As filed with the Securities and Exchange Commission on June 14, 2021

Registration No. 333-254363

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

AMENDMENT NO. 1 TO FORM S-3

REGISTRATION STATEMENT
UNDER
THE SECURITIES ACT OF 1933

Capricor Therapeutics, Inc.

(Exact name of Registrant as specified in its charter)

Delaware	**88-0363465**
(State or other jurisdiction of incorporation or organization)	**(I.R.S. Employer Identification 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)

Karen G. Krasney, Esq.
Capricor Therapeutics, Inc.
8840 Wilshire Blvd., 2nd Floor
Beverly Hills, CA 90211
(310) 358-3200
(Name, address, including zip code, and telephone number, including area code, of agent for service)

Copies to:
Robert R. Carlson, Esq.
Sidley Austin LLP
1001 Page Mill Road, Building 1
Palo Alto, California 94304
Telephone: (650) 565-7000

Approximate date of commencement of proposed sale to the public: From time to time after the effective date of this registration statement.

If the only securities being registered on this form are being offered pursuant to dividend or interest reinvestment plans, please check the following box☐

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 registration statement pursuant to General Instruction I.D. or a post-effective amendment thereto that shall become effective upon filing with the Commission pursuant to Rule 462(e) under the Securities Act, check the following box. ☐

If this Form is a post-effective amendment to a registration statement filed pursuant to General Instruction I.D. filed to register additional securities or additional classes of securities pursuant to Rule 413(b) under the Securities Act, check the following box. ☐

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	Amount to be Registered	Proposed Maximum Offering Price per Unit	Proposed Maximum Aggregate Offering Price(3)	Amount of Registration Fee(3)
Common Stock, $0.001 par value per share	(1)	(2)	(2)	—
Preferred Stock, $0.001 par value per share	(1)	(2)	(2)	—
Debt Securities	(1)	(2)	(2)	—
Warrants	(1)	(2)	(2)	—
Units	(1)	(2)	(2)	—
Total	(1)		$ 150,000,000	$ 16,365(4)

(1) There are being registered hereunder such indeterminate number of shares of common stock and preferred stock, such indeterminate principal amount of debt securities, such indeterminate number of warrants to purchase common stock, preferred stock and/or debt securities and such indeterminate number of units consisting of any combination of common stock, preferred stock, debt securities and/or warrants as may be sold by the Registrant as shall have an aggregate initial offering price not to exceed $150,000,000. Any securities registered hereunder may be sold separately or in combination with other securities registered hereunder. The proposed maximum offering price of the securities will be determined, from time to time, by the Registrant in connection with the issuance by the Registrant of the securities registered hereunder. If any debt securities are issued at an original issue discount, then the offering price of such debt securities shall be in such greater principal amount as shall result in an aggregate offering price not to exceed $150,000,000, less the aggregate dollar amount of all securities previously issued hereunder. The securities registered hereunder also include such indeterminate number of shares of common stock and preferred stock and amount of debt securities as may be issued upon conversion of or exchange for preferred stock or debt securities that provide for conversion or exchange, or upon exercise of warrants or units or pursuant to anti-dilution provisions of any such securities. In addition, pursuant to Rule 416 under the Securities Act of 1933, as amended, the shares of common stock and preferred stock being registered hereunder include such indeterminate number of shares of common stock and preferred stock as may be issuable with respect to such shares being registered hereunder as a result of stock splits, stock dividends or similar transactions, as applicable.

(2) The proposed maximum aggregate offering price per class of security will be determined from time to time by the Registrant in connection with the issuance by the Registrant of the securities registered hereunder and is not specified as to each class of security pursuant to General Instruction II.D. of Form S-3 under the Securities Act of 1933, as amended.

(3) Calculated pursuant to Rule 457(o), based on the Proposed Maximum Aggregate Offering Price. In accordance with Rule 415(a)(6) under the Securities Act of 1933, the securities registered pursuant to this registration statement include unsold securities in the amount of $35,041,435.08 that previously were registered pursuant to the registration statement on Form S-3 (File No. 333-227955), initially effective on July 18, 2019. Pursuant to Rule 415(a)(6), the registration fees in the amount of $4,247.02 previously paid with respect to such unsold securities will continue to be applied to such unsold securities.

(4) $12,497.35 of the registration fee was previously paid in connection with the prior filing of the registration statement.

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 that specifically states that this Registration Statement shall thereafter become effective in accordance with Section 8(a) of the Securities Act of 1933, as amended, or until the Registration Statement shall become effective on such date as the Securities and Exchange Commission, acting pursuant to said Section 8(a), may determine.

EXPLANATORY NOTE

This Amendment No. 1 (this "Amendment") to the Registration Statement on Form S-3, File No. 333-254363 (the "Registration Statement") of Capricor Therapeutics, Inc., is being filed for the purpose of making certain updates including (i) updating the calculation of registration fee table and paying additional registration fees, (ii) updating information regarding the number of outstanding shares and latest share price of the common stock, (iii) incorporating by reference additional documents, and (iv) including an updated auditor's consent filed herewith as Exhibit 23.1.

The information in this prospectus is not complete and may be changed. These securities may not be sold until the registration statement filed with the Securities and Exchange Commission is effective. This prospectus is not an offer to sell these securities, 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 JUNE 14, 2021

PROSPECTUS

CAPRICOR THERAPEUTICS, INC.

$150,000,000
COMMON STOCK
PREFERRED STOCK
DEBT SECURITIES
WARRANTS

UNITS

We may offer and sell up to $150,000,000 in the aggregate of any combination of the securities identified above from time to time in one or more offerings, either individually or in combination with other securities. We may also offer common stock or preferred stock upon conversion of debt securities, common stock upon conversion of preferred stock, or common stock, preferred stock or debt securities upon the exercise of warrants.

Each time we offer and sell securities, we will provide a supplement to this prospectus that contains specific information about the offering and the amounts, prices and terms of the securities. We may also authorize one or more free writing prospectuses to be provided to you in connection with these offerings. The prospectus supplement and any related free writing prospectuses may also add, update or change information contained in this prospectus with respect to that offering. You should carefully read this prospectus and the applicable prospectus supplement and any related free writing prospectus, as well as any documents incorporated by reference, before you invest in any of our securities.

We may offer and sell the securities described in this prospectus and any prospectus supplement to or through one or more underwriters, dealers and agents, or directly to purchasers, or through a combination of these methods. If any underwriters, dealers or agents are involved in the sale of any of the securities, their names and any applicable purchase price, fee, commission or discount arrangement between or among them will be set forth, or will be calculable from the information set forth, in the applicable prospectus supplement. See the sections of this prospectus entitled "About this Prospectus" and "Plan of Distribution" for more information. No securities may be sold without delivery of this prospectus and the applicable prospectus supplement describing the method and terms of the offering of such securities.

Investing in our securities involves a high degree of risk. You should review carefully the risks and uncertainties described under the heading "Risk Factors" beginning on page 6 of this prospectus, any applicable prospectus supplement and in any applicable free writing prospectuses, and under similar headings in the documents that are incorporated by reference into this prospectus.

Our common stock is currently listed on the NASDAQ Capital Market under the symbol "CAPR". On June 11, 2021, the last reported sales price for our common stock was $4.45 per share. The applicable prospectus supplement will contain information, where applicable, as to any other listing on the NASDAQ Capital Market or any securities market or other exchange of the securities, if any, covered by the applicable prospectus supplement.

Neither the Securities and Exchange Commission nor any state securities commission has approved or disapproved of these securities or determined if this prospectus is truthful or complete. Any representation to the contrary is a criminal offense.

_____, 2021

TABLE OF CONTENTS

ABOUT THIS PROSPECTUS

This prospectus is part of a registration statement on Form S-3 that we filed with the Securities and Exchange Commission, or the SEC, utilizing a "shelf" registration process. Under this shelf registration process, we may offer and sell shares of our common stock and preferred stock, various series of debt securities, warrants to purchase any of such securities and/or units consisting of any combination of such securities, either individually or in combination with other securities, in one or more offerings, up to a total dollar amount of $150,000,000. This prospectus provides you with a general description of the securities we may offer.

Each time we offer securities under this prospectus, we will provide a prospectus supplement that will contain more specific information about the terms of that offering. We may also authorize one or more free writing prospectuses to be provided to you that may contain material information relating to these offerings. The prospectus supplement and any related free writing prospectus we have authorized for use in connection with a specific offering may also add, update or change any of the information contained in this prospectus or in the documents that we have incorporated by reference into this prospectus. We urge you to read carefully this prospectus, any applicable prospectus supplement and any free writing prospectuses we have authorized for use in connection with a specific offering, together with the information incorporated herein by

reference as described under the section entitled "Important Information Incorporated by Reference", before buying any of the securities being offered.

THIS PROSPECTUS MAY NOT BE USED TO CONSUMMATE A SALE OF SECURITIES UNLESS IT IS ACCOMPANIED BY A PROSPECTUS SUPPLEMENT.

You should rely only on the information contained in, or incorporated by reference into, this prospectus and any applicable prospectus supplement, along with the information contained in any free writing prospectuses we have authorized for use in connection with a specific offering. We have not authorized anyone to provide you with different or additional information. This prospectus is an offer to sell only the securities offered hereby, but only under circumstances and in jurisdictions where it is lawful to do so.

The information appearing in this prospectus, any applicable prospectus supplement or any related free writing prospectus is accurate only as of the date on the front of the document and any information we have incorporated by reference is accurate only as of the date of the document incorporated by reference, regardless of the time of delivery of this prospectus, any applicable prospectus supplement or any related free writing prospectus, or any sale of a security. Our business, financial condition, results of operations and prospects may have changed since those dates.

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, or as exhibits to documents incorporated by reference, and you may obtain copies of those documents as described below under the heading "Where You Can Find More Information".

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.

Overview

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

Cell Therapy (CAP-1002) Program

CAP-1002 - Duchenne Muscular Dystrophy Program

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

CAP-1002 - COVID-19 Program

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

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

Exosomes Program

Exosomes-Based Vaccine

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

Exosome-Based Therapeutics

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

Our platform builds on advances in fundamental RNA science, targeting technology and manufacturing, providing us the opportunity to build a broad pipeline of potential new therapeutic candidates. At this time, we are developing therapeutics and vaccines for infectious diseases, monogenic diseases and other indications. We recently entered into an Exclusive License Agreement with Johns Hopkins University for its co-owned interest in certain intellectual property rights related to exosome-mRNA vaccines and therapeutics.

CDC-Derived Exosomes (CAP-2003)

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

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

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

Our Technologies

Cardiosphere-Derived Cells (CAP-1002)

Our core cell therapy technology is based on cardiosphere-derived cells, or CDCs, a cardiac-derived cell therapy that was first identified in the academic laboratory of Capricor's scientific founder, Dr. Eduardo Marbán. Since the initial publication in 2007, CDCs have been the subject of over 100 peer-reviewed scientific publications and have been administered to over 200 human subjects across several clinical trials. CDCs have been shown to exert potent immunomodulatory activity and to alter the immune system's activity to encourage cellular regeneration. We have been developing allogeneic CDCs (CAP-1002) as a product candidate for the treatment of DMD and investigating their effects on skeletal and cardiac function. Preclinical and clinical data support the therapeutic concept of administering CDCs as a means to address conditions in which the heart or skeletal muscle has been damaged.

In a variety of preclinical experimental models of heart injury, CDCs have been shown to stimulate cell proliferation and blood vessel growth and to inhibit programmed cell death and scar formation. Published data by CSMC, which tested the effectiveness of CDCs in a mouse model of DMD, showed for the first time that the skeletal and cardiac improvements could be directly attributed to treatment with CDCs. The data also provide further evidence of the potential of CDCs to stimulate tissue repair and regeneration by first reducing inflammation, which then enables new healthy muscle to form, as was shown in the mouse model of DMD.

CDCs are derived from cardiospheres, or CSps, which are self-adherent multicellular clusters derived from the heart. CDCs are sufficiently small that, within acceptable dose limits, they can be infused into a coronary artery or into the peripheral vasculature. Capricor has performed clinical studies to establish the range of CDC dose levels that appear to be safe via intracoronary administration and peripheral venous access.

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

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

Exosomes

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

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

The following table summarizes our active product development programs:

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

Exosome-VLP vaccine	SARS-CoV-2	Preclinical
Engineered Exosomes (biologics delivery)	Evaluating	Discovery

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

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

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

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.

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 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, 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."

Summary Risk Factors

Our business is subject to a number of risks, including risks that may prevent us from achieving our business objectives or may adversely affect our business, clinical and commercialization activities, the manufacturing of our product candidates, intellectual property, third-party relationships, competition factors, product and environmental liability, and common stock. These risks are discussed more fully below and include, but are not limited to, risks related to:

Risks Related to Our Business

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

Risks Related to Clinical and Commercialization Activities

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

Risks Related to the Manufacturing of our Product Candidates

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

Risks Related to Our Intellectual Property

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

Risks Related to Our Relationships with Third Parties

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

Risks Related to Competitive Factors

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

Risks Related to Product and Environmental Liability

- our products may expose us to potential product liability;

Risks Related to Our Common Stock

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

Risks Related to this Offering

- management will have broad discretion as to the use of proceeds from this offering, if any, and may not use the proceeds effectively;
- if you purchase any common stock which may be sold in this offering, you will experience immediate dilution as a result of this offering and future equity issuances; and
- future sales of our common stock in the public market could cause our stock price to fall.

Risks Related to Our Business

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

Developing biopharmaceutical products, including conducting preclinical studies and clinical trials and establishing manufacturing capabilities, is expensive. As of December 31, 2020, we had cash and cash equivalents totaling approximately $32.7 million. We have not generated any revenues from the commercial sale of products. We will not be able to generate any product revenues until, and only if, we receive approval to sell our drug candidates from the FDA or other regulatory authorities.

From inception, we have financed our operations through public and private sales of our equity securities, grants from the National Institutes of Health, or NIH, and the Department of Defense, or DoD, and a loan commitment and grant award from the California Institute for Regenerative Medicine, or CIRM. As we have not generated any revenue from commercial sales to date and we do not expect to generate revenue for several years, if ever, we will need to raise substantial additional capital in order to fund our general corporate activities and to fund our research and development, including our ongoing clinical trials and plans for new clinical trials and product development.

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

If we are unable to raise sufficient funds to support our current and planned operations, we may elect to discontinue certain of our ongoing activities or programs. The inability to raise additional funds could also prevent us from taking advantage of opportunities to pursue promising new or existing programs in the future.

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

- the scope, rate of progress, cost and results of our research and development activities, especially our CAP-1002 and exosomes programs;
- the next steps in the development of our Duchenne muscular dystrophy, or DMD, program, which may potentially include a Phase III clinical trial for our CAP-1002 product candidate in DMD;
- the availability of funding from government programs including the NIH, and DoD, if applicable;
- the costs of developing adequate manufacturing processes and facilities;
- the costs associated with and timing of regulatory approval;
- the costs of filing, prosecuting, defending and enforcing any patent claims and other intellectual property rights;
- the costs and risks involved in conducting clinical trials and manufacturing operations in the U.S. and internationally;
- the effect of competing technological and market developments;
- the terms and timing of any collaboration, licensing or other arrangements that we may establish;
- the cost and timing of technology transfer for, and completion of, clinical and commercial-scale outsourced manufacturing activities; and
- the costs of establishing sales, marketing and distribution capabilities for any product candidates for which we may receive regulatory approval.

We have a history of net losses, and we expect losses to continue for the foreseeable future. In addition, a number of factors may cause our operating results to fluctuate on

a quarterly and annual basis, which may make it difficult to predict our future performance.

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

- our need for substantial additional capital to fund our trials and development programs;
- delays in the commencement, enrollment, and timing of clinical testing;
- the viability of CAP-1002 as a potential product candidate for the treatment of DMD and COVID-19 and its development through all stages of clinical development;
- the viability of our exosome technologies as potential product candidates and the advancement of our exosome technologies through all stages of its preclinical and clinical development;
- any delays in regulatory review and approval of our product candidates in clinical development;
- our ability to receive regulatory approval or commercialize our product candidates, within and outside the United States;
- potential side effects of our current or future products and product candidates that could delay or prevent commercialization or cause an approved treatment drug to be taken off the market;
- market acceptance of our product candidates;
- our ability to establish an effective sales and marketing infrastructure once our products are commercialized or to establish partnerships with other companies who have greater sales and marketing capabilities;
- our ability to establish or maintain collaborations, licensing or other arrangements, including strategic partnerships for CAP-1002 and our exosomes technologies;
- our ability and third parties' abilities to obtain and protect intellectual property rights;
- competition from existing products or new products that may emerge;
- guidelines and recommendations of therapies published by various organizations;
- the ability of patients to obtain coverage of, or sufficient reimbursement for, our products;
- our ability to maintain adequate insurance policies;
- our ability to successfully manufacture our product candidates in sufficient quantities and on a timely basis to meet clinical trial and potential commercial demand;
- our dependency on third parties to formulate and manufacture our product candidates;
- our ability to maintain our current manufacturing facility, including our ability to achieve and maintain current Good Manufacturing Practices, or cGMP, certification, and to secure other facilities as determined to be necessary;
- costs related to and outcomes of potential intellectual property litigation;
- compliance with obligations under intellectual property licenses with third parties;
- our ability to implement additional internal systems and infrastructure;
- our ability to adequately support future growth;
- if our products are approved for commercial sale, the ability to secure reimbursement for our products;
- our ability to attract and retain key personnel to manage our business effectively; and
- the ability of members of our senior management who have limited experience in managing a public company to manage our business and operations.

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

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

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

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

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

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

- the availability of coverage and adequate reimbursement and pricing by third-party payors and government authorities;
- the availability, perceived advantages, relative cost, relative safety and relative efficacy of alternative and competing treatments; and
- our ability to compete with other therapies.

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

Business disruptions such as natural disasters, widespread infectious diseases or pandemics could seriously harm our future revenues and financial condition and increase our costs and expenses.

Our corporate headquarters and manufacturing facilities are located in the greater Los Angeles, California area, a region known for seismic activity, as well as being susceptible to drought and fires. A significant natural disaster, such as an earthquake, flood or fire, occurring at our headquarters or manufacturing facilities, or at the facilities of any third-party manufacturer or vendor, could have a material adverse effect on our business, financial condition and results of operations. In addition, outbreaks of viruses, infectious diseases or pandemics (including, for example, the outbreak of the novel coronavirus (COVID-19)), terrorist acts or acts of war targeted at the United States, and specifically the Los Angeles, California region, could cause damage or disruption to us, our employees, facilities, contractors and collaborators, which could have a material adverse effect on our business, financial condition and results of operations.

The coronavirus outbreak could adversely impact our business.

An epidemic or pandemic disease outbreak, including the 2019 novel coronavirus (COVID-19), could severely disrupt our operations or the operations of third parties that we depend on, including our single third-party contract manufacturer, our CROs, clinical data management organizations, medical institutions and clinical investigators, and have a material adverse effect on our business, results of operations, financial condition and prospects. In December 2019, it was first reported that there had been an outbreak of a novel strain of coronavirus (COVID-19), in China. COVID-19 has since spread globally and while cases and hospitalization are currently on the decline in the US, there can be no assurances they will not continue at the current rate or increase in the future especially in light of the number of variants that are emerging across the world. Governments in the United States and elsewhere have taken and are continuing to take severe measures to slow the spread of COVID-19, including requiring that certain businesses close or conduct only the minimum necessary operations.

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

- delays or difficulties in enrolling patients in our clinical trials and having patients complete their assessments in accordance with the clinical protocol;
- restrictions preventing trial investigators, patients or other critical staff from traveling to our trial sites;
- diversion of healthcare resources to address COVID-19, which could limit the availability of medical facilities for our clinical trials;
- forced closures, or reductions in operations, at our facilities or the facilities of third parties with whom we do business;
- supply chain disruptions, which could have a material adverse effect on the availability or cost of materials for our product candidates; and
- disruptions to our workforce, or the workforces of third parties with whom we do business, caused by sickness, travel restrictions or quarantines, including but not limited to the announcement on March 19, 2020 by the Governor of the State of California ordering all individuals living in the State of California to stay at home or at their place of residence.

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

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

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

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

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

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

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

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

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

Risks Related to Clinical and Commercialization Activities

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

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

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

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

Even if our preclinical studies and clinical trials are completed as planned, we cannot be certain that their results will support the claims of our product candidates. Positive results in preclinical testing and early clinical trials do not ensure that results from later clinical trials will also be positive, and we cannot be sure that the results of later clinical trials will replicate the results of prior clinical trials and preclinical testing.

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

Despite the results reported in earlier clinical trials for our product candidates, we do not know whether any Phase II, Phase III or other clinical trial which we may conduct will demonstrate adequate efficacy and safety to result in regulatory approval to market our product candidates. A number of companies in the pharmaceutical industry, including those with greater resources and experience, have suffered significant setbacks in Phase II or Phase III clinical trials, even after seeing promising results in earlier clinical trials.

Our exosome technologies are based on a novel therapeutic approach which makes it difficult to predict the time and cost of development and of subsequently obtaining regulatory approval, if at all.

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

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

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

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

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

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

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

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

We hope to file additional investigational new drug applications, or INDs, over the next several years, including with respect to our exosome technologies in one or more indications. However, the timing of our filing of these INDs is primarily dependent on receiving further data from our preclinical studies and having sufficient processes in place in connection with the manufacturing of the exosomes.

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

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

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

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

- the withdrawal of clinical trial participants;
- the termination of clinical trial sites or entire trial programs;

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

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

Delays in the commencement, enrollment or completion of clinical testing could significantly affect our product development costs. The current pandemic has had an impact on the ability to conduct clinical trials due to inabilities to enroll or even get subjects to complete the trials due to lockdowns, reluctance to travel, limitations set by trial sites and other reasons. We cannot predict how long this will exist and while the hospitalization rates and number of cases seem to be on the decline, no assurance it will not revert to prior critical levels. A clinical trial may be suspended or terminated by the Company, the FDA, or other regulatory authorities due to a number of factors. The commencement and completion of clinical trials require us to identify and maintain a sufficient number of trial sites, many of which may already be engaged in other clinical trial programs for the same indication as our product candidates or may otherwise be resource constrained. We may be required to withdraw from a clinical trial as a result of changing standards of care, or we may become ineligible to participate in clinical studies. We do not know whether planned clinical trials will begin on time or be completed on schedule, if at all. The commencement, enrollment and completion of clinical trials can be delayed for a number of reasons, including, but not limited to, delays related to:

- findings in preclinical studies;
- reaching agreements on acceptable terms with prospective CROs, vendors and trial sites, the terms of which can be subject to extensive negotiation and may vary significantly among different CROs, vendors and trial sites;
- obtaining regulatory clearance to commence a clinical trial;
- complying with conditions imposed by a regulatory authority regarding the scope or term of a clinical trial, or being required to conduct additional trials before moving on to the next phase of trials;
- obtaining institutional review board, or IRB, approval to conduct a clinical trial at numerous prospective sites;
- recruiting and enrolling patients to participate in clinical trials for a variety of reasons, including the size of the patient population, nature of trial protocol, meeting the enrollment criteria for our studies, screening failures, the inability of the sites to conduct trial procedures properly, the inability of the sites to devote their resources to the trial, the availability of approved effective treatments for the relevant disease and competition from other clinical trial programs for similar indications;
- the impact of COVID-19 on patient screening and patient enrollment;
- developing and validating any companion diagnostic to be used in the trial, to the extent we are required to do so;

- patients failing to comply with the clinical trial protocol or dropping out of a trial;
- clinical trial sites failing to comply with the clinical trial protocol or dropping out of a trial;
- addressing any conflicts with new or existing laws or regulations;
- the need to add new clinical trial sites;
- retaining patients who have initiated their participation in a clinical trial but may be prone to withdraw due to the treatment protocol, lack of efficacy, personal issues, or side effects from the therapy, or who are lost to further follow-up;
- manufacturing sufficient quantities of a product candidate for use in clinical trials on a timely basis;
- obtaining advice from regulatory authorities regarding the statistical analysis plan to be used to evaluate the clinical trial data or other trial design issues;
- demonstrating the bioequivalence of products we manufacture to prior products manufactured on our behalf;
- complying with design protocols of any applicable special protocol assessment we receive from the FDA;
- severe or unexpected drug-related side effects experienced by patients in a clinical trial;
- collecting, analyzing and reporting final data from the clinical trials;
- breaches in quality of manufacturing runs that compromise all or some of the doses made; positive results in FDA-required viral testing; karyotypic abnormalities in our cell product; or contamination in our manufacturing facilities, all of which events would necessitate disposal of all cells made from that source;
- availability of materials provided by third parties necessary to manufacture our product candidates;
- availability of adequate amounts of acceptable tissue for preparation of master cell banks for our products;
- requirements to conduct additional trials and studies, and increased expenses associated with the services of the Company's CROs and other third parties; and
- meeting logistical requirements for the delivery of investigational product.

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

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

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

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

- we may receive feedback from regulatory authorities that requires us to modify the design of our clinical trials;

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

As the pandemic has continued, the SARS-CoV-2 virus continues to evolve, and new strains of the virus or those that are already in circulation may prove more transmissible or cause more severe forms of COVID-19 disease than the predominant strains to date. There is a risk that any vaccine product candidates we develop will not be as effective in protecting against variant strains of the SARS-CoV-2 virus. The failure to adapt our vaccine product candidate to other variants of the SARS-CoV-2 virus could

lead to significant reputational harm, in addition to adversely affecting our financial results. It is also possible that we may expend significant resources adapting our COVID-19 vaccine to protect against variants of the SARS-CoV-2 virus, but that a market for this adapted vaccine does not develop or demand does not align with our projections or cost expenditures.

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

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

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

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

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

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

Negative perception of the efficacy, safety, or tolerability of any investigational medicines that we develop, or of other products similar to products we are developing, such as mRNA medicines and COVID-19 vaccines, could adversely affect our ability to conduct our business, advance our investigational medicines, or obtain regulatory approvals.

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

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

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

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

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

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

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

- the efficacy and safety of the product;
- the potential advantages of the product compared to alternative therapies;
- the prevalence and severity of any side effects;
- whether the product is designated under physician and other provider treatment guidelines as a first-, second- or third-line therapy;
- our ability, or the ability of any future collaborators, to offer the product for sale at competitive prices;
- the product’s convenience and ease of administration for patients and healthcare practitioners compared to alternative treatments;
- the willingness of the target patient population to try, and of physicians to prescribe, the product;
- limitations or warnings, including distribution or use restrictions and safety information contained in the product’s approved labeling;

- the strength of sales, marketing and distribution support;
- changes in the standard of care for the targeted indications for the product; and
- the availability of coverage by, and the amount of reimbursement from, government payors, managed care plans and other third-party payors.

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

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

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

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

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

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

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

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

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

CAP-1002 has received rare pediatric disease designation from the FDA for the treatment of DMD. The FDA generally define “a "rare pediatric disease" as a serious or life-threatening disease that affects fewer than 200,000 individuals in the U.S. primarily under the age of 18 years old. Under the FDA's Rare Pediatric Disease Priority Review Voucher program, upon the approval of a NDA or BLA for the treatment of a rare pediatric disease, the sponsor of such application would be eligible for a Rare Pediatric Disease Priority Review Voucher that can be used to obtain priority review for a subsequent NDA or BLA. The Priority Review Voucher may be sold or transferred an unlimited number of times. A drug designated as a drug for a rare pediatric disease by December 18, 2020, and approved by December 18, 2022, may receive a voucher. This program has been subject to criticism, including by the FDA, and it is possible that even if we obtain approval for CAP-1002 and qualify for such a Priority Review Voucher, the program may no longer be in effect at the time of approval.

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

In addition to manufacturing CAP-1002 for its own clinical trials, Capricor has agreed to provide CAP-1002 for investigational purposes in two clinical trials sponsored by CSMC. The first trial is known as “Regression of Fibrosis and Reversal of Diastolic Dysfunction in HFpEF Patients Treated with Allogeneic CDCs.” The second trial is known as “Pulmonary Arterial Hypertension treated with Cardiosphere-derived Allogeneic Stem Cells.” In both studies, Capricor is providing the necessary number of doses and will receive a negotiated amount of monetary compensation in exchange for doing so.

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

trials will be completed, there is a risk that product designated for the trials will have expired at the time they are required. Additionally, there is a risk that our product may encounter some kind of contamination internally in our leased facility, at our contracted shipping facility or in transit which may have an adverse effect on our business or operations.

Our products face a risk of failure due to adverse immunological reactions.

A potential risk of an allogeneic therapy such as that being tested by the Company with CAP-1002 is that patients might develop an immune response to the cells being infused. Such an immune response may induce adverse clinical effects which would impact the safety and efficacy of the Company's products and the success of our trials. Additionally, if research subjects have pre-existing antibodies or other immune sensitization to our cells, our cells and the therapy could potentially be rendered ineffective which could have a negative impact on the regulatory pathway for our product as well as the viability for other potential indications. After a patient in the HOPE-2 trial had a serious adverse event in the form of anaphylaxis, we put a voluntary hold on dosing in December 2018 to develop a plan to manage potential allergic reactions. The investigation suggests that the patient may have been allergic to something contained in the investigational product, including possibly an excipient, or inactive ingredient, in the formulation. To reduce the risk of future events, we initiated a pre-medication strategy commonly used by physicians to prevent and treat allergic reactions. We cannot provide any assurances that this will not happen again in any future studies. If these or other reactions continue to occur, it could have a material adverse impact on the effectiveness of the product, our ability to receive approval of our product candidates, and could result in substantial delays, increased costs and potentially termination of the trial.

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

Our research and development activities, preclinical studies, clinical trials, and manufacturing and marketing of our potential products are subject to extensive regulation by the FDA and other regulatory authorities in the United States, as well as by regulatory authorities in other countries. In the United States, our product candidates are subject to regulation as biological products or as combination biological products/medical devices under the Federal Food, Drug and Cosmetic Act, the Public Health Service Act and other statutes, and as further provided in the Code of Federal Regulations. Different regulatory requirements may apply to our products depending on how they are categorized by the FDA under these laws. These regulations can be subject to substantial and significant interpretation, addition, amendment or revision by the FDA and by the legislative process. The FDA may determine that we will need to undertake clinical trials beyond those currently planned. Furthermore, the FDA may determine that results of clinical trials do not support approval for the product. Similar determinations may be encountered in foreign countries. The FDA will continue to monitor products in the market after approval, if any, and may determine to withdraw its approval or otherwise seriously affect the marketing efforts for any such product. The same possibilities exist for trials to be conducted outside of the United States that are subject to regulations established by local authorities and local law. Any such determinations would delay or deny the introduction of our product candidates to the market and have a material adverse effect on our business, financial condition, and results of operations.

Drug manufacturers are subject to ongoing periodic unannounced inspection by the FDA, the Drug Enforcement Agency, other federal agencies and corresponding state agencies to ensure strict compliance with good manufacturing practices, and other government regulations and corresponding foreign standards. We do not have control over third-party manufacturers' compliance with these regulations and standards, nor can we guarantee that we will maintain compliance with such regulations in regards to our own manufacturing processes. Other risks include:

- regulatory authorities may require the addition of labeling statements, specific warnings, a contraindication, or field alerts to physicians and pharmacies;
- regulatory authorities may withdraw their approval of the IND or the product or require us to take our approved products off the market;
- we may be required to change the way the product is manufactured or administered, and we may be required to conduct additional clinical trials or change the labeling of our products;
- we may be required to change the way the product is manufactured or administered, and we may be required to conduct additional clinical trials or change the labeling of our products;
- we will be required to manufacture or retain the services of a commercial manufacturer to develop product suitable for commercial sale;
- we may have limitations on how we promote our products; and
- we may be subject to litigation or product liability claims.

There are additional risks involved in conducting clinical trials internationally.

If we decide to expand one or more of our clinical trials to investigative sites in Europe or other countries outside of the United States, we will have additional regulatory requirements that we will have to meet in connection with our manufacturing, distribution, use of data and other matters. For example, if we decide to conduct our trials in Europe, we will have to either move our manufacturing facility to a facility located in Europe, enter into an agreement with a European manufacturer to manufacture our product candidates for us or enter into an agreement with a domestic manufacturer who maintains an acceptable cGMP facility. Any of those options would involve a significant monetary investment, time delays, and increased risk and may impact the progress of our clinical trials and regulatory approvals.

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

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

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

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

Given the number of recent high-profile adverse safety events with certain drug products, the FDA may require, as a condition of approval, costly risk management programs, which may include safety surveillance, restricted distribution and use, patient education, enhanced labeling, special packaging or labeling, expedited reporting of

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

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

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

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

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

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

- the U.S. federal Anti-Kickback Statute, which prohibits, among other things, persons from soliciting, receiving, offering or providing remuneration, directly or indirectly, to induce either the referral of an individual for a healthcare item or service, or the purchasing or ordering of an item or service, for which payment may be made, in whole or in part, under a federal healthcare program such as Medicare or Medicaid. The term remuneration has been broadly interpreted to include anything of value. The Patient Protection and Affordable Care Act, as amended by the Health Care and Education Reconciliation Act of 2010, or collectively the Affordable Care Act, or the ACA, among other things, amended the intent requirement of the federal Anti-Kickback Statute to clarify that a person or entity need not have actual knowledge of this statute or specific intent to violate it. The Anti-Kickback Statute applies to arrangements between pharmaceutical manufacturers on the one hand and individuals, such as healthcare providers and prescribers, patients, purchasers, pharmacy benefit managers, group purchasing organizations, third-party payors, wholesalers and distributors on the other hand, including, for example, consulting/speaking arrangements, discount and rebate offers, certain pricing arrangements, grants, charitable contributions, and patient support offerings, among others. Although there are a number of statutory exceptions and regulatory safe harbors protecting some common activities from prosecution, the exceptions and safe harbors are drawn narrowly. Practices that involve remuneration that may be alleged to be intended to induce prescribing, purchases or recommendations may be subject to scrutiny if they do not qualify for an exception or safe harbor. Violations of the federal Anti-Kickback Statute may result in significant civil monetary penalties for each violation, plus up to three times the remuneration involved. Civil penalties for such conduct can further be assessed under the federal False Claims Act. Violations can also result in criminal penalties, including criminal fines and imprisonment. Similarly, violations can result in exclusion from participation in government healthcare programs, including Medicare and Medicaid;
- the federal False Claims Act imposes civil penalties, including through civil whistleblower or qui tam actions, against individuals or entities for knowingly presenting, or causing to be presented, to the federal government, claims for payment that are false or fraudulent, knowingly making, using or causing to be made or used, a false record or statement material to a false or fraudulent claim, or knowingly making or causing to be made, a false statement to avoid, decrease or conceal an obligation to pay money to the federal government. In addition, the government may assert that a claim including items or services resulting from a violation of the federal Anti-Kickback Statute constitutes a false or fraudulent claim for purposes of the False Claims Act. When an entity is determined to have violated the federal civil False Claims Act, the government may impose significant civil fines and penalties for each false claim, plus treble damages, and exclude the entity from participation in Medicare, Medicaid and other federal healthcare programs. As a result of a modification made by the Fraud Enforcement and Recovery Act of 2009, a claim includes "any request or demand" for money or property presented to the U.S. government. In addition, manufacturers can be held liable under the federal False Claims Act even when they do not submit claims directly to government payors if they are deemed to "cause" the submission of false or fraudulent claims
- the Federal Criminal Statute on False Statements Relating to Health Care Matters makes it a crime to knowingly and willfully falsify, conceal, or cover up a material fact, make any materially false, fictitious, or fraudulent statements or representations, or make or use any materially false writing or document knowing the same to contain any materially false, fictitious, or fraudulent statement or entry in connection with the delivery of or payment for healthcare benefits, items, or services;
- the Federal Civil Monetary Penalties Law authorizes the imposition of substantial civil monetary penalties against an entity, such as a pharmaceutical manufacturer, that engages in activities including, among others (1) knowingly presenting, or causing to be presented, a claim for services not provided as claimed or that is otherwise false or fraudulent in any way; (2) arranging for or contracting with an individual or entity that is excluded from participation in federal health care programs to provide items or services reimbursable by a federal health care program; (3) violations of the federal Anti-Kickback Statute; or (4) failing to report and return a known overpayment;

- the Health Insurance Portability and Accountability Act, or HIPAA, includes a fraud and abuse provision referred to as the HIPAA All-Payor Fraud Law, which imposes criminal and civil liability for executing a scheme to defraud any healthcare benefit program, or knowingly and willfully falsifying, concealing or covering up a material fact or making any materially false statement in connection with the delivery of or payment for healthcare benefits, items or services. Similar to the federal Anti-Kickback Statute, a person or entity does not need to have actual knowledge of the statute or specific intent to violate it in order to have committed a violation;
- HIPAA, as amended by the Health Information Technology for Economic and Clinical Health Act, or HITECH, and its implementing regulations, which impose obligations on certain covered entity healthcare providers, health plans, and healthcare clearinghouses as well as their business associates that perform certain services involving the use or disclosure of individually identifiable health information, including mandatory contractual terms, with respect to safeguarding, the privacy, security, and transmission of individually identifiable health information, and require notification to affected individuals and regulatory authorities of certain breaches of security of individually identifiable health information;
- federal and state consumer protection and unfair competition laws, which broadly regulate marketplace activities and activities that potentially harm consumers;
- the federal Physician Payments Sunshine Act, which requires certain manufacturers of drugs, devices, biologics, and medical supplies for which payment is available under Medicare, Medicaid or the Children's Health Insurance Program (with certain exceptions) to report annually to the government information related to payments or other "transfers of value" made to, at the request of, or on behalf of "covered recipients," which include physicians, certain other healthcare providers, and teaching hospitals, and requires applicable manufacturers and group purchasing organizations to report annually to the government ownership and investment interests held by physicians and their immediate family members; and
- analogous state laws and regulations, such as, state anti-kickback and false claims laws potentially applicable to sales or marketing arrangements and claims involving healthcare items or services reimbursed by nongovernmental third party payors, including private insurers; and some state laws require pharmaceutical companies to comply with the pharmaceutical industry's voluntary compliance guidelines and the relevant compliance guidance promulgated by the federal government in addition to requiring drug manufacturers to report information related to payments to physicians and other healthcare providers or marketing expenditures, and state laws governing the privacy and security of health information in certain circumstances, many of which differ from each other in significant ways and often are not preempted by HIPAA, thus complicating compliance efforts.

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

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

Although effective compliance programs can mitigate the risk of investigation and prosecution for violations of these laws, these risks cannot be entirely eliminated. Any action against us for an alleged or suspected violation, even the mere issuance of a subpoena or the fact of an investigation alone, regardless of the merit, could result in negative publicity, a drop in our share price, or other harm to our business, financial condition and results of operations. Defending against any such actions could cause us to incur significant legal expenses and could divert our management's attention from the operation of our business, even if our defense is successful. In addition, achieving and sustaining compliance with applicable laws and regulations may be costly to us in terms of money, time and resources.

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

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

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

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

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

- the product is reasonable and necessary for the diagnosis or treatment of the illness or injury for which the product is administered according to accepted standards of medical practice;

- the product is typically furnished incident to a physician's services;
- the indication for which the product will be used is included or approved for inclusion in certain Medicare-designated pharmaceutical compendia (when used for an off-label use); and
- the product has been approved by the FDA.

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

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

There have been, and continue to be, several legislative and regulatory changes and proposed changes regarding the healthcare system that could prevent or delay marketing approval of product candidates, restrict or regulate post approval activities and affect our ability to profitably sell any product candidates for which we obtain marketing approval. Among policy makers and payors in the United States there is significant interest in promoting changes in healthcare systems with the stated goals of containing healthcare costs, improving quality and/or expanding access and the pharmaceutical industry has been a particular focus of these efforts and has been significantly affected by major legislative initiatives. We expect that these and other healthcare reform measures that may be adopted in the future, may result in more rigorous coverage criteria and lower reimbursement, and in additional downward pressure on the price that we receive for any approved product. Any reduction in reimbursement from Medicare or other government-funded programs may result in a similar reduction in payments from private payors. The implementation of cost containment measures or other healthcare reforms may prevent us from being able to generate revenue, attain profitability or commercialize our drugs, once marketing approval is obtained.

A number of legislative and regulatory changes in the healthcare system in the U.S. and other major healthcare markets have been proposed, and such efforts have expanded substantially in recent years. These developments could, directly or indirectly, affect our ability to sell our products, if approved, at a favorable price. For example, in the U.S., in 2010, the U.S. Congress passed the ACA, a sweeping law intended to broaden access to health insurance, reduce or constrain the growth of health spending, enhance remedies against fraud and abuse, add new transparency requirements for the healthcare and health insurance industries, impose new taxes and fees on the healthcare industry and impose additional policy reforms.

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

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

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

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

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

requiring group and health insurance issuers offering health insurance coverage to report information on certain pharmacy benefit and drug costs to the Secretaries of HHS, Labor, and the Treasury. We believe that the efforts of governments and third-party payors to contain or reduce the cost of healthcare and legislative and regulatory proposals to broaden the availability of healthcare will continue to affect the business and financial condition of pharmaceutical and biopharmaceutical companies.

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

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

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

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

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

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

U.S. federal government agencies currently face potentially significant spending reductions. For example, as a result of the Budge Control Act of 2011, the Bipartisan Budget Act, or BBA, and the CARES Act, an annual 2% reduction to Medicare payments took effect on April 1, 2013, and has been extended through 2030 (though the reduction was temporarily suspended from May 1, 2020 through March 31, 2021 in connection with COVID-19 relief related legislation). The U.S. federal budget remains in flux, however, which could, among other things, result in a cut to Medicare payments to providers and otherwise affect federal spending on clinical and preclinical research and development. The Medicare program is frequently mentioned as a target for spending cuts. The full impact on our business of any future cuts in Medicare or other programs is uncertain. In addition, we cannot predict any impact which the actions of President Biden's administration and the U.S. Congress may have on the federal budget. Following the most recent federal elections, Congress has again focused on reducing the cost of drugs and other medical treatments. If federal spending is reduced, anticipated budgetary shortfalls may also impact the ability of relevant agencies, such as the FDA or the National Institutes of Health, to continue to function at current levels. Amounts allocated to federal grants and contracts may be reduced or eliminated. These reductions may also impact the ability of relevant agencies to timely review and approve drug research and development, manufacturing, and marketing activities, which may delay our ability to develop, market and sell any products we may develop.

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

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

- There may be limited access to, and supply of, normal and diseased tissue samples, cell lines, media pathogens, bacteria, viral strains, synthesized nucleic acids, including mRNA and other biological materials. In addition, government regulations in multiple jurisdictions, such as the United States and the EU, could result in restricted access to, or transport or use of, such materials. If the Company in unable to access sufficient sources of such materials, or if tighter restrictions are imposed on the use of such materials, the Company may not be able to conduct research or product development activities as planned and may incur additional costs.
- The development, manufacturing and marketing of vaccines are subject to regulation by the FDA, the EMA and other regulatory bodies that are often more complex and extensive than the regulations applicable to other pharmaceutical products. For example, in the United States, a BLA, including both preclinical and clinical trial data and extensive data regarding the manufacturing procedures, is required for human vaccine candidates, and FDA approval is generally required for the release of each manufactured commercial lot.
- Vaccines are frequently costly to manufacture because production ingredients are inactive biological materials derived from virus, animals, or plants and most biologics and vaccines cannot be made synthetically. In particular, keeping up with the demand for vaccines may be difficult due to the complexity of producing vaccines.

Risks Related to the Manufacturing of our Product Candidates

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

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

Our plans to use this facility for future trials could change if we decide to expand any of our clinical trials to include international sites, such as in Europe or if we fail to meet the specifications necessary to produce our product in a qualified manner. Currently, we also intend to utilize our premises at CSMC to develop and manufacture our exosomes technologies. Currently, our Facilities Lease pertaining to our research and development facility is scheduled to expire on July 31, 2021. We have an additional 1-year option enabling us to extend the term of our Facilities Lease to July 31, 2022. There can be no assurance that the Facilities Lease for the manufacturing space will be continued beyond July 31, 2022. If the Facilities Lease with CSMC is terminated or expires, we would have to secure alternative facilities in which to manufacture our products, which would involve a significant monetary investment and would negatively impact the progress of our clinical trials and regulatory approvals. At this time, we are actively considering new facilities for our research, development and/or manufacturing activities or the possible extension of our current lease.

If we were to initiate a Phase III study for DMD, we are unsure at this time if the FDA would allow us to produce doses in our current facility or whether the FDA would require us to use a cGMP facility. If we were required to use a cGMP facility to produce product for a Phase III study, it may result in delays and significant expenses which would have a negative impact on our business and product development.

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

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

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

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

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

We are in the early stages of technology transfer of our CAP-1002 product with Lonza Houston, Inc. We can provide no assurances that they will be able to meet product demand for potential late-stage clinical trials or commercial use.

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

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

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

We have not established our own manufacturing facilities sufficient for the production of CAP-1002 or our exosome technologies for commercial purposes. While we plan to potentially utilize our currently manufactured product for a potential Phase III trial, there is no assurance that the FDA will not require that the product used in the Phase III trial be manufactured under cGMP conditions. Also, our resources and expertise to formulate or manufacture this product candidate on a large or commercial scale basis are limited. In 2020, we initiated a technology transfer with Lonza Houston, Inc., to prepare for commercial or possibly late-stage clinical manufacturing of CAP-1002. Additionally, if the field of mRNA and other nucleic acid medicines continues to expand, we may encounter increasing competition for these supplies, materials and services. Demand for third-party manufacturing or testing facilities may grow at a faster rate than their existing capacity, which could disrupt our ability to find and retain third-party manufacturers capable of producing sufficient quantities of such raw materials, components, parts, and consumables required to manufacture our exosome-based RNA products. If CAP-1002 or any of our exosome technologies receives FDA approval, we may need to rely on one or more third-party contractors to manufacture supplies of these drug products which may cause delays in our ability to sell commercially. Our current and anticipated future reliance on a limited number of third-party manufacturers exposes us to the following risks:

- We may be unable to identify manufacturers needed to manufacture our product candidates on acceptable terms or at all, because the number of potential manufacturers is limited, and subsequent to approval of an NDA or BLA, the FDA must approve any replacement contractor. This approval would require new testing and compliance inspections. In addition, a new manufacturer may have to be educated in, or develop substantially equivalent processes for, production of our products or the devices after receipt of FDA approval, if any, FDA may also exercise oversight over manufacturing facilities for products authorized under an EUA.
- Our third-party manufacturers may not be able to formulate and manufacture our drugs in the volume and of the quality required to meet our clinical and commercial needs, if any.
- Our third-party manufacturers may not be able to manufacture or supply us with sufficient quantities of acceptable materials necessary for the development or use of our product candidates.
- Our future contract manufacturers may not perform as agreed or may not remain in the contract manufacturing business for the time required to supply our clinical trials or to successfully produce, store, and distribute our products or the materials needed to manufacture or utilize our product candidates.
- Our contract manufacturers may elect to terminate our agreements with them.

- Drug manufacturers are subject to ongoing periodic unannounced inspection by the FDA, the Drug Enforcement Agency, and corresponding state agencies to ensure strict compliance with good manufacturing practices and other government regulations and corresponding foreign standards. We do not have control over third-party manufacturers' compliance with these regulations and standards.

Each of these risks could delay our clinical trials, the approval, if any, of our product candidates by the FDA, or the commercialization of our product candidates, or result in higher costs or deprive us of potential product revenues.

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

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

Risks Related to Our Intellectual Property

We may face uncertainty and difficulty in obtaining and enforcing our patents and other proprietary rights.

Our success will depend in large part on our ability to obtain, maintain, and defend patents on our product candidates, obtain licenses to use third-party technologies, protect our trade secrets and operate without infringing the proprietary rights of others. Legal standards regarding the scope of claims and validity of biotechnology patents are uncertain and evolving. There can be no assurance that our pending, in-licensed or owned patent applications will be approved, or that challenges will not be instituted against the validity or enforceability of any patent licensed-in or owned by us. Additionally, we have entered into various confidentiality agreements with employees and third parties. There is no assurance that such agreements will be honored by such parties or enforced in whole or part by the courts. The cost of litigation to uphold the validity and prevent infringement of a patent is substantial. Furthermore, there can be no assurance that others will not independently develop substantially equivalent technologies not covered by patents to which we have rights or obtain access to our know-how. In addition, the laws of certain countries may not adequately protect our intellectual property. Our competitors may possess or obtain patents on products or processes that are necessary or useful to the development, use, or manufacture of our product candidates.

There can also be no assurance that our proposed technology will not infringe upon patents or proprietary rights owned by others, with the result that others may bring infringement claims against us and require us to license such proprietary rights, which may not be available on commercially reasonable terms, if at all. Any such litigation, if instituted, could have a material adverse effect, potentially including monetary penalties, diversion of management resources, and injunction against continued manufacture, use, or sale of certain products or processes.

Some of our technology has resulted and/or will result from research funded by agencies of the U.S. government and the State of California. As a result of such funding, the U.S. government and the State of California have certain rights in the technology developed with the funding. These rights include a non-exclusive, non-transferable, irrevocable, paid-up, worldwide license to practice or have practiced for or on behalf of the government(s) such inventions. In addition, the government(s) has the right to "march in" and require us to grant third parties licenses to such technology, in certain circumstances, such as if we fail to take effective steps to achieve practical application of such inventions.

The licenses by which we have obtained some of our intellectual property are subject to the rights of the funding agencies. We also rely upon non-patented proprietary know-how and trade secrets. There can be no assurance that we can adequately protect our rights in such non-patented proprietary know-how and trade secrets, or that others will not independently develop substantially equivalent proprietary information or techniques or gain access to our proprietary know-how and trade secrets. Any of the foregoing events could have a material adverse effect on us. In addition, if any of our trade secrets, know-how or other proprietary information were to be disclosed, or misappropriated, the value of our trade secrets, know-how and other proprietary rights would be significantly impaired and our business and competitive position would suffer.

In September 2011, the Leahy-Smith America Invents Act, or the Leahy-Smith Act, was signed into law. The Leahy-Smith Act includes a number of significant changes to U.S. patent law. These include provisions that affect the way patent applications will be prosecuted and may also affect patent litigation. In particular, under the Leahy-Smith Act, the United States transitioned in March 2013 to a "first to file" system in which the first inventor to file a patent application will be entitled to the patent. Third parties are allowed to submit prior art before the issuance of a patent by the U.S. Patent and Trademark Office, or USPTO, and may become involved in derivation, post-grant review, or *inter partes* review, proceedings challenging our patent rights or the patent rights of our licensors. An adverse determination in any such submission, proceeding or litigation could reduce the scope of, or invalidate, our or our licensors' patent rights, which could adversely affect our competitive position.

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

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

We have licensed certain patent and other intellectual property rights that cover cardiospheres (CSps), and cardiosphere-derived cells (CDCs), (including our CAP-1002 product candidate) from Università Degli Studi Di Roma La Sapienza, or the University of Rome, The Johns Hopkins University, or JHU, and CSMC. We have also licensed certain patent and other intellectual property rights from CSMC that cover extracellular vesicles, such as exosomes and microvesicles derived from CDCs. Under the license agreements with the University of Rome and JHU, those institutions prosecute and maintain their patents and patent applications in collaboration with us. We rely on these institutions to file, prosecute, and maintain patent applications, and otherwise protect the intellectual property to which we have a license, and we have not had and do not have primary control over these activities for certain of these patents or patent applications and other intellectual property rights. We cannot be certain that such activities by these institutions have been or will be conducted in compliance with applicable laws and regulations, or will result in valid and enforceable patents and other intellectual property rights. Under our Amended and Restated Exclusive License Agreement with CSMC and our Exclusive License Agreement with CSMC, as the same have been amended, we have assumed, in coordination with CSMC, financial responsibility for the prosecution and maintenance of certain patents and patent applications thereunder. Our enforcement of certain of these licensed patents or defense of any claims asserting the invalidity and/or unenforceability of these patents would also be subject to the cooperation of the University of Rome, JHU, and/or CSMC.

The patent positions of pharmaceutical and biopharmaceutical companies can be highly uncertain and involve complex legal and factual questions for which important legal principles remain unresolved. No consistent laws regarding the breadth of claims allowed in biopharmaceutical patents has emerged to date in the United States. The biopharmaceutical patent situation outside the United States is even more uncertain. Changes in either the patent laws or in interpretations of patent laws in the United States

and other countries may diminish the value of our intellectual property. Accordingly, we cannot predict the breadth of claims that may be allowed or enforced in the patents we own or that are in-licensed. Further, if any of our owned or in-licensed patents are determined by legal authority to be invalid or unenforceable, it could impact our ability to commercialize or license our technology.

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

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

We also may rely on trade secrets to protect our technology, especially where we do not believe patent protection is appropriate or obtainable. However, trade secrets are difficult to protect. Although we use reasonable efforts to protect our trade secrets, our employees, consultants, contractors, outside scientific collaborators, and other advisors may unintentionally or willfully disclose our information to competitors. In addition, courts outside the United States are sometimes less willing to protect trade secrets. Moreover, our competitors may independently develop equivalent knowledge, methods, and know-how.

If any of our trade secrets, know-how or other proprietary information is improperly disclosed, the value of our trade secrets, know-how and other proprietary rights would be significantly impaired and our business and competitive position would suffer.

Our viability also depends upon the skills, knowledge and experience of our scientific and technical personnel, our consultants and advisors, as well as our licensors and contractors. To help protect our proprietary know-how and our inventions for which patents may be unobtainable or difficult to obtain, we rely on trade secret protection and confidentiality agreements. To this end, we require all of our employees, consultants, advisors and contractors to enter into agreements which prohibit unauthorized disclosure and use of confidential information and, where applicable, require disclosure and assignment to us of the ideas, developments, discoveries and inventions important to our business. These agreements are often limited in duration and may not provide adequate protection for our trade secrets, know-how or other proprietary information in the event of any unauthorized use or disclosure or the lawful development by others of such information. In addition, enforcing a claim that a third party illegally obtained and is using any of our trade secrets is expensive and time consuming, and the outcome is unpredictable. If any of our trade secrets, know-how or other proprietary information is improperly disclosed, the value of our trade secrets, know-how and other proprietary rights would be significantly impaired and our business and competitive position would suffer.

We may incur substantial costs as a result of litigation or other adversarial proceedings relating to patent and other intellectual property rights and we may be unable to protect our rights to, or use of, our technology.

If we choose to go to court to stop a third party from using the inventions covered by our patents, that individual or company has the right to ask the court to rule that such patents are invalid and/or should not be enforced against that third party. These lawsuits are expensive and would consume time and other resources, even if we were successful in discontinuing the infringement of our patents. In addition, there is a risk that the court will determine that these patents are not valid and that we do not have the right to stop the other party from using the inventions. There is also the risk that, even if the validity of these patents is upheld, the court will refuse to stop the other party on the ground that such other party's activities do not infringe our rights to these patents. In addition, the U.S. Supreme Court has modified certain legal tests so as to make it harder to obtain patents from the USPTO, and to defend issued patents against invalidity challenges. As a consequence, issued patents may be found to contain invalid claims according to the revised legal standards. Some of our own or in-licensed patents may be subject to challenge and subsequent invalidation in a variety of post-grant proceedings, before the Patent Trial and Appeal Board (the PTAB) of the USPTO or in litigation under the revised legal standards, which make it more difficult to defend the validity of claims in already issued patents.

Furthermore, a third party may claim that we or our manufacturing or commercialization partners are using inventions covered by the third party's patent rights and may go to court to stop us from engaging in our normal operations and activities, including making or selling our product candidates. These lawsuits are costly and could affect the results of our operations and divert the attention of managerial and technical personnel. There is a risk that a court could determine that we or our commercialization partners are infringing the third party's patents and order us or our partners to stop the activities covered by the patents. In addition, there is a risk that a court could order us or our partners to pay the other party damages for having violated the other party's patents. We have agreed to indemnify certain of our commercial partners against certain patent infringement claims brought by third parties. The biotechnology industry has produced a proliferation of patents, and it is not always clear to industry participants, including us, which patents cover various types of products, manufacturing processes or methods of use. The coverage of patents is subject to claim construction by the courts, which is not always predictable or reasonable. If we are sued for patent infringement, we would need to demonstrate that our products, manufacturing processes or methods of use either do not infringe the patent claims of the relevant patent and/or that the patent claims are invalid, and we may not be able to do this. Proving invalidity, in particular, is difficult since it requires a proof by clear and convincing evidence to overcome the presumption of validity enjoyed by issued patents.

As some patent applications in the United States may be maintained in secrecy until the patents are issued, because patent applications in the United States and many foreign jurisdictions are typically not published until eighteen months after filing, and because publications in the scientific literature often lag behind actual discoveries, we cannot be certain that others have not filed patent applications for technology covered by our issued patents or our pending applications, or that we were the first to invent the technology. Our competitors may have filed, and may in the future file, patent applications covering technology similar to ours. Any such patent applications may have priority over our patent applications or patents, which could further require us to obtain licenses to these issued patents covering such technologies. For patent applications filed before the Leahy-Smith Act, if another party has filed a United States patent application on inventions similar to ours, we may have to participate in an interference proceeding declared by the USPTO to determine priority of invention in the United States. The costs of these proceedings could be substantial, and it is possible that such efforts would be unsuccessful if, unbeknownst to us, the other party had independently arrived at the same or similar invention prior to our own invention, resulting in a loss of our U.S. patent position with respect to such inventions.

Some of our competitors may be able to sustain the costs of complex patent litigation more effectively than we can because they have substantially greater resources. In addition, any uncertainties resulting from the initiation and continuation of any litigation or *inter partes* review proceedings could have a material adverse effect on our ability to raise the funds necessary to continue our operations.

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

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

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

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

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

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

Risks Related to Our Relationships with Third Parties

We are largely dependent on our relationships with our licensors and collaborators and there is no guarantee that such relationships will be maintained or continued.

We have entered into certain license agreements for certain intellectual property rights which are essential to enable us to develop and commercialize our products. Agreements have been entered into with the University of Rome, JHU and CSMC, the latter of which is also a stockholder of ours. Each of those agreements provides for an exclusive license to certain patents and other intellectual property and requires the payment of fees, milestone payments and/or royalties to the institutions that will reduce our net revenues, if and to the extent that we have future revenues. Each of those agreements also contains additional obligations that we are required to satisfy. There is no guarantee that we will be able to satisfy all of our obligations under our license agreements to each of the institutions and that such license agreements will not be terminated. Each of the institutions receives funding from independent sources such as the NIH and other private or not-for-profit sources and are investigating scientific and clinical questions of interest to their own principal investigators as well as the scientific and clinical communities at large. These investigators (including Capricor, Inc.'s founder, Dr. Eduardo Marbán, who is the Director of the Smidt Heart Institute at CSMC) and Dr. Stephen Gould (Johns Hopkins University) are under no obligation to conduct, continue, or conclude either current or future studies utilizing our cell therapy or exosomes technology, and they are not compelled to license any further technologies or intellectual property rights to us except as may be stated in the applicable licensing agreements or research agreements between those institutions and us. Changes in these collaborators' research interests or their funding sources away from our technology would have a material adverse effect on us. Further, the failure of any third-party licensor to comply with its licensing obligations under its respective agreement with us would have a material adverse effect on us. We are substantially dependent on our relationships with these institutions from which we license the rights to our technologies and know-how. If requirements under our license agreements are not met, including meeting defined milestones, we could suffer significant harm, including losing rights to our product candidates.

In addition, we are responsible for the cost of filing and prosecuting certain patent applications and maintaining certain issued patents licensed to us. If we do not meet our obligations under our license agreements in a timely manner, we could lose the rights to the proprietary technology.

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

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

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

In September 2016, Capricor was approved for a grant award from the DoD in the amount of approximately $2.4 million to be used toward developing a scalable, commercially-ready process to manufacture our exosomes. Under the terms of the award, disbursements were made to Capricor, subject to annual and quarterly reporting requirements. The Company utilized approximately $2.3 million of the $2.4 million under the terms of the award. We are currently completing all close-out documentation associated with this award.

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

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

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

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

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

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

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

Risks Related to Competitive Factors

Our products will likely face intense competition.

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

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

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

Because of the specialized nature of our technology, we are dependent upon existing key personnel and on our ability to attract and retain qualified executive officers

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

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

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

We have also developed a close working relationship between the academic lab of Dr. Stephen Gould at Johns Hopkins University and our research and development team where employees and consultants of both entities contribute time and services to the research being performed by the other. As a result, it can sometimes be unclear whether intellectual property developed out of these services would be owned by JHU or by the Company, although if owned by JHU, the Company may have rights to that intellectual property under the terms of its license and research agreements with JHU.

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

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

An element of our business strategy includes potentially partnering with pharmaceutical, biotechnology and other companies to obtain assistance for the development and potential commercialization of our product candidates, including the cash and other resources we need for such development and potential commercialization. We may not be able to negotiate strategic partnerships on acceptable terms, or at all. If we are unable to negotiate strategic partnerships for our product candidates, we may be forced to curtail the development of a particular candidate, reduce, delay, or terminate its development program, delay its potential commercialization, reduce the scope of our sales or marketing activities or undertake development or commercialization activities at our own expense. In addition, we will bear all risk related to the development of that product candidate. If we elect to increase our expenditures to fund development or commercialization activities on our own, we will need to obtain substantial additional capital, which may not be available to us on acceptable terms, or at all. If we do not secure sufficient funds, we will not be able to complete our trials or bring our product candidates to market and generate product revenue. We have announced that our goal is pursue a partnership for the continued development of CAP-1002 in DMD.

We have no experience selling, marketing, or distributing products and no current internal capability to do so.

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

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

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

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

Our ability to effectively promote and sell our product candidates in the marketplace will also depend on pricing, including our ability to manufacture a product at a competitive price. We will also need to demonstrate acceptable evidence of safety and efficacy and may need to demonstrate relative convenience and ease of administration. Market acceptance could be further limited depending on the prevalence and severity of any expected or unexpected adverse side effects associated with our product candidates. If our product candidates are approved but do not achieve an adequate level of acceptance by physicians, health care payors, and patients, we may not generate sufficient

revenue from these products, and we may not become or remain profitable. In addition, our efforts to educate the medical community and third-party payors on the benefits of our product candidates may require significant resources and may never be successful. If our approved drugs fail to achieve market acceptance, we will not be able to generate significant revenue, if any.

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

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

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

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

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

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

Further, there have been a number of legislative and regulatory proposals to change the healthcare system that could affect our ability to sell any future drugs profitably. The U.S. government, state legislatures, and foreign governments have shown significant interest in implementing cost-containment programs, including price controls, restrictions on reimbursement, and requirements for substitution by generic products. We anticipate additional state and federal healthcare reform measures will be adopted in the future. These may include price controls and cost-containment measures, or more restrictive policies in jurisdictions with existing controls and measures, any of which could limit the amounts that federal and state governments will pay for healthcare products and services, and potentially could reduce demand for our products once approved, create additional pricing pressures, or ultimately limit our net revenue and results. There can be no assurance that any of our product candidates, if approved, will be considered medically reasonable and necessary, that they will be considered cost-effective by third-party payors, that coverage or an adequate level of reimbursement will be available, or that reimbursement policies and practices in the United States and in foreign countries where our products are sold will not harm our ability to sell our product candidates profitably, if they are approved for sale.

Risks Related to Product and Environmental Liability

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

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

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

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

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

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

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

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

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

Risks Related to Our Common Stock

We expect that our stock price will continue to fluctuate significantly.

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

- our financial condition, including our need for additional capital, as well as the impact of any terms imposed on our business and operations by the providers of additional capital;
- results from, delays in, or discontinuation of, any of the clinical trials for our drug candidates, including delays resulting from slower than expected or suspended patient enrollment or discontinuations resulting from a failure to meet pre-defined clinical endpoints;
- announcements concerning clinical trials and regulatory developments;
- failure or delays in entering drug candidates into clinical trials;
- failure or discontinuation of any of our research or development programs;
- developments in establishing and maintaining new strategic alliances or with existing alliances or collaborators;
- failure to satisfy licensing obligations, including our ability to meet milestone requirements under our license agreements;
- market conditions in the pharmaceutical, biotechnology and other healthcare related sectors;
- actual or anticipated fluctuations in our quarterly financial and operating results;
- developments or disputes concerning our intellectual property or other proprietary rights;
- introduction of technological innovations or new commercial products by us or our competitors;
- issues in manufacturing our drug candidates or drugs;
- issues with the supply or manufacturing of any devices or materials needed to manufacture or utilize our drug candidates;
- FDA or other U.S. or foreign regulatory actions affecting us or our industry;
- the risks and costs of increased operations, including clinical and manufacturing operations, on an international basis;
- market acceptance of our drugs, when they enter the market;
- third-party healthcare coverage and reimbursement policies;

- litigation or public concern about the safety of our drug candidates or drugs or the operations of the Company;
- issuance of new or revised securities analysts' reports or recommendations;
- additions or departures of key personnel;
- potential delisting of our stock from the Nasdaq Stock Market; or
- volatility in the stock prices of other companies in our industry.

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

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

We may issue shares of blank check preferred stock without stockholder approval in the future.

Our certificate of incorporation authorizes the issuance of up to 5,000,000 shares of preferred stock, none of which are currently issued or currently outstanding. If issued, our Board of Directors will have the authority to fix and determine the relative rights and preferences of preferred shares, as well as the authority to issue such shares, without further stockholder approval. As a result, our Board of Directors could authorize the issuance of a series of preferred stock that is senior to our common stock that would grant to holders preferred rights to our assets upon liquidation, the right to receive dividends, additional registration rights, anti-dilution protection, and the right to the redemption of such shares, together with other rights, none of which will be afforded holders of our common stock.

Market and economic conditions may adversely affect our industry, business and ability to obtain financing.

Recent global market and economic conditions have been unpredictable and challenging. These conditions and any adverse impact on the financial markets may adversely affect our liquidity and financial condition, including our ability to access the capital markets to meet our liquidity needs.

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

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

The operational and other projections and forecasts that we may make from time to time are subject to inherent risks, many of which are beyond our control.

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

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

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

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

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

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

As of December 31, 2020, there were approximately 20.6 million shares of common stock outstanding and approximately 0.1 million common warrants outstanding, as well as outstanding awards to purchase approximately 2.4 million shares of common stock under various incentive stock plans of the Company. Additionally, as of December 31, 2020, there were approximately 1.0 million shares of common stock available for future issuance under various incentive plans. We may issue additional common stock, warrants and other convertible securities from time to time to finance our operations. We may also issue additional shares to fund potential acquisitions or in connection with additional stock options or other equity awards granted to our employees, officers, directors and consultants under our various incentive plans. The issuance of additional shares of common stock, warrants or other convertible securities and the perception that such issuances may occur or exercise of outstanding warrants or options may have a dilutive impact on other stockholders and could have a material negative effect on the market price of our common stock.

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

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

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

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

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

controls and procedures and internal control over financial reporting. In order to maintain and, if required, improve our disclosure controls and procedures and internal control over financial reporting to meet this standard, significant resources and management oversight is required. In addition, these rules and regulations make it more difficult and more expensive for us to obtain director and officer liability insurance. As a result, management's attention may be diverted from other business concerns, which could harm our business and operating results. Although we have hired employees in order to comply with these requirements, we may need to hire more employees in the future, which will increase our costs and expenses.

Failure to achieve and maintain effective internal controls in accordance with Section 404 of the Sarbanes-Oxley Act of 2002 could have a material adverse effect on our business and stock price.

The Sarbanes-Oxley Act of 2002, as amended, or Sarbanes-Oxley, as well as rules implemented by the Securities and Exchange Commission, Nasdaq and any market on which the Company's shares may be listed in the future, impose various requirements on public companies, including those related to corporate governance practices. The Company's management and other personnel will need to devote a substantial amount of time to these requirements. Moreover, these rules and regulations will increase the Company's legal and financial compliance costs and will make some activities more time consuming and costly.

Section 404 of Sarbanes-Oxley, or Section 404, requires that we establish and maintain an adequate internal control structure and procedures for financial reporting. Our annual reports on Form 10-K must contain an assessment by management of the effectiveness of our internal control over financial reporting and must include disclosure of any material weaknesses in internal control over financial reporting that we have identified. The requirements of Section 404 are ongoing and also apply to future years. We expect that our internal control over financial reporting will continue to evolve as our business develops. Although we are committed to continue to improve our internal control processes and we will continue to diligently and vigorously review our internal control over financial reporting in order to ensure compliance with Section 404 requirements, any control system, regardless of how well designed, operated and evaluated, can provide only reasonable, not absolute, assurance that its objectives will be met. Therefore, we cannot be certain that in the future material weaknesses or significant deficiencies will not exist or otherwise be discovered. If material weaknesses or other significant deficiencies occur, these weaknesses or deficiencies could result in misstatements of our results of operations, restatements of our consolidated financial statements, a decline in our stock price, or other material adverse effects on our business, reputation, results of operations, financial condition or liquidity.

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

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

If our business plans are not successful, our stockholders may lose their entire investment in us.

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

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

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

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

Our common stock is listed on The NASDAQ Capital Market. For continued listing on The NASDAQ Capital Market, we will be required to comply with the continued listing requirements, including the minimum market capitalization standard, the minimum stockholders' equity requirement, the corporate governance requirements and the minimum closing bid price requirement, maintaining Board diversity among other requirements. In the event that we fail to satisfy any of the listing requirements of The NASDAQ Capital Market, our common stock may be delisted. If our securities are delisted from trading on The NASDAQ Stock Market, however, and we are not able to list our securities on another exchange or to have them quoted on The NASDAQ Stock Market, our securities could be quoted on the OTC Markets or on the "pink sheets." As a result, we could face significant adverse consequences including:

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

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

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

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

Our board of directors includes one female director, and no directors from an "underrepresented community." If we do not add at least two female directors and at least one director from an "underrepresented community" to our board of directors prior to December 31, 2021, we would be out of compliance with SB 826 or AB 979,

respectively. An initial violation of either law can result in a fine from the California Secretary of State in the amount of $100,000, with each subsequent violation resulting in a fine of $300,000.

Risks Related to this Offering

Management will have broad discretion as to the use of 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 research related to our product candidates, working capital and general corporate purposes, which may include, without limitation, engaging in acquisitions or other business combinations. 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.

If you purchase any common stock sold in this offering, you will experience immediate dilution as a result of this offering and future equity issuances.

Because the price per share of our common stock which may be offered may be higher than the book value per share of our common stock, you will suffer immediate substantial dilution in the net tangible book value of the common stock you purchase in any such offering. The issuance of additional shares of our common stock could be dilutive to stockholders if they do not invest in future offerings. Moreover, to the extent that we issue options or warrants to purchase, or securities convertible into or exchangeable for, shares of our common stock in the future and those options, warrants or other securities are exercised, converted or exchanged, stockholders may experience further dilution.

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 June 11, 2021, we had 22,877,930 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.

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 and vaccine candidates, including when we expect to undertake, initiate and complete clinical trials of our candidates;
- the expectation, plans, projections, initiation, timing, progress and results of our research and development programs, preclinical studies, any clinical trials, Investigational New Drug, or IND, filings, Clinical Trial Application, or CTA, filings, New Drug Application, or NDA, filings, and other regulatory submissions;
- the regulatory approval of any of our drug and vaccine candidates;
- our use of clinical research centers, third party manufacturers and other contractors;
- our ability to find collaborative partners for research, development and commercialization of 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

Except as described in any applicable prospectus supplement or in any free writing prospectuses we have authorized for use in connection with a specific offering, we currently intend to use the net proceeds from this offering, if any, for research related to our product candidates, working capital and general corporate purposes, which may include, without limitation, engaging in acquisitions or other business combinations.

The amounts and timing of our use of the net proceeds from this offering will depend on a number of factors, such as the timing and progress of our research and development efforts, the timing of commercialization efforts, technological advances and the competitive environment for our products. As of the date of this prospectus, we cannot specify with certainty all of the particular uses for the net proceeds to us from this offering. Accordingly, our management will have broad discretion in the timing and application of these proceeds. Pending application of the net proceeds as described above, we intend to temporarily invest the proceeds in short-term, interest-bearing instruments.

DESCRIPTION OF CAPITAL STOCK

The following description summarizes the most important terms of our capital stock. Because the following description is only a summary, it does not contain all of the information that may be important to you. For a complete description of the matters set forth in this "Description of Capital Stock," you should refer to our Certificate of Incorporation, as amended, and our Bylaws, and to the applicable provisions of Delaware law.

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 June 11, 2021, there were 22,877,930 shares of our common stock outstanding, held by 136 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, our Board of Directors has 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.

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 June 11, 2021, there were options outstanding to purchase an aggregate of 3,649,675 shares of our common stock with a range of exercise prices from $1.18 to $12.10 per share and an average weighted exercise price of $2.54 per share. The options were issued pursuant to our equity incentive plans, which consist of (i) the 2006 Stock Option Plan, (ii) the 2012 Restated Equity Incentive Plan, as amended, (iii) the 2012 Non-Employee Director Stock Option Plan, and (iv) the 2020 Equity Incentive 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.

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 therefore) 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 in 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.

DESCRIPTION OF DEBT SECURITIES

We may issue debt securities from time to time, in one or more series, as either senior or subordinated debt or as senior or subordinated convertible debt. While the terms we have summarized below will apply generally to any debt securities that we may offer under this prospectus, we will describe the particular terms of any debt securities that we may offer in more detail in the applicable prospectus supplement. The terms of any debt securities offered under a prospectus supplement may differ from the terms described below. Unless the context requires otherwise, whenever we refer to the indenture, we also are referring to any supplemental indentures that specify the terms of a particular series of debt securities.

We will issue the debt securities under the indenture that we will enter into with the trustee named in the indenture. The indenture will be qualified under the Trust Indenture Act of 1939, as amended, or the Trust Indenture Act. We have filed the form of indenture as an exhibit to the registration statement of which this prospectus is a part, and supplemental indentures and forms of debt securities containing the terms of the debt securities being offered will be filed as exhibits to the registration statement of which this prospectus is a part or will be incorporated by reference from reports that we file with the SEC. The following summary of material provisions of the debt securities and the indenture is subject to, and qualified in its entirety by reference to, all of the provisions of the indenture applicable to a particular series of debt securities. We urge you to read the applicable prospectus supplements and any related free writing prospectuses we authorize for use in connection with a specific offering of debt securities, as well as the complete indenture that contains the terms of the debt securities.

General Matters

Unless we provide otherwise in the applicable prospectus supplement, the indenture will not limit the amount of debt securities that we may issue. Unless we provide otherwise in the applicable prospectus supplement, it will provide that we may issue debt securities up to the principal amount that we may authorize and in any currency or currency unit that we may designate. Unless we provide otherwise in the applicable prospectus supplement, except for the limitations on consolidation, merger and sale of all or substantially all of our assets contained in the indenture, the terms of the indenture will not contain any covenants or other provisions designed to give holders of any debt securities protection against changes in our operations or financial condition or transactions involving us. We may issue the debt securities issued under the indenture as "discount securities", which means they may be sold at a discount below their stated principal amount. These debt securities, as well as other debt securities that are not issued at a discount, may be issued with "original issue discount", or OID, for U.S. federal income tax purposes because of interest payment and other characteristics or terms of the debt securities. Material U.S. federal income tax considerations applicable to debt securities issued with OID will be described in more detail in any applicable prospectus supplement.

We will describe in the applicable prospectus supplement the terms of the series of debt securities being offered, including:

- the title of the series of debt securities;
- any limit upon the aggregate principal amount that may be issued;
- the maturity date or dates;
- the form of the debt securities of the series;
- the applicability of any guarantees;
- whether or not the debt securities will be secured or unsecured, and the terms of any secured debt;
- whether the debt securities rank as senior debt, senior subordinated debt, subordinated debt or any combination thereof, and the terms of any subordination;
- if the price (expressed as a percentage of the aggregate principal amount thereof) at which the debt securities will be issued is a price other than the principal amount thereof, the portion of the principal amount thereof payable upon declaration of acceleration of the maturity thereof, or if applicable, the portion of the principal amount of such debt securities that is convertible into another security or the method by which any such portion shall be determined;
- the interest rate or rates, which may be fixed or variable, or the method for determining the rate and the date interest will begin to accrue, the dates interest will be payable and the regular record dates for interest payment dates or the method for determining such dates;
- our right, if any, to defer payment of interest and the maximum length of any such deferral period;
- if applicable, the date or dates after which, or the period or periods during which, and the price or prices at which, we may, at our option, redeem the series of debt securities pursuant to any optional or provisional redemption provisions and the terms of those redemption provisions;
- the date or dates, if any, on which, and the price or prices at which we are obligated, pursuant to any mandatory sinking fund or analogous fund provisions or otherwise, to redeem, or at the holder's option to purchase, the series of debt securities and the currency or currency unit in which the debt securities are payable;
- the denominations in which we will issue the series of debt securities, if other than denominations of $1,000 and any integral multiple thereof;
- any and all terms, if applicable, relating to any auction or remarketing of the debt securities of that series and any security for our obligations with respect to such debt securities and any other terms which may be advisable in connection with the marketing of debt securities of that series;
- whether the debt securities of the series shall be issued in whole or in part in the form of a global security or securities; the terms and conditions, if any, upon which such global security or securities may be exchanged in whole or in part for other individual securities, and the depositary for such global security or securities;
- if applicable, the provisions relating to conversion or exchange of any debt securities of the series and the terms and conditions upon which such debt securities will be so convertible or exchangeable, including the conversion or exchange price, as applicable, or how it will be calculated and may be adjusted, any mandatory or optional (at our option or at the holders' option) conversion or exchange features, the applicable conversion or exchange period and the manner of settlement for any conversion or exchange;
- if other than the full principal amount thereof, the portion of the principal amount of debt securities of the series which shall be payable upon declaration of acceleration of the maturity thereof;
- additions to or changes in the covenants applicable to the particular debt securities being issued, including, among others, the consolidation, merger or sale covenant;
- additions to or changes in the events of default with respect to the securities and any change in the right of the trustee or the holders to declare the principal, premium, if any, and interest, if any, with respect to such securities to be due and payable;
- additions to or changes in or deletions of the provisions relating to covenant defeasance and legal defeasance;
- additions to or changes in the provisions relating to satisfaction and discharge of the indenture;

- additions to or changes in the provisions relating to the modification of the indenture both with and without the consent of the holders of the debt securities issued under the indenture;

- the currency of payment of the debt securities if other than U.S. dollars and the manner of determining the equivalent amount in U.S. dollars;
- whether interest will be payable in cash or additional debt securities at our or the holders' option and the terms and conditions upon which the election may be made;
- the terms and conditions, if any, upon which we will pay amounts in addition to the stated interest, premium, if any, and principal amounts of the debt securities of the series to any holder that is not a "United States person" for federal tax purposes;
- any restrictions on transfer, sale or assignment of the debt securities of the series; and
- any other specific terms, preferences, rights or limitations of, or restrictions on, the debt securities, any other additions or changes in the provisions of the indenture, and any terms that may be required by us or advisable under applicable laws or regulations.

Conversion or Exchange Rights

We will set forth in the applicable prospectus supplement the terms on which a series of debt securities may be convertible into or exchangeable for our common stock or our other securities. We will include provisions as to settlement upon conversion or exchange and whether conversion or exchange is mandatory, at the option of the holder or at our option. We may include provisions pursuant to which the number of shares of our common stock or our other securities that the holders of the series of debt securities receive would be subject to adjustment.

Consolidation, Merger or Sale

Unless we provide otherwise in the prospectus supplement applicable to a particular series of debt securities, the indenture will not contain any covenant that restricts our ability to merge or consolidate, or sell, convey, transfer or otherwise dispose of our assets as an entirety or substantially as an entirety. However, any successor to or acquirer of such assets (other than a subsidiary of ours) must assume all of our obligations under the indenture or the debt securities, as appropriate.

Events of Default under the Indenture

Unless we provide otherwise in the prospectus supplement applicable to a particular series of debt securities, the following are events of default under the indenture with respect to any series of debt securities that we may issue:

- if we fail to pay any installment of interest on any series of debt securities, as and when the same shall become due and payable, and such default continues for a period of 90 days; provided, however, that a valid extension of an interest payment period by us in accordance with the terms of any indenture supplemental thereto shall not constitute a default in the payment of interest for this purpose;
- if we fail to pay the principal of, or premium, if any, on any series of debt securities as and when the same shall become due and payable whether at maturity, upon redemption, by declaration or otherwise, or in any payment required by any sinking or analogous fund established with respect to such series; provided, however, that a valid extension of the maturity of such debt securities in accordance with the terms of any indenture supplemental thereto shall not constitute a default in the payment of principal or premium, if any;
- if we fail to observe or perform any other covenant or agreement contained in the debt securities or the indenture, other than a covenant specifically relating to another series of debt securities, and our failure continues for a period of 90 days after we receive written notice of such failure, requiring the same to be remedied and stating that such is a notice of default thereunder, from the trustee or holders of at least a majority of the aggregate principal amount of the outstanding debt securities of the applicable series; and
- if specified events of bankruptcy, insolvency or reorganization occur.

If an event of default with respect to debt securities of any series occurs and is continuing, other than certain specified events of bankruptcy, insolvency or reorganization, the trustee or the holders of at least a majority of the aggregate principal amount of the outstanding debt securities of that series, by notice to us in writing, and to the trustee if notice is given by such holders, may declare the unpaid principal, premium, if any, and accrued interest, if any, of such series of debt securities immediately due and payable. If certain specified events of bankruptcy, insolvency or reorganization occur with respect to us, the principal amount and accrued interest, if any, of each issue of debt securities then outstanding shall be due and payable without any notice or other action on the part of the trustee or any holder.

The holders of a majority of the principal amount of the outstanding debt securities of an affected series may waive any default or event of default with respect to the series and its consequences, except defaults or events of default regarding payment of principal, premium, if any, or interest, unless we have cured the default or event of default in accordance with the indenture. Any waiver shall cure the default or event of default.

Subject to the terms of the indenture, if an event of default under an indenture shall occur and be continuing, the trustee will be under no obligation to exercise any of its rights or powers under such indenture at the request or direction of any of the holders of the applicable series of debt securities, unless such holders have offered the trustee reasonable indemnity. The holders of a majority of the principal amount of the outstanding debt securities of any series will have the right to direct the time, method and place of conducting any proceeding for any remedy available to the trustee, or exercising any trust or power conferred on the trustee, with respect to the debt securities of that series, provided that:

- the direction so given by the holder is not in conflict with any law or the applicable indenture; and
- subject to its duties under the Trust Indenture Act, the trustee need not take any action that might involve it in personal liability or might be unduly prejudicial to the holders not involved in the proceeding.

A holder of the debt securities of any series will have the right to institute a proceeding under the indenture or to appoint a receiver or trustee, or to seek other remedies, only if:

- the holder has given written notice to the trustee of a continuing event of default with respect to that series;
- the holders of at least a majority of the aggregate principal amount of the outstanding debt securities of that series have made a written request,
- such holders have offered to the trustee indemnity satisfactory to it against the costs, expenses and liabilities to be incurred by the trustee in compliance with the request; and
- the trustee does not institute the proceeding, and does not receive from the holders of a majority of the aggregate principal amount of the outstanding debt securities of that series other conflicting directions within 90 days after the notice, request and offer.

These limitations do not apply to a suit instituted by a holder of debt securities if we default in the payment of the principal of, or the premium, if any, or interest on, the

debt securities.

We will periodically file statements with the trustee regarding our compliance with specified covenants in the indenture.

Modification of Indenture; Waiver

Unless we provide otherwise in the prospectus supplement applicable to a particular series of debt securities, we and the trustee may change an indenture without the consent of any holders with respect to specific matters, including, but not limited to, the following:

- to cure any ambiguity, defect or inconsistency in the indenture or in the debt securities of any series;
- to comply with the provisions described above under "—Consolidation, Merger or Sale";
- to provide for uncertificated debt securities in addition to or in place of certificated debt securities;
- to add to our covenants, restrictions, conditions or provisions such new covenants, restrictions, conditions or provisions for the benefit of the holders of all or any series of debt securities, to make the occurrence, or the occurrence and the continuance, of a default in any such additional covenants, restrictions, conditions or provisions an event of default or to surrender any right or power conferred upon us in the indenture;
- to add to, delete from or revise the conditions, limitations and restrictions on the authorized amount, terms or purposes of issue, authentication and delivery of debt securities, as set forth in the indenture;
- to make any change that does not adversely affect the interests of any holder of debt securities of any series in any material respect;
- to provide for the issuance of, and to establish the form and terms and conditions of, the debt securities of any series as provided above under "—General Matters", to establish the form of any certifications required to be furnished pursuant to the terms of the indenture or any series of debt securities, or to add to the rights of the holders of any series of debt securities;
- to evidence and provide for the acceptance of appointment under any indenture by a successor trustee; or
- to comply with any requirements of the SEC in connection with the qualification of any indenture under the Trust Indenture Act.

In addition, under the indenture, the rights of holders of a series of debt securities may be changed by us and the trustee with the written consent of the holders of at least a majority of the aggregate principal amount of the outstanding debt securities of each series that is affected. However, unless we provide otherwise in the prospectus supplement applicable to a particular series of debt securities, we and the trustee may make the following changes only with the consent of each holder of any outstanding debt securities affected:

- extending the fixed maturity of any debt securities of any series;
- reducing the principal amount, reducing the rate of or extending the time of payment of interest, or reducing any premium payable upon the redemption of any series of debt securities; or
- reducing the percentage of debt securities, the holders of which are required to consent to any amendment, supplement, modification or waiver.

Discharge

Unless we provide otherwise in the applicable prospectus supplement, the indenture will provide that we can elect to be discharged from our obligations with respect to one or more series of debt securities, except for specified obligations, including, but not limited to, the following obligations to:

- provide for payment;
- register the transfer or exchange of debt securities of the series;
- replace stolen, lost or mutilated debt securities of the series;
- pay principal of and premium and interest on any debt securities of the series;
- maintain paying agencies;
- hold monