." A director from an "underrepresented community" means a director who self-identifies as Black, African American, Hispanic, Latino, Asian, Pacific Islander, Native American, Native Hawaiian, Alaska Native, gay, lesbian, bisexual or transgender. By December 31, 2021, each public company with principal executive offices in California is required to have at least one director from an underrepresented community. By December 31, 2022, a public company with more than four but fewer than nine directors will be required to have a minimum of two directors from underrepresented communities, and a public company with nine or more directors will need to have a minimum of three directors from underrepresented communities.

Our board of directors includes one female director, and no directors from an "underrepresented community." If we do not add at least one female director and at least one director from an "underrepresented community" to our board of directors prior to December 31, 2021, we would be out of compliance with SB 826 or AB 979, respectively. An initial violation of either law can result in a fine from the California Secretary of State in the amount of $100,000, with each subsequent violation resulting in a fine of $300,000.

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, 2021, 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, 2021. The lease is terminable by either party upon 90 days' written notice to the other party. The monthly rental payment is $13,073 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. In July 2020, Capricor exercised its option to extend the term of the Facilities Lease for an additional 12-month period through July 31, 2021 with a monthly lease payment of $15,805. The Company has a further option to extend the Facilities Lease with respect to a portion of the leased premises through July 31, 2022 and a monthly lease payment of $10,707. At this time, we are actively considering new facilities for our research, development and/or manufacturing activities or the possible extension of our current lease. 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, 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
Year ended December 31, 2020		
First Quarter	$ 2.02	$ 0.94
Second Quarter	8.50	1.00
Third Quarter	9.81	4.08
Fourth Quarter	5.23	3.70

Holders

According to the records of our transfer agent, American Stock Transfer & Trust Company, as of March 12, 2021, we had 138 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 2021 Annual Meeting of Stockholders, to be filed with the SEC within 120 days after the end of the fiscal year ended December 31, 2020, 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

Not applicable.

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.

Company Overview

Capricor Therapeutics, Inc. is a biotechnology company focused on the development oftransformative cell- and exosome-based therapeutics for the treatment and prevention of a broad spectrum of diseases.

Cell Therapy (CAP-1002) Program

CAP-1002 - Duchenne Muscular Dystrophy Program

We have completed HOPE-2, a Phase II clinical trial in the United States with our product candidate, CAP-1002, a cardiac cell derived therapy which was used to treat patients with late-stage Duchenne muscular dystrophy, or DMD. The 12-month final top-line data showed improvements in multiple measures of upper limb, cardiac and respiratory functions. Following receipt of the 12-month data, we discussed this program with the FDA in a Type B meeting focusing on the data, next steps and a pathway to approval of a Biologics License Application, or BLA, for CAP-1002 in DMD. The FDA has continued to encourage us to conduct a Phase III study; at this time, however, we are still discussing the pathway forward for this program with the FDA and have not initiated a Phase III study. Additionally, we are actively seeking partners for this program.

CAP-1002 - COVID-19 Program

In 2020, under an Expanded Access (or Compassionate Use) program, seven patients hospitalized with severe COVID-19 (also referred to sometimes as SARS-CoV-2) symptoms, six of whom were ventilated, were treated with CAP-1002. Four of the seven patients were fully discharged and three died between one- and two-months post-treatment. Previously published data has shown that COVID-19 patients on ventilators experience higher mortality rates. While we are unable to definitively ascertain whether CAP-1002 improved patient outcomes, by analyzing blood samples and other tests, it was determined that CAP-1002 was associated with identifiable improvements in certain patients such as a decrease in white blood cell count, a decrease in IL-6, a decrease in C-reactive protein, and/or reduced reliance on supplemental oxygen. However, the efficacy of CAP-1002 in treating COVID-19 was not demonstrated due to the small sample size, the fact that seven patients were contemporaneously on other experimental medications, and the lack of an established control group, among other factors.

In August 2020, we received FDA acceptance of our IND application for a clinical study of CAP-1002 in patients with severe or critical COVID-19. The INSPIRE trial is a Phase II, randomized, double-blind, placebo-controlled study that is enrolling up to 60 patients from several trial sites in the United States. The study is enrolling patients who have a diagnosis of SARS-CoV-2 and require supplemental oxygen. Various outcome measures will be analyzed including, but not limited to, safety, cytokine biomarkers, all-cause mortality, cardiac biomarkers and hospitalization length. We expect to have top-line data available in the third quarter of 2021. Following receipt of this data, we will discuss next steps for the program with FDA. Additionally, we are actively seeking partners for this program.

Exosomes Program

Exosome-Based Vaccines

We are currently engaged in the development of two vaccine candidates for the potential prevention of COVID-19.The first vaccine candidate is a tripartite exosome-mRNA vaccine which is designed to elicit a protective, long-lasting immune response to SARS-CoV-2 by targeting multiple structural proteins of the virus. In December 2020, we announced positive preclinical data from a study using our exosome-mRNA vaccine approach We recently met with the FDA in a pre-IND meeting and are planning on filing an IND by the third quarter of 2021, subject to regulatory approval, for this vaccine for SARS-CoV-2. We have also been investigating an exosomal antigen vaccine which is a vesicle-based, nucleic acid-free formulation carrying multiple structural proteins of SARS-CoV-2.

Exosome-Based Therapeutics

We are also developing our exosomes platform technology as a next-generation therapeutic platform. Our current focus is on the development of exosomes loaded with nucleic acids, including mRNA, to treat a variety of diseases. mRNA medicines are not small molecules, like traditional pharmaceutical drugs and they are not traditional biologics (such as recombinant proteins and monoclonal antibodies) – which were the origins of the biotech industry. Instead, mRNA medicines are sets of instructions. And these instructions direct cells in the body to make all the proteins required for life as well as to prevent or fight disease.

Our platform builds on advances in fundamental RNA science, targeting technology and manufacturing, providing us the opportunity to build a broad pipeline of potential new therapeutic candidates. At this time, we are developing therapeutics and vaccines for infectious diseases, monogenic diseases and other indications.

CDC-Derived Exosomes (CAP-2003)

In April 2020, we filed an IND with the FDA to investigate the use of CAP-2003 in patients with DMD. At this time, the FDA has requested more information related to manufacturing and we are evaluating the next steps for this program. We need to submit further information to FDA to support the potential acceptance of this IND.

Additionally, in July 2018, we entered into a Cooperative Research and Development Agreement with the U.S. Army Institute of Surgical Research, or USAISR, pursuant to which we agreed to cooperate in research and development on the evaluation of our CAP-2003 for the treatment of trauma related injuries and conditions.

Aspects of our exosomes pipeline have been supported through collaborations and alliances. We have entered into a Sponsored Research Agreement with Johns Hopkins University, or JHU, pursuant to which researchers in the lab of Dr. Stephen Gould will perform certain research activities in connection with our exosomes program and the further development of the platform. Additional collaborations include the Department of Defense, the National Institutes of Health and Cedars-Sinai Medical Center, or CSMC.

Our executive offices are located at 8840 Wilshire Blvd., 2nd Floor, Beverly Hills, California 90211. Our telephone number is (310) 358-3200 and our Internet address is *www.capricor.com*.

Our Technologies

Cardiosphere-Derived Cells (CAP-1002)

Our core cell therapy 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 over 200 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 DMD and investigating their effects on skeletal and cardiac function. Preclinical 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 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 and 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

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. Our preclinical data has shown that CDCs mediate most of their therapeutic activities through the secretion of extracellular vesicles.

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, preclinical 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.

