As filed with the Securities and Exchange Commission on December 5, 2019

Registration No. 333-

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

FORM S-1

REGISTRATION STATEMENT
UNDER
THE SECURITIES ACT OF 1933

Capricor Therapeutics, Inc.

(Exact name of Registrant as specified in its charter)

Delaware	**2834**	**88-0363465**
(State or other jurisdiction of incorporation or organization)	**(Primary Standard Industrial Classification Code Number)**	**(I.R.S. Employer Identification Number)**

Capricor Therapeutics, Inc.
8840 Wilshire Blvd., 2nd Floor
Beverly Hills, CA 90211
(310) 358-3200
(Address, including zip code, and telephone number, including area code, of Registrant's principal executive offices)

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Approximate date of commencement of proposed sale to the public: As soon as practicable after this Registration Statement becomes effective.

If any of the securities being registered on this Form are to be offered on a delayed or continuous basis pursuant to Rule 415 under the Securities Act of 1933, other than securities offered only in connection with dividend or interest reinvestment plans, check the following box: ☒

If this Form is filed to register additional securities for an offering pursuant to Rule 462(b) under the Securities Act, please check the following box and list the Securities Act registration statement number of the earlier effective registration statement for the same offering. ☐

If this Form is a post-effective amendment filed pursuant to Rule 462(c) under the Securities Act, check the following box and list the Securities Act registration statement number of the earlier effective registration statement for the same offering. ☐

If this Form is a post-effective amendment filed pursuant to Rule 462(d) under the Securities Act, check the following box and list the Securities Act registration statement number of the earlier effective registration statement for the same offering. ☐

Indicate by check mark whether the registrant is a large accelerated filer, an accelerated filer, a non-accelerated filer, 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 7(a)(2)(B) of the Securities Act. ☐

CALCULATION OF REGISTRATION FEE

Title of each class of securities to be registered	Proposed maximum aggregate offering price (1)	Amount of registration fee
Common Stock, par value $0.001 per share (2)	$	$
Pre-funded warrants to purchase shares of common stock and common stock issuable upon exercise thereof (2)(4)	-	-
Warrants to purchase shares of common stock and common stock issuable upon exercise thereof (2)(4)	$	$
Placement Agent's Warrant to purchase shares of Common Stock and common stock issuable upon exercise thereof (3)(4)	$	$
Total	$ 5,000,000 (5)	$ 649

(1) Estimated solely for the purpose of calculating the amount of the registration fee in accordance with Rule 457(o) under the Securities Act.

(2) The proposed maximum aggregate offering price of the common stock proposed to be sold in the offering will be reduced on a dollar-for-dollar basis based on the aggregate offering price of the pre-funded warrants offered and sold in the offering (plus the aggregate exercise price of the common stock issuable upon exercise of the pre-funded warrants), and as such the proposed aggregate maximum offering price of the common stock and pre-funded warrants (including the common stock issuable upon exercise of the pre-funded warrants), if any, is $.

(3) Represents warrants issuable to H.C. Wainwright & Co., LLC, or the Placement Agent's Warrants, to purchase a number of shares of common stock equal to 5% of the number of shares of common stock and pre-funded warrants being offered at an exercise price equal to 125% of the public offering price of the common stock. See "Plan of Distribution."

(4) Resales of the common warrants, the pre-funded warrants and the Placement Agent's Warrants on a delayed or continuous basis pursuant to Rule 415 under the Securities Act of 1933, as amended, are registered hereby. Resales of shares of common stock issuable upon exercise of the Placement Agent's Warrants, the pre-funded warrants and the common stock warrants are also being registered on a delayed or continuous basis hereby.

(5) Pursuant to Rule 416 under the Securities Act, the securities being registered hereunder include such indeterminate number of additional securities as may be issued after the date hereof as a result of stock splits, stock dividends or similar transactions.

The registrant hereby amends this registration statement on such date or dates as may be necessary to delay its effective date until the registrant shall file a further amendment which specifically states that this registration statement shall thereafter become effective in accordance with Section 8(a) of the Securities Act of 1933 or until this registration statement shall become effective on such date as the Commission, acting pursuant to said Section 8(a), may determine.

The information in this preliminary prospectus is not complete and may be changed. We may not sell these securities until the registration statement filed with the Securities and Exchange Commission is effective. This preliminary prospectus is not an offer to sell nor does it seek an offer to buy these securities in any jurisdiction where the offer or sale is not permitted.

Subject to Completion, dated December 5, 2019

Preliminary Prospectus

Shares of Common Stock

Pre-Funded Warrants to Purchase Shares of Common Stock

Common Warrants to Purchase up to Shares of Common Stock

We are offering shares of our common stock and common warrants to purchase up to shares of common stock and the shares of common stock that are issuable from time to time upon exercise of the common warrants. We are also offering to certain purchasers whose purchase of shares of common stock in this offering would otherwise result in the purchaser, together with its affiliates and certain related parties, beneficially owning more than 4.99% (or, at the election of the purchaser, 9.99%) of our outstanding common stock immediately following the consummation of this offering, the opportunity to purchase, if any such purchaser so chooses, pre-funded warrants, in lieu of shares of common stock that would otherwise result in such purchaser's beneficial ownership exceeding 4.99% (or, at the election of the purchaser, 9.99%) of our outstanding common stock. The purchase price of each pre-funded warrant will be equal to the price at which a share of common stock is sold to the public in this offering, minus $0.001, and the exercise price of each pre-funded warrant will be $0.001 per share. The pre-funded warrants will be immediately exercisable and may be exercised at any time until all of the pre-funded warrants are exercised in full. For each pre-funded warrant we sell, the number of shares of common stock we are offering will be decreased on a one-for-one basis. Therefore the number of common warrants sold in this offering will not change as a result of a change in the mix of the shares of our common stock and pre-funded warrants sold. The shares of common stock and pre-funded warrants, and the accompanying common warrants, can only be purchased together in this offering but will be issued separately and will be immediately separable upon issuance. Each common warrant will have an exercise price of $ per share of common stock, will be exercisable upon issuance and will expire five years from the date of issuance.

Our common stock is traded on the Nasdaq Capital Market under the symbol "CAPR." On December 2, 2019, the last reported sale price of our common stock on the Nasdaq Capital Market was $1.69 per share. The public offering price per share of common stock and any pre-funded warrant and the accompanying common warrant will be determined at the time of pricing, and may be at a discount to the then current market price. There is no established public trading market for the pre-funded warrants, the common warrants and the Placement Agent's Warrants and we do not expect a market to develop. Without an active trading market, the liquidity of the warrants will be limited. In addition, we do not intend to list the pre-funded warrants, common warrants or the Placement Agent's Warrants on the Nasdaq Capital Market, any other national securities exchange or any other trading system.

This offering is being conducted on a best efforts basis. There is no minimum number of securities or minimum aggregate amount of proceeds for this offering to close. The offering of the securities will terminate on the first date that we enter into securities purchase agreements to sell the securities pursuant to this prospectus.

Investing in our securities involves a high degree of risk. See "Risk Factors" beginning on page 9 of this prospectus and elsewhere in this prospectus for a discussion of information that should be considered in connection with an investment in our securities.

Neither the Securities and Exchange Commission nor any state securities commission has approved or disapproved of these securities or passed upon the adequacy or accuracy of this prospectus. Any representation to the contrary is a criminal offense.

	Per Share and Common Warrant	Per Pre-Funded Warrant and Common Warrant	Total
Public offering price	$	$	$
Placement Agent's fees (1)	$	$	$
Proceeds, before expenses, to us (2)	$	$	$

(1) We have agreed to reimburse H.C. Wainwright & Co., LLC, or the Placement Agent, for certain of its expenses. In addition, we have agreed to issue to the Placement Agent warrants to purchase up to a number of shares of our common stock equal to 5% of the number of shares of common stock and pre-funded warrants sold in this offering. See "Plan of Distribution" for additional information and a description of the compensation payable to the Placement Agent.

(2) We estimate the total expenses of this offering payable by us, excluding the Placement Agent's fees, will be approximately $.

We engaged H.C. Wainwright & Co., LLC as our exclusive placement agent to use its reasonable best efforts to solicit offers to purchase the securities in this offering. The Placement Agent has no obligation to buy any of the securities from us or to arrange for the purchase or sale of any specific number or dollar amount of the securities.

The securities are expected to be delivered to purchasers on or about , 2019.

H.C. Wainwright & Co.

The date of this prospectus is , 2019

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The registration statement we filed with the Securities and Exchange Commission, or the SEC, includes exhibits that provide more detail of the matters discussed in this prospectus. You should read this prospectus, the related exhibits filed with the SEC, and the documents incorporated by reference herein before making your investment decision. You should rely only on the information provided in this prospectus and the documents incorporated by reference herein or any amendment thereto. In addition, this prospectus contains summaries of certain provisions contained in some of the documents described herein, but reference is made to the actual documents for complete information. All of the summaries are qualified in their entirety by the actual documents. Copies of some of the documents referred to herein have been filed, will be filed or will be incorporated by reference as exhibits to the registration statement of which this prospectus is a part, and you may obtain copies of those documents as described below under the heading "Where You Can Find Additional Information." Information contained in later-dated documents incorporated by reference will automatically supplement, modify or supersede, as applicable, the information contained in this prospectus or in earlier-dated documents incorporated by reference.

We have not authorized anyone to provide any information or to make any representations other than those contained in this prospectus, the documents incorporated by reference herein or in any free writing prospectuses prepared by or on behalf of us or to which we have referred you. We take no responsibility for, and can provide no assurance as to the reliability of, any other information that others may give you. The information contained in this prospectus, the documents incorporated by reference herein or in any applicable free writing prospectus is current only as of its date, regardless of its time of delivery or any sale of our securities. Our business, financial condition, results of operations and prospects may have changed since that date.

This prospectus is an offer to sell only the securities offered hereby, and only under circumstances and in jurisdictions where it is lawful to do so. We are not, and the Placement Agent is not, making an offer to sell these securities in any state or jurisdiction where the offer or sale is not permitted.

PROSPECTUS SUMMARY

This summary highlights information contained elsewhere in this prospectus. Because it is a summary, it may not contain all of the information that is important to you. Accordingly, you are urged to carefully read the entire prospectus, any applicable prospectus supplement and any related free writing prospectus, including the risks of investing in our securities discussed under the heading "Risk Factors" contained in any applicable prospectus supplement and any related free writing prospectus, and under similar headings in the other documents that are incorporated by reference into this prospectus. You should also carefully read the information incorporated by reference into this prospectus, including our financial statements, and the exhibits to the registration statement of which this prospectus is a part. References to the "Company," "Capricor Therapeutics," "we," "us" or "our" in this prospectus refer to Capricor Therapeutics, Inc., a Delaware corporation, and its subsidiaries, unless the context indicates otherwise.

Company Overview

Capricor Therapeutics, Inc. is a clinical-stage biotechnology company focused on the discovery, development and commercialization of first-in-class biological therapies for the treatment of diseases, with a focus on Duchenne muscular dystrophy, or DMD, and other rare disorders.

We were originally incorporated in Delaware in August 2005 under the name Nile Pharmaceuticals, Inc. and we changed our name to Nile Therapeutics, Inc., or Nile, in January 2007. On November 20, 2013, pursuant to that certain Agreement and Plan of Merger and Reorganization dated as of July 7, 2013, as amended by that certain First Amendment to Agreement and Plan of Merger and Reorganization dated as of September 27, 2013, or as amended, the Merger Agreement, by and among Nile, Nile's wholly-owned subsidiary, Bovet Merger Corp., a Delaware corporation, or Merger Sub, and Capricor, Inc., or Capricor, Merger Sub merged with and into Capricor and Capricor became a wholly-owned subsidiary of Nile (referred to herein as the Merger). Immediately prior to the effective time of the Merger, and in connection therewith, Nile filed certain amendments to its certificate of incorporation which, among other things, (i) effected a 1-for-50 reverse split of its common stock, (ii) changed its corporate name from "Nile Therapeutics, Inc." to "Capricor Therapeutics, Inc.," and (iii) effected a reduction in the total number of authorized shares of common stock from 100,000,000 to 50,000,000, and a reduction in the total number of authorized shares of preferred stock from 10,000,000 to 5,000,000.

Capricor, our wholly-owned subsidiary, was founded in 2005 as a Delaware corporation based on the innovative work of its founder, Eduardo Marbán, M.D., Ph.D., and his collaborators. First located in Baltimore, Maryland, adjacent to The Johns Hopkins University, or JHU, where Dr. Marbán was chief of cardiology, Capricor moved to Los Angeles, California in 2007 when Dr. Marbán became Director of the Heart Institute at Cedars-Sinai Medical Center, or CSMC. Capricor's laboratories and manufacturing facilities are located in space that Capricor leases from CSMC.

On June 4, 2019, we effected a reverse stock split of our outstanding shares of common stock at a ratio of one-for-ten pursuant to a Certificate of Amendment to our Certificate of Incorporation filed with the Secretary of State of the State of Delaware. The reverse stock split was reflected on Nasdaq beginning with the opening of trading on June 5, 2019. The primary purpose of the reverse stock split, which was approved by our stockholders at our Annual Stockholders Meeting on May 29, 2019, was to enable us to regain compliance with the $1.00 minimum bid price requirement for continued listing on Nasdaq. Pursuant to the reverse stock split, every ten shares of our 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 this prospectus give effect to the reverse stock split, including for periods before the effective date of the reverse stock split. Amounts of common stock resulting from the reverse stock split were rounded down to the nearest whole share and any resulting fractional shares were cancelled for cash. The number of authorized shares of our common stock remained unchanged. The reverse stock split affected all issued and outstanding shares of our common stock, and the respective numbers of shares of common stock underlying outstanding stock options, outstanding warrants and our equity incentive plans were proportionately adjusted.

Our Technologies

Cardiosphere-Derived Cells (CAP-1002)

Our core therapeutic technology is based on cardiosphere-derived cells, or CDCs, a cardiac-derived cell therapy that was first identified in the academic laboratory of Capricor's scientific founder, Dr. Eduardo Marbán. Since the initial publication in 2007, CDCs have been the subject of over 100 peer-reviewed scientific publications and have been administered to approximately 150 human subjects across several clinical trials. CDCs have been shown to exert potent immunomodulatory activity and to alter the immune system's activity to encourage cellular regeneration. We have been developing allogeneic CDCs (CAP-1002) as a product candidate for the treatment of Duchenne muscular dystrophy, or DMD and investigating their effects on skeletal and cardiac function. Pre-clinical and clinical data support the therapeutic concept of administering CDCs as a means to address conditions in which the heart or skeletal muscle has been damaged.

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

CDCs are derived from cardiospheres, or CSps, which are self-adherent multicellular clusters derived from the heart. CDCs are sufficiently small that, within acceptable dose limits, they can be infused into a coronary artery or into the peripheral vasculature. Capricor has performed clinical studies to establish the range of CDC dose levels that appear to be safe via intracoronary administration or peripheral venous access. Additionally, in pre-clinical studies, it has been shown that intravenous administration of CDCs increases exercise capacity and diaphragmatic function in a mouse model of DMD.

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.

Cardiosphere-Derived Cell Exosomes

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

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

Our Strategy

Our strategy is to discover, develop and commercialize first-in-class cell-derived therapies for the treatment of diseases. Our drug candidates in active development consist of CAP-1002 (allogeneic off-the-shelf CDCs) and our exosome technologies. We have established that CDC-exosomes are primarily responsible for the mechanism of action of our cell therapy product. We are now positioning ourselves to advance our exosome product candidates into a platform technology for clinical development.

Exosomes in Pre-clinical Development

Our exosomes program consists of exosomes derived from CDCs (CAP-2003) and engineered exosomes, both of which are in various stages of preclinical development. While CAP-2003 was the initial technology used in preclinical development, we have expanded Capricor's pipeline to include additional exosomes technologies.

Bioactivity

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

Immunomodulation

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

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

Biodistribution

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

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

Manufacturing

We have also made significant progress on the manufacturing process for our exosome product candidates. These developments will enable us to significantly scale up our manufacturing capabilities and should allow us to manufacture enough material for clinical development.

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

Engineered Exosomes

To build upon the natural ability of exosomes for intercellular communication, we have initiated a program to engineer exosomes and load them with different macromolecules. Our preliminary results demonstrated that it is possible to load exosomes with specific miRNAs which pave the way to use our exosomes to deliver miRNAs to specific target tissue. We are in the early stages of developing technology to engineer exosomal membranes to modify their tropism and to deliver additional molecules which may include nucleic acids and proteins.

Investigation of Potential Indications for our Exosomes Technologies

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

Evaluation and determination of the first-in-human indication will be based on multiple factors and we plan to file an IND with the FDA in the first half of 2020.

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

CAP-1002 for the Treatment of Duchenne muscular dystrophy (DMD)

We are currently developing CAP-1002 for the treatment of DMD. We reported positive interim results from the HOPE-2 Phase II clinical trial in the third quarter of 2019 and we expect to report 12-month results by the second quarter of 2020. We recently had another meeting with the FDA to discuss, among other things, the results of the 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 this time. The FDA did, however, indicate its support of a Phase III trial of CAP-1002 for the treatment of DMD. Prior to the meeting, we had submitted a draft protocol for the Phase III trial which calls for up to 70 patients. 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. We are now in the planning stages of a Phase III trial for DMD, however, 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 and/or our ability to partner with another company to advance the development of CAP-1002 for DMD, as well as other factors, some of which are not known at this time. We are also exploring potential strategic alternatives with respect to the Company as well as our product candidates.

Our clinical development of CAP-1002 includes the completion of multiple clinical trials including the HOPE-Duchenne Phase I/II clinical trial in subjects with DMD, the DYNAMIC trial, a Phase I clinical trial of CAP-1002 in subjects with advanced heart failure, and the ALLSTAR trial, a Phase I/II clinical trial of CAP-1002 in subjects who have suffered a myocardial infarction, or MI, which is commonly known as a heart attack.

These programs represent our core technologies.

Our Product Candidates

Our drug candidates which are in various stages of active development, consist of CAP-1002, our CDC-derived cells, and our exosome technologies. In 2018 we commenced enrollment of patients with DMD in a Phase II clinical trial of CAP-1002 called HOPE-2. CAP-1002 was also the subject of three previous clinical trials conducted by us. CAP-1002 is also currently being investigated in two additional trials sponsored by Cedars-Sinai Medical Center, or CSMC, which are the REGRESS trial investigating heart failure with preserved ejection fraction and the ALPHA trial investigating pulmonary arterial hypertension. Although we are not the sponsor of these two trials, we are providing the investigational product for use in the trials. We are also evaluating our exosomes in pre-clinical studies for the treatment of various indications.

The following table summarizes our active product development programs:

Product	Indication/Population	Development Stage	Commercial Rights
CAP-1002	Duchenne Muscular Dystrophy*	HOPE-3 Phase III – in planning stages HOPE-2 Phase II • 12 month data expected by Q2-2020 • 6-month interim analysis completed HOPE-Duchenne Phase I/II completed**	Capricor
Exosomes	Cardiovascular indications	Pre-clinical	Capricor
	Neuromuscular indications	Pre-clinical	Capricor
	Ophthalmologic indications	Pre-clinical	Capricor

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

**We completed an Open Label Extension, or OLE, for the usual care only comparator arm of the HOPE-Duchenne trial.

Risks Associated with Our Business and this Offering

Our business is subject to numerous risks and uncertainties, including those highlighted in the section entitled "Risk Factors" immediately following this prospectus summary. These risks include, but are not limited to, the following:

- We have had a history of recurring losses and negative cash flows from operating activities, and we face many uncertainties regarding the adequacy of our liquidity to pursue or complete our business objectives, including future clinical trials;
- We may be unable to successfully carry out our research, development and commercialization plans;
- We may be unable to manufacture our product candidates on a commercial scale on our own or in collaborations with third parties;
- We may be unable to complete preclinical testing and clinical trials as anticipated, and in the case of our lead product candidate, CAP-1002, in DMD, we will likely need to find a strategic partner to continue development;
- We may be unable to adequately protect and enforce rights to our intellectual property;
- We may have difficulties in obtaining financing on commercially reasonable terms, or at all;
- We face intense competition in our industry, with competitors having substantially greater financial, technological, research and development, regulatory and clinical, manufacturing, marketing and sales, distribution and personnel resources than we do;
- We may face new competitors and products and potential technological obsolescence of our products;
- We may face adverse market and economic conditions;
- We may lose of one or more of our key executives or scientists; and
- We may be unable to secure regulatory approval to market our product candidates.

Implications of Being a Smaller Reporting Company

We are a "smaller reporting company" and accordingly have elected to take advance of certain of the reduced disclosure obligations in the registration statement of which this prospectus is a part and may elect to take advantage of other reduced reporting requirements in future filings. As a result, the information that we provide to our stockholders may be different than you might receive from other public reporting companies in which you hold equity interests.

Recent Developments

Recent Offerings

August 2019 ATM Program.

On August 29, 2019, we initiated an at-the-market offering under a prospectus supplement for aggregate sales proceeds of up to $1.95 million, or the August 2019 ATM Program, with the common stock to be distributed at the market prices prevailing at the time of sale. The August 2019 ATM Program was established under a Common Stock Sales Agreement, or the July 2019 Sales Agreement, with 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 August 2019 ATM Program have been and will be issued pursuant to our shelf registration statement on Form S-3 (File No. 333-227955), which was initially filed with the Securities and Exchange Commission, or the SEC, on October 24, 2018, amended on July 17, 2019 and declared effective by the SEC on July 18, 2019. Since August 29, 2019 and through December 2, 2019, we have sold an aggregate of 360,316 common shares under the August 2019 ATM Program at an average price of approximately $3.07 per common share for gross proceeds of approximately $1.1 million. We paid cash commissions on the gross proceeds, plus reimbursement of expenses of the placement agent and legal fees in the aggregate amount of approximately $0.1 million.

July 2019 Common Stock Sales Agreement.

On July 22, 2019, we initiated an at-the-market offering under a prospectus supplement for aggregate sales proceeds of up to $1.8 million, or the July 2019 ATM Program, with the common stock to be distributed at the market prices prevailing at the time of sale. The July 2019 ATM Program was established under the July 2019 Sales Agreement, which provides that Wainwright will be entitled to compensation for its services at a commission rate of 3.0% of the gross sales price per share of common stock sold. All shares issued pursuant to the July 2019 ATM Program were issued pursuant to our shelf registration statement on Form S-3 (File No. 333-227955), which was initially filed with the SEC on October 24, 2018, amended on July 17, 2019 and declared effective by the SEC on July 18, 2019. As of the expiration of the July 2019 ATM Program, we sold an aggregate of 418,450 common shares under the July 2019 ATM Program at an average price of approximately $4.30 per common share for gross proceeds of approximately $1.8 million. We 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.

Corporate Information

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.* We do not incorporate the information on, or accessible through, our website into this prospectus, and you should not consider any information on, or accessible through, our website as part of this prospectus. We have included our website address in this prospectus solely as an inactive textual reference.

THE OFFERING

Common stock offered by us in this offering	shares.
Pre-funded warrants offered by us in this offering	We are also offering to certain purchasers whose purchase of shares of common stock in this offering would otherwise result in the purchaser, together with its affiliates and certain related parties, beneficially owning more than 4.99% (or, at the election of the purchaser, 9.99%) of our outstanding common stock immediately following the closing of this offering, the opportunity to purchase, if such purchasers so choose, pre-funded warrants to purchase shares of common stock, in lieu of shares of common stock that would otherwise result in any such purchaser's beneficial ownership exceeding 4.99% (or, at the election of the purchaser, 9.99%) of our outstanding common stock. Each pre-funded warrant will be exercisable for one share of our common stock. The purchase price of each pre-funded warrant and accompanying common warrant (as described below) will be equal to the price at which a share of common stock and accompanying common warrant is being sold to the public in this offering, minus $0.001, and the exercise price of each pre-funded warrant will be $0.001 per share. The pre-funded warrants will be exercisable immediately and may be exercised at any time until all of the pre-funded warrants are exercised in full. This offering also relates to the shares of common stock issuable upon exercise of any pre-funded warrants sold in this offering. For each pre-funded warrant we sell, the number of shares of common stock we are offering will be decreased on a one-for-one basis. Because we will issue a common warrant for each share of our common stock and for each pre-funded warrant to purchase one share of our common stock sold in this offering, the number of common warrants sold in this offering will not change as a result of a change in the mix of the shares of our common stock and pre-funded warrants sold. For more information, see the section entitled “Description of Capital Stock” on page 44 of this prospectus.
Common warrants offered by us in this offering	Warrants to purchase up to shares, which may be exercised beginning on their date of issuance. The warrants are exercisable until the five year anniversary of the original issuance date. The warrants have an exercise price of $ per share of common stock, subject to adjustment. For more information, see the section entitled “Description of Capital Stock” on page 44 of this prospectus.
Common stock to be outstanding after this offering	shares, assuming no sales of pre-funded warrants, which, if sold, would reduce the number of shares of common stock that we are offering on a one-for-one basis and assuming no exercise of any common warrants issued in this offering.
Use of proceeds	We intend to use the net proceeds from this offering to fund the research and development of our exosome technologies to support the filing of an IND in an indication to be designated by us, for related manufacturing costs to support the development of our exosome technologies, for hiring additional personnel to support our R&D and manufacturing capabilities, for business development and general corporate purposes, which may include additional work around CAP-1002 either alone or in collaboration with a third party. See “Use of Proceeds.”
Risk factors	See “Risk Factors” beginning on page 9 and the other information included elsewhere in this prospectus for a discussion of factors you should carefully consider before deciding to invest in our equity securities.
Nasdaq Capital Market symbol	Our common stock is listed on the Nasdaq Capital Market under the symbol “CAPR.”

The number of shares of common stock to be outstanding after this offering is based on 4,174,856 shares of common stock outstanding as of September 30, 2019, and excludes, as of such date:

- 755,225 shares of common stock issuable upon the exercise of options outstanding with a weighted-average exercise price of approximately $12.63 per share;
- 65,762 shares of common stock reserved for future issuance under our (1) 2012 Restated Equity Incentive Plan; and (2) 2012 Non-Employee Director Stock Option Plan; and
- 71,369 shares of common stock sold under the August 2019 ATM Program after September 30, 2019 at an average price of approximately $2.96 per share.

Unless otherwise indicated, all information contained in this prospectus assumes no sale of pre-funded warrants, which, if sold, would reduce the number of shares of common stock that we are offering on a one-for-one basis and no exercise of any common warrants issued in this offering.

RISK FACTORS

Investing in any securities offered pursuant to this prospectus and the applicable prospectus supplement involves a high degree of risk. Before making an investment decision, you should carefully consider the risks described under "Risk Factors" in this prospectus, in any applicable prospectus supplement, and in our most recent Annual Report on Form 10-K, or any updates in our Quarterly Reports on Form 10-Q, together with all of the other information appearing in or incorporated by reference into this prospectus and any applicable prospectus supplement, as well as any free writing prospectus which we may file, before deciding whether to purchase any of the securities being offered. Our business, financial condition or results of operations could be materially adversely affected by any of these risks. The occurrence of any of these risks might cause you to lose all or part of your investment in the offered securities.

The risks described in these documents are not the only ones we face. There may be other unknown or unpredictable economic, business, competitive, regulatory or other factors that could have material adverse effects on our future results. Further, past financial performance may not be a reliable indicator of future performance, and historical trends should not be used to anticipate results or trends in future periods. Please also read carefully the section below entitled "Special Note Regarding Forward-Looking Statements."

Risks Related to Our Business

We need substantial additional funding before we can complete the development of our product candidates. If we are unable to obtain such additional capital, we will be forced to delay, reduce or eliminate our product development and clinical programs and may not have the capital required to otherwise operate our business.

Developing biopharmaceutical products, including conducting pre-clinical studies and clinical trials and establishing manufacturing capabilities, is expensive. As of September 30, 2019, we had cash and cash resources, including restricted cash, totaling approximately $6.8 million. We have not generated any revenues from the commercial sale of products. We will not be able to generate any product revenues until, and only if, we receive approval to sell our drug candidates from the FDA or other regulatory authorities.

From inception, we have financed our operations through public and private sales of our equity and debt securities, grants from the National Institutes of Health, or NIH, and the Department of Defense, or DoD, and a loan commitment and grant award from the California Institute for Regenerative Medicine, or CIRM. In December 2013 we also entered into a collaboration agreement with Janssen Biotech, Inc., or Janssen, which provided funding for the development of our cell manufacturing program, including CAP-1002. As we have not generated any revenue from commercial sales to date and we do not expect to generate revenue for several years, if ever, we will need to raise substantial additional capital in order to fund our general corporate activities and to fund our research and development, including our ongoing clinical trials and plans for new clinical trials and product development.

Earlier in 2019, we implemented certain cost cutting measures including a reduction in the size of our workforce in order to conserve cash resources. Based on our available cash resources, we do not have sufficient cash on hand to support current operations for at least the next twelve months from the date of filing of this Registration Statement on Form S-1. Therefore, there is substantial doubt about the Company's ability to continue as a going concern. Other than our cash on hand and the funds expected to be received from our supplying product for clinical trials sponsored by CSMC and the DoD grant award which funds ongoing pre-clinical work for our exosomes, as well as potential sales under our August 2019 ATM Program, we currently have no commitments or arrangements for any additional financing to fund the research and clinical development of CAP-1002 or our exosomes.

We may seek to raise additional funds through various potential sources, such as equity and debt financings, or through strategic collaborations and license agreements. We can give no assurances that we will be able to secure such additional sources of funds to support our operations or, if such funds are available to us, that such additional financing will be sufficient to meet our needs. Moreover, to the extent that we raise additional funds by issuing equity securities, our stockholders may experience additional significant dilution, and debt financing, if available, may involve restrictive covenants. To the extent that we raise additional funds through collaboration and licensing arrangements, it may be necessary to relinquish some rights to our technologies or our product candidates, or grant licenses on terms that may not be favorable to us.

Given our capital constraints, we need to prioritize spending on our clinical and pre-clinical programs. If we are unable to raise sufficient funds to support our current and planned operations, we may elect to discontinue certain of our ongoing activities or programs. Our inability to raise additional funds could also prevent us from taking advantage of opportunities to pursue promising new or existing programs in the future.

Our forecasts regarding our beliefs in the sufficiency of our financial resources to support our current and planned operations are forward-looking statements and involve significant risks and uncertainties, and actual results could vary as a result of a number of factors, including the factors discussed elsewhere in this "Risk Factors" section. We have based these estimates on assumptions that may prove to be wrong, and we could utilize our available capital resources sooner than we currently expect. Our future funding requirements will depend on many factors, including, but not limited to:

- the scope, rate of progress, cost and results of our research and development activities, especially our HOPE-2 clinical trial and our ongoing exosomes program;
- the next steps in the development of our DMD program, which may include a Phase III clinical trial for our CAP-1002 product candidate in DMD;

- the availability of funding from government programs including the NIH and DoD;
- the costs of developing adequate manufacturing processes and facilities;
- the costs associated with and timing of regulatory approval;
- the costs of filing, prosecuting, defending and enforcing any patent claims and other intellectual property rights;
- the costs and risks involved in conducting clinical trials and manufacturing operations internationally;
- the effect of competing technological and market developments;
- the terms and timing of any collaboration, licensing or other arrangements that we may establish;
- the cost and timing of completion of clinical and commercial-scale outsourced manufacturing activities; and
- the costs of establishing sales, marketing and distribution capabilities for any product candidates for which we may receive regulatory approval.

We and our auditors have substantial doubt about our ability to continue as a going concern, which may hinder our ability to obtain further financing.

Our recurring losses from operations raise substantial doubt about our ability to continue as a going concern. As a result, our independent registered public accounting firm included an explanatory paragraph in its report on our financial statements for the year ended December 31, 2018 with respect to this uncertainty. Our 2018 financial statements do not include any adjustments to reflect the possible future effects on the recoverability and classification of assets or the amounts and classification of liabilities that may result from the outcome of this uncertainty. Our ability to continue as a going concern will require us to obtain additional funding. If we are unable to raise capital when needed or on acceptable terms, we would be forced to delay, reduce or eliminate our research and development programs, and our stockholders could lose all, or a significant portion, of their investment in us.

We have a history of net losses, and we expect losses to continue for the foreseeable future. In addition, a number of factors may cause our operating results to fluctuate on a quarterly and annual basis, which may make it difficult to predict our future performance.

We have a history of net losses, expect to continue to incur substantial net losses for the foreseeable future, and may never achieve or maintain profitability. Our operations to date have been primarily limited to organizing and staffing our company, developing our technology, and undertaking pre-clinical studies and clinical trials of our product candidates. We have not yet obtained regulatory approval for any of our product candidates. Specifically, our financial condition and operating results have varied significantly in the past and will continue to fluctuate from quarter-to-quarter and year-to-year in the future due to a variety of factors, many of which are beyond our control. Factors relating to our business that may contribute to these fluctuations include the following factors:

- our need for substantial additional capital to fund our trials and development programs;
- delays in the commencement, enrollment, and timing of clinical testing;
- the viability of CAP-1002 as a potential product candidate for the treatment of DMD and its development through all stages of clinical development;
- the viability of our exosome technologies as potential product candidates and the advancement of our exosome technologies through all stages of its pre-clinical and clinical development;
- any delays in regulatory review and approval of our product candidates in clinical development;
- our ability to receive regulatory approval or commercialize our product candidates, within and outside the United States;
- potential side effects of our current or future products and product candidates that could delay or prevent commercialization or cause an approved treatment drug to be taken off the market;
- market acceptance of our product candidates;
- our ability to establish an effective sales and marketing infrastructure once our products are commercialized or to establish partnerships with other companies who have greater sales and marketing capabilities;
- our ability to establish or maintain collaborations, licensing or other arrangements, including strategic partnerships for CAP-1002 in DMD;
- our ability and third parties' abilities to obtain and protect intellectual property rights;
- competition from existing products or new products that may emerge;
- guidelines and recommendations of therapies published by various organizations;
- the ability of patients to obtain coverage of, or sufficient reimbursement for, our products;
- our ability to maintain adequate insurance policies;
- our ability to successfully manufacture our product candidates in sufficient quantities and on a timely basis to meet clinical trial and potential commercial demand;
- our dependency on third parties to formulate and manufacture our product candidates;
- our ability to maintain our current manufacturing facility, including our ability to achieve and maintain current Good Manufacturing Practices, or cGMP, certification, and to secure other facilities as determined to be necessary;
- costs related to and outcomes of potential intellectual property litigation;
- compliance with obligations under intellectual property licenses with third parties;
- our ability to implement additional internal systems and infrastructure;
- our ability to adequately support future growth;
- if our products are approved for commercial sale, the ability to secure reimbursement for our products;
- our ability to attract and retain key personnel to manage our business effectively; and
- the ability of members of our senior management who have limited experience in managing a public company to manage our business and operations.

The Company's technology is not yet proven and each of our product candidates is still in clinical or pre-clinical development.

Each of the Company's two active product candidates, CAP-1002 and our exosome technologies, are in development and each requires further and, in some cases, extensive clinical testing before it may be approved by the FDA, or another regulatory authority in a jurisdiction outside the United States, which could take several years to complete, if ever. The Company's failure to establish the efficacy of its technologies would have a material adverse effect on the Company. We cannot predict with any certainty the results of such clinical testing, including the results of our HOPE-2 trial or any subsequent 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, or whether our current trials will yield sufficient data to permit us to proceed with additional clinical development and ultimately submit an application for regulatory approval of our product candidates in the United States or abroad, or whether such applications will be accepted by the appropriate regulatory agencies. We are also unable to predict whether our pre-clinical studies of our exosomes product will result in a viable clinical development program.

Business disruptions such as natural disasters 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, 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.

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

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

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

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

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

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

Should we achieve our near-term milestones, of which no assurance can be given, our long-term viability will depend upon the expansion of our operations and the effective management of our growth, which will place a significant strain on our management and on our administrative, operational and financial resources, especially if we expand our business and operations internationally. To manage this growth, we may need to expand our facilities, augment our operational, financial and management systems and hire and train additional qualified personnel. If we are unable to manage our growth effectively, our business would be harmed.

Risks Related to Clinical and Commercialization Activities

Our success depends upon the viability of our product candidates and we cannot be certain any of them will receive regulatory approval to be commercialized.

We will need FDA approval to market and sell any of our product candidates in the United States and approvals from FDA-equivalent regulatory authorities in foreign jurisdictions to commercialize our product candidates in those jurisdictions. In order to obtain FDA approval of any of our product candidates, we must submit to the FDA a new drug application, or NDA, or a biologics license application, or BLA, demonstrating that the product candidate is safe for humans and effective for its intended use. This demonstration requires significant research and animal tests, which are referred to as pre-clinical studies, as well as human tests, which are referred to as clinical trials. Satisfaction of the FDA's regulatory requirements typically takes many years, depends upon the type, complexity, and novelty of the product candidate, and requires substantial resources for research, development, testing and manufacturing. We cannot predict whether our research and clinical approaches will result in drugs that the FDA considers safe for humans and effective for indicated uses. The FDA has substantial discretion in the drug approval process and may require us to conduct additional pre-clinical and clinical testing or to perform post-marketing studies. The approval process may also be delayed by changes in government regulation, future legislation, administrative action or changes in FDA policy that occur prior to or during our regulatory review.

Even if we comply with all FDA requests, the FDA may ultimately reject one or more of our NDAs or BLAs, as applicable. We cannot be sure that we will ever obtain regulatory clearance for our product candidates. Failure to obtain FDA approval of any of our product candidates will reduce our number of potentially salable products and, therefore, corresponding product revenues, and will have a material and adverse impact on our business.

As the results of earlier pre-clinical studies or clinical trials are not necessarily predictive of future results, any product candidate we advance into clinical trials may not have favorable results in later clinical trials or receive regulatory approval.

Even if our pre-clinical studies and clinical trials are completed as planned, we cannot be certain that their results will support the claims of our product candidates. Positive results in pre-clinical testing and early clinical trials do not ensure that results from later clinical trials will also be positive, and we cannot be sure that the results of later clinical trials will replicate the results of prior clinical trials and pre-clinical testing. Results of our interim analysis conducted at 6 months may not be predictive of the final results of the trial and having seen the unblinded results has impacted our ability to use the data from the HOPE-2 trial as originally contemplated. A number of companies in the pharmaceutical industry, including those with greater resources and experience, have suffered significant setbacks in Phase II or Phase III clinical trials, even after seeing promising results in earlier clinical trials.

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

Despite the results reported in earlier clinical trials for our product candidates, we do not know whether any Phase II, Phase III or other clinical trials we may conduct will demonstrate adequate efficacy and safety to result in regulatory approval to market our product candidates.

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 exosomes technologies as they proceed through preclinical studies and clinical trials. In addition, because we have only conducted preclinical studies with our exosomes 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 EMA and other regulatory authorities and the criteria these regulators use to determine the safety and efficacyof a product candidate vary substantially according to the type, complexity and intended use and market of the product candidate. As a result, the regulatory approval process for our exosomes is uncertain and may be more expensive and take longer than the approval process for other product candidates. It is difficult to determine how long it will take or how much it will cost to obtain regulatory approvals for our exosomes in either the United States or the European Union or other regions of the world or how long it will take to commercialize our product candidates, if at all. Delay or failure to obtain, or unexpected costs in obtaining, the regulatory approval necessary to bring a potential product candidate to market could decrease our ability to generate sufficient product revenue, and our business, financial condition, results of operations and prospects may be harmed.

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

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

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

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

We hope to file additional investigational new drug applications, or INDs, over the next several years, including with respect to our exosome technologies in one or more indications. However, the timing of our filing of these INDs is primarily dependent on receiving further data from our pre-clinical studies, and our timing of filing on all product candidates is subject to further research. Additionally, our submission of INDs is contingent upon having sufficient financial resources to prepare and complete the application.

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

The Company has limited experience in conducting clinical trials, which are complex and subject to strict regulatory oversight.

The Company has limited human clinical trial experience with respect to its product candidates. The clinical testing process is governed by stringent regulation and is highly complex, costly, time-consuming, and uncertain as to outcome, and pharmaceutical products and products used in the regeneration of tissue may invite particularly close scrutiny and requirements from the FDA and other regulatory bodies. Our failure or the failure of our collaborators to conduct human clinical trials successfully or our failure to capitalize on the results of human clinical trials for our product candidates would have a material adverse effect on the Company. If our clinical trials of our product candidates or future product candidates do not sufficiently enroll or produce results necessary to support regulatory approval in the United States or elsewhere, or if they show undesirable side effects, we will be unable to commercialize these product candidates.

To receive regulatory approval for the commercial sale of our product candidates, we must conduct adequate and well-controlled clinical trials to demonstrate efficacy and safety in humans. Clinical failure can occur at any stage of testing. Our clinical trials may produce negative or inconclusive results, and we may decide, or regulators may require us, to conduct additional clinical and/or non-clinical testing. In addition, the results of our clinical trials may show that our product candidates are ineffective or may cause undesirable side effects, which could interrupt, delay or halt clinical trials, resulting in the denial of regulatory approval by the FDA and other regulatory authorities. Furthermore, negative, delayed or inconclusive results may result in:

- the withdrawal of clinical trial participants;
- the termination of clinical trial sites or entire trial programs;
- costly litigation arising out of the trials;
- substantial monetary awards to patients or other claimants;
- the requirement that additional trials be conducted;
- impairment of our business reputation;
- loss of revenues; and
- the inability to commercialize our product candidates.

Delays in the commencement, enrollment, and completion of clinical testing could result in increased costs to us and delay or limit our ability to obtain regulatory approval for our product candidates.

Delays in the commencement, enrollment or completion of clinical testing could significantly affect our product development costs. A clinical trial may be suspended or terminated by the Company, the FDA, or other regulatory authorities due to a number of factors. The commencement and completion of clinical trials require us to identify and maintain a sufficient number of trial sites, many of which may already be engaged in other clinical trial programs for the same indication as our product candidates or may otherwise be resource constrained. We may be required to withdraw from a clinical trial as a result of changing standards of care, or we may become ineligible to participate in clinical studies. We do not know whether planned clinical trials will begin on time or be completed on schedule, if at all. The commencement, enrollment and completion of clinical trials can be delayed for a number of reasons, including, but not limited to, delays related to:

- findings in pre-clinical studies;
- reaching agreements on acceptable terms with prospective CROs, vendors and trial sites, the terms of which can be subject to extensive negotiation and may vary significantly among different CROs, vendors and trial sites;
- obtaining regulatory clearance to commence a clinical trial;
- complying with conditions imposed by a regulatory authority regarding the scope or term of a clinical trial, or being required to conduct additional trials before moving on to the next phase of trials;
- obtaining institutional review board, or IRB, approval to conduct a clinical trial at numerous prospective sites;
- recruiting and enrolling patients to participate in clinical trials for a variety of reasons, including the size of the patient population, nature of trial protocol, meeting the enrollment criteria for our studies, screening failures, the inability of the sites to conduct trial procedures properly, the inability of the sites to devote their resources to the trial, the availability of approved effective treatments for the relevant disease and competition from other clinical trial programs for similar indications;
- retaining patients who have initiated their participation in a clinical trial but may be prone to withdraw due to the treatment protocol, lack of efficacy, personal issues, or side effects from the therapy, or who are lost to further follow-up;
- manufacturing sufficient quantities of a product candidate for use in clinical trials on a timely basis;
- complying with design protocols of any applicable special protocol assessment we receive from the FDA;
- severe or unexpected drug-related side effects experienced by patients in a clinical trial;
- collecting, analyzing and reporting final data from the clinical trials;
- breaches in quality of manufacturing runs that compromise all or some of the doses made; positive results in FDA-required viral testing; karyotypic abnormalities in our cell product; or contamination in our manufacturing facilities, all of which events would necessitate disposal of all cells made from that source;
- availability of materials provided by third parties necessary to manufacture our product candidates;
- availability of adequate amounts of acceptable tissue for preparation of master cell banks for our products;
- requirements to conduct additional trials and studies, and increased expenses associated with the services of the Company's CROs and other third parties; and
- meeting logistical requirements for the delivery of investigational product.

If we are required to conduct additional clinical trials or other testing of our product candidates beyond those that we currently contemplate, we or our development partners, if any, may be delayed in obtaining, or may not be able to obtain or maintain, clinical or marketing approval for these product candidates. We may not be able to obtain approval for indications that are as broad as intended, or we may be able to obtain approval only for indications that are entirely different from those indications for which we sought approval.

Changes in regulatory requirements and guidance may occur, and we may need to amend clinical trial protocols to reflect these changes with appropriate regulatory authorities. Amendments may require us to resubmit our clinical trial protocols to IRBs for re-examination, which may impact the costs, timing, or successful completion of a clinical trial. If we experience delays in the completion of, or if we terminate, our clinical trials, the commercial prospects for our product candidates will be harmed, and our ability to generate product revenues will be delayed or will not be realized. In addition, many of the factors that cause, or lead to, a delay in the commencement or completion of clinical trials may also ultimately lead to the denial of regulatory approval of a product candidate. Even if we are able to ultimately commercialize our product candidates, other therapies for the same or similar indications may have been introduced to the market and already established a competitive advantage. Any delays in obtaining regulatory approvals may:

- delay commercialization of, and our ability to derive product revenues from, our product candidates;
- impose costly procedures on us; or
- diminish any competitive advantages that we may otherwise enjoy.

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

Under the Orphan Drug Act, the FDA may grant orphan designation to a drug or biologic intended to treat a rare disease or condition or for which there is no reasonable expectation that the cost of developing and making available in the United States a drug or biologic for a disease or condition will be recovered from sales in the United States for that drug or biologic. If a biological product that has orphan drug designation subsequently receives the first FDA approval for the disease for which it has such designation, the product is entitled to orphan product exclusivity, which means that the FDA may not approve any other applications, including a full Biologics License Application, or BLA, to market the same biologic for the same indication for seven years, except in limited circumstances, such as a showing of clinical superiority to the product with orphan drug exclusivity.

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

We have also obtained an RMAT designation for CAP-1002 for the treatment of DMD. The RMAT designation program is intended to fulfill the Cures Act requirement that the FDA facilitate an efficient development program for, and expedite review of, any drug that meets the following criteria: (1) it qualifies as a RMAT, which is defined as a cell therapy, therapeutic tissue engineering product, human cell and tissue product, or any combination product using such therapies or products, with limited exceptions; (2) it is intended to treat, modify, reverse, or cure a serious or life-threatening disease or condition; and (3) preliminary clinical evidence indicates that the drug has the potential to address unmet medical needs for such a disease or condition. Like breakthrough therapy designation, RMAT designation provides potential benefits that include more frequent meetings with FDA to discuss the development plan for the product candidate, and eligibility for rolling review and priority review. Products granted RMAT designation may also be eligible for accelerated approval on the basis of a surrogate or intermediate endpoint reasonably likely to predict long-term clinical benefit, or may be able to rely upon data obtained from a meaningful number of sites, including through expansion to additional sites. RMAT designation does not change the standards for product approval, and there is no assurance that such designation will result in expedited review or approval or that the approved indication will not be narrower than the indication covered by the RMAT designation. Additionally, RMAT designation can be revoked if the criteria for eligibility cease to be met as clinical data emerges.

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

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

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

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

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

In addition to manufacturing CAP-1002 for its own clinical trials, Capricor has agreed to provide CAP-1002 for investigational purposes in two clinical trials sponsored by CSMC. The first trial is known as “Regression of Fibrosis and Reversal of Diastolic Dysfunction in HFpEF Patients Treated with Allogeneic CDCs.” The second trial is known as “Pulmonary Arterial Hypertension treated with Cardiosphere-derived Allogeneic Stem Cells.” In both studies, Capricor 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.

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 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 the HOPE-2 trial or in any future studies. If these or other reactions continue to occur, it could have a material adverse impact on the effectiveness of the product, our ability to receive approval of our product candidates, and could result in substantial delays, increased costs and potentially termination of the trial.

Our business faces significant government regulation, and there is no guarantee that our product candidates will receive regulatory approval.

Our research and development activities, pre-clinical studies, human 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, would involve increased risk and may impact the progress of our clinical trials and regulatory approvals.

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

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

Even if our product candidates receive regulatory approval, we may still face future development and regulatory difficulties.

Even if U.S. regulatory approval is obtained, the FDA may still impose significant restrictions on a product's indicated uses or marketing, or impose ongoing requirements for potentially costly post-approval studies. If any of our products were granted accelerated approval, the FDA could require post-marketing confirmatory trials to verify and describe the anticipated effect on irreversible morbidity or mortality or other clinical benefit. FDA may withdraw approval of a drug or indication approved under the accelerated approval pathway if any of the following were to occur: a trial required to verify the predicted clinical benefit of the product fails to verify such benefit; other evidence demonstrates that the product is not shown to be safe or effective under the conditions of use; the applicant fails to conduct any required post-approval trial of the drug with due diligence; or the applicant disseminates false or misleading promotional materials relating to the product. In addition, the FDA currently requires as a condition for accelerated approval the pre-approval of promotional materials, which could adversely impact the timing of the commercial launch of the product.

Given the number of recent high-profile adverse safety events with certain drug products, the FDA may require, as a condition of approval, costly risk management programs, which may include safety surveillance, restricted distribution and use, patient education, enhanced labeling, special packaging or labeling, expedited reporting of certain adverse events, pre-approval of promotional materials, and restrictions on direct-to-consumer advertising. Furthermore, heightened Congressional scrutiny on the adequacy of the FDA's drug approval process and the FDA's efforts to assure the safety of marketed drugs have resulted in the proposal of new legislation addressing drug safety issues. If enacted, any new legislation could result in delays or increased costs during the period of product development, clinical trials, and regulatory review and approval, as well as increased costs to assure compliance with any new post-approval regulatory requirements. Any of these restrictions or requirements could force us to conduct costly studies or increase the time for us to become profitable. For example, any labeling approved for any of our product candidates may include a restriction on the term of its use, or it may not include one or more of our intended indications.

Our product candidates will also be subject to ongoing FDA requirements for the labeling, packaging, storage, advertising, promotion, record-keeping, and submission of safety and other post-market information on the drug. New issues may arise during a product lifecycle that did not exist, or were unknown, at the time of product approval, such as adverse events of unanticipated severity or frequency, or problems with the facility where the product is manufactured. Since approved products, manufacturers, and manufacturers' facilities are subject to continuous review and periodic inspections, these new issues post-approval may result in voluntary actions by Capricor or may result in a regulatory agency imposing restrictions on that product or us, including requiring withdrawal of the product from the market or for use in a clinical trial. If our product candidates fail to comply with applicable regulatory requirements, such as good manufacturing practices, a regulatory agency may:

- issue warning letters;
- require us to enter into a consent decree, which can include imposition of various fines, reimbursements for inspection costs, required due dates for specific actions, and penalties for noncompliance;
- impose other civil or criminal penalties;
- suspend regulatory approval;
- suspend any ongoing clinical trials;
- refuse to approve pending applications or supplements to approved applications filed by us;
- impose restrictions on operations, including costly new manufacturing requirements; or
- seize or detain products or require a product recall.

In order to market and commercialize any product candidate outside of the United States, we must establish and comply with numerous and varying regulatory requirements of other countries regarding manufacturing, safety and efficacy. Approval procedures vary among countries and can involve additional product testing and additional administrative review periods. The time required to obtain approval in other countries might differ from that required to obtain FDA approval. The regulatory approval process in other countries may include all of the risks detailed above regarding FDA approval in the United States as well as other risks. Regulatory approval in one country does not ensure regulatory approval in another, but a failure or delay in obtaining regulatory approval in one country may have a negative effect on the regulatory approval process in others. Failure to obtain regulatory approval in other countries, or any delay or setback in obtaining such approval, could have the same adverse effects detailed above regarding FDA approval in the United States. Such effects include the risks that our product candidates may not be approved for all indications requested, which could limit the uses of our product candidates and have an adverse effect on product sales and potential royalties, and that such approval may be subject to limitations on the indicated uses for which the product may be marketed or require costly, post-marketing follow-up studies.

If we or current or future collaborators, manufacturers, or service providers fail to comply with healthcare laws and regulations, we or they could be subject to enforcement actions and substantial penalties, which could affect our ability to develop, market and sell our products and may harm our reputation.

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

- the U.S. federal Anti-Kickback Statute, which prohibits, among other things, persons from soliciting, receiving, offering or providing remuneration, directly or indirectly, to induce either the referral of an individual for a healthcare item or service, or the purchasing or ordering of an item or service, for which payment may be made, in whole or in part, under a federal healthcare program such as Medicare or Medicaid;
- federal civil and criminal false claims laws and civil monetary penalty laws, such as the U.S. federal False Claims Act, or FCA, which imposes criminal and civil penalties, including through civil whistleblower or *qui tam* actions, against, individuals or entities for knowingly presenting or causing to be presented, to the federal government, claims for payment that are false or fraudulent or making a false statement to avoid, decrease or conceal an obligation to pay money to the federal government. In addition, the government may assert that a claim including items and services resulting from a violation of the federal Anti-Kickback Statute constitutes a false or fraudulent claim for purposes of the FCA;
- the Health Insurance Portability and Accountability Act, or HIPAA, includes a fraud and abuse provision referred to as the HIPAA All-Payor Fraud Law, which imposes criminal and civil liability for executing a scheme to defraud any healthcare benefit program, or knowingly and willfully falsifying, concealing or covering up a material fact or making any materially false statement in connection with the delivery of or payment for healthcare benefits, items or services. Similar to the federal Anti-Kickback Statute, a person or entity does not need to have actual knowledge of the statute or specific intent to violate it in order to have committed a violation;
- HIPAA, as amended by the Health Information Technology for Economic and Clinical Health Act, or HITECH, and its implementing regulations, which impose obligations on certain covered entity healthcare providers, health plans, and healthcare clearinghouses as well as their business associates that perform certain services involving the use or disclosure of individually identifiable health information, including mandatory contractual terms, with respect to safeguarding, the privacy, security, and transmission of individually identifiable health information, and require notification to affected individuals and regulatory authorities of certain breaches of security of individually identifiable health information;
- federal and state consumer protection and unfair competition laws, which broadly regulate marketplace activities and activities that potentially harm consumers;
- the federal Physician Payment Sunshine Act and the implementing regulations, also referred to as "Open Payments," issued under the Patient Protection and Affordable Care Act, as amended by the Health Care and Education Affordability Reconciliation Act of 2010, collectively referred to as the ACA, which require that manufacturers of pharmaceutical and biological drugs reimbursable under Medicare, Medicaid, and Children's Health Insurance Programs report to the Department of Health and Human Services all consulting fees, travel reimbursements, research grants, and other payments, transfers of value or gifts made to physicians and teaching hospitals with limited exceptions; and
- analogous state laws and regulations, such as, state anti-kickback and false claims laws potentially applicable to sales or marketing arrangements and claims involving healthcare items or services reimbursed by nongovernmental third party payors, including private insurers; and some state laws require pharmaceutical companies to comply with the pharmaceutical industry's voluntary compliance guidelines and the relevant compliance guidance promulgated by the federal government in addition to requiring drug manufacturers to report information related to payments to physicians and other healthcare providers or marketing expenditures, and state laws governing the privacy and security of health information in certain circumstances, many of which differ from each other in significant ways and often are not preempted by HIPAA, thus complicating compliance efforts.

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

Ensuring that our business arrangements with third-parties comply with applicable healthcare laws and regulations could involve substantial costs. If our operations are found to be in violation of any such requirements, we may be subject to penalties, including civil or criminal penalties, monetary damages, the curtailment or restructuring of our operations, or exclusion from participation in government contracting, healthcare reimbursement or other government programs, including Medicare and Medicaid, any of which could adversely affect our financial results. Although effective compliance programs can mitigate the risk of investigation and prosecution for violations of these laws, these risks cannot be entirely eliminated. Any action against us for an alleged or suspected violation could cause us to incur significant legal expenses and could divert our management's attention from the operation of our business, even if our defense is successful. In addition, achieving and sustaining compliance with applicable laws and regulations may be costly to us in terms of money, time and resources.

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

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

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

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

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

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

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

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

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

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

- increases to pharmaceutical manufacturer rebate liability under the Medicaid Drug Rebate Program due to an increase in the minimum basic Medicaid rebate on most branded prescription drugs and the application of Medicaid rebate liability to drugs used in risk-based Medicaid managed care plans;
- the expansion of the 340B Drug Pricing Program to require discounts for "covered outpatient drugs" sold to certain children's hospitals, critical access hospitals, freestanding cancer hospitals, rural referral centers, and sole community hospitals;
- requirements imposed on pharmaceutical companies are required to offer discounts on brand-name drugs to patients who fall within the Medicare Part D coverage gap, commonly referred to as the "Donut Hole";
- requirements imposed on pharmaceutical companies to pay an annual non-tax-deductible fee to the federal government based on each company's market share of prior year total sales of branded drugs to certain federal healthcare programs, such as Medicare, Medicaid, Department of Veterans Affairs and Department of Defense; and
- for products classified as biologics, marketing approval for a follow-on biologic product may not become effective until 12 years after the date on which the reference innovator biologic product was first licensed by the FDA, with a possible six-month extension for pediatric products. After this exclusivity ends, it may be possible for biosimilar manufacturers to enter the market, which is likely to reduce the pricing for the innovator product and could affect our profitability if our products are classified as biologics.

Recently, the U.S. administration and U.S. Congress have expressed a desire to modify, repeal, or otherwise invalidate all or certain provisions of the ACA, which contributes to the uncertainty of the ongoing implementation and impact of the ACA and also underscores the potential for additional health care reform going forward. For example, a recently enacted federal income tax law effective January 1, 2019 repealed what is commonly referred to as the "individual mandate," a tax-based shared responsibility payment imposed by the ACA on certain individuals who fail to maintain qualifying health coverage.

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

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

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

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

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

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

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

HIPAA prohibits, among other offenses, knowingly and willfully executing a scheme to defraud any health care benefit program, including private payors, or falsifying, concealing or covering up a material fact or making any materially false, fictitious or fraudulent statement in connection with the delivery of or payment for items or services under a health care benefit program. To the extent that we act as a business associate to a healthcare provider engaging in electronic transactions, we may also be subject to the privacy and security provisions of HIPAA, as amended by HITECH, which restricts the use and disclosure of patient-identifiable health information, mandates the adoption of standards relating to the privacy and security of patient-identifiable health information, and requires the reporting of certain security breaches to healthcare provider customers with respect to such information. Additionally, many states have enacted similar laws that may impose more stringent requirements on entities like ours. Failure to comply with applicable laws and regulations could result in substantial penalties and adversely affect our financial condition and results of operations.

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

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

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

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

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

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

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

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

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

U.S. federal government agencies currently face potentially significant spending reductions. The Bipartisan Budget Act of 2015 extended sequestration for Medicare through fiscal year 2027. The U.S. federal budget remains in flux, however, which could, among other things, result in a cut to Medicare payments to providers and otherwise affect federal spending on clinical and pre-clinical research and development. The Medicare program is frequently mentioned as a target for spending cuts. The full impact on our business of any future cuts in Medicare or other programs is uncertain. In addition, we cannot predict any impact which the actions of President Trump's administration and the U.S. Congress may have on the federal budget. Following the most recent federal elections, Congress has again focused on reducing the cost of drugs and other medical treatments. If federal spending is reduced, anticipated budgetary shortfalls may also impact the ability of relevant agencies, such as the FDA or the National Institutes of Health, to continue to function at current levels. Amounts allocated to federal grants and contracts may be reduced or eliminated. These reductions may also impact the ability of relevant agencies to timely review and approve drug research and development, manufacturing, and marketing activities, which may delay our ability to develop, market and sell any products we may develop.

Risks Related to the Manufacturing of our Product Candidates

We have limited manufacturing capability and may not be able to maintain our manufacturing licenses.

We presently maintain our laboratories, research and manufacturing facilities in leased premises at CSMC in Los Angeles, California. In that portion of the leased premises where we manufacture CAP-1002 and plan to manufacture our exosomes, we believe that we follow good manufacturing practices sufficient for an investigational stage product, but it is not a cGMP approved facility and would not be adequate for manufacturing product for commercial use. Capricor manufactured CAP-1002 in this facility for our previous clinical studies as well as our HOPE-2 clinical trial. In addition to manufacturing CAP-1002 for its own clinical trials, Capricor has agreed to provide CAP-1002 for investigational purposes in two clinical trials sponsored by CSMC.

Our plans to use this facility for future trials could change if we decide to expand any of our clinical trials to include international sites, such as in Europe or if we fail to meet the specifications necessary to produce our product in a qualified manner. Currently, we also intend to utilize our premises at CSMC to develop and manufacture our exosomes. Currently, our Facilities Lease is scheduled to expire on July 31, 2020 although we have an additional 1-year option enabling us to extend the term of our Facilities Lease to July 31, 2021. There can be no assurance that the Facilities Lease will be continued beyond July 31, 2021. If the Facilities Lease with CSMC is terminated or expires, we would have to secure alternative facilities in which to operate our research and development activities and/or manufacture our products, which would involve a significant monetary investment and would negatively impact the progress of our clinical trials and regulatory approvals.

Furthermore, given our recent reductions in force in our manufacturing group, and the scale required for any commercial sale of products, we will have to establish a collaboration agreement with a third party or build out our own manufacturing facility for any commercial scale manufacturing or possibly to support a Phase III trial. We are currently exploring various CROs for the production of cGMP doses to meet potential demand. In November 2017, Capricor entered into a Master Services Agreement with WuXi AppTech, Inc., or WuXi, for the potential development, manufacturing and testing of our CAP-1002 product candidate. The Agreement allowed us to begin our technology transfer process in anticipation of potential commercial scale and/or later stage clinical trials. We completed the initial stages of the technology transfer process and subsequently decided to terminate the agreement to conserve resources. Concurrently, Capricor is internally developing additional process development improvements in anticipation of commercial scale and/or later stage clinical trials which may affect the timing of our technology transfer.

We are required to obtain and maintain certain licenses in connection with our manufacturing facilities and activities. We have been issued a Manufacturing License and a Tissue Bank License from the State of California. There is no guarantee that any licenses issued to us will not be revoked or forfeited by operation of law or otherwise. If we were denied any required license or if any of our licenses were to be revoked or forfeited, we would suffer significant harm. Additionally, if a serious adverse event in any of our clinical trials were to occur during the period in which any required license was not in place, we could be exposed to additional liability if it were determined that the event was due to our fault and we had not secured the required license. Other states may impose additional licensing requirements upon us which, until obtained, would limit our ability to conduct our trials in such states.

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

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

Our manufacturing experience has been limited to manufacturing CAP-1002 for the ALLSTAR, DYNAMIC and HOPE-Duchenne clinical trials, the ongoing CSMC trials and our current HOPE-2 clinical trial. Our experience in the manufacturing of exosomes is limited to producing product for pre-clinical use. We have no prior history or experience in manufacturing our allogeneic product or any other product for any other clinical use and no experience manufacturing any product for large clinical trials or commercial use. Our product candidates have not previously been tested in any large trials to show safety or efficacy, nor are they available for commercial use. We face risks of manufacturing failures and risks of making products that are not proven to be safe or effective.

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

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

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

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

- We may be unable to identify manufacturers needed to manufacture our product candidates on acceptable terms or at all, because the number of potential manufacturers is limited, and subsequent to approval of an NDA or BLA, the FDA must approve any replacement contractor. This approval would require new testing and compliance inspections. In addition, a new manufacturer may have to be educated in, or develop substantially equivalent processes for, production of our products or the devices after receipt of FDA approval, if any.
- Our third-party manufacturers might be unable to formulate and manufacture our drugs in the volume and of the quality required to meet our clinical and commercial needs, if any.
- Our third-party manufacturers might be unable to manufacture or supply us with sufficient quantities of acceptable materials necessary for the development or use of our product candidates.
- Our future contract manufacturers may not perform as agreed or may not remain in the contract manufacturing business for the time required to supply our clinical trials or to successfully produce, store, and distribute our products or the materials needed to manufacture or utilize our product candidates.
- Drug manufacturers are subject to ongoing periodic unannounced inspection by the FDA, the Drug Enforcement Agency, and corresponding state agencies to ensure strict compliance with good manufacturing 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 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 such inventions. In addition, the government 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.

The USPTO has developed new regulations and procedures to govern the full implementation of the Leahy-Smith Act, and many of the substantive changes to patent law associated with the Leahy-Smith Act, and in particular, the "first to file" provisions, only became effective in March 2013. The Leahy-Smith Act has also introduced procedures that may make it easier for third parties to challenge issued patents, as well as to intervene in the prosecution of patent applications. Finally, the Leahy-Smith Act contains new statutory provisions that still require the USPTO to issue new regulations for their implementation, and it may take the courts years to interpret the provisions of the new statute. Accordingly, it is not clear what, if any, impact the Leahy-Smith Act will have on the operation of our business. The Leahy-Smith Act and its implementation could increase the uncertainties and costs surrounding the prosecution of our patent applications and the enforcement or defense of our issued patents and those licensed to us.

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

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

We have licensed certain patent and other intellectual property rights that cover 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 (EVs), such as exosomes derived from CDCs. Under the license agreements with the University of Rome and JHU, those institutions prosecute and maintain their patents and patent applications in collaboration with us. We rely on these institutions to file, prosecute, and maintain patent applications, and otherwise protect the intellectual property to which we have a license, and we have not had and do not have primary control over these activities for certain of these patents or patent applications and other intellectual property rights. We cannot be certain that such activities by these institutions have been or will be conducted in compliance with applicable laws and regulations, or will result in valid and enforceable patents and other intellectual property rights. Under our Amended and Restated Exclusive License Agreement with CSMC and our Exclusive License Agreement with CSMC, as the same have been amended, we have assumed, in coordination with CSMC, financial responsibility for the prosecution and maintenance of all patents and patent applications. Our enforcement of certain of these licensed patents or defense of any claims asserting the invalidity of these patents would also be subject to the cooperation of the University of Rome, JHU, and/or CSMC.

Additionally, in 2018, Capricor and CSMC entered into a Sixth Amendment to the Exosomes License Agreement. Under the Sixth License Amendment, the milestone deadline for filing an IND for at least one product has been extended to December 31, 2019. If the Company does not file an IND by December 31, 2019, or negotiate an additional extension of the milestone deadline, CSMC would have the option to convert the exclusive license to a non-exclusive license or to a co-exclusive license or terminate the license under Title 35, Section 203 of the United States Code. Prior to exercising such option, Capricor has the opportunity to cure the failure to file an IND for a period of 90 days after its receipt of written notice from CSMC of its intent to exercise its option.

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 to which we have a license for third-party patents. Further, if any of our in-licensed patents are determined by legal authority to be invalid and unenforceable, it could impact our ability to commercialize or license our technology.

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

- others may be able to make products that are similar to our product candidates but that are not covered by the claims of any of our patents;
- we might not have been the first to make the inventions covered by any issued patents or patent applications we may have (or third parties from whom we license intellectual property may have);
- we might not have been the first to file patent applications for these inventions;
- it is possible that any pending patent applications we may have will not result in issued patents;
- any issued patents may not provide us with any competitive advantages, or may be held invalid or unenforceable as a result of legal challenges by third parties;
- we may not develop additional proprietary technologies that are patentable or protectable under trade secrets law; 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 shareholder of ours. Each of those agreements provides for an exclusive license to certain patents and other intellectual property and requires the payment of fees, milestone payments and/or royalties to the institutions that will reduce our net revenues, if and to the extent that we have future revenues. Each of those agreements also contains additional obligations that we are required to satisfy. There is no guarantee that we will be able to satisfy all of our obligations under our license agreements to each of the institutions and that such license agreements will not be terminated. Each of the institutions receives funding from independent sources such as the NIH and other private or not-for-profit sources and are investigating scientific and clinical questions of interest to their own principal investigators as well as the scientific and clinical communities at large. These investigators (including Capricor, Inc.'s founder, Dr. Eduardo Marbán, who is the Director of the Smidt Heart Institute at CSMC) are under no obligation to conduct, continue, or conclude either current or future studies utilizing our cell therapy or exosomes technology, and they are not compelled to license any further technologies or intellectual property rights to us except as may be stated in the applicable licensing agreements between those institutions and us. Changes in these collaborators' research interests or their funding sources away from our technology would have a material adverse effect on us. Further, the failure of any third-party licensor to comply with its licensing obligations under its respective agreement with us would have a material adverse effect on us. We are substantially dependent on our relationships with these institutions from which we license the rights to our technologies and know-how. If requirements under our license agreements are not met, including meeting defined milestones, we could suffer significant harm, including losing rights to our product candidates.

In addition, we are responsible for the cost of filing and prosecuting certain patent applications and maintaining certain issued patents licensed to us. If we do not meet our obligations under our license agreements in a timely manner, we could lose the rights to our 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. If we fail to meet these requirements, the NIH or DoD could cease further funding.

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

On February 5, 2013, we entered into the CIRM Loan Agreement, pursuant to which CIRM agreed to disburse approximately $19.8 million to us over a period of approximately three and one-half years to support Phase II of our ALLSTAR clinical trial. Under the CIRM Loan Agreement, we were required to repay the CIRM loan with interest at maturity. So long as we were not in default, the Loan Agreement had provisions allowing for forgiveness of the debt after the end of the project period, if we elected to abandon the project under certain circumstances. On November 17, 2017, we gave notice to CIRM that we were electing to abandon the CIRM-funded project pursuant to the Loan Agreement and on December 11, 2017, Capricor and CIRM entered into Amendment No. 3 to the CIRM Notice of Loan Award whereby the total loan balance under the CIRM Loan Agreement was forgiven by CIRM thereby terminating Capricor's and the Company's obligation to repay the loan balance. The Company classified the forgiveness of the loan payable, consisting of principal and accrued interest, of approximately $15.7 million as "other income" in our Consolidated Statement of Operations and Comprehensive Income (Loss). The decision to terminate the Loan Award and forgive the loan balance was due to the abandonment of the ALLSTAR project at the end of the project period in accordance with Section 4.10 of the Loan Agreement and Article VII, Section I of the CIRM Loan Administration Policy. Additionally, on June 16, 2016, Capricor entered into the CIRM Award with CIRM in the amount of approximately $3.4 million to fund, in part, the HOPE-Duchenne trial. Pursuant to terms of the CIRM Award, disbursements were tied to the achievement of specified operational milestones. The CIRM Award is further subject to the conditions and requirements set forth in the CIRM Grants Administration Policy for Clinical Stage Projects. Such requirements include, without limitation, the filing of quarterly and annual reports with CIRM, the sharing of intellectual property pursuant to Title 17, California Code of Regulations (CCR) Sections 100600-100612, and the sharing with the State of California of a fraction of licensing revenue received from a CIRM funded research project and net commercial revenue from a commercialized product which resulted from the CIRM funded research as set forth in Title 17, CCR Section 100608. The maximum royalty on net commercial revenue that Capricor may be required to pay to CIRM is equal to nine times the total amount awarded and paid to Capricor.

If we enter into strategic partnerships, we may be required to relinquish important rights to and control over the development of our product candidates or otherwise be subject to terms unfavorable to us.

We are actively looking into potential strategic partnerships for our product candidates, particularly for our CAP-1002 product candidate. If we do not establish strategic partnerships, we potentially will have to undertake development and commercialization efforts with respect to our product candidates on our own, which would be costly and adversely impact our ability to commercialize any future products or product candidates. If we enter into any strategic partnerships with pharmaceutical, biotechnology or other life science companies, we will be subject to a number of risks, including:

- we may not be able to control the amount and timing of resources that our strategic partners devote to the development or commercialization of product candidates;
- strategic partners may delay clinical trials, provide insufficient funding, terminate a clinical trial or abandon a product candidate, repeat or conduct new clinical trials or require a new version of a product candidate for clinical testing;
- strategic partners may not pursue further development and commercialization of products resulting from the strategic partnering arrangement or may elect to discontinue research and development programs;
- strategic partners may not commit adequate resources to the marketing and distribution of any future products, limiting our potential revenues from these products;
- disputes may arise between us and our strategic partners that result in the delay or termination of the research, development or commercialization of our product candidates or that result in costly litigation or arbitration that diverts management's attention and consumes resources;
- strategic partners may experience financial difficulties;
- strategic partners may not properly maintain or defend our intellectual property rights or may use our proprietary information in a manner that could jeopardize or invalidate our proprietary information or expose us to potential litigation;
- business combinations or significant changes in a strategic partner's business strategy may also adversely affect a strategic partner's willingness or ability to complete its obligations under any arrangement; and
- strategic partners could independently move forward with a competing product candidate developed either independently or in collaboration with others, including our competitors.

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

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

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

Risks Related to Competitive Factors

Our products will likely face intense competition.

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

Our future success will depend in part on our ability to maintain a competitive position with respect to evolving therapies as well as other novel technologies. Existing or future therapies developed by others may render our potential products obsolete or noncompetitive. The drugs that we are attempting to develop will have to compete with existing therapies. In addition, companies pursuing different but related fields represent substantial competition. These organizations also compete with us to attract qualified personnel and parties for acquisitions, joint ventures, or other collaborations.

If we are unable to retain and recruit qualified scientists and advisors, or if any of our key executives, key employees or key consultants discontinues his or her employment or consulting relationship with us, it may delay our development efforts or otherwise harm our business. In addition, several of our consultants render services on a part-time basis to other entities which may result in the creation of intellectual property rights in favor of those entities.

Because of the specialized nature of our technology, we are dependent upon existing key personnel and on our ability to attract and retain qualified executive officers and scientific personnel for research, clinical studies, and development activities conducted or sponsored by us. There is intense competition for qualified personnel in our fields of research and development, and there can be no assurance that we will be able to continue to attract additional qualified personnel necessary for the development and commercialization of our product candidates or retain our current personnel. Dr. Frank Litvack, our Executive Chairman, is only a part-time consultant to the Company and provides services to other non-competing enterprises.

We have experienced employee turnover from time to time, including involving some of our key employees. The loss of any of our current key employees or key consultants could impede the achievement of our research and development objectives. Furthermore, recruiting and retaining qualified scientific personnel to perform research and development work in the future is critical to the Company's success, both to enable the Company to grow, and to allow the Company to replace any employees or consultants whose relationships with the Company have been terminated. The market for employees with experience in the cell therapy and exosome industries is especially competitive, and we may not be able to recruit employees needed to develop and manufacture our products, or be able to retain the employees whom we do recruit. In early 2019, in an effort to reduce costs and preserve our capital, we reduced our workforce by 21 employees, most of whom were engaged in manufacturing and product development.

There is a close working relationship between the academic lab at CSMC and our research and development team where employees and consultants of both entities contribute time and services to the research being performed by the other. As a result, it is unclear whether intellectual property developed out of these services for CSMC would be owned by CSMC or by the Company, although if owned by CSMC, the Company may have rights to that intellectual property under the terms of its license agreements with CSMC.

The Company may be unable to attract and retain personnel on acceptable terms given the competition among biotechnology, biopharmaceutical, and health care companies, universities, and non-profit research institutions for experienced scientists. Certain of the Company's officers, directors, scientific advisors, and/or consultants or certain of the officers, directors, scientific advisors, and/or consultants hereafter appointed may from time to time serve as officers, directors, scientific advisors, and/or consultants of other biopharmaceutical or biotechnology companies. The Company currently does not maintain "key man" insurance policies on any of its officers or employees. All of the Company's employees will be employed "at will" and, therefore, each employee may leave the employment of the Company at any time. If we are unable to retain our existing employees, including qualified scientific personnel, and attract additional qualified candidates, the Company's business and results of operations could be adversely affected.

If we do not establish strategic partnerships, we will have to undertake development and commercialization efforts on our own, which would be costly and delay our ability to commercialize any future products or product candidates.

An element of our business strategy includes potentially partnering with pharmaceutical, biotechnology and other companies to obtain assistance for the development and potential commercialization of our product candidates, including the cash and other resources we need for such development and potential commercialization. We may not be able to negotiate strategic partnerships on acceptable terms, or at all. If we are unable to negotiate strategic partnerships for our product candidates, we may be forced to curtail the development of a particular candidate, reduce, 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 no experience selling, marketing, or distributing products and no current internal capability to do so.

The Company currently has no sales, marketing, or distribution capabilities. We do not anticipate having resources in the foreseeable future to allocate to the sales and marketing of our proposed products. Our future success depends, in part, on our ability to enter into and maintain sales and marketing collaborative relationships, or on our ability to build sales and marketing capabilities internally. If we enter into a sales and marketing collaborative relationship, then we will be dependent upon the collaborator's strategic interest in the products under development, and such collaborator's ability to successfully market and sell any such products. If any of our product candidates are cleared for commercialization, we intend to pursue collaborative arrangements regarding the sales and marketing of our products, however, there can be no assurance that we will be able to establish or maintain such collaborative arrangements, or if able to do so, that such collaborators will have effective sales forces. To the extent that we decide not to, or are unable to, enter into collaborative arrangements with respect to the sales and marketing of our proposed products, significant capital expenditures, management resources, and time will be required to establish and develop an in-house marketing and sales force with sufficient technical expertise. There can also be no assurance that we will be able to establish or maintain relationships with third-party collaborators or develop in-house sales and distribution capabilities. To the extent that we depend on third parties for marketing and distribution, any revenues we receive will depend upon the efforts of such third parties, and there can be no assurance that such efforts will be successful.

If any of our product candidates for which we receive regulatory approval do not achieve broad market acceptance, the revenues that we generate from their sales, if any, will be limited.

The commercial viability of our product candidates for which we may obtain marketing approval from the FDA or other regulatory authorities will depend upon their acceptance among physicians, the medical community, and patients, and coverage and reimbursement of them by third-party payors, including government payors. The degree of market acceptance of any of our approved products will depend on a number of factors, including:

- limitations or warnings contained in a product's FDA-approved labeling;
- changes in the standard of care for the targeted indications for any of our product candidates, which could reduce the marketing impact of any claims that we could make following FDA approval;
- limitations inherent in the approved indication for any of our product candidates compared to more commonly understood or addressed conditions;
- lower demonstrated clinical safety and efficacy compared to other products;
- prevalence and severity of adverse effects;
- ineffective marketing and distribution efforts;
- lack of availability of reimbursement from managed care plans and other third-party payors;
- lack of cost-effectiveness;
- timing of market introduction and perceived effectiveness of competitive products;
- availability of alternative therapies at similar costs; and
- potential product liability claims.

Our ability to effectively promote and sell our product candidates in the marketplace will also depend on pricing, including our ability to manufacture a product at a competitive price. We will also need to demonstrate acceptable evidence of safety and efficacy and may need to demonstrate relative convenience and ease of administration. Market acceptance could be further limited depending on the prevalence and severity of any expected or unexpected adverse side effects associated with our product candidates. If our product candidates are approved but do not achieve an adequate level of acceptance by physicians, health care payors, and patients, we may not generate sufficient revenue from these products, and we may not become or remain profitable. In addition, our efforts to educate the medical community and third-party payors on the benefits of our product candidates may require significant resources and may never be successful. If our approved drugs fail to achieve market acceptance, we will not be able to generate significant revenue, if any.

Our ability to generate product revenues will be diminished if our drugs sell for inadequate prices or patients are unable to obtain adequate levels of reimbursement.

Our ability to generate significant sales of our products, if approved, depends on the availability of adequate coverage and reimbursement from third-party payors. Healthcare providers that purchase medicine or medical products for treatment of their patients generally rely on third-party payors to reimburse all or part of the costs and fees associated with the products. Adequate coverage and reimbursement from governmental payors, such as Medicare and Medicaid, and commercial payors is critical to new product acceptance. Patients are unlikely to use our products if they do not receive reimbursement adequate to cover the cost of our products. Orphan drugs in particular have received recent negative publicity for the perceived high prices charged for them by their manufacturers, and as a result, other orphan drug developers such as us may be negatively impacted by such publicity and any U.S. or other government regulatory response.

In addition, the market for our future products will depend significantly on access to third-party payors' drug formularies, or lists of medications for which third-party payors provide coverage and reimbursement. Industry competition to be included in such formularies results in downward pricing pressures on pharmaceutical companies.

All third-party payors, whether governmental or commercial, whether inside the United States or outside, are developing increasingly sophisticated methods of controlling healthcare costs. In addition, in the United States, no uniform policy of coverage and reimbursement for medical technology exists among all these payors. Therefore, coverage of and reimbursement for medical products can differ significantly from payor to payor.

Further, we believe that future coverage and reimbursement may be subject to increased restrictions both in the United States and in international markets. Third-party coverage and reimbursement for our products may not be available or adequate in either the United States or international markets, limiting our ability to sell our products on a profitable basis.

Significant uncertainty exists as to the reimbursement status of newly approved healthcare products. Healthcare payors, including Medicare, are challenging the prices charged for medical products and services. Government and other healthcare payors increasingly attempt to contain healthcare costs by limiting both coverage and the level of reimbursement for drugs. Even if our product candidates are approved by the FDA, insurance coverage may not be available, and reimbursement levels may be inadequate, to cover our drugs. If government and other healthcare payors do not provide adequate coverage and reimbursement levels for any of our products, once approved, market acceptance of our products could be reduced.

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

Risks Related to Product and Environmental Liability

Our products may expose us to potential product liability, and there is no guarantee that we will be able to obtain and maintain adequate insurance to cover these liabilities.

The testing, marketing, and sale of human cell therapeutics, pharmaceuticals, and services entail an inherent risk of adverse effects or medical complications to patients and, as a result, product liability claims may be asserted against us. A future product liability claim or product recall could have a material adverse effect on the Company. There can be no assurance that product liability insurance will be available to us in the future on acceptable terms, if at all, or that coverage will be adequate to protect us against product liability claims. In the event of a successful claim against the Company, insufficient or lack of insurance or indemnification rights could result in liability to us, which could have a material adverse effect on the Company and its future viability. The use of our product candidates in clinical trials and the sale of any products for which we obtain marketing approval, if at all, expose the Company to the risk of product liability claims. Product liability claims might be brought against the Company by consumers, health care providers or others using, administering or selling our products. If we cannot successfully defend ourselves against these claims, we will incur substantial liabilities. Regardless of merit or eventual outcome, liability claims may result in:

- withdrawal of clinical trial participants;
- termination of clinical trial sites or entire trial programs;
- costs of related litigation;
- substantial monetary awards to patients or other claimants;
- decreased demand for our product candidates;
- impairment of our business reputation;
- loss of revenues; and
- the inability to commercialize our product candidates.

The Company has obtained clinical trial insurance coverage for its clinical trials. However, such insurance coverage may not reimburse the Company or the levels of coverage may not be sufficient to reimburse it for expenses or losses it may suffer or for its indemnification obligations. Moreover, insurance coverage is becoming increasingly expensive, and, in the future, we may not be able to maintain insurance coverage at a reasonable cost or in sufficient amounts to protect the Company against losses due to liability. We intend to expand our insurance coverage to include the sale of commercial products if we obtain marketing approval for our product candidates in development, but we may be unable to obtain commercially reasonable product liability insurance for any products approved for marketing. On occasion, large judgments have been awarded in class action lawsuits based on drugs that had unanticipated side effects. A successful product liability claim or series of claims brought against the Company could have a material adverse effect on us and, if judgments exceed our insurance coverage, could significantly decrease our cash position and adversely affect our business.

Our business involves risk associated with handling hazardous and other dangerous materials.

Our research and development activities involve the controlled use of hazardous materials, chemicals, human blood and tissue, animal blood and blood products, animal tissue, biological waste, and various radioactive compounds. The risk of accidental contamination or injury from these materials cannot be completely eliminated. The failure to comply with current or future regulations could result in the imposition of substantial fines against the Company, suspension of production, alteration of our manufacturing processes, or cessation of operations.

Our business depends on compliance with ever-changing environmental and human health and safety laws.

We cannot accurately predict the outcome or timing of future expenditures that may be required to comply with comprehensive federal, state and local environmental laws and regulations, as well as laws and regulations designed to protect employees and others who handle hazardous materials. We must comply with environmental laws that govern, among other things, all emissions, waste water discharge and solid and hazardous waste disposal, and the remediation of contamination associated with generation, handling and disposal activities. To date, the Company has not incurred significant costs and is not aware of any significant liabilities associated with its compliance with federal, state and local environmental laws and regulations. However, both federal and state environmental laws have changed in recent years and the Company may become subject to stricter environmental standards in the future and may face large capital expenditures to comply with environmental laws. We have limited capital and we are uncertain whether we will be able to pay for significantly large capital expenditures that may be required to comply with new laws. Also, future developments, administrative actions or liabilities relating to environmental matters may have a material adverse effect on our financial condition or results of operations.

Risks Related to Our Common Stock and This Offering

This is a best efforts offering, no minimum amount of securities is required to be sold, and we may not raise the amount of capital we believe is required for our business plans.

The placement agent has agreed to use its reasonable best efforts to solicit offers to purchase the securities in this offering. The placement agent has no obligation to buy any of the securities from us or to arrange for the purchase or sale of any specific number or dollar amount of the securities. There is no required minimum number of securities that must be sold as a condition to completion of this offering. Because there is no minimum offering amount required as a condition to the closing of this offering, the actual offering amount, placement agent fees and proceeds to us are not presently determinable and may be substantially less than the maximum amounts set forth above. We may sell fewer than all of the securities offered hereby, which may significantly reduce the amount of proceeds received by us, and investors in this offering will not receive a refund in the event that we do not sell an amount of securities sufficient to fund research and development of our lead product candidates, CAP-1002 and our exosomes. Thus, we may not raise the amount of capital we believe is required for our operations in the short-term and may need to raise additional funds, which may not be available or available on terms acceptable to us.

We expect that our stock price will fluctuate significantly, and you may not be able to resell your shares at or above your investment price.

The stock market, particularly in recent years, has experienced significant volatility, particularly with respect to pharmaceutical, biotechnology and other life sciences company stocks. Our operating results may fluctuate from period to period for a number of reasons, and as a result our stock price may be subject to significant fluctuations. Factors that could cause volatility in the market price of our common stock include, but are not limited to:

- our financial condition, including our need for additional capital, as well as the terms of that additional capital;
- results from, delays in, or discontinuation of, any of the clinical trials for our drug candidates, including delays resulting from slower than expected or suspended patient enrollment or discontinuations resulting from a failure to meet pre-defined clinical endpoints;
- announcements concerning clinical trials and regulatory developments;
- failure or delays in entering drug candidates into clinical trials;
- failure or discontinuation of any of our research or development programs;
- developments in establishing new strategic alliances or with existing alliances;
- 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.

The projections and forecasts that our management may provide from time to time (including, but not limited to, those relating to timing, progress and anticipated results of clinical development, regulatory processes, clinical trial timelines and any anticipated benefits of our product candidates) reflect numerous assumptions made by management, including assumptions with respect to our specific as well as general business, economic, market and financial conditions and other matters, all of which are difficult to predict and many of which are beyond our control. Accordingly, there is a risk that the assumptions made in preparing the projections, or the projections themselves, will prove inaccurate. There will be differences between actual and projected results, and actual results may be materially different from those contained in the projections. The inclusion of the projections in (or incorporated by reference in) this prospectus should not be regarded as an indication that we or our management or representatives considered or consider the projections to be a reliable prediction of future events, and the projections should not be relied upon as such. Additionally, final data may differ significantly from preliminary reported data.

Our certificate of incorporation and by-laws contain provisions that may discourage, delay or prevent a change in our management team that stockholders may consider favorable.

Our certificate of incorporation, our bylaws and Delaware law contain provisions that may have the effect of preserving our current management, such as:

- authorizing the issuance of "blank check" preferred stock without any need for action by stockholders;
- eliminating the ability of stockholders to call special meetings of stockholders; and
- establishing advance notice requirements for nominations for election to the board of directors or for proposing matters that can be acted on by stockholders at stockholder meetings.

These provisions could make it more difficult for our stockholders to affect our corporate policies or make changes in our Board of Directors and for a third party to acquire us, even if doing so would benefit our stockholders.

Ownership of the Company's common stock is highly concentrated, which may prevent you and other stockholders from influencing significant corporate decisions and may result in conflicts of interest that could cause the Company's stock price to decline.

As of December 2, 2019, our executive officers, directors and holders of five percent or more of our outstanding common stock (based upon our review of documents filed with the SEC by such holders), together with their respective affiliates, owned approximately 25% of our outstanding common stock. The interests of these stockholders may not be the same as, or may even conflict with the interests of our other stockholders. These stockholders, acting individually or as a group, will have substantial influence over the outcome of a corporate action of the Company requiring stockholder approval, including the election of directors, any merger, consolidation or sale of all or substantially all of the Company's assets or any other significant corporate transaction. These stockholders may also exert influence in delaying or preventing a change in control of the Company, even if such change in control would benefit the other stockholders of the Company. In addition, the significant concentration of stock ownership may adversely affect the market value of the Company's common stock due to investors' perception that conflicts of interest may exist or arise.

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

As of September 30, 2019, there were approximately 4.2 million shares of common stock outstanding, as well as outstanding awards to purchase approximately 0.8 million shares of common stock under various incentive stock plans of the Company. Additionally, as of September 30, 2019, there were approximately 0.1 million shares of common stock available for future issuance under various incentive plans. We may issue additional common stock, warrants and other convertible securities from time to time to finance our operations. We may also issue additional shares to fund potential acquisitions or in connection with additional stock options or other equity awards granted to our employees, officers, directors and consultants under our various incentive plans. The issuance of additional shares of common stock, warrants or other convertible securities and the perception that such issuances may occur or exercise of outstanding warrants or options may have a dilutive impact on other stockholders and could have a material negative effect on the market price of our common stock.

The Company's ability to utilize Nile's net operating loss and tax credit carryforwards in the future is subject to substantial limitations and may further be limited as a result of the merger with Capricor.

Federal and state income tax laws impose restrictions on the utilization of net operating loss, or NOL, and tax credit carryforwards in the event that an "ownership change" occurs for tax purposes, as defined by Section 382 of the Internal Revenue Code of 1986, as amended, or the Code. In general, an ownership change occurs when shareholders owning 5% or more of a "loss corporation" (a corporation entitled to use NOL or other loss carryforwards) have increased their aggregate ownership of stock in such corporation by more than 50 percentage points during any three-year period. If an "ownership change" occurs, Section 382 of the Code imposes an annual limitation on the amount of post-ownership change taxable income that may be offset with pre-ownership change NOLs of the loss corporation experiencing the ownership change. The annual limitation is calculated by multiplying the loss corporation's value immediately before the ownership change by the greater of the long-term tax-exempt rate determined by the IRS in the month of the ownership change or the two preceding months. This annual limitation may be adjusted to reflect any unused annual limitation for prior years and certain recognized built-in gains and losses for the year. Section 383 of the Code also imposes a limitation on the amount of tax liability in any post-ownership change year that can be reduced by the loss corporation's pre-ownership change tax credit carryforwards.

The merger between Nile Therapeutics, Inc., or Nile, and Capricor resulted in an "ownership change" of Nile. In addition, previous or current changes in the Company's stock ownership may have triggered or, in the future, may trigger an "ownership change," some of which may be outside our control. Accordingly, the Company's ability to utilize Nile's NOL and tax credit carryforwards may be substantially limited. These limitations could, in turn, result in increased future tax payments for the Company, which could have a material adverse effect on the business, financial condition, or results of operations of the Company.

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

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

Management will have broad discretion as to the use of the proceeds from this offering, if any, and may not use the proceeds effectively.

We currently anticipate that any net proceeds from this offering will be used for development related to our product candidates, working capital and general corporate purposes. However, we have not determined the specific allocation of the net proceeds from this offering, if any, among these potential uses. Our management will have broad discretion as to the application of the net proceeds from this offering, if any, and could use them for purposes other than those contemplated at the time of the offering. Our management may use the net proceeds for corporate purposes that may not improve our financial condition or market value.

Future sales of our common stock in the public market could cause our stock price to fall.

Sales of a substantial number of shares of our common stock in the public market, or the perception that these sales might occur, could depress the market price of our common stock and could impair our ability to raise capital through the sale of additional equity securities. As of December 2, 2019, we had 4,246,225 shares of common stock outstanding, all of which shares, other than shares held by our directors and certain officers, were eligible for sale in the public market, subject in some cases to compliance with the requirements of Rule 144, including the volume limitations and manner of sale requirements. In addition, shares of common stock issuable upon exercise of outstanding options and shares reserved for future issuance under our stock incentive plans will become eligible for sale in the public market to the extent permitted by applicable vesting requirements and subject in some cases to compliance with the requirements of Rule 144.

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 in this offering. 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 in this offering, 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 in this offering.

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

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

We may be at risk of securities class action litigation.

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

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

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

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

If you purchase our common stock, pre-funded warrants and common warrants in this offering, you will incur immediate and substantial dilution in the book value of your shares.

The combined public offering price in this offering is substantially higher than the net tangible book value per share of our common stock. Investors purchasing common stock and warrants in this offering will pay a price per share that substantially exceeds the book value of our tangible assets after subtracting our liabilities. As a result, investors purchasing common stock and warrants in this offering will incur immediate dilution of $ per share, based on the assumed combined public offering price of $ per share.

As a result of the dilution to investors purchasing shares in this offering, investors may receive significantly less than the purchase price paid in this offering, if anything, in the event of our liquidation. For a further description of the dilution that you will incur as a result of purchasing shares in this offering, see "Dilution."

The pre-funded warrants and common warrants are speculative in nature.

Neither the pre-funded warrants nor the common warrants offered hereby confer any rights of common stock ownership on their holders, such as voting rights or the right to receive dividends, but rather merely represent the right to acquire shares of common stock at a fixed price. Specifically, commencing on the date of issuance, holders of the pre-funded warrants may acquire the common stock issuable upon exercise of such warrants at an exercise price of $0.001 per share of common stock and holders of the common warrants may acquire the common stock issuable upon exercise of such warrants at an exercise price of $ per share. Moreover, following this offering, the market value of the pre-funded warrants and common warrants is uncertain and there can be no assurance that the market value of the pre-funded warrants or the common warrants will equal or exceed their public offering price. There can be no assurance that the market price of the common stock will ever equal or exceed the exercise price of the pre-funded warrants or common warrants, and consequently, whether it will ever be profitable for holders of the pre-funded warrants to exercise the pre-funded warrants or the holders of the common warrants to exercise the common warrants.

Holders of the pre-funded warrants and common warrants will have no voting rights as common stockholders until they acquire our common stock.

Until you acquire shares of our common stock upon exercise of the pre-funded warrants and common warrants, you will have no voting rights with respect to our common stock issuable upon exercise of the pre-funded warrants or common warrants. Upon exercise of your pre-funded warrants or common warrants, you will be entitled to exercise all the voting rights of a common stockholder only as to matters for which the record date occurs after the exercise date.

Significant holders or beneficial holders of our common stock may not be permitted to exercise pre-funded warrants or common warrants that they hold.

The pre-funded warrants and common warrants being offered hereby will prohibit a holder from exercising its pre-funded warrants or common warrants if doing so would result in such holder (together with such holder's affiliates and any other persons acting as a group together with such holder or any of such holder's affiliates) beneficially owning more than 4.99% of our common stock outstanding immediately after giving effect to the exercise, provided that, at the election of a holder and notice to us, such beneficial ownership limitation as to such holder shall be 9.99% of our common stock outstanding immediately after giving effect to the exercise. As a result, if you hold a significant amount of our securities, you may not be able to exercise your pre-funded warrants or common warrants for shares of our common stock, in whole or in part, at a time when it would be financially beneficial for you to do so.

There is no public market for the pre-funded warrants or common warrants to purchase shares of common stock being offered in this offering.

There is no established public trading market for the pre-funded warrants or common warrants being offered in this offering, and we do not expect a market to develop. In addition, we do not intend to apply to list the pre-funded warrants or common warrants on any national securities exchange or other trading system, including the Nasdaq Capital Market. Without an active market, the liquidity of the pre-funded warrants or common warrants will be limited.

An investment in the pre-funded warrants, common warrants and our common stock has numerous tax consequences.

There are numerous tax consequences to investors as a result of their investment in the Company. We encourage investors to seek advice from competent tax advisors as to the consequences of an investment in our pre-funded warrants, common warrants and common stock (See "Material U.S. Federal Income Tax Considerations").

SPECIAL NOTE REGARDING FORWARD-LOOKING STATEMENTS

This prospectus, together with any accompanying prospectus supplement, includes and incorporates by reference "forward-looking statements" within the meaning of the U.S. Private Securities Litigation Reform Act of 1995 and releases issued by the SEC and within the meaning of Section 27A of the Securities Act of 1933, as amended, and Section 21E of the Securities Exchange Act of 1934, as amended, which statements involve substantial risks and uncertainties. Forward-looking statements generally relate to future events or our future financial or operating performance. All statements other than statements of historical fact are "forward-looking statements" for purposes of this prospectus. In some cases, you can identify forward-looking statements because they contain words such as "may," "will," "would," "should," "could," "expect," "plan," "anticipate," "intend," "target," "project," "contemplate," "believe," "estimate," "predict," "seek," "potential," "ongoing," "goal," or "continue," or the negative of these words or other similar terms or expressions that concern our expectations, strategy, plans or intentions. Forward-looking statements contained in this prospectus include, but are not limited to, statements about:

- how long we expect to maintain liquidity to fund our planned level of operations and our ability to obtain additional funds for our operations;
- the identification and development of our drug candidates, including when we expect to undertake, initiate and complete clinical trials of our product candidates;
- the expectation, plans, projections, initiation, timing, progress and results of our research and development programs, preclinical studies, any clinical trials, Investigational New Drug filings, Clinical Trial Application filings, New Drug Application, or NDA, filings, and other regulatory submissions;
- the regulatory approval of any of our drug candidates;
- our use of clinical research centers, third party manufacturers and other contractors;
- our ability to find collaborative partners for research, development and commercialization of our product candidates and retain commercial rights for our product candidates in the collaborations;
- our ability to manufacture products for clinical and commercial use;
- our reliance on third party suppliers and manufacturers to supply the materials and components for, and manufacture, our research and development, preclinical and clinical trial drug supplies;
- our ability to protect our patents and other intellectual property;
- our ability to commercialize and market any of our products;
- the implementation of our business model and strategic plans for our business, technologies and product candidates;
- our estimates of our expenses, ongoing losses, future revenue and capital requirements;
- our ability to secure and maintain adequate protection for our patents and other intellectual property protection for our technologies and product candidates;
- our ability to operate our business without infringing the intellectual property rights of others;
- our reliance on third parties to conduct our preclinical studies or any clinical trials;
- our ability to compete against other companies and research institutions;
- our ability to expand our operations internationally;
- the effect of potential strategic transactions on our business;
- the rate and degree of acceptance of our product candidates by doctors, patients or payors and the availability of reimbursement for our product candidates;
- our financial performance;
- our ability to attract and retain key personnel; and
- the volatility of our stock price.

We caution you that the forward-looking statements highlighted above do not encompass all of the forward-looking statements made in this prospectus.

These forward-looking statements relate to future events or to our future financial performance and involve known and unknown risks, uncertainties and other factors that may cause our actual results, performance or achievements to be materially different from any future results, performance or achievements expressed or implied by these forward-looking statements. You should not rely upon forward-looking statements as predictions of future events. In evaluating such forward-looking statements, you should specifically consider various factors that may cause actual results to differ materially from current expectations, including the risks outlined under the heading "Risk Factors" contained in this prospectus, any prospectus supplement and any related free writing prospectus, and in any other documents incorporated herein or therein (including in our most recent annual report on Form 10-K, subsequent quarterly reports on Form 10-Q and other filings we make with the SEC pursuant to Section 13(a), 13(c), 14 or 15(d) of the Exchange Act). We have based the forward-looking statements contained in this prospectus primarily on our current expectations and projections about future events and trends that we believe may affect our business, financial condition, results of operations and prospects. The outcome of the events described in these forward-looking statements is subject to risks, uncertainties and other factors described in the section of this prospectus entitled "Risk Factors" and elsewhere in this prospectus, any prospectus supplement and any related free writing prospectus. Moreover, we operate in a very competitive and challenging environment. New risks and uncertainties emerge from time to time, and it is not possible for us to predict all risks and uncertainties that could have an impact on the forward-looking statements contained in this prospectus. We cannot assure you that the results, events and circumstances reflected in the forward-looking statements will be achieved or occur, and actual results, events or circumstances could differ materially from those described in the forward-looking statements. Additionally, final data may differ significantly from preliminary data reported in this document.

The forward-looking statements made in this prospectus, any accompanying prospectus supplement, any related free writing prospectus and any document incorporated herein by reference relate only to events as of the date on which the statements are made. We undertake no obligation to update any forward-looking statements made in this prospectus to reflect events or circumstances after the date of this prospectus or to reflect new information or the occurrence of unanticipated events, except as required by law. We may not actually achieve the plans, intentions or expectations disclosed in our forward-looking statements, and you should not place undue reliance on our forward-looking statements. Our forward-looking statements do not reflect the potential impact of any future acquisitions, mergers, dispositions, joint ventures or investments we may make.

This prospectus, together with any accompanying prospectus supplement, also contains statistical data, estimates, forecasts, and projections that are based on independent industry publications or other publicly available information, as well as other information based on our internal sources. Information that is based on statistical data, estimates, forecasts, projections or similar methodologies is inherently subject to uncertainties and actual events or circumstances may differ materially from events and circumstances reflected in this information. Unless otherwise expressly stated, we obtained these industry, business, market and other data from reports, research surveys, studies and similar data prepared by third parties, industry, medical and general publications, government data and similar sources. In some cases, we do not expressly refer to the sources from which these data are derived. Although we believe that the third-party sources referred to in this prospectus are reliable, we have not independently verified the information provided by these third parties. While we are not aware of any misstatements regarding any third-party information presented in this prospectus, their estimates, in particular, as they relate to projections, involve numerous assumptions, are subject to risks and uncertainties, and are subject to change based on various factors, including those discussed under the section of this prospectus entitled "Risk Factors" and elsewhere in this prospectus.

USE OF PROCEEDS

We estimate that we will receive net proceeds of approximately $ from the sale of the securities offered by us in this offering, based on the assumed combined public offering price of $ per share of common stock and common warrant (the last reported sale price of our common stock on the Nasdaq Capital Market on , 2019), assuming no sales of pre-funded warrants, which, if sold, would reduce the number of shares of common stock that we are offering on a one-for-one basis, and after deducting the estimated Placement Agent's fees and estimated offering expenses payable by us. However, because this is a best efforts offering and there is no minimum offering amount required as a condition to the closing of this offering, the actual offering amount, Placement Agent's fees and net proceeds to us are not presently determinable and may be substantially less than the maximum amounts set forth on the cover page of this prospectus.

A $0.10 increase (decrease) in the assumed combined public offering price of $ per share of common stock and common warrant would increase (decrease) the net proceeds to us from this offering by approximately $, assuming that the number of shares of common stock and common warrants offered by us, as set forth on the cover page of this prospectus, remains the same and after deducting the Placement Agent's fees and estimated offering expenses payable by us and excluding the proceeds, if any, from the exercise of the pre-funded warrants issued pursuant to this offering.

Similarly, a one hundred thousand share increase (decrease) in the number of shares of common stock and accompanying common warrants offered by us, as set forth on the cover page of this prospectus, would increase (decrease) the net proceeds to us by approximately $ and $, respectively, assuming the assumed combined public offering price of $ per share of common stock and common warrant remains the same, and after deducting estimated Placement Agent's fees and estimated offering expenses payable by us and excluding the proceeds, if any, from the exercise of the pre-funded warrants issued pursuant to this offering.

We intend to use the net proceeds from this offering to fund the research and development of our exosome technologies to support the filing of an IND in an indication to be designated by us, for related manufacturing costs to support the development of our exosome technologies, for hiring additional personnel to support our R&D and manufacturing capabilities, for business development and general corporate purposes, which may include additional work around CAP-1002 either alone or in collaboration with a third party. Our expected use of net proceeds from this offering represents our current intentions based upon our present plans and business condition. As of the date of this prospectus, we cannot currently allocate specific percentages of the net proceeds that we may use for the purposes specified above, and we cannot predict with certainty all of the particular uses for the net proceeds to be received upon the completion of this offering, or the amounts that we will actually spend on the uses set forth above. The amounts and timing of our actual use of the net proceeds will vary depending on numerous factors, including our ability to obtain additional financing, the progress, cost and results of our preclinical and clinical development programs, and whether we are able to enter into future licensing or collaboration arrangements. We may find it necessary or advisable to use the net proceeds for other purposes, and our management will have broad discretion in the application of the net proceeds, and investors will be relying on our judgment regarding the application of the net proceeds from this offering.

DIVIDEND POLICY

We have never declared nor paid cash dividends on our common stock. We currently intend to retain all of our future earnings, if any, to finance the growth and development of our business. We do not intend to pay cash dividends in respect of our common stock in the foreseeable future.

CAPITALIZATION

The following table sets forth cash and capitalization as of September 30, 2019:

- on an actual basis;
- on an as adjusted basis to give effect to the assumed issuance and sale of shares of common stock and warrants in this offering at the assumed combined public offering price of $ per share of common stock and common warrant (but excluding shares of common stock to be issued and any proceeds received upon exercise of the common warrants) (the last reported sale price of our common stock on the Nasdaq Capital Market on , 2019), assuming no sales of pre-funded warrants, which, if sold, would reduce the number of shares of common stock that we are offering on a one-for-one basis, after deducting estimated Placement Agent's fees and estimated offering expenses payable by us.

The pro forma information set forth in the table below is illustrative only and will be adjusted based on the actual public offering price and other terms of this offering determined at pricing.

(unaudited)	Actual as of September 30, 2019	As Adjusted as of September 30, 2019
Cash and cash equivalents	$ 6,827,570	$
Stockholders' equity:		
Common stock, par value $0.001 per share; 50,000,000 shares authorized, 4,174,856 shares issued and outstanding actual; 50,000,000 shares authorized, shares issued and outstanding as adjusted	$ 4,175	
Additional paid-in capital	$ 76,477,572	$
Accumulated deficit	$ (72,911,313)	$
Total stockholders' equity	$ 3,570,434	$
Total capitalization	$ 3,570,434	$

The preceding data is based on 4,174,856 shares outstanding as of September 30, 2019 and this number excludes the following, all of which, if issued by the Company, would be dilutive to our stockholders:

- 755,225 shares of common stock issuable upon the exercise of options with a weighted-average exercise price of approximately $12.63 per share;
- 65,762 shares of common stock reserved for future issuance under our (1) 2012 Restated Equity Incentive Plan; and (2) 2012 Non-Employee Director Stock Option Plan; and
- 71,369 shares of common stock sold under the August 2019 ATM Program after September 30, 2019 at an average price of approximately $2.96 per share.

DILUTION

If you invest in our common stock in this offering, your interest will be diluted to the extent of the difference between the combined public offering price per share of our common stock and accompanying common warrant and the net tangible book value per share of our common stock upon consummation of this offering. Dilution results from the fact that the combined public offering price is substantially in excess of the book value per share attributable to the existing stockholders for the presently outstanding stock.

The historical net tangible book value of our common stock as of September 30, 2019 was approximately $3.6 million, or approximately $0.85 per share of common stock. Historical net tangible book value (deficit) per share is determined by dividing the number of outstanding shares of common stock into its total tangible assets (total assets less intangible assets) less total liabilities and preferred shares, if any.

Investors purchasing securities in this offering will incur immediate and substantial dilution. After giving effect to the sale of securities offered in this offering assuming a combined public offering price of $ per share of common stock and common warrant, the closing price of our common stock on the Nasdaq Capital Market on , 2019 (but excluding any shares of common stock to be issued and any proceeds to be received upon exercise of the common warrants), and after deducting the estimated Placement Agent's fees and estimated offering costs payable by us, our as adjusted net tangible book value as of September 30, 2019 would have been approximately $, or approximately $ per share of common stock. This represents an immediate decrease in net tangible book value of $ per share to existing stockholders, and an immediate dilution in the as adjusted net tangible book value of $ per share to investors purchasing shares of our common stock and common warrants in this offering.

The following table illustrates this per share dilution:

Assumed combined public offering price per share of common stock and common warrant		$
Historical net tangible book value per share as of September 30, 2019	$ 0.85	
Decrease in net tangible book value per share attributable to this offering		
As adjusted net tangible book value as of September 30, 2019 (giving effect to this offering)		
Dilution per share to investors		$

The dilution information discussed above is illustrative only and will change based on the actual combined public offering price and other terms of this offering determined at pricing. A $0.10 increase or decrease in the assumed combined public offering price of $ per share of common stock and common warrant would increase or decrease the as adjusted net tangible book value per share by $, or approximately $ per share, and the dilution per share to investors participating in this offering by approximately $ per share, assuming the number of shares of common stock and common warrants offered by us, as set forth on the cover page of this prospectus, remains the same and after deducting the estimated Placement Agent's fees and estimated offering expenses payable by us.

The discussion and table above assume (i) no sales of pre-funded warrants, which, if sold, would reduce the number of shares of common stock that we are offering on a one-for-one basis, and (ii) no exercise of common warrants accompanying the shares of common stock and pre-funded warrants, if any, sold in this offering.

To the extent that stock options are exercised or new stock options are issued under our equity incentive plans, there will be further dilution to investors purchasing common stock in this offering. In addition, we will need to raise additional capital because of market conditions and strategic considerations. If we raise additional capital through the sale of equity or convertible debt securities, the issuance of these securities could result in further dilution to our stockholders.

PRICE RANGE FOR OUR COMMON STOCK

Our common stock is traded on the Nasdaq Capital Market under the symbol “CAPR”. The following table lists the high and low closing sales prices of our common stock as quoted, in U.S. dollars, by Nasdaq for the periods indicated. The per share prices reflect a 1-for-10 reverse stock split effected on June 4, 2019. The quotations reflect inter-dealer prices, without retail markup, markdown or commission, and may not represent actual transactions. Consequently, the information provided below may not be indicative of our common stock price under different conditions.

	High	Low
Year ended December 31, 2018		
First Quarter	$ 20.90	$ 12.80
Second Quarter	15.80	12.60
Third Quarter	14.90	10.20
Fourth Quarter	10.80	3.20
Year ended December 31, 2019		
First Quarter	$ 6.80	$ 4.10
Second Quarter	6.40	2.75
Third Quarter	6.23	2.38
Fourth Quarter (through December 2, 2019)	3.55	1.55

Holders

According to the records of our transfer agent, American Stock Transfer & Trust Company, as of December 2, 2019, we had 108 holders of record of common stock, not including holders who held in “street name.”

DESCRIPTION OF CAPITAL STOCK

General

Our Certificate of Incorporation, as amended, authorizes the issuance of 55,000,000 shares of capital stock, including: (i) 50,000,000 shares of our common stock, $0.001 par value per share, and (ii) 5,000,000 shares of preferred stock, $0.001 par value per share.

As of December 2, 2019, there were 4,246,225 shares of our common stock outstanding, held by 108 stockholders of record, not including those held in "street name," and no shares of our preferred stock outstanding. Subject to certain conditions, our Board of Directors is authorized to issue additional shares of our authorized capital stock without stockholder approval.

Common Stock

General

The rights, preferences and privileges of the holders of our common stock are subject to, and may be adversely affected by, the rights of the holders of any series of preferred stock that we may designate in the future. In addition, subject to compliance with NASDAQ rules, our Board of Directors has the authority to issue the authorized but unissued shares of our common stock without further action by our stockholders.

Voting Rights

Holders of 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 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 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 Non-Assessable

All outstanding shares of our common stock are fully paid and non-assessable.

Pre-Funded Warrants

The material terms and provisions of the pre-funded warrants being issued in this offering are summarized below. The following description is subject to, and qualified in its entirety by, the form of pre-funded warrant which will be filed herewith as an exhibit. You should review the form of pre-funded warrant for a complete description of the terms and conditions applicable to the pre-funded warrants. See "Information Incorporated by Reference and Available Information" below.

Duration and Exercise Price. Each pre-funded warrant offered hereby will have an initial exercise price per share equal to $0.001. The pre-funded warrants will be immediately exercisable and may be exercised at any time until the pre-funded warrants are exercised in full. The exercise price and number of shares of common stock issuable upon exercise is subject to appropriate adjustment in the event of stock dividends, stock splits, reorganizations or similar events affecting our common stock and the exercise price.

Exercisability. The pre-funded warrants will be exercisable, at the option of each holder, in whole or in part, by delivering to us a duly executed exercise notice accompanied by payment in full for the number of shares of our common stock purchased upon such exercise (except in the case of a cashless exercise as discussed below). A holder (together with its affiliates) may not exercise any portion of the pre-funded warrant to the extent that the holder would own more than 4.99% of the outstanding common stock immediately after exercise, except that upon at least 61 days' prior notice from the holder to us, the holder may increase the amount of ownership of outstanding stock after exercising the holder's pre-funded warrants up to 9.99% of the number of shares of our common stock outstanding immediately after giving effect to the exercise, as such percentage ownership is determined in accordance with the terms of the pre-funded warrants. Purchasers of pre-funded warrants in this offering may also elect prior to the issuance of the pre-funded warrants to those purchasers to have the initial exercise limitation set at 9.99% of our outstanding common stock.

Transferability. Subject to applicable laws, the pre-funded warrants are separately tradeable immediately after issuance at the option of the holders and may be transferred at the option of the holders upon surrender of the pre-funded warrant to us together with the appropriate instruments of transfer.

No Listing. There is no established public trading market for the pre-funded warrants and we do not expect a market to develop. In addition, we do not intend to apply for listing of the pre-funded warrants on any securities exchange or trading system. Without an active market, the liquidity of the pre-funded warrants will be limited.

Fundamental Transactions. In the event of a "fundamental transaction," as defined in the pre-funded warrants and generally including any reorganization, recapitalization or reclassification of our common stock, the sale, transfer or other disposition of all or substantially all of our properties or assets, our consolidation or merger with or into another person, the acquisition of more than 50% of our outstanding common stock, or any person or group becoming the beneficial owner of 50% of the voting power represented by our outstanding common stock, the holders of the pre-funded warrants will be entitled to receive upon exercise of the pre-funded warrants the kind and amount of securities, cash or other property that the holders would have received had they exercised the pre-funded warrants immediately prior to such fundamental transaction.

Cashless Exercise. If, at the time a holder exercises its pre-funded warrants, a registration statement registering the issuance of the shares of common stock underlying the pre-funded warrants under the Securities Act is not then effective or available, then in lieu of making the cash payment otherwise contemplated to be made to us upon such exercise in payment of the aggregate exercise price, the holder may elect instead to receive upon such exercise (either in whole or in part) the net number of shares of common stock determined according to a formula set forth in the pre-funded warrants.

Rights as a Stockholder. Except as otherwise provided in the pre-funded warrant or by virtue of a holder's ownership of shares of our common stock, the holders of the pre-funded warrants do not have the rights or privileges of holders of our common stock, including any voting rights, until they exercise their pre-funded warrants.

Amendments. Amendments and waivers of the terms of the pre-funded warrants require the written consent of the holders of pre-funded warrants on the one hand and the Company on the other hand.

No Fractional Shares. No fractional shares or scrip representing fractional shares shall be issued upon the exercise of the pre-funded warrants. As to any fraction of a share which the holder would otherwise be entitled to purchase upon such exercise, we shall or shall cause, at our option, the payment of a cash adjustment in respect of such final fraction in an amount equal to such fraction multiplied by the exercise price of the pre-funded warrant per whole share or round such fractional share up to the nearest whole share.

Common Warrants

The material terms and provisions of the common warrants being issued in this offering are summarized below. The following description is subject to, and qualified in its entirety by, the form of common warrant which will be filed herewith as an exhibit. You should review the form of common warrant for a complete description of the terms and conditions applicable to the common warrants. See "Information Incorporated by Reference and Available Information" below.

General. Each purchaser of shares will receive a common warrant to purchase one share of common stock for each share purchased in the offering.

Exercisability. The common warrants may be exercised at any time on or after their date of issuance, will have an exercise price of $ per share and are exercisable until the fifth year anniversary of the date of issuance. The common warrants will be exercisable, at the option of each holder, in whole or in part by delivering a duly executed exercise notice to us accompanied by payment in full for the number of shares of our common stock purchased upon such exercise. The exercise price of the common warrant is subject to adjustment in the event of stock dividends and distributions, stock splits, stock combinations, reclassifications or similar events affecting our common stock.

Exercise Limitations. A holder of a common warrant will not have the right to exercise any portion of the common warrant if the holder (together with its affiliates) would beneficially own in excess of 4.99% (or, at election of holder, 9.99%) of the number of shares of our common stock outstanding immediately after giving effect to the exercise, as such percentage ownership is determined in accordance with the terms of the common warrants. However, any holder may increase or decrease such percentage to any other percentage not in excess of 9.99% upon notice to us provided that any increase shall not be effective until 61 days following notice to us.

Transferability. Subject to applicable laws, the common warrants are separately tradeable immediately after issuance at the option of the holders and may be transferred at the option of the holders upon surrender of the common warrant to us together with the appropriate instruments of transfer.

No Listing. There is no established public trading market for the common warrants and we do not expect a market to develop. In addition, we do not intend to apply for listing of the common warrants on any securities exchange or trading system. Without an active market, the liquidity of the common warrants will be limited.

Fundamental Transactions. In the event of a "fundamental transaction," as defined in the warrant agreement and generally including any reorganization, recapitalization or reclassification of our common stock, the sale, transfer or other disposition of all or substantially all of our properties or assets, our consolidation or merger with or into another person, the acquisition of more than 50% of our outstanding common stock, or any person or group becoming the beneficial owner of 50% of the voting power represented by our outstanding common stock, the holders of the common warrants will be entitled to receive upon exercise of the common warrants the kind and amount of securities, cash or other property that the holders would have received had they exercised the common warrants immediately prior to such fundamental transaction.

Cashless Exercise. If, at the time a holder exercises its common warrant, there is no effective registration statement registering, or the prospectus contained therein is not available for an issuance of, the shares underlying the common warrant to the holder, and the holder is not able to sell the shares issuable upon exercise of the common warrant without limitations on volume pursuant to Rule 144, then in lieu of making the cash payment otherwise contemplated to be made to us upon such exercise in payment of the aggregate exercise price, the holder may elect instead to receive upon such exercise (either in whole or in part) the net number of shares of our common stock determined according to a formula set forth in the common warrant. In the event of a cashless exercise, if we fail to timely deliver the shares underlying the common warrants, we will be subject to certain buy-in provisions.

Rights as a Stockholder. Except as otherwise provided in the common warrant or by virtue of a holder's ownership of shares of our common stock, the holders of the common warrants do not have the rights or privileges of holders of our common stock, including any voting rights, until they exercise their common warrants.

Amendments. Amendments and waivers of the terms of the common warrants require the written consent of the holders of common warrants on the one hand and the Company on the other hand.

No Fractional Shares. No fractional shares or scrip representing fractional shares shall be issued upon the exercise of the common warrants. As to any fraction of a share which the holder would otherwise be entitled to purchase upon such exercise, we shall or shall cause, at our option, the payment of a cash adjustment in respect of such final fraction in an amount equal to such fraction multiplied by the exercise price of the common warrant per whole share or round such fractional share up to the nearest whole share.

Preferred Stock

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, powers and restrictions of each such series. The issuance of preferred stock could have the effect of restricting dividends on common stock, diluting the voting power of common stock, impairing the liquidation rights of common stock or delaying or preventing a change in control of the Company without further action by the stockholders.

Options

As of September 30, 2019, there were options outstanding to purchase an aggregate of 755,225 shares of our common stock with a range of exercise prices from $1.90 to $57.80 per share and an average weighted exercise price of $12.63 per share. The options were issued pursuant to (i) the Capricor Therapeutics, Inc. 2006 Stock Option Plan, (ii) the 2012 Restated Equity Incentive Plan, as amended, and (iii) the 2012 Non-Employee Director Stock Option Plan.

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

The provisions of the General Corporation Law of the State of Delaware, or 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 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.

Concentration of Ownership

Our executive officers, directors and holders of five percent or more of our outstanding common stock, together with their respective affiliates, beneficially own or control a significant portion of the outstanding shares of the Company. Accordingly, these stockholders will have substantial influence over the outcome of a corporate action of the Company requiring stockholder approval, including the election of directors, any merger, consolidation or sale of all or substantially all of the Company's assets or any other significant corporate transaction. These stockholders may also exert influence in delaying or preventing a change in control of the Company, even if such change in control would benefit the other stockholders of the Company.

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. 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.

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 the Company's 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.

Special Meetings of Stockholders

Our Bylaws provide that special meetings of stockholders may be called by the Chairman of the Board, the President or the 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.

Filling of Vacancies on the Board of Directors

Our Bylaws provide that a vacancy on the 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.

Listing

Our common stock is currently traded on the NASDAQ Capital Market under the symbol "CAPR".

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.

Amendment of Our Bylaws

Our Board of Directors is expressly authorized to adopt, amend or repeal our Bylaws.

PLAN OF DISTRIBUTION

Pursuant to an engagement agreement dated November 29, 2019, we have engaged H.C. Wainwright & Co., LLC, or the Placement Agent, to act as our exclusive placement agent in connection with this offering, on a reasonable best efforts basis, of our shares of common stock, pre-funded warrants, and common warrants pursuant to this prospectus. The terms of this offering were subject to market conditions and negotiations between us, the Placement Agent and prospective investors. The engagement agreement does not give rise to any commitment by the Placement Agent to purchase any of our securities, and the Placement Agent will have no authority to bind us by virtue of the engagement agreement. Further, the Placement Agent does not guarantee that it will be able to raise new capital in any prospective offering. The Placement Agent may engage sub-agents or selected dealers to assist with the offering.

We will enter into a securities purchase agreement directly with institutional investors in connection with this offering. Investors who do not enter into a securities purchase agreement shall rely solely on this prospectus in connection with the purchase of our securities in this offering.

We will deliver the securities being issued to the investors upon receipt of investor funds for the purchase of the securities offered pursuant to this prospectus. We expect to deliver the shares of our common stock being offered pursuant to this prospectus on or about , 2019.

Fees and Expenses

We have agreed to pay to the Placement Agent a cash fee equal to 7.0% of the aggregate gross proceeds raised in this offering. The following table shows the per share and common warrant and per pre-funded warrant and common warrant Placement Agent's fees payable to the Placement Agent by us in connection with this offering. The total Placement Agent's fee below assumes the purchase of all of the securities we are offering.

Per share of common stock and accompanying common warrant placement agent cash fees	$
Per pre-funded warrant and accompanying common warrant placement agent cash fee	$
Total	$

We estimate the total expenses payable by us for this offering to be approximately $, which amount includes (i) a Placement Agent's fee of $, assuming the purchase of all of the securities we are offering; (ii) a management fee equal to 1% of the aggregate gross proceeds raised in this offering; (iii) a $35,000 non-accountable expense allowance payable to the Placement Agent; (iv) reimbursement of the accountable expenses of the Placement Agent equal to $100,000 including the legal fees of the Placement Agent being paid by us (none of which has been paid in advance); (v) the Placement Agent's clearing expenses in the amount of $10,000 in connection with this offering; and (vi) other estimated expenses of approximately $100,000 which include legal, accounting, printing costs and various fees associated with the registration and listing of our shares. In addition, we have agreed to issue the Placement Agent's Warrants to the Placement Agent. See "Placement Agent's Warrants" below for additional detail.

Placement Agent's Warrants

We have agreed to issue to the Placement Agent Warrants to purchase shares of our common stock which represent 5.0% of the number of shares of common stock and pre-funded warrants being sold in this offering. The Placement Agent's Warrants will have a term of five years from the effective date of this prospectus and an exercise price per share equal to $ per share, which represents 125% of the public offering price for the shares sold in this offering. Pursuant to FINRA Rule 5110(g), the Placement Agent's Warrants and any shares issued upon exercise of the Placement Agent's Warrants shall not be sold, transferred, assigned, pledged, or hypothecated, or be the subject of any hedging, short sale, derivative, put or call transaction that would result in the effective economic disposition of the securities by any person for a period of 180 days immediately following the date of effectiveness or commencement of sales of this offering, except the transfer of any security: (i) by operation of law or by reason of our reorganization; (ii) to any FINRA member firm participating in the offering and the officers or partners thereof, if all securities so transferred remain subject to the lock-up restriction set forth above for the remainder of the time period; (iii) if the aggregate amount of our securities held by the Placement Agent or related persons does not exceed 1% of the securities being offered; (iv) that is beneficially owned on a pro rata basis by all equity owners of an investment fund, provided that no participating member manages or otherwise directs investments by the fund and the participating members in the aggregate do not own more than 10% of the equity in the fund; or (v) the exercise or conversion of any security, if all securities remain subject to the lock-up restriction set forth above for the remainder of the time period.

Lock-Up Agreements

We and each of our officers and directors have agreed with the Placement Agent to be subject to a lock-up period of 90 days following the date of this prospectus. This means that, during the applicable lock-up period, we may not offer for sale, contract to sell, or sell any shares of our common stock or any securities convertible into, or exercisable or exchangeable for, shares of our common stock subject to certain customary exception such as issuing stock options to directors, officers, employees and consultants under our existing plan and issuances of shares issuable upon the exercise of our outstanding warrants, including the warrants issued pursuant to this Prospectus. The Placement Agent may, in its sole discretion and without notice, waive the terms of any of these lock-up agreements.

Nasdaq Capital Market Listing

Our stock is currently traded on the Nasdaq Capital Market under the symbol "CAPR." On December 2, 2019, the last reported sale price of our common stock was $1.69 per share. We do not plan to list the common warrants, the pre-funded warrants or the Placement Agent's Warrants on the Nasdaq Capital Market or any other securities exchange or trading market.

Indemnification

We have agreed to indemnify the Placement Agent and specified other persons against some civil liabilities, including liabilities under the Securities Act, and the Securities Exchange Act of 1934, as amended, or the Exchange Act, and to contribute to payments that the Placement Agent may be required to make in respect of such liabilities.

Regulation M

The Placement Agent may be deemed to be an underwriter within the meaning of Section 2(a)(11) of the Securities Act and any fees received by it and any profit realized on the sale of the securities by it while acting as principal might be deemed to be underwriting discounts or commissions under the Securities Act. The Placement Agent will be required to comply with the requirements of the Securities Act and the Exchange Act including, without limitation, Rule 10b-5 and Regulation M under the Exchange Act. These rules and regulations may limit the timing of purchases and sales of our securities by the Placement Agent. Under these rules and regulations, the Placement Agent may not (i) engage in any stabilization activity in connection with our securities; and (ii) bid for or purchase any of our securities or attempt to induce any person to purchase any of our securities, other than as permitted under the Exchange Act, until they have completed their participation in the distribution.

Other Relationships

The Placement Agent and its respective affiliates have in the past and may in the future engage in investment banking and other commercial dealings in the ordinary course of business with us or our affiliates. The Placement Agent has received, or may in the future receive, customary fees and commissions for these transactions.

MATERIAL U.S. FEDERAL INCOME TAX CONSIDERATIONS

The following is a general discussion of the material U.S. federal income considerations applicable to the ownership and disposition of shares of our common stock and warrants acquired in this offering. This discussion is for general information only and is not tax advice. Accordingly, all prospective holders of our common stock and warrants should consult their own tax advisors with respect to the U.S. federal, state, local and non-U.S. tax consequences of the purchase, ownership and disposition of our common stock and warrants. This discussion is based on current provisions of the U.S. Internal Revenue Code of 1986, as amended, which we refer to as the Code, existing and proposed U.S. Treasury Regulations promulgated thereunder, current administrative rulings and judicial decisions, all as in effect as of the date of this prospectus, all of which are subject to change or to differing interpretation, possibly with retroactive effect. Any change could alter the tax consequences described in this prospectus. We assume in this discussion that each holder holds shares of our common stock and warrants as capital assets within the meaning of Section 1221 of the Code (generally property held for investment).

This discussion does not address all aspects of U.S. federal income taxation that may be relevant to a particular holder in light of that holder's individual circumstances, does not address the alternative minimum or Medicare contribution taxes, and does not address any aspects of U.S. state, local or non-U.S. taxes or any U.S. federal taxes other than income tax. This discussion also does not consider any specific facts or circumstances that may apply to a holder and does not address aspects of U.S. federal income taxation that may be applicable to holders that are subject to special tax rules, including without limitation:

- insurance companies;
- tax-exempt organizations;
- financial institutions;
- brokers or dealers in securities;
- regulated investment companies;
- real estate investment trusts;
- pension plans, individual retirement accounts and other tax deferred accounts;
- persons that mark their securities to market;
- controlled foreign corporations;
- passive foreign investment companies;
- "dual resident" corporations;
- persons that receive our common stock or warrants as compensation for the performance of services;
- owners that hold our common stock or warrants as part of a straddle, hedge, conversion transaction, synthetic security or other integrated investment;
- owners that own, or are deemed to own, more than 5% of our capital stock (except to the extent specifically set forth below);
- persons that have a functional currency other than the U.S. dollar; and
- certain U.S. expatriates.

In addition, this discussion does not address the tax treatment of partnerships or other pass-through entities for U.S. federal income tax purposes, or persons who hold our common stock or warrants through partnerships or other pass-through entities for U.S. federal income tax purposes. A partner in a partnership or other pass-through entity that will hold our common stock or warrants should consult his, her or its own tax advisor regarding the tax consequences of acquiring, holding and disposing of our common stock or warrants through a partnership or other pass-through entity, as applicable.

As used in this prospectus supplement, the term "U.S. holder" means a beneficial owner of common stock or warrants that is for U.S. federal income tax purposes:

- a citizen or individual resident of the United States;
- a corporation (or other entity properly classified as a corporation for U.S. federal income tax purposes) created or organized in or under the laws of the United States, any state within the United States, or the District of Columbia;
- an estate, the income of which is subject to U.S. federal income taxation regardless of its source; or
- a trust, if (i) a U.S. court is able to exercise primary supervision over the trust's administration and one or more "United States persons" (as defined in the Code) have the authority to control all substantial decisions of the trust, or (ii) in the case of a trust that was treated as a domestic trust under the laws in effect before 1997, a valid election is in place under applicable U.S. Treasury regulations to treat such trust as a domestic trust.

The term "non-U.S. holder" means any beneficial owner of common stock or warrants that is not a U.S. holder and is not a partnership or other entity properly classified as a partnership for U.S. federal income tax purposes. For the purposes of this prospectus supplement, U.S. holders and non-U.S. holders are referred to collectively as "holders."

There can be no assurance that the Internal Revenue Service, which we refer to as the IRS, will not challenge one or more of the tax consequences described herein. We have not obtained, nor do we intend to obtain, a ruling from the IRS with respect to the U.S. federal income tax consequences of the purchase, ownership or disposition of our common stock or warrants.

Allocation of Purchase Price Between Share of Common Stock or Pre-Funded Warrant and Accompanying Common Warrant

Each share of common stock (or, in lieu of common stock, each pre-funded warrant) and the accompanying common warrant issued pursuant to this offering should be treated as an "investment unit" consisting of one share of common stock or pre-funded warrant, as the case may be, and the accompanying common warrant. The purchase price for each investment unit will be allocated between these components in proportion to their relative fair market values at the time the investment unit is purchased by the holder. This allocation will establish a holder's initial tax basis for U.S. federal income tax purposes in his, her or its share of common stock (or, in lieu of common stock, pre-funded warrant) and common warrant included in each investment unit. We will not be providing holders with such allocation, and it is possible that different holders will reach different determinations regarding such allocation. A holder's allocation of purchase price between each share of common stock (or, in lieu of common stock, each pre-funded warrant) and the accompanying common warrant is not binding on the IRS or the courts, and no assurance can be given that the IRS or the courts will agree with a holder's allocation.

Accordingly, each prospective holder should consult his, her or its own tax advisor with respect to the allocation, and the risks associated with such allocation, of the holder's purchase price for the investment unit between our shares of common stock (or, in lieu of common stock, pre-funded warrants) and common warrants.

Treatment of Pre-Funded Warrants

Although it is not entirely free from doubt, a pre-funded warrant should be treated as a share of our common stock for U.S. federal income tax purposes and a holder of pre-funded warrants should generally be taxed in the same manner as a holder of common stock, as described below. Accordingly, no gain or loss should be recognized upon the exercise of a pre-funded warrant and, upon exercise, the holding period of a pre-funded warrant should carry over to the share of common stock received. Similarly, the tax basis of the pre-funded warrant should carry over to the share of common stock received upon exercise, increased by the exercise price of $0.001 per share. Each holder should consult his, her or its own tax advisor regarding the risks associated with the acquisition of pre-funded warrants pursuant to this offering (including potential alternative characterizations). The balance of this discussion generally assumes that the characterization described above will be respected for U.S. federal income tax purposes.

Tax Consequences to U.S. Holders

Exercise or Expiration of Common Warrants

Subject to the discussion below with respect to the cashless exercise of a common warrant, a U.S. holder will not recognize income, gain or loss on the exercise of a common warrant. A U.S. holder's tax basis in the common stock received upon the exercise of a common warrant will equal the sum of (i) the initial tax basis of the common warrant exercised (as determined pursuant to the rules discussed above under "Allocation of Purchase Price Between Common Stock or Pre-Funded Warrant and Accompanying Common Warrant to Purchase Our Common Stock") and (ii) the exercise price of the common warrant. The U.S. holder's holding period for the common stock received upon exercise of a common warrant will begin on the day after such exercise (or possibly on the date of exercise) and will not include the period during which the U.S. holder held the common warrant.

The tax consequences of a cashless exercise of a common warrant are not clear under current U.S. tax law. A cashless exercise may be tax-free, either because the exercise is not a realization event or because the exercise is treated as a recapitalization for U.S. federal income tax purposes. In either case, a U.S. holder's basis in the common stock received in connection with the cashless exercise would equal the U.S. holder's basis in the common warrants surrendered in connection with the cashless exercise. If the cashless exercise was not a realization event, it is unclear whether a U.S. holder's holding period for the common stock would be treated as commencing on the date of exercise or on the day following the date of exercise. If the cashless exercise were treated as a recapitalization, the holding period of the common stock would include the holding period of the common warrants surrendered in connection with the cashless exercise.

It is possible that a cashless exercise could be treated in part as a taxable exchange in which gain or loss would be recognized. In such event, a U.S. holder could be deemed to have surrendered common warrants having an aggregate fair market value equal to the exercise price for the total number of common warrants to be exercised. The U.S. holder would recognize capital gain or loss in an amount equal to the difference between the amount deemed realized (*i.e.*, the exercise price for the common warrants exercised) and the U.S. holder's tax basis in the common warrants deemed surrendered to pay the exercise price. In this case, a U.S. holder's tax basis in the common stock received would equal the sum of the U.S. holder's initial investment in the exercised common warrants and the exercise price for such common warrants. It is unclear whether a U.S. holder's holding period for the common stock would commence on the date of exercise of the common warrants or the day following the date of exercise of the common warrants.

Due to the absence of authority on the U.S. federal income tax treatment of a cashless exercise, there can be no assurance which, if any, of the alternative approaches described above would be adopted by the IRS or a court of law. Accordingly, U.S. holders should consult their own tax advisors regarding the tax consequences of a cashless exercise.

If a common warrant is allowed to lapse unexercised, a U.S. holder generally will recognize a capital loss equal to such holder's tax basis in the common warrant. The deductibility of capital losses is subject to significant limitations.

Distributions on Our Common Stock

As discussed above under "Dividend Policy", we do not currently expect to make distributions on our common stock. In the event that we do make distributions on our common stock to a U.S. holder, those distributions generally will constitute dividends for U.S. federal income tax purposes to the extent paid from our current or accumulated earnings and profits as determined under U.S. federal income tax principles. If a distribution exceeds our current and accumulated earnings and profits, the excess will be treated as a tax-free return of the U.S. holder's investment, up to such U.S. holder's tax basis in the common stock. Any remaining excess will be treated as capital gain, subject to the tax treatment described below in "—Gain on Sale, Exchange or Other Taxable Disposition of Our Common Stock and Warrants." Dividends paid by us generally will be eligible for the reduced rates of tax for qualified dividend income allowed to individual U.S. holders and for the dividends received deduction allowed to corporate U.S. holders, in each case assuming that certain holding period and other requirements are satisfied.

Constructive Distributions on Our Warrants

Under Section 305 of the Code, an adjustment to the number of shares of common stock that will be issued on the exercise of our warrants (whether pre-funded warrants or common warrants), or an adjustment to the exercise price of such warrants, may be treated as a constructive distribution to a U.S. Holder of the warrants if, and to the extent that, such adjustment has the effect of increasing such U.S. Holder's proportionate interest in our "earnings and profits" or assets, depending on the circumstances of such adjustment (for example, if such adjustment is to compensate for a distribution of cash or other property to holders of our common stock). Adjustments to the exercise price of a warrant made pursuant to a bona fide reasonable adjustment formula that has the effect of preventing dilution of the interest of the holder of the warrant should generally not result in a constructive distribution. Any constructive distributions generally would be subject to the tax treatment described above under "-- Distributions on our Common Stock".

Sale, Exchange or Other Taxable Disposition of Our Common Stock or Warrants

Upon the sale, exchange, or other taxable disposition of our common stock or warrants (whether pre-funded warrants or common warrants), a U.S. holder will recognize gain or loss equal to the difference between the amount realized upon the disposition and the U.S. holder's tax basis in the common stock or warrants sold or exchanged. Any gain or loss generally will be capital gain or loss, and will be long-term capital gain or loss if the U.S. holder's holding period for the common stock or common warrants exceeded one year at the time of the disposition. Certain U.S. holders (including individuals) are currently eligible for preferential rates of U.S. federal income taxation in respect of long-term capital gains. The deductibility of capital losses is subject to significant limitations.

Information Reporting and Backup Withholding

In general, information reporting requirements may apply to distributions (whether actual or constructive) paid to a U.S. holder on our common stock or warrants, and to the proceeds of the sale, exchange or other disposition of our common stock and warrants, unless the U.S. holder is an exempt recipient. Backup withholding will apply to such payments if the U.S. holder fails to provide a taxpayer identification number, a certification of exempt status or has been notified by the IRS that it is subject to backup withholding (and such notification has not been withdrawn). Backup withholding is not an additional tax. Any amounts withheld under the backup withholding rules will be allowed as a refund or a credit against a U.S. holder's U.S. federal income tax liability provided the required information is timely furnished to the IRS.

Tax Consequences to Non-U.S. Holders

Exercise or Expiration of Common Warrants

In general, a non-U.S. holder will not be required to recognize income, gain or loss upon the exercise of a common warrant by payment of the exercise price. To the extent that a cashless exercise results in a taxable exchange, the consequences would be similar to those described below under "Disposition of our Common Stock or Warrants".

The expiration of a common warrant will be treated as if the non-U.S. holder sold or exchanged the common warrant and recognized a capital loss equal to the non-U.S. holder's basis in the common warrant. A non-U.S. holder will not be able to utilize a loss recognized upon expiration of a common warrant against the Non-U.S. holder's U.S. federal income tax liability, however, unless the loss (i) is effectively connected with the non-U.S. holder's conduct of a trade or business within the United States (and, if an income tax treaty applies, is attributable to a "permanent establishment" or "fixed base" in the United States) or (ii) is treated as a U.S. source loss and the non-U.S. holder is present in the United States 183 days or more in the taxable year of disposition and certain other conditions are met.

Distributions on Our Common Stock

As discussed above under "Dividend Policy", we do not currently expect to make distributions on our common stock. In the event that we do make distributions to holders of our common stock or if we are treated as making a constructive distribution to holders of our warrants or pre-funded warrants, those distributions generally will constitute dividends for U.S. federal income tax purposes to the extent paid from our current or accumulated earnings and profits, as determined under U.S. federal income tax principles. If a distribution exceeds our current and accumulated earnings and profits, the excess will be treated as a tax-free return of the non-U.S. holder's investment, up to such non-U.S. holder's tax basis in the common stock. Any remaining excess will be treated as capital gain, subject to the tax treatment described below in "-- Gain on Sale, Exchange or Other Taxable Disposition of Our Common Stock."

Distributions (including constructive distributions) made to a non-U.S. holder that are treated as dividends generally will be subject to withholding of U.S. federal income tax at a rate of 30% of the gross amount or such lower rate as may be specified by an applicable income tax treaty between the United States and such holder's country of residence, unless such dividends are effectively connected with a trade or business conducted by a non U.S. holder within the U.S (as discussed below). A non-U.S. holder of our common stock who claims the benefit of an applicable income tax treaty between the United States and such holder's country of residence generally will be required to provide a properly executed IRS Form W-8BEN or W-8BEN-E (or successor form), as applicable, and satisfy applicable certification and other requirements. Non-U.S. holders are urged to consult their own tax advisors regarding their entitlement to benefits under a relevant income tax treaty. A non-U.S. holder that is eligible for a reduced rate of U.S. withholding tax under an income tax treaty may be able to obtain a refund or credit of any excess amounts withheld by timely filing the required information with the IRS.

Dividends that are treated as effectively connected with a trade or business conducted by a non-U.S. holder within the United States and, if an applicable income tax treaty so provides, that are attributable to a "permanent establishment" or a "fixed base" maintained by the non-U.S. holder within the United States, generally are exempt from the 30% withholding tax if the non-U.S. holder satisfies applicable certification and disclosure requirements. U.S. effectively connected income, net of specified deductions and credits, is generally taxed at the same graduated U.S. federal income tax rates applicable to United States persons (as defined in the Code). Any U.S. effectively connected income received by a non-U.S. holder that is a corporation may also be subject to an additional "branch profits tax" at a 30% rate or such lower rate as may be specified by an applicable income tax treaty between the United States and such holder's country of residence.

Constructive Distributions on Our Warrants

As described above under "—Tax Consequences to U.S. Holders—Constructive Distributions on our Warrants," an adjustment to the warrants could result in a constructive distribution to a non-U.S. holder, which would be treated as described under "--Distributions on Our Common Stock" above. Any resulting withholding tax attributable to deemed dividends would be collected from other amounts payable or distributable to the non-U.S. holder. Non U.S. holders should consult their tax advisors regarding the proper treatment of any adjustments to the warrants.

In addition, regulations governing "dividend equivalents" under Section 871(m) of the Code may apply to the pre-funded warrants. Under those regulations, an implicit or explicit payment made to the holder of pre-funded warrants that references a distribution on our common stock would generally be taxable to a non-U.S. holder in the manner described under "Distributions on our Common Stock" below. Such dividend equivalent amount would be taxable and subject to withholding whether or not there is actual payment of cash or other property, and we may satisfy any withholding obligations by withholding from other amounts due to the non-U.S. holder. Non-U.S. holders are encouraged to consult their own tax advisors regarding the application of Section 871(m) of the Code to the pre-funded warrants.

Sale, Exchange or Other Taxable Disposition of Our Common Stock or Warrants

In general, a non-U.S. holder will not be subject to any U.S. federal income tax on any gain realized upon such holder's sale, exchange or other taxable disposition of shares of our common stock or warrants unless:

- the gain is effectively connected with the non-U.S. holder's conduct of a U.S. trade or business and, if an applicable income tax treaty so provides, is attributable to a "permanent establishment" or a "fixed base" maintained by such non-U.S. holder in the United States, in which case the non-U.S. holder generally will be taxed on such gain at the graduated U.S. federal income tax rates applicable to United States persons (as defined in the Code) and, if the non-U.S. holder is a foreign corporation, the branch profits tax described above in "--Tax Consequences to Non-U.S. Holders—Distributions on Our Common Stock" also may apply to such gain;
- the non-U.S. holder is a nonresident alien individual who is present in the United States for 183 days or more in the taxable year of the taxable disposition and certain other conditions are met, in which case the non-U.S. holder will be subject to a 30% tax (or such lower rate as may be specified by an applicable income tax treaty between the United States and such holder's country of residence) on the net gain derived from the taxable disposition, which may be offset by certain U.S. source capital losses of the non-U.S. holder, if any; or
- we are, or have been, at any time during the five-year period preceding such taxable disposition (or the non-U.S. holder's holding period, if shorter) a "U.S. real property holding corporation," unless our common stock is regularly traded on an established securities market and the non-U.S. holder holds no more than 5% of our outstanding common stock, directly or indirectly, during the shorter of the 5-year period ending on the date of the taxable disposition or the period that the non-U.S. holder held our common stock. If we are determined to be a U.S. real property holding corporation and the foregoing exception does not apply, then a purchaser may withhold 15% of the proceeds payable to a non-U.S. holder from a sale of our common stock or warrants, and the non-U.S. holder generally will be taxed on its net gain derived from the disposition at the graduated U.S. federal income tax rates applicable to United States persons (as defined in the Code). Generally, a corporation is a U.S. real property holding corporation only if the fair market value of its U.S. real property interests equals or exceeds 50% of the sum of the fair market value of its worldwide real property interests plus its other assets used or held for use in a trade or business. Although there can be no assurance, we do not believe that we are, or have been, a U.S. real property holding corporation, or that we are likely to become one in the future. No assurance can be provided that our common stock will be regularly traded on an established securities market for purposes of the rules described above.

Information Reporting and Backup Withholding

We must report annually to the IRS and to each non-U.S. holder the gross amount of the distributions paid on our common stock (and constructive distributions on our warrants) to such holder and the tax withheld, if any, with respect to such distributions. Non-U.S. holders may have to comply with specific certification procedures to establish that the holder is not a United States person (as defined in the Code) in order to avoid backup withholding at the applicable rate with respect to dividends on our common stock or warrants. Dividends paid to non-U.S. holders subject to the U.S. withholding tax, as described above in "Non-U.S. Holders—Distributions on Our Common Stock," generally will be exempt from U.S. backup withholding.

Information reporting and backup withholding generally will apply to the proceeds of a disposition of our common stock and warrants by a non-U.S. holder effected by or through the U.S. office of any broker, U.S. or foreign, unless the holder certifies its status as a non-U.S. holder and satisfies certain other requirements, or otherwise establishes an exemption. Generally, information reporting and backup withholding will not apply to a payment of disposition proceeds to a non-U.S. holder where the transaction is effected outside the United States through a non-U.S. office of a broker. However, for information reporting purposes, dispositions effected through a non-U.S. office of a broker with substantial U.S. ownership or operations generally will be treated in a manner similar to dispositions effected through a U.S. office of a broker. Non-U.S. holders should consult their own tax advisors regarding the application of the information reporting and backup withholding rules to them.

Copies of information returns may be made available to the tax authorities of the country in which the non-U.S. holder resides or is incorporated under the provisions of a specific treaty or agreement.

Backup withholding is not an additional tax. Any amounts withheld under the backup withholding rules from a payment to a non-U.S. holder can be refunded or credited against the non-U.S. holder's U.S. federal income tax liability, if any, provided that an appropriate claim is filed with the IRS.

Foreign Accounts

The Foreign Account Tax Compliance Act, or FATCA, generally imposes a 30% withholding tax on dividends (including constructive dividends) on, and gross proceeds from the sale or other disposition of, our common stock and Warrants if paid to a non-U.S. entity unless (i) if the non-U.S. entity is a "foreign financial institution," the non-U.S. entity undertakes certain due diligence, reporting, withholding, and certification obligations, (ii) if the non-U.S. entity is not a "foreign financial institution," the non-U.S. entity identifies certain of its U.S. investors, if any, or (iii) the non-U.S. entity is otherwise exempt under FATCA.

Withholding under FATCA generally will apply to payments of dividends (including constructive dividends) on our common stock and warrants. While withholding under FATCA may apply to payments of gross proceeds from a sale or other disposition of our common stock or warrants, under proposed U.S. Treasury Regulations withholding on payments of gross proceeds is not required. Although such regulations are not final, applicable withholding agents may rely on the proposed regulations until final regulations are issued.

An intergovernmental agreement between the United States and an applicable foreign country may modify the requirements described in this section. Under certain circumstances, a holder may be eligible for refunds or credits of the tax. Non-U.S. holders should consult their own tax advisors regarding the possible implications of FATCA on their investment in our common stock or warrants.

The preceding discussion of material U.S. federal income tax considerations is for informational purposes only. It is not tax advice. Prospective investors should consult their own tax advisors regarding the particular U.S. federal, state, local and non-U.S. tax consequences of purchasing, holding and disposing of our common stock or warrants, including the consequences of any proposed changes in applicable laws.

LEGAL MATTERS

Unless otherwise indicated in the applicable prospectus supplement, Sidley Austin LLP, Palo Alto, California, will pass upon the validity of the securities offered by this prospectus and any supplement hereto. The Placement Agent is being represented by Ellenoff Grossman & Schole LLP, New York, New York.

EXPERTS

The audited consolidated financial statements of the Company appearing in the Company's Annual Report on Form 10-K for the year ended December 31, 2018 have been audited by Rose, Snyder and Jacobs LLP, an independent registered public accounting firm, as set forth in their report thereon, included therein, and incorporated herein by reference. Such financial statements are incorporated herein by reference in reliance upon such report given on the authority of such firm as experts in accounting and auditing.

WHERE YOU CAN FIND ADDITIONAL INFORMATION

We are a reporting company and file annual, quarterly and current reports, proxy statements and other information with the SEC. We have filed with the SEC a registration statement under the Securities Act with respect to the securities being offered under this prospectus. This prospectus does not contain all of the information set forth in the registration statement and the exhibits to the registration statement. For further information with respect to us and the securities being offered under this prospectus, we refer you to the registration statement and the exhibits and schedules filed as a part of the registration statement. You may read and copy the registration statement, as well as our reports, proxy statements and other information, at the SEC's Public Reference Room at 100 F Street, N.E., Washington, D.C. 20549. Please call the SEC at 1-800-SEC-0330 for more information about the operation of the Public Reference Room. The SEC maintains an Internet site that contains reports, proxy and information statements, and other information regarding issuers that file electronically with the SEC, including Capricor Therapeutics, Inc. The SEC's Internet site can be found at *http://www.sec.gov*.

We are subject to the informational and reporting requirements of the Securities Exchange Act of 1934, as amended, and have filed and will file annual, quarterly and current reports, proxy statements and other information with the SEC. These periodic reports, proxy statements and other information will be available for inspection and copying at the SEC's public reference facilities and the website of the SEC referred to above. We also maintain a website at *www.capricor.com*. You may access these materials free of charge as soon as reasonably practicable after they are electronically filed with, or furnished to, the SEC. Information contained on our website is not a part of this prospectus and the inclusion of our website address in this prospectus is an inactive textual reference only.

MARKET AND INDUSTRY DATA AND FORECASTS

This prospectus contains estimates, projections and other information concerning our industry and our business, including estimated market size, projected growth rates and the incidence of certain medical conditions. Unless otherwise expressly stated, we obtained this industry, business, market, medical and other information from reports, research surveys, studies and similar data prepared by third parties, industry, medical and general publications, government data and similar sources. In some cases, we do not expressly refer to the sources from which this information is derived. In that regard, when we refer to one or more sources of this type of information in any paragraph, you should assume that other information of this type appearing in the same paragraph is derived from the same sources, unless otherwise expressly stated or the context otherwise requires.

This industry, business, market, medical and other information involves a number of assumptions and limitations, and you are cautioned not to give undue weight to such estimates. We have not independently verified any third-party information included in this prospectus. Although we are responsible for all of the disclosure contained in this prospectus and we believe the market position, market opportunity, market size and medical information included in this prospectus is reliable, such information is inherently imprecise. In addition, projections, assumptions and estimates of our future performance and the future performance of the industry in which we operate is necessarily subject to a high degree of uncertainty and risk due to a variety of factors, including those described in the section titled "Risk Factors" and elsewhere in this prospectus. These and other factors could cause results to differ materially from those expressed in the estimates made by the independent parties and by us.

INCORPORATION OF DOCUMENTS BY REFERENCE

The SEC allows us to "incorporate by reference" into this prospectus the information we file with it, which means that we can disclose important information to you by referring you to those documents. The information we incorporate by reference is an important part of this prospectus and information that we subsequently file with the SEC will automatically update and supersede information in this prospectus and in our other filings with the SEC.

We incorporate by reference the documents listed below, which we have already filed with the SEC, and any filings we make with the SEC under Section 13(a), 13(c), 14 or 15(d) of the Exchange Act (1) on or after the date of filing of the registration statement of which this prospectus forms a part and (2) on or after the date of this prospectus until the earlier of the date on which all of the securities registered hereunder have been sold or the registration statement of which this prospectus is a part has been withdrawn (in each case, other than information that is deemed, under SEC rules, not to have been filed):

- our Annual Report on Form 10-K for the fiscal year ended December 31, 2018, filed with the SEC on March 29, 2019 and as amended by Amendment No. 1 to Annual Report on Form 10-K/A filed with the SEC on April 1, 2019;
- our Quarterly Reports on Form 10-Q for the fiscal quarters ended March 31, 2019, June 30, 2019, and September 30, 2019, filed with the SEC on May 14, 2019, August 8, 2019, and on November 8, 2019;
- our Definitive Proxy Statement on Schedule 14A, filed with the SEC on April 30, 2019;
- our Current Reports on Form 8-K, filed with the SEC on (i) January 2, 2019; (ii) January 22, 2019; (iii) February 6, 2019; (iv) June 3, 2019; (v) June 4, 2019; (vi) June 20, 2019; (vii) July 15, 2019; (viii) July 16, 2019; (ix) July 22, 2019; (x) August 6, 2019; (xi) August 19, 2019; (xii) August 29, 2019; and (xiii) November 14, 2019; and
- the description of our common stock contained in our Registration Statement on Form 8-A filed on March 5, 2015, including any amendment or report filed for the purpose of updating such description.

We also incorporate by reference any future filings (other than current reports furnished under Item 2.02 or Item 7.01 of Form 8-K and exhibits filed on such form that are related to such items unless such Form 8-K expressly provides to the contrary) made with the SEC pursuant to Sections 13(a), 13(c), 14 or 15(d) of the Exchange Act, including those made after the date of the initial filing of the registration statement of which this prospectus is a part and those made after the effectiveness of such registration statement, until the termination of the offering of the common stock made by this prospectus, and such filings will become a part of this prospectus from the respective dates that such documents are filed with the SEC. Information in such future filings updates and supplements the information provided in this prospectus. Any statements in any such future filings will automatically be deemed to modify and supersede any information herein or in any document we previously filed with the SEC that is incorporated or deemed to be incorporated hereinby reference to the extent that statements in the later filed document modify or replace such earlier statements.

We will provide without charge to each person, including any beneficial owner, to whom this prospectus is delivered, upon written or oral request, a copy of any or all of the foregoing documents incorporated herein by reference (other than exhibits unless such exhibits are specifically incorporated by reference in such documents). Requests for such documents should be made to us at the following address or telephone number: Capricor Therapeutics, Inc., Attn: General Counsel, 8840 Wilshire Blvd. 2nd Floor, Beverly Hills, California 90211, or by calling (310) 358-3200.

Shares of Common Stock

Pre-Funded Warrants to Purchase Shares of Common Stock

Warrants to Purchase up to Shares of Common Stock

PROSPECTUS

H.C. Wainwright & Co.

, 2019

PART II

INFORMATION NOT REQUIRED IN PROSPECTUS

Item 13. ***Other Expenses of Issuance and Distribution***

The following table sets forth all expenses to be paid by Capricor Therapeutics, Inc. (the Registrant), in connection with the offering. All amounts shown are estimates except for the SEC registration fee and the FINRA filing fee.

SEC registration fee	$	649
FINRA filing fee		1,250
Legal fees and expenses		*
Accounting fees and expenses		*
Blue-sky qualification fees and expenses		*
Transfer agent and registrar fees and expenses		*
Miscellaneous fees and expenses		*
Total	$	*

*To be filed by amendment.

Item 14. ***Indemnification of Directors and Officers***

Section 145 of the General Corporation Law of the State of Delaware, or the DGCL, authorizes a corporation's board of directors to grant, and authorizes a court to award, indemnity to officers, directors and other corporate agents.

The Registrant's Certificate of Incorporation, as amended, or the Certificate, requires the Registrant to indemnify its directors and officers to the fullest extent permitted by the DGCL as it presently exists or as may hereafter be amended. Therefore, a director of the Registrant will not be liable to the Registrant or the Registrant's stockholders for monetary damages for any breach of fiduciary duty as a director, provided that the individual acted in good faith and in a manner the individual reasonably believed to be in or not opposed to the best interests of the corporation and, with respect to any criminal action or proceeding, had no reasonable cause to believe his or her conduct was unlawful. Any amendment to, or repeal of, these provisions will not eliminate or reduce the effect of these provisions in respect of any act, omission or claim that occurred or arose prior to that amendment or repeal. If the DGCL is amended to provide for further limitations on the personal liability of directors of corporations, then the personal liability of the Registrant's directors will be further limited to the greatest extent permitted by the DGCL.

Additionally, the provisions of the Certificate and of the Registrant's bylaws require the Registrant to indemnify and hold harmless, to the fullest extent permitted by applicable law as it presently exists or as may hereafter be amended, any person who was or is made or is threatened to be made a party or is otherwise involved in any action, suit or proceeding, whether civil, criminal, administrative or investigative, by reason of the fact that he or she, or a person for whom he or she is the legal representative, is or was a director or officer of the Registrant or, while a director or officer of the Registrant, is or was serving at the request of the Registrant as a director, officer, employee or agent of another corporation or of a partnership, joint venture, trust, enterprise or nonprofit entity, including service with respect to employee benefit plans, against all liability and loss suffered and expenses (including attorneys' fees) reasonably incurred by such person. Notwithstanding the preceding sentence, the Registrant shall be required to indemnify such a person in connection with a proceeding (or part thereof) commenced by such person only if the commencement of such proceeding (or part thereof) by the person was authorized in the specific case by the Board of Directors. The Registrant's bylaws also provide that the Registrant shall, to the fullest extent not prohibited by applicable law, promptly pay the expenses, including attorneys' fees, incurred by a director or officer in defending any proceeding in advance of its final disposition, subject to certain limited exceptions.

The Registrant's bylaws permit the Registrant to purchase and maintain insurance on behalf of any person that the Registrant is permitted to indemnify in accordance with the bylaws against any liability asserted again any such person and incurred by such person, whether or not the Registrant would have the power to indemnify such person against such liability under the DGCL. In accordance with the provisions of the bylaws, the Registrant currently maintains directors' and officers' liability insurance, which may insure against director or officer liability arising under the Securities Act. In addition, the Registrant has entered into various agreements whereby it has agreed to indemnify its directors and officers for specific liabilities that they may incur while serving in such capacities. These indemnification agreements provide for the maximum indemnity allowed to directors and officers by applicable law. The Registrant believes that these agreements are necessary to attract and retain qualified individuals to serve as directors and executive officers.

The limitation of liability and indemnification provisions that are included in the Certificate, the Registrant's bylaws and in indemnification agreements that the Registrant enters into with its directors and officers may discourage stockholders from bringing a lawsuit against the Registrant's directors and officers for breach of their fiduciary duties. They may also reduce the likelihood of derivative litigation against the Registrant's directors and officers, even though an action, if successful, might benefit the Registrant and other stockholders. Further, a stockholder's investment may be adversely affected to the extent that the Registrant pays the costs of settlement and damage awards against directors and executive officers as required by the applicable indemnification provisions. At present, the Registrant is not aware of any pending litigation or proceeding involving any person who is or was one of its directors, officers, employees or other agents or is or was serving at its request as a director, officer, employee or agent of another corporation, partnership, joint venture, trust or other enterprise, for which indemnification is sought, and the Registrant is not aware of any threatened litigation that may result in claims for indemnification.

The foregoing statements are subject to the detailed provisions of the DGCL and the full text of the corporate documents and agreements referenced above.

Reference is made to Item 17 for the Registrant's undertakings with respect to indemnification for liabilities arising under the Securities Act of 1933, as amended.

Item 15. ***Recent Sales of Unregistered Securities***

None.

Item 16. ***Exhibits and Financial Statement Schedules***

See the Exhibit Index attached to this registration statement on Form S-1, which Exhibit Index is incorporated by reference.

Item 17. ***Undertakings***

The undersigned registrant hereby undertakes:

(1) To file, during any period in which offers or sales are being made, a post-effective amendment to this registration statement:

(i) To include any prospectus required by Section 10(a)(3) of the Securities Act of 1933;

(ii) To reflect in the prospectus any facts or events arising after the effective date of the registration statement (or the most recent post-effective amendment thereof) which, individually or in the aggregate, represent a fundamental change in the information set forth in the registration statement. Notwithstanding the foregoing, any increase or decrease in volume of securities offered (if the total dollar value of securities offered would not exceed that which was registered) and any deviation from the low or high end of the estimated maximum offering range may be reflected in the form of prospectus filed with the Commission pursuant to Rule 424(b) if, in the aggregate, the changes in volume and price represent no more than a 20% change in the maximum aggregate offering price set forth in the "Calculation of Registration Fee" table in the effective registration statement; and

(iii) To include any material information with respect to the plan of distribution not previously disclosed in the registration statement or any material change to such information in the registration statement;

Provided, however, that:

Paragraphs (1)(i), (1)(ii) and (1)(iii) of this section do not apply if the information required to be included in a post-effective amendment by those paragraphs is contained in reports filed with or furnished to the Commission by the registrant pursuant to section 13 or section 15(d) of the Securities Exchange Act of 1934 that are incorporated by reference in the registration statement, or, as to a registration statement on Form S-3, Form SF-3 or Form F-3, is contained in a form of prospectus filed pursuant to Rule 424(b) that is part of the registration statement.

(2) That, for the purpose of determining any liability under the Securities Act of 1933, each such post-effective amendment shall be deemed to be a new registration statement relating to the securities offered therein, and the offering of such securities at that time shall be deemed to be the initial bona fide offering thereof.

(3) To remove from registration by means of a post-effective amendment any of the securities being registered which remain unsold at the termination of the offering.

(4) That, for the purpose of determining liability of the registrant under the Securities Act of 1933 to any purchaser in the initial distribution of the securities, the undersigned registrant undertakes that in a primary offering of securities of the undersigned registrant pursuant to this registration statement, regardless of the underwriting method used to sell the securities to the purchaser, if the securities are offered or sold to such purchaser by means of any of the following communications, the undersigned registrant will be a seller to the purchaser and will be considered to offer or sell such securities to such purchaser:

(i) Any preliminary prospectus or prospectus of the undersigned registrant relating to the offering required to be filed pursuant to Rule 424;

(ii) Any free writing prospectus relating to the offering prepared by or on behalf of the undersigned registrant or used or referred to by the undersigned registrant;

(iii) The portion of any other free writing prospectus relating to the offering containing material information about the undersigned registrant or its securities provided by or on behalf of the undersigned registrant; and

(iv) Any other communication that is an offer in the offering made by the undersigned registrant to the purchaser.

(5) That, for purposes of determining any liability under the Securities Act of 1933, each filing of the registrant's annual report pursuant to Section 13(a) or 15(d) of the Securities Exchange Act of 1934 (and, where applicable, each filing of an employee benefit plan's annual report pursuant to Section 15(d) of the Securities Exchange Act of 1934) that is incorporated by reference in the registration statement shall be deemed to be a new registration statement relating to the securities offered therein, and the offering of such securities at that time shall be deemed to be the initial bona fide offering thereof.

(6) That, for purposes of determining any liability under the Securities Act of 1933:

(i) the information omitted from the form of prospectus filed as part of this registration statement in reliance upon Rule 430A and contained in a form of prospectus filed by the registrant pursuant to Rule 424(b)(l) or (4) or 497(h) under the Securities Act of 1933 shall be deemed to be a part of this registration statement as of the time it was declared effective; and

(ii) each post-effective amendment that contains a form of prospectus shall be deemed to be a new registration statement relating to the securities offered therein, and the offering of such securities at that time shall be deemed to be the initial bona fide offering thereof.

Insofar as indemnification for liabilities arising under the Securities Act of 1933 may be permitted to directors, officers and controlling persons of the registrant pursuant to the foregoing provisions, or otherwise, the registrant has been advised that in the opinion of the Securities and Exchange Commission such indemnification is against public policy as expressed in the Act and is, therefore, unenforceable. In the event that a claim for indemnification against such liabilities (other than the payment by the registrant of expenses incurred or paid by a director, officer or controlling person of the registrant in the successful defense of any action, suit or proceeding) is asserted by such director, officer or controlling person in connection with the securities being registered, the registrant will, unless in the opinion of its counsel the matter has been settled by controlling precedent, submit to a court of appropriate jurisdiction the question whether such indemnification by it is against public policy as expressed in the Act and will be governed by the final adjudication of such issue.

EXHIBIT INDEX

1.1	Form of Placement Agency Agreement+
1.2	Form of Securities Purchase Agreement+
2.1	Agreement and Plan of Merger and Reorganization, dated as of July 7, 2013, by and among Nile Therapeutics, Inc., Bovet Merger Corp. and Capricor, Inc. (incorporated by reference to Exhibit 2.1 to the Company's Current Report on Form 8-K, filed with the Commission on July 9, 2013).
2.2	First Amendment to Agreement and Plan of Merger and Reorganization, dated as of September 27, 2013, by and between Nile Therapeutics, Inc., Bovet Merger Corp. and Capricor, Inc. (incorporated by reference to Exhibit 2.1 to the Company's Current Report on Form 8-K, filed with the Commission on October 3, 2013).
4.1	Certificate of Incorporation of the Company (incorporated by reference to Exhibit 3.1 to the Company's Current Report on Form 8-K, filed with the Commission on February 9, 2007).
4.2	Certificate of Amendment of Certificate of Incorporation of the Company (incorporated by reference to Exhibit 3.1 to the Company's Current Report on Form 8-K, filed with the Commission on November 26, 2013).
4.3	Bylaws of the Company (incorporated by reference to Exhibit 3.2 to the Company's Current Report on Form 8-K, filed with the Commission on February 9, 2007).
4.4	Form of Common Warrant+
4.5	Form of Pre-Funded Warrant+
4.6	Form of Placement Agent Warrant+
5.1	Opinion of Sidley Austin LLP.+
23.1	Consent of Rose Snyder & Jacobs, LLP.*
23.2	Consent of Sidley Austin LLP (included in Exhibit 5.1).+
24.1	Power of Attorney (included on the signature page to this Registration Statement)*

* Filed herewith.
+ To be filed by amendment or as an exhibit to a Current Report on Form 8-K and incorporated herein by reference, if applicable.
++ Previously filed.

SIGNATURES

Pursuant to the requirements of the Securities Act of 1933, the registrant certifies that it has reasonable grounds to believe that it meets all of the requirements for filing on Form S-1 and has duly caused this Registration Statement to be signed on its behalf by the undersigned, thereunto duly authorized, in the City of Beverly Hills, State of California, on December 5, 2019.

CAPRICOR THERAPEUTICS, INC.

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

KNOW ALL PERSONS BY THESE PRESENTS, that each person whose signature appears below constitutes and appoints Linda Marbán, Anthony J. Bergmann and Karen G. Krasney and each of them, as such person's true and lawful attorneys-in-fact and agents, with full power of substitution and resubstitution, for such person and in such person's name, place and stead, in any and all capacities, to sign any and all amendments (including post-effective amendments) to this Registration Statement and to sign any registration statement for the same offering covered by the Registration Statement that is to be effective upon filing pursuant to Rule 462 promulgated under the Securities Act of 1933, and to file the same, with all exhibits thereto, and other documents in connection therewith, with the Securities and Exchange Commission, granting unto said attorneys-in-fact and agents, and each of them, full power and authority to do and perform each and every act and thing requisite and necessary to be done in connection therewith and about the premises, as fully to all intents and purposes as such person might or could do in person, hereby ratifying and confirming all that said attorneys-in-fact and agents, or any of them, or their or such person's substitute or substitutes, may lawfully do or cause to be done by virtue hereof.

Pursuant to the requirements of the Securities Act of 1933, this Registration Statement has been signed by the following persons in the capacities and on the dates indicated.

Signature	Title	Date
/s/ Linda Marbán Linda Marbán, Ph.D.	Chief Executive Officer and Director *(Principal Executive Officer)*	December 5, 2019
/s/ Anthony J. Bergmann Anthony J. Bergmann	Chief Financial Officer *(Principal Financial and Accounting Officer)*	December 5, 2019
/s/ Frank Litvack Frank Litvack, M.D.	Executive Chairman and Director	December 5, 2019
/s/ Earl M. Collier Jr. Earl M. Collier, Jr.	Director	December 5, 2019
/s/ Louis Manzo Louis V. Manzo	Director	December 5, 2019
/s/ George W. Dunbar, Jr. George W. Dunbar, Jr.	Director	December 5, 2019
/s/ David B. Musket David B. Musket	Director	December 5, 2019

Exhibit 23.1

CONSENT OF INDEPENDENT REGISTERED PUBLIC ACCOUNTING FIRM

We hereby consent to the incorporation by reference, in this Registration Statement on Form S-1 of our report dated March 28, 2019, with respect to the consolidated financial statements of Capricor Therapeutics, Inc. and Subsidiary appearing in the Company's Annual Report on Form 10-K for the year ended December 31, 2018. Our report relating to the consolidated financial statements contains an explanatory paragraph regarding the Company's ability to continue as a going concern.

We also consent to the reference to our Firm under the caption "Experts" in such Registration Statement.

/s/ Rose, Snyder & Jacobs LLP
Rose, Snyder & Jacobs LLP

Encino, California
December 4, 2019