The following table summarizes our active product development programs:

Product	Indication/Population	Development Stage
CAP-1002	Duchenne Muscular Dystrophy*	HOPE-3 Phase III – in planning stages HOPE-2 Phase II completed*** HOPE-Duchenne Phase I/II completed**
CAP-1002	SARS-CoV-2	INSPIRE Phase II enrolling
Exosome-mRNA vaccine	SARS-CoV-2	Preclinical
Engineered Exosomes (RNA delivery)	Monogenic Diseases	Discovery
CDC-Exosomes (CAP-2003)	Duchenne Muscular Dystrophy	IND submitted
Exosome-VLP vaccine	SARS-CoV-2	Preclinical
Engineered Exosomes (biologics delivery)	Evaluating	Discovery

* 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 currently conducting an OLE of the HOPE-2 trial.

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 and our exosome technologies. As we proceed with the clinical development of CAP-1002, and as we further develop our exosome technologies, 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 recent major sources of working capital have been primarily proceeds from private and public equity sales of securities. While we pursue our preclinical and clinical programs, we continue to explore potential partnerships for the development of 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 preclinical, 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, 2020 and 2019

Revenue

Grant Income. Grant income for the years ended December 31, 2020 and 2019 was approximately $0.2 million and $0.5 million, respectively. The decrease in grant income of approximately $0.3 million in 2020 as compared to 2019 is primarily due to the timing of grant activities. The DoD grant award came to completion during the third quarter of 2020.

Miscellaneous Income. Miscellaneous income for the years ended December 31, 2020 and 2019 was approximately $0.1 million and $0.5 million, respectively. The miscellaneous income was related to providing CAP-1002 for investigational purposes for clinical trials sponsored by CSMC. The decrease in miscellaneous income is due to delays in the clinical trials sponsored by CSMC caused by the COVID-19 pandemic.

Operating Expenses

General and Administrative Expenses. G&A expenses for the years ended December 31, 2020 and 2019 were approximately $5.5 million and $3.6 million, respectively. The increase of approximately $1.9 million in G&A expenses in the year ended December 31, 2020 compared to the year ended December 31, 2019 is attributable to an approximately $1.2 million increase in stock-based compensation expense, an approximately $0.5 million increase in salaries and recruiting related expenses, an approximately $0.3 million increase in investor relations expenses, and an approximately $0.1 million increase in insurance costs, partially offset by a decrease of approximately $0.2 million in rent and other general corporate expenses.

Research and Development Expenses. R&D expenses for the years ended December 31, 2020 and 2019 were approximately $8.5 million and $5.1 million, respectively. The increase of approximately $3.4 million for the year ended December 31, 2020 as compared to the year ended December 31, 2019 is primarily due to the timing of clinical development activities of CAP-1002 (DMD and COVID-19 clinical trials). These activities resulted in a net increase of approximately $0.4 million. Furthermore, for the year ended December 31, 2020, there was an increase of approximately $1.7 million in research and development expenses primarily related to our exosomes program and an increase of approximately $1.1 million in technology transfer and manufacturing related activities of CAP-1002. Lastly, there was an increase of approximately $0.1 million in stock-based compensation expenses allocable to R&D for the year ended December 31, 2020 as compared to December 31, 2019.

Other Income

Investment Income. Investment income for the years ended December 31, 2020 and 2019 was $32,943 and $94,791, respectively. The decrease in investment income in 2020 as compared to 2019 is due to reduced interest rates offered on our savings and money market fund accounts.

Products Under Active Development

CAP-1002 – CAP-1002 is in its developmental stages. We expect to spend approximately $4.0 million to $6.0 million during 2021 on the development of CAP-1002 for DMD and COVID-19, which expenses are primarily related to clinical, regulatory, and manufacturing-related expenses, including our technology transfer with Lonza Houston, Inc. These figures are largely dependent on the next steps in our DMD and COVID-19 programs, the regulatory status of our programs with the FDA, and our ability to secure a partner for the potential future further clinical development of CAP-1002 for DMD, if necessary, and various other factors.

Exosome Technologies – We expect to spend approximately $10.0 million to $12.0 million during 2021 on development expenses related to our exosomes program, which includes preclinical and manufacturing related expenses for these technologies. Our expenses for this program are primarily related to our exosome-mRNA vaccine, which may include expenses related conducting a clinical trial, subject to regulatory approval, as well as expenses focused on the expansion of our engineered exosomes platform. Furthermore, we have expenses in connection with our Sponsored Research Agreement with Johns Hopkins University for further research related to our exosome platform technology.

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;
- the costs, requirements and timing of, and the ability to secure, regulatory approvals; and
- additional delays caused by the COVID-19 pandemic.

Liquidity and Capital Resources for the fiscal years ended December 31, 2020 and 2019

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, 2020	December 31, 2019
Cash, cash equivalents and marketable securities	$ 32,666	$ 9,885
Working capital	$ 30,706	$ 9,647
Stockholders' equity	$ 28,200	$ 6,839

Cash flow data	Years ended December 31, 2020	2019
Cash provided by (used in):		
Operating activities	$ (10,055)	$ (6,822)
Investing activities	5,439	(3,002)
Financing activities	33,382	9,178
Net increase (decrease) in cash and cash equivalents	$ 28,766	$ (646)

Our total cash, cash equivalents and marketable securities as of December 31, 2020 was approximately $32.7 million compared to approximately $9.9 million as of December 31, 2019. The increase in cash, cash equivalents and marketable securities from December 31, 2020 as compared to December 31, 2019 was primarily due to net financing activities of approximately $33.0 million and a net loss of approximately $13.7 million in 2020. As of December 31, 2020, we had approximately $6.4 million in total liabilities. As of December 31, 2020, we had approximately $30.7 million in net working capital. We had a net loss of approximately $13.7 million for the year ended December 31, 2020.

Cash used in operating activities was approximately $10.1 million and $6.8 million for the years ended December 31, 2020 and 2019, respectively. The difference of approximately $3.3 million in cash from operating activities is primarily due to an increase of approximately $6.0 million in net loss for the year ended December 31, 2020 as compared to the same period in 2019. Furthermore, there was a change of approximately $1.3 million in stock-based compensation expense and a change of approximately $0.6 million in prepaid expenses and other current assets for the year ended December 31, 2020 as compared to the same period in 2019. To the extent we obtain sufficient capital and/or long-term debt funding and are able to continue developing our product candidates, including if we expand our technology portfolio, engage in further research and development activities, and, in particular, conduct preclinical 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 $5.4 million and $(3.0) million for the years ended December 31, 2020 and 2019, respectively. The increase in cash provided by investing activities for the year ended December 31, 2020 as compared to the same period of 2019 is primarily due to the net effect from purchases, sales, and maturities of marketable securities as well as purchases of property and equipment.

We had cash flow provided by financing activities of approximately $33.4 million and $9.2 million for the years ended December 31, 2020 and 2019, respectively. The increase in cash provided by financing activities for the year ended December 31, 2020 as compared to the same period of 2019 is primarily due to the net proceeds from the sale of common stock. During 2020 we received net proceeds from the sale of equities of approximately $33.0 million compared to approximately $9.2 million over the same period of 2019. Furthermore, we received $0.3 million under the SBA Paycheck Protection Program of the CARES Act in 2020.

From inception through December 31, 2020, we financed our operations primarily through private and public sales of our equity securities, NIH and DoD grants, a payment from a former collaboration partner, 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 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, government grants, 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. At this time, we believe our cash resources are sufficient to fund our operations for at least the next twelve months. 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 preclinical 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, and the progress of efforts with parties with whom we may enter into commercial manufacturing agreements;
- 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.

As a result of the spread of the COVID-19 coronavirus, uncertainties have arisen that could potentially impact enrollment of clinical trials, deliverables related to contract performance, payments from trial sponsors, workforce stability, 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 its expected duration. In addition to potential impact on grant disbursements, there may be risks to the Company's ability to obtain financing from other sources, due to the impact of the coronavirus. There could be other financial impacts on our business of the coronavirus, the specifics of which are unknown at this time.

Financing Activities by the Company

May 2020 ATM Program. On May 4, 2020, the Company initiated an at-the-market offering under a prospectus supplement for aggregate sales proceeds of up to $40.0 million, or the May 2020 ATM Program, with the common stock to be distributed at the market prices prevailing at the time of sale. The May 2020 ATM Program was established under a Common Stock Sales Agreement, or the July 2019 Sales Agreement, with H.C. Wainwright & Co. LLC, or 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 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. Since May 4, 2020 and through March 12, 2021, the Company has sold an aggregate of 5,947,852 shares of common stock under the May 2020 ATM Program at an average price of approximately $6.16 per share for gross proceeds of approximately $36.6 million. Approximately $3.4 million of common stock may still be sold pursuant to the May 2020 ATM Program. The Company paid cash commissions on the gross proceeds, plus reimbursement of expenses of

Wainwright and legal fees in the aggregate amount of approximately $1.2 million.

March 2020 Warrant Inducement. On March 25, 2020, the Company entered into a letter agreement, or the Exercise Agreement, with a holder of December 2019 Common Warrants (as defined below), or the Exercising Holder. Pursuant to the Exercise Agreement, in connection with the exercise by the Exercising Holder of the remaining 4,000,000 December 2019 Common Warrants held by the Exercising Holder which had not been previously exercised, the Company agreed to issue 4,000,000 additional warrants, or the New Warrants, to purchase Common Stock. The December 2019 Common 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 December 2019 Common 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 were not registered under the Securities Act of 1933, as amended, or the Securities Act, and were offered pursuant to the exemption provided in Section 4(a)(2) under the Securities Act or Rule 506(b) promulgated thereunder. The New Warrants are exercisable immediately upon issuance, and have a term of exercise of 5 1/2 years.

The Company received aggregate gross proceeds of approximately $4.9 million from the exercise of the December 2019 Common Warrants by the Exercising Holder. These gross proceeds were 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, certain employees of the placement agent received new warrants, or the March 2020 Placement Agent Warrants, for shares of Common Stock equal to 5.0% of the New Warrants issued, or 200,000 shares. These March 2020 Placement Agent Warrants are exercisable immediately and have a term of exercise of 5 years. The holders of each of the New Warrants and of the March 2020 Placement Agent Warrants have the option to make a cashless exercise of such warrant if no resale registration statement covering the shares of the Company's Common Stock underlying such warrant is effective after six months. On May 7, 2020, the Company filed a resale registration statement on Form S-3 for the shares underlying the New Warrants and March 2020 Placement Agent Warrants, and that resale registration statement was declared effective by the SEC on May 19, 2020. As of December 31, 2020, 65,000 March 2020 Placement Agent Warrants remained outstanding under the March 2020 Warrant Inducement.

December 2019 Public Offering. In December 2019, the Company completed a public offering, or the December Offering, pursuant to which the Company issued (i) 531,173 shares of its common stock, (ii) warrants, or the December 2019 Common 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. As of December 31, 2020, 61,173 December 2019 Common Warrants remained outstanding under the December 2019 Financing.

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 the July 2019 Sales Agreement, which provided that Wainwright was 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 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. At the expiration of the August 2019 ATM Program, the Company had 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. As of May 4, 2020, the August 2019 ATM Program has expired and been replaced with the May 2020 ATM Program.

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 was 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.

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, 2020, 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 was 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 were made to Capricor over a period of approximately four 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. The Company utilized approximately $2.3 million of the $2.4 million under the terms of the award. We are currently completing all close-out documentation associated with this 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, 2020.

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.

Leases

Effective January 1, 2019, the Company adopted ASC 842, using the optional transition method utilizing the effective date as its date of initial application, for which prior periods are presented in accordance with the previous guidance in ASC 840.

At the inception of an arrangement, the Company determines whether the arrangement is or contains a lease based on the unique facts and circumstances present in the arrangement. Leases with a term greater than 12 months are recognized on the balance sheet as right of use assets and short-term and long-term lease liabilities, as applicable. The Company has elected not to recognize on the balance sheet leases with terms of 12 months or less. The Company typically only includes an initial lease term in its assessment of a lease arrangement. Options to renew a lease are not included in the Company's assessment unless there is reasonable certainty that the Company will renew. The Company monitors its plans to renew its leases no less than on a quarterly basis. In addition, the Company's lease agreements generally do not contain any residual value guarantees or restrictive covenants.

Operating lease liabilities and their corresponding right of use assets are recorded based on the present value of future lease payments over the expected remaining lease term at lease commencement. Lease cost for operating leases is recognized on a straight-line basis over the lease term as an operating expense. Certain adjustments to the right of use asset may be required for items such as lease prepayments or incentives received. The interest rate implicit in lease contracts is typically not readily determinable. As a result, the Company utilizes its incremental borrowing rate, which reflects the fixed rate at which the Company could borrow on a collateralized basis the amount of the lease payments in the same currency, for a similar term, in a similar economic environment. In transition to ASC 842, the Company utilized the remaining lease term of its leases in determining the appropriate incremental borrowing rate.

In accordance with ASC 842, components of a lease should be bifurcated between lease components and non-lease components. The fixed and in-substance fixed contract consideration identified must then be allocated based on the respective relative fair values to the lease components and non-lease components. However, ASC 842 provides a practical expedient that allows an accounting policy election to not separate lease and non-lease components by class of underlying asset. In using this expedient, the lease component and non-lease components are accounted for together as a single component. For real estate leases, the Company has elected to account for the lease and non-lease components together for existing classes of underlying assets and allocates the contract consideration to the lease component only. This practical expedient is not elected for manufacturing facilities and equipment embedded in product supply arrangements.

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. In June, 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. 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 preclinical, clinical and manufacturing, and certain legal expenses resulting from intellectual property prosecution, stock compensation expense and other expenses relating to the design, development, testing and enhancement of our product candidates. Except for certain capitalized intangible assets, R&D costs are expensed as incurred.

Our cost accruals for clinical trials and other R&D activities are based on estimates of the services received and efforts expended pursuant to contracts with numerous clinical trial centers and contract research organizations, or CROs, clinical study sites, laboratories, consultants or other clinical trial vendors that perform activities in connection with a trial. Related contracts vary significantly in length and may be for a fixed amount, a variable amount based on actual costs incurred, capped at a certain limit, or for a combination of fixed, variable and capped amounts. Activity levels are monitored through close communication with the CROs and other clinical trial vendors, including detailed invoice and task completion review, analysis of expenses against budgeted amounts, analysis of work performed against approved contract budgets and payment schedules, and recognition of any changes in scope of the services to be performed. Certain CRO and significant clinical trial vendors provide an estimate of costs incurred but not invoiced at the end of each quarter for each individual trial. These estimates are reviewed and discussed with the CRO or vendor as necessary, and are included in R&D expenses for the related period. For clinical study sites which are paid periodically on a per-subject basis to the institutions performing the clinical study, we accrue an estimated amount based on subject screening and enrollment in each quarter. All estimates may differ significantly from the actual amount subsequently invoiced, which may occur several months after the related services were performed.

In the normal course of business, we contract with third parties to perform various R&D activities in the on-going development of our product candidates. The financial terms of these agreements are subject to negotiation, vary from contract to contract and may result in uneven payment flows. Payments under the contracts depend on factors such as the achievement of certain events, the successful enrollment of patients, and the completion of portions of the clinical trial or similar conditions. The objective of the accrual policy is to match the recording of expenses in the financial statements to the actual services received and efforts expended. As such, expense accruals related to clinical trials and other R&D activities are recognized based on our estimates of the degree of completion of the event or events specified in the applicable contract.

No adjustments for material changes in estimates have been recognized in any period presented.

Stock-Based Compensation

Our results include non-cash compensation expense as a result of the issuance of stock, stock options and warrants, as applicable. We have issued stock options to employees, directors and consultants under our four stock option plans: (i) the 2006 Stock Option Plan, (ii) the 2012 Restated Equity Incentive Plan (which superseded the 2006 Stock Option Plan), (iii) the 2012 Non-Employee Director Stock Option Plan, and (iv) the 2020 Equity Incentive Plan, or the 2020 Plan.

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

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 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 clarify 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. The Company adopted ASU 2018-18 and all subsequent updates related to this topic in the first quarter of 2020. The adoption of this update did not have a material impact on the Company's financial statements.

In October 2019, the FASB issued ASU 2019-12, which affects general principles within Topic 740, Income Taxes. The amendments of ASU 2019-12 are meant to simplify and reduce the cost of accounting for income taxes. For public business entities, the amendments in this Update are effective for fiscal years, and interim periods within those fiscal years, beginning after December 15, 2020. The Company believes that the adoption of this new accounting guidance will not have a material impact on its financial statements and footnote disclosures.

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, 2020, the fair value of our cash and cash equivalents was approximately $32.7 million. Additionally, as of December 31, 2020, Capricor's investment portfolio was classified as cash and cash equivalents, 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, 2020 and 2019, 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, 2020, 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, 2020 and 2019, and the consolidated results of its operations and its cash flows for each of the years in the two-year period ended December 31, 2020, 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.

Critical Audit Matters

Critical audit matters arising from the current period audit of the financial statements that were communicated or required to be communicated to the audit committee and that: (1) relate to accounts or disclosures that are material to the financial statements and (2) involved our especially challenging, subjective, or complex judgements. We determined that there are no critical audit matters.

/s/ Rose, Snyder & Jacobs LLP

Rose, Snyder & Jacobs LLP

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

Encino, California
March 15, 2021

CAPRICOR THERAPEUTICS, INC.
CONSOLIDATED BALANCE SHEETS
DECEMBER 31, 2020 AND 2019

ASSETS

	December 31, 2020	December 31, 2019
CURRENT ASSETS		
Cash and cash equivalents	$ 32,665,874	$ 3,899,328
Marketable securities	-	5,986,050
Grant receivable	-	87,968
Prepaid expenses and other current assets	1,011,209	571,382
TOTAL CURRENT ASSETS	33,677,083	10,544,728
PROPERTY AND EQUIPMENT, net	850,847	442,806
OTHER ASSETS		
Intangible assets, net of accumulated amortization of $257,517 and $253,187, respectively	2,165	6,495
Other assets	88,701	119,608
TOTAL ASSETS	$ 34,618,796	$ 11,113,637
LIABILITIES AND STOCKHOLDERS' EQUITY		
CURRENT LIABILITIES		
Accounts payable and accrued expenses	$ 2,724,593	$ 897,992
Note payable, current	246,689	-
TOTAL CURRENT LIABILITIES	2,971,282	897,992
LONG-TERM LIABILITIES		
Note payable, net of current	71,471	-
CIRM liability	3,376,259	3,376,259

TOTAL LONG-TERM LIABILITIES	3,447,730	3,376,259
TOTAL LIABILITIES	6,419,012	4,274,251
COMMITMENTS AND CONTINGENCIES (NOTE 7)		
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, 20,577,123 and 5,227,398 shares issued and outstanding, respectively	20,577	5,227
Additional paid-in capital	116,216,966	81,215,647
Accumulated other comprehensive income (loss)	-	(757)
Accumulated deficit	(88,037,759)	(74,380,731)
TOTAL STOCKHOLDERS' EQUITY	28,199,784	6,839,386
TOTAL LIABILITIES AND STOCKHOLDERS' EQUITY	$ 34,618,796	$ 11,113,637

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, 2020 AND 2019

	Years ended December 31,	
	2020	2019
REVENUE		
Revenue	$ 310,250	$ 1,005,028
TOTAL REVENUE	310,250	1,005,028
OPERATING EXPENSES		
Research and development	8,457,000	5,141,805
General and administrative	5,543,221	3,597,111
TOTAL OPERATING EXPENSES	14,000,221	8,738,916
LOSS FROM OPERATIONS	(13,689,971)	(7,733,888)
OTHER INCOME (EXPENSE)		
Investment income	32,943	94,791
Loss on disposal of fixed asset	-	(2,720)
TOTAL OTHER INCOME (EXPENSE)	32,943	92,071
NET LOSS	(13,657,028)	(7,641,817)
OTHER COMPREHENSIVE INCOME (LOSS)		
Net unrealized gain (loss) on marketable securities	757	(13,150)
COMPREHENSIVE LOSS	$ (13,656,271)	$ (7,654,967)
Net loss per share, basic and diluted	$ (0.88)	$ (2.06)
Weighted average number of shares, basic and diluted	15,571,056	3,711,333

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, 2018 THROUGH DECEMBER 31, 2020

	COMMON STOCK		ADDITIONAL PAID-IN CAPITAL	OTHER COMPREHENSIVE INCOME (LOSS)	ACCUMULATED DEFICIT	TOTAL STOCKHOLDERS' EQUITY
	SHARES	AMOUNT				
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
Issuance of common stock, net of fees	4,173,478	4,174	27,338,895	-	-	27,343,069
Exercise of pre-funded common stock warrants	3,158,304	3,158	-	-	-	3,158
Exercise of common warrants	4,417,219	4,417	5,680,943	-	-	5,685,360
Issuance of shares in abeyance	3,555,500	3,556	(3,556)	-	-	-
Stock-based compensation	-	-	1,952,679	-	-	1,952,679
Stock options exercised	45,224	45	32,358	-	-	32,403
Unrealized gain on marketable securities	-	-	-	757	-	757
Net loss	-	-	-	-	(13,657,028)	$ (13,657,028)
Balance at December 31, 2020	20,577,123	$ 20,577	$ 116,216,966	$ -	$ (88,037,759)	$ 28,199,784

See accompanying notes to the audited consolidated financial statements.

CAPRICOR THERAPEUTICS, INC.
CONSOLIDATED STATEMENTS OF CASH FLOWS
FOR THE YEARS ENDED DECEMBER 31, 2020 AND 2019

	Years ended December 31,	
	2020	2019
CASH FLOWS FROM OPERATING ACTIVITIES:		
Net loss	$ (13,657,028)	$ (7,641,817)
Adjustments to reconcile net loss to net cash used in operating activities:		
Loss on disposal of fixed asset	-	2,720
Depreciation and amortization	143,890	171,956
Stock-based compensation	1,952,679	700,984
Change in assets - (increase) decrease:		
Receivables	87,968	116,900
Prepaid expenses and other current assets	(439,827)	152,802
Other assets	30,907	32,180
Change in liabilities - increase (decrease):		
Accounts payable and accrued expenses	1,826,601	(357,226)
NET CASH USED IN OPERATING ACTIVITIES	(10,054,810)	(6,821,501)
CASH FLOWS FROM INVESTING ACTIVITIES:		
Purchase of marketable securities	(6,130,193)	(6,002,050)
Proceeds from sales and maturities of marketable securities	12,117,000	3,000,000
Purchases of property and equipment	(547,601)	-
NET CASH PROVIDED BY (USED IN) INVESTING ACTIVITIES	5,439,206	(3,002,050)
CASH FLOWS FROM FINANCING ACTIVITIES:		
Net proceeds from sale of common stock	27,343,069	9,174,753
Proceeds from note payable	318,160	-
Proceeds from exercise of warrants	5,688,518	450
Repurchase of fractional shares pursuant to reverse stock split	-	(193)
Proceeds from stock options	32,403	2,772
NET CASH PROVIDED BY FINANCING ACTIVITIES	33,382,150	9,177,782
NET INCREASE (DECREASE) IN CASH AND CASH EQUIVALENTS	28,766,546	(645,769)
Cash and cash equivalents balance at beginning of period	3,899,328	4,545,097

Cash and cash equivalents balance at end of period	$ 32,665,874	$ 3,899,328
SUPPLEMENTAL DISCLOSURES:		
Interest paid in cash	$ -	$ -
Income taxes paid in cash	$ -	$ -

See accompanying notes to the audited consolidated financial statements.

CAPRICOR THERAPEUTICS, INC.
NOTES TO CONSOLIDATED FINANCIAL STATEMENTS
DECEMBER 31, 2020 AND 2019

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" or "we"),is a biotechnology company focused on the development of transformative cell- and exosome-based therapeutics for the treatment and prevention of a broad spectrum of diseases. 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. All intercompany transactions have been eliminated in consolidation.

Reclassification

Certain reclassification of prior period amounts has been made to conform to the current year presentation.

Liquidity

The Company has historically financed its research and development activities as well as operational expenses from equity financings, government grants, a payment from a former collaboration partner 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, 2020 were approximately $32.7 million, compared to approximately $9.9 million as of December 31, 2019. 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 (see Note 3 – "Stockholders' Equity").

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

The Company's options for raising additional capital 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, in particular if it elects to expand its clinical programs as contemplated by its current business plan. 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.

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

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. 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. 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. 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 and Cash Equivalents

The Company considers all highly liquid investments with a maturity of less than 30 days at the date of purchase to be cash equivalents.

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 $139,560 and $128,680 for the years ended December 31, 2020 and 2019, respectively.

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

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

	2020	2019
Furniture and fixtures	$ 48,676	$ 43,617
Laboratory equipment	1,473,708	931,166
Leasehold improvements	47,043	47,043
	1,569,427	1,021,826
Less accumulated depreciation	(718,580)	(579,020)
Property and equipment, net	$ 850,847	$ 442,806

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 $4,330 and $43,276 for the years ended December 31, 2020 and 2019, respectively. A summary of future amortization expense as of December 31, 2020 is as follows:

Years ended	Amortization Expense
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, 2020 and 2019.

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, 2020 and 2019.

Leases

Effective January 1, 2019, the Company adopted ASC Topic 842, "Leases" ("ASC 842"), using the optional transition method utilizing the effective date as its date of initial application, for which prior periods are presented in accordance with the previous guidance in ASC Topic 840, "Leases" ("ASC 840").

At the inception of an arrangement, the Company determines whether the arrangement is or contains a lease based on the unique facts and circumstances present in the arrangement. Leases with a term greater than 12 months are recognized on the balance sheet as right of use assets and short-term and long-term lease liabilities, as applicable. The Company has elected not to recognize on the balance sheet leases with terms of 12 months or less. The Company typically only includes an initial lease term in its assessment of a lease arrangement. Options to renew a lease are not included in the Company's assessment unless there is reasonable certainty that the Company will renew. The Company monitors its plans to renew its leases no less than on a quarterly basis. In addition, the Company's lease agreements generally do not contain any residual value

guarantees or restrictive covenants.

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

Operating lease liabilities and their corresponding right of use assets are recorded based on the present value of future lease payments over the expected remaining lease term at lease commencement. Lease cost for operating leases is recognized on a straight-line basis over the lease term as an operating expense. Certain adjustments to the right of use asset may be required for items such as lease prepayments or incentives received. The interest rate implicit in lease contracts is typically not readily determinable. As a result, the Company utilizes its incremental borrowing rate, which reflects the fixed rate at which the Company could borrow on a collateralized basis the amount of the lease payments in the same currency, for a similar term, in a similar economic environment. In transition to ASC 842, the Company utilized the remaining lease term of its leases in determining the appropriate incremental borrowing rate.

In accordance with ASC 842, components of a lease should be bifurcated between lease components and non-lease components. The fixed and in-substance fixed contract consideration identified must then be allocated based on the respective relative fair values to the lease components and non-lease components. However, ASC 842 provides a practical expedient that allows an accounting policy election to not separate lease and non-lease components by class of underlying assets. In using this expedient, the lease component and non-lease components are accounted for together as a single component. For real estate leases, the Company has elected to account for the lease and non-lease components together for existing classes of underlying assets and allocates the contract consideration to the lease component only. This practical expedient is not elected for manufacturing facilities and equipment embedded in product supply arrangements.

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.

Government Research Grants

Generally, government research grants that provide funding for research and development activities are recognized as income when the related expenses are incurred, as applicable. Because the terms of the CIRM Award allow Capricor to elect to convert the grant into a loan after the end of the project period, the CIRM Award is being classified as a liability rather than income (see Note 6 - “Government Grant Awards”). Grant income is due upon submission of a 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 9 – “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.

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.

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

As of December 31, 2020, the Company had federal net operating loss carryforwards of approximately $107.6 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 $31.5 million will carryforward indefinitely, but may be subject to an 80% limitation upon utilization. As of December 31, 2020, the Company had state net operating loss carryforwards of approximately $103.7 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 $3.1 million of federal orphan drug credits, available to offset future taxable income. These federal research and development and orphan drug credits begin to expire in 2027 and 2035, respectively.

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

The Company's policy is to include interest and penalties related to unrecognized tax benefits in income tax expense. The Company incurred no interest or penalties for the years ended December 31, 2020 and 2019. The Company files income tax returns with the IRS and the California Franchise Tax Board.

Research and Development

Costs relating to the design and development of new products are expensed as research and development as incurred in accordance with Financial Accounting Standards Board ("FASB") ASC 730-10, *Research and Development*. Research and development costs amounted to approximately $8.5 million and $5.1 million for the years ended December 31, 2020 and 2019, 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 $13.7 million and $7.7 million for the years ended December 31, 2020 and 2019, 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, 2020 and 2019, the Company's other comprehensive income (loss) was $757 and $(13,150), 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 ("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.

Business Uncertainty Related to the Coronavirus

As a result of the spread of the COVID-19 coronavirus, uncertainties have arisen that could potentially impact enrollment of and the ability to conduct clinical trials, deliverables related to contract performance, payments from trial sponsors including Cedars-Sinai Medical Center, as we describe further below, workforce stability, 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 its expected duration and as a result, the Company is considering the impact of COVID-19 on its ability to conduct both preclinical development and clinical studies. In addition to potential impact on grant disbursements, there may be risks to the Company's ability to obtain financing from other sources due to the impact of the coronavirus. There could be other financial impacts on our business due to the coronavirus, the specifics of which are unknown at this time.

In light of the increased uncertainties due to COVID-19 and its economic and other impacts and to uncertainties around the timing and availability of grant disbursements, the loss of revenue from the delays of the REGRESS and ALPHA trials as well as any potential equity and debt financings, the Company applied for a loan under the Small Business Administration (the "SBA") Paycheck Protection Program of the Coronavirus Aid, Relief and Economic Security Act of 2020 (the "CARES Act"). On April 29, 2020, the Company was approved and received a loan of $318,160 (the "Loan") under the SBA Paycheck Protection Program of the CARES Act. The Company utilized the funds for covered payroll costs, all which the Company believes were in accordance with the relevant terms and conditions of the CARES Act (see Note 2 – "Note Payable").

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.

CAPRICOR THERAPEUTICS, INC.
NOTES TO CONSOLIDATED FINANCIAL STATEMENTS
DECEMBER 31, 2020 AND 2019

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

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 FASB 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, 2020 and 2019 were as follows:

	December 31, 2020	December 31, 2019
Numerator		
Net loss	$ (13,657,028)	$ (7,641,817)
Denominator		
Weighted-average number of shares of common stock outstanding	15,571,056	3,711,333
Dilutive effect of stock options	-	-
Common stock and common stock equivalents used for diluted loss per share	15,571,056	3,711,333

For the years ended December 31, 2020 and 2019, warrants and options to purchase 2,488,046 and 8,256,609 shares of common stock, respectively, have been excluded from the computation of potentially dilutive securities. Potentially dilutive common shares, which primarily consist of stock options issued to employees, consultants, and directors as well as warrants issued, have been excluded from the diluted loss per share calculation because their effect is anti-dilutive. 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, 2020 and 2019.

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

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 whatmarket 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

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.

Recent Accounting Pronouncements

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 clarify 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 to 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. The Company adopted ASU 2018-18 and all subsequent updates related to this topic in the first quarter of 2020. The adoption of this update did not have a material impact on the Company's financial statements.

In October 2019, the FASB issued ASU 2019-12, which affects general principles within Topic 740, Income Taxes. The amendments of ASU 2019-12 are meant to simplify and reduce the cost of accounting for income taxes. For public business entities, the amendments in this Update are effective for fiscal years, and interim periods within those fiscal years, beginning after December 15, 2020. The Company believes that the adoption of this new accounting guidance will not have a material impact on its financial statements and footnote disclosures.

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. NOTE PAYABLE

Paycheck Protection Program Loan

In the second quarter of 2020, Capricor applied to City National Bank ("CNB") under the SBA Paycheck Protection Program of the CARES Act for the Loan in the amount of $318,160. The Loan was approved and Capricor received the Loan proceeds, which we used for covered payroll costs in accordance with the relevant terms and conditions of the CARES Act.

The Loan, which took the form of a promissory note issued by Capricor (the "Promissory Note"), has a two-year term, matures on April 29, 2022, and bears interest at a rate of 1.0% per annum. Monthly principal and interest payments, less the amount of any potential forgiveness, will commence 10 months after the end of the covered period for the borrower's loan forgiveness (either 8 or 24 weeks). Loan payments are deferred for borrowers who apply for loan forgiveness until SBA remits the borrower's loan forgiveness amount to the lender. Capricor did not provide any collateral or guarantees for the Loan, nor did Capricor pay any facility charge to obtain the Loan. The Promissory Note provides for customary events of default, including, among others, those relating to failure to make payment, bankruptcy, breaches of representations and material adverse events. Capricor may prepay the principal of the Loan at any time without incurring any prepayment charges.

The Loan may be forgiven partially or fully if the Loan proceeds are used for eligible purposes, including payroll costs, rent and utilities, provided that such amounts are incurred during an 8 or 24-week period that commenced on April 29, 2020. Any forgiveness of the Loan will be subject to approval by the SBA and CNB and will require Capricor to apply for such treatment. The Company submitted a loan forgiveness application to CNB in the first quarter of 2021. CNB has 60 days to review and comment on the loan forgiveness application, otherwise, it will be sent to the SBA, who has 90 days to review from date of submission from CNB. In the event the Loan, or any portion thereof, is forgiven pursuant to the SBA, the amount forgiven is applied to the outstanding principal. Any unforgiven portion of the Loan will be payable in accordance with the terms of the Promissory Note as described above. While the Company currently believes that its use of the loan proceeds will meet the conditions for forgiveness of the Loan, it cannot be sure that it will be eligible for forgiveness, in whole or in part.

3. STOCKHOLDER'S EQUITY

ATM Programs

Since July 2019, the Company has established multiple "at-the-market", or ATM, programs pursuant to a Common Stock Sales Agreement with Wainwright by which Wainwright sold and may continue to sell our 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 "July 2019 ATM Program," the "August 2019 ATM Program," and the "May 2020 ATM Program" based on when each program was initiated. In addition, the Company completed a public offering of its common stock in December 2019 and a warrant inducement offer in March 2020.

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. From August 29, 2019 through May 4, 2020, the Company 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. As of May 4, 2020, the August 2019 ATM Program has expired and been replaced with the May 2020 ATM Program described below.

3. STOCKHOLDER'S EQUITY (Continued)

May 2020 ATM Program

On May 4, 2020, the Company initiated the May 2020 ATM Program. The Company filed the May 2020 ATM with an aggregate offering price of up to $40.0 million. Since May 4, 2020 and through March 12, 2021, the Company has sold an aggregate of 5,947,852 shares of common stock under the May 2020 ATM Program at an average price of approximately $6.16 per share for gross proceeds of approximately $36.6 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 $1.2 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 (the "December 2019 Common 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 "December 2019 Placement Agent Warrants") to purchase an aggregate of 203,915 shares of common stock. The December 2019 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. As of December 31, 2020, 61,173 December 2019 Common Warrants remained outstanding under the December 2019 Financing.

March 2020 Warrant Inducement

On March 25, 2020, the Company entered into a letter agreement (the "Exercise Agreement") with a holder of December 2019 Common Warrants (the "Exercising Holder"). Pursuant to the Exercise Agreement, in connection with exercise by the Exercising Holder of the remaining 4,000,000 December 2019 Common 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 December 2019 Common 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 December 2019 Common 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. A total of 724,500 shares were issued to the Exercising Holder, with the remaining 3,275,500 shares being held in abeyance until such time as it would not result in the Exercising Holder exceeding its beneficial ownership limitation of 4.99% of the Company's outstanding common stock. In the second quarter of 2020, the Company issued all shares that were being held in abeyance.

The New Warrants and the shares of Common Stock issuable upon the exercise of the New Warrants were not registered under the Securities Act of 1933, as amended (the "Securities Act"), and were offered pursuant to the exemption provided in Section 4(a)(2) under the Securities Act or Rule 506(b) promulgated thereunder. The New Warrants are exercisable immediately upon issuance, and have a term of exercise of 5 1/2 years.

3. STOCKHOLDER'S EQUITY (Continued)

The exercise of December 2019 Common Warrants by the Exercising Holder generated gross proceeds of approximately $4.9 million. Fees paid in conjunction with the Exercise Agreement, which included placement agent commissions, legal costs, and other offering expenses, amount to approximately $0.4 million. In connection with the Exercise Agreement, certain employees of the placement agent were issued new warrants (the "March 2020 Placement Agent Warrants") to purchase an aggregate of 200,000 shares of common stock. The March 2020 Placement Agent Warrants have an exercise price of $1.5313 per share and expire in March 2025. The holders of each of the New Warrants and of the March 2020 Placement Agent Warrants have the option to make a cashless exercise of such warrant if no resale registration statement covering the shares of the Company's Common Stock underlying such warrant is effective after six months. On May 7, 2020, the Company filed a resale registration statement on Form S-3 for the shares underlying the New Warrants and March 2020 Placement Agent Warrants, and that resale registration statement was declared effective by the SEC on May 19, 2020. As of December 31, 2020, 65,000 March 2020 Placement Agent Warrants remained outstanding under the March 2020 Warrant Inducement.

Outstanding Shares

At December 31, 2020, the Company had 20,577,123 shares of common stock issued and outstanding.

4. STOCK AWARDS, WARRANTS AND OPTIONS

Warrants

The following table summarizes all warrant activity for the years ended December 31, 2020 and 2019:

	Warrants	Weighted Average Exercise Price
Outstanding at January 1, 2019	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
Granted	4,200,000	1.28
Exercised	(11,575,523)	0.87
Outstanding at December 31, 2020	126,173	$ 1.32

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

Type	Grant Date	December 31, 2020	December 31, 2019	Exercise Price per Share	Expiration Date
Common Warrants	12/19/2019	61,173	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
Common Warrants	3/27/2020	65,000	-	$ 1.5313	3/27/2025
		126,173	**7,501,696**		

4. STOCK AWARDS, WARRANTS AND OPTIONS (Continued)

Stock Options

The Company's Board of Directors (the "Board") has approved four stock option plans: (i) the 2006 Stock Option Plan, (ii) the 2012 Restated Equity Incentive Plan (which superseded the 2006 Stock Option Plan) (the "2012 Plan"), (iii) the 2012 Non-Employee Director Stock Option Plan (the "2012 Non-Employee Director Plan"), and (iv) the 2020 Equity Incentive Plan (the "2020 Plan").

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 number of shares 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.

On June 5, 2020, at the Company's annual stockholder meeting, the stockholders approved the 2020 Plan with 2,500,000 shares of common stock reserved under the 2020 Plan for the issuance of stock awards. The number of Shares available for issuance under the 2020 Plan shall be automatically increased on January 1 of each year, commencing with January 1, 2021, by an amount equal to the lesser of (i) four percent (4%) of the outstanding shares of Common Stock as of the last day of the immediately preceding fiscal year or (ii) such number of shares of Common Stock determined by the Compensation Committee in its sole discretion. For the fiscal year beginning on January 1, 2021, the number of shares added was equal to 823,084 shares.

As of December 31, 2020, 999,887 options remain available for issuance under the respective stock option plans.

Each of the Company's stock option plans are administered by the Board, or the compensation committee of 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. 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 2020 and 2019 were approximately $3.93 and $2.73 per share, respectively.

4. STOCK AWARDS, WARRANTS AND OPTIONS (Continued)

The Company estimates the fair value of each option award using the Black-Scholes option-pricing model. The Company used the following assumptions to estimate the fair value of stock options issued in the years ended December 31, 2020 and 2019:

	December 31, 2020	December 31, 2019
Expected volatility	104% – 124%	106% – 128%
Expected term	5 – 6 years	5 – 6 years
Dividend yield	0%	0%
Risk-free interest rates	0.4 – 1.5%	1.4 – 1.6%

Employee and non-employee stock-based compensation expense for the years ended December 31, 2020 and 2019 was as follows:

	2020	2019
General and administrative	$ 1,705,477	$ 509,212
Research and development	247,202	191,772
Total	$ 1,952,679	$ 700,984

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. 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.

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 and designated service providers of the Company were 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 approximately $171,000 was recognized in the first quarter of 2020 stock-based compensation expense with the remainder to be expensed over the remaining unvested period terms.

The following table summarizes information about stock options outstanding and exercisable at December 31, 2020:

	Options Outstanding		
Range of Ex. Prices	Options Outstanding	Weighted Average Term (yrs.)	Weighted Average Exercise Price
$ 1.18	48,000	9.16	$ 1.18
$ 1.39	1,995,876	7.46	$ 1.39
$1.50 - $12.10	317,997	9.43	$ 5.12
	2,361,873		$ 1.89

Options Exercisable

Range of Ex. Prices	Options Exercisable	Weighted Average Term (yrs.)	Weighted Average Exercise Price
$ 1.18	18,000	9.16	$ 1.18
$ 1.39	866,183	5.35	$ 1.39
$1.50 - $12.10	29,068	7.76	$ 4.97
	913,251		**$ 1.50**

CAPRICOR THERAPEUTICS, INC.
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4. STOCK AWARDS, WARRANTS AND OPTIONS (Continued)

As of December 31, 2020, the total unrecognized fair value compensation cost related to non-vested stock options was approximately $5.7 million, which is expected to be recognized over a weighted average period of approximately 1.6 years.

The following is a schedule summarizing employee and non-employee stock option activity for the years ended December 31, 2020 and 2019:

	Number of Options	Weighted Average Exercise Price	Aggregate Intrinsic Value
Outstanding at January 1, 2019	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	$ -
Granted	1,878,058	2.14	
Exercised	(63,774)	3.19	$ 329,035
Expired/Cancelled	(207,324)	5.73	
Outstanding at December 31, 2020	2,361,873	$ 1.89	$ 4,236,737
Exercisable at December 31, 2020	913,251	$ 1.50	$ 1,813,910

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.

5. CONCENTRATIONS

Cash Concentration

The Company has historically maintained checking accounts at two financial institutions. These accounts are each insured by the Federal Deposit Insurance Corporation for up to $250,000. Historically, the Company has not experienced any significant losses in such accounts and believes it is not exposed to any significant credit risk on cash, cash equivalents and marketable securities. As of December 31, 2020, the Company maintained approximately $32.2 million of uninsured deposits.

6. GOVERNMENT GRANT AWARDS

CIRM Grant Award (HOPE)

On June 16, 2016, Capricor entered into the CIRM Award with CIRM in the amount of approximately $3.4 million to fund, in part, Capricor's Phase I/II HOPE-Duchenne clinical trial investigating CAP-1002 for the treatment of Duchenne muscular dystrophy-associated cardiomyopathy. Pursuant to terms of the CIRM Award, the disbursements 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.

CAPRICOR THERAPEUTICS, INC.
NOTES TO CONSOLIDATED FINANCIAL STATEMENTS
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6. 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.

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. As of December 31, 2020, Capricor's liability balance for the CIRM Award was approximately $3.4 million.

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. The Company utilized approximately $0.7 million under the terms of the NIH grant award. In the second quarter of 2019, the award was closed, and all filings were completed.

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 were made to Capricor over a period of approximately four 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. The Company utilized approximately $2.3 million under the terms of the award. We are currently completing all close-out documentation associated with this award.

7. COMMITMENTS AND CONTINGENCIES

Leases

Capricor leases space for its corporate offices from The Bubble Real Estate Company, LLC ("Bubble Real Estate") 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, 2021, 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, 2021. The lease is terminable by either party upon 90 days' written notice to the other party. The monthly rental payment is $13,073 for this annual period.

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. In July 2020, Capricor exercised its option to extend the term of the Facilities Lease for an additional 12-month period through July 31, 2021 with a monthly lease payment of $15,805. The Company has a further option to extend the Facilities Lease with respect to a portion of the leased premises through July 31, 2022 and a monthly lease payment of $10,707. At this time, we are actively considering new facilities for our research, development and/or manufacturing activities or the possible extension of our current lease.

7. COMMITMENTS AND CONTINGENCIES (Continued)

Included within the table below, future minimum rental payments to related parties totaled $110,635. A summary of future minimum rental payments required under operating leases as of December 31, 2020 is as follows:

Years ended	Operating Leases
2021	$ 110,635

Expenses incurred under operating leases to unrelated parties for the years ended December 31, 2020 and 2019 were $194,748 and $317,404, respectively. Expenses incurred under operating leases to related parties for the years ended December 31, 2020 and 2019 were $189,660 and $197,562, 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.

Other Funding Commitments

The Company is a party to various agreements, principally relating to licensed technology, that require future payments relating to milestones that may be met in subsequent periods or royalties on future sales of specified products (see Note 8 – "License Agreements").

Additionally, the Company is a party to various agreements with contract research organizations and contract manufacturers that generally provide for termination upon notice, with the exact amounts owed in the event of termination to be based on the timing of the termination and the terms of the agreement.

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, 2020.

8. LICENSE AGREEMENTS

Capricor's Technology - CAP-1002 and Exosomes

Capricor has entered into exclusive license agreements for intellectual property rights related to certain cardiac-derived cells with Università Degli Studi Di Roma La Sapienza, or the University of Rome, JHU and CSMC. Capricor has also entered into an exclusive license agreement for intellectual property rights related to exosomes with CSMC and a non-exclusive license agreement with JHU related to the imaging-based serology technology for COVID-19. 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.

8. 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 Agreements

License Agreement for CDCs

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 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, or 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. At this time, it is uncertain as to whether the $250,000 milestone payment will become 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.

License Agreement for Serology Diagnostic

Capricor and JHU entered into a Nonexclusive License Agreement, effective January 6, 2021, or the JHU Serology License Agreement, which provides for the grant of a non-exclusive, world-wide, non-royalty-bearing license by JHU to Capricor to develop and commercialize licensed products under the licensed patent rights for COVID-19.

8. LICENSE AGREEMENTS (Continued)

Cedars-Sinai Medical Center License Agreements

License Agreement for CDCs

On January 4, 2010, Capricor entered into an Exclusive License Agreement with CSMC, 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.

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, August 5, 2016, December 26, 2017, and June 20, 2018, Capricor and CSMC entered into a number of amendments to the Amended CSMC License Agreement, pursuant to which the parties agreed to add and delete certain patent applications from the list of scheduled patents. Capricor reimbursed CSMC for certain attorneys' fees and filing fees incurred in connection with the 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.

8. LICENSE AGREEMENTS (Continued)

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, June 10, 2015, August 5, 2016, December 26, 2017, June 20, 2018, September 25, 2018, August 19, 2020, and August 28, 2020 Capricor and CSMC entered into a number of amendments to the Exosomes License Agreement. These amendments added additional patent applications and patent families to the Exosomes License Agreement, added certain defined product development milestone payments, modified certain milestone deadlines, and added certain performance milestones with respect to product candidates covered by certain future patent rights in order to maintain an exclusive license to those future patent rights; failure to meet those milestones would cause CSMC to have the right to convert the license from exclusive to non-exclusive or co-exclusive, or to terminate the license, subject to Capricor's right to license such patent rights for internal research purposes on a non-exclusive basis. These amendments also obligated Capricor to reimburse CSMC for certain attorneys' fees and filing fees in connection with the additional patent applications and patent families.

Sponsored Research Agreement with Johns Hopkins University

On April 1, 2020 we entered into a Sponsored Research Agreement, or the SRA, with JHU pursuant to which researchers in the lab of Dr. Stephen Gould will perform certain research activities in connection with our exosomes program. Pursuant to the SRA, we have agreed to fund certain research activities and will have the right to negotiate for exclusive or non-exclusive rights to intellectual property that may result from such research activities.

9. RELATED PARTY TRANSACTIONS

Lease and Sub-Lease Agreement

As noted above, Capricor is a party to lease agreements with CSMC(see Note 7 – "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 has participated 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 was on a month-to-month basis and was terminated effective September 1, 2020. For the years ended December 31, 2020 and 2019, Capricor recognized $20,000 and $30,000, respectively, in sublease income from the related party. Sublease income is recorded as a reduction to general and administrative expenses.

9. RELATED PARTY TRANSACTIONS (Continued)

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.

In July 2020, Capricor entered into an Advisory Services Agreement with Dr. Eduardo Marbán whereby he was granted an option to purchase 50,000 shares of the Company's common stock.

Payables to Related Party

As of December 31, 2020 and 2019, the Company had accounts payable and accrued expenses to related parties totaling $8,972 and $22,315, respectively. CSMC accounts for $8,972 and $12,315 of the total accounts payable and accrued expenses to related parties as of December 31, 2020 and 31, 2019, respectively. CSMC expenses relate to research and development costs, license and patent fees, and facilities rent. During the years ended December 31, 2020 and 2019, the Company paid CSMC approximately $307,000 and $336,000, respectively, for such costs.

Related Party Clinical Trials

Capricor has agreed to provide CAP-1002 for investigational purposes in two clinical trials sponsored by CSMC. This product was 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", or REGRESS. Dr. Eduardo Marbán is the named principal investigator under the study. The second trial is known as "Pulmonary Arterial Hypertension treated with Cardiosphere-derived Allogeneic Stem Cells" or ALPHA. 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. For the years ended December 31, 2020 and 2019, the Company recognized approximately $120,000 and $460,000, respectively, as revenue. As of December 31, 2020, and 2019, approximately $56,000 and $58,000, respectively, is outstanding and recorded in prepaid expenses and other current assets. As of December 31, 2020, there remains approximately $0.6 million to be received by the Company, subject to enrollment and certain conditions under the agreements. Due to the current COVID-19 pandemic, additional testing in each of the ALPHA and REGRESS trials has been delayed and as a result, purchases of additional doses of CAP-1002 have been delayed.

10. SUBSEQUENT EVENTS

Corporate Offices Lease Amendment

Effective January 1, 2021, the Company entered into a Sixth Amendment with the Bubble Real Estate Company, LLC pursuant to which we extended our lease for an additional year ending December 31, 2021 and reduced the square footage. The monthly rental payment is $13,073 for this annual period.

Stock Option Grants

In January 2021, the Company granted a total of 1,333,824 stock options to its employees, certain non-employee consultants, and directors.

Additional Sales Under May 2020 ATM Program

Subsequent to December 31, 2020 and through March 12, 2021, the Company sold an aggregate of 2,281,874 common shares under the May 2020 ATM Program at an average price of approximately $5.85 per common share for gross proceeds of approximately $13.0 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.

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, 2020, 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, 2020 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, 2020.

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, 2020 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 2021 Annual Meeting of Stockholders, or our 2021 Proxy Statement, to be filed with the SEC within 120 days after the end of the fiscal year ended December 31, 2020, and is incorporated herein by reference.

ITEM 11. EXECUTIVE COMPENSATION.

The information required by this item will be set forth in the section entitled "2020 Executive Compensation" and "Compensation of Directors" in our 2021 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 2021 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 2021 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 2021 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 90.

(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).
3.5	Certificate of Amendment of the Bylaws of the Company (incorporated by reference to Exhibit 3.1 to the Company's Current Report on Form 8-K, filed with the Commission on August 25, 2020).
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).
4.5	Form of Common Stock Purchase Warrant #1 (incorporated by reference to Exhibit 4.1 to the Company's Quarterly Report on Form 10-Q, filed with the Commission on May 15, 2020).

4.6	Form of Common Stock Purchase Warrant #2 (incorporated by reference to Exhibit 4.2 to the Company's Quarterly Report on Form 10-Q, filed with the Commission on May 15, 2020).
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	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). +
10.23	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).
10.24	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). +
10.25	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).
10.26	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). +
10.27	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).
10.28	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). +
10.29	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).
10.30	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). +

10.31	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).

10.32	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). +
10.33	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). +
10.34	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). †
10.35	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). †
10.36	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).
10.37	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).
10.38	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).
10.39	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). +
10.40	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). +
10.41	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). +
10.42	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). +
10.43	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).†
10.44	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).†
10.45	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).†

10.46	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).
10.47	Letter Agreement dated March 25, 2020 (incorporated by reference to Exhibit 10.1 to the Company's Current Report on Form 8-K, filed with the Commission on March 26, 2020).
10.48	Capricor Therapeutics, Inc. 2020 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 June 17, 2020).
10.49	Form of Stock Option Agreement for Capricor Therapeutics, Inc. 2020 Equity Incentive Plan (incorporated by reference to Exhibit 4.10 to the Company's Registration Statement on Form S-8, filed with the Commission on June 17, 2020).
10.50	Seventh Amendment to Exclusive License Agreement, dated as of August 20, 2020, 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 11, 2020).+
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, 2020 and 2019, (ii) Consolidated Statements of Operations and Comprehensive Loss for the years ended December 31, 2020 and 2019, (iii) Consolidated Statement of Stockholders' Equity for the period from December 31, 2018 through December 31, 2020, (iv) Consolidated Statements of Cash Flows for the years ended December 31, 2020 and 2019, and (v) Notes to Consolidated Financial Statements.*

* Filed herewith.
† Indicates management contract or compensatory plan or arrangement.

+ Portions of the exhibit have been excluded because it both (i) is not material and (ii) would be competitively harmful if publicly disclosed.

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 15, 2021.

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 15, 2021
/s/ Anthony J. Bergmann Anthony J. Bergmann	Chief Financial Officer *(Principal Financial and Accounting Officer)*	March 15, 2021
/s/ Frank Litvack, M.D. Frank Litvack, M.D.	Executive Chairman and Director	March 15, 2021
/s/ Earl M. Collier Earl M. Collier	Director	March 15, 2021
/s/ Louis V. Manzo Louis V. Manzo	Director	March 15, 2021
/s/ George W. Dunbar George W. Dunbar	Director	March 15, 2021
/s/ David B. Musket David B. Musket	Director	March 15, 2021

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, 2020, 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, 333-215510, 333-239241 and 333-253083), Form S-3 (File Nos. 333-161339, 333-165167, 333- 207149, 333-212017, 333-219188, 333-227955, and 333-238088), and Form S-1 (File No. 333-235358) of our report dated March 15, 2021, 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 15, 2021

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 15, 2021

/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 15, 2021

/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, 2020 (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 15, 2021

/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, 2020 (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 15, 2021

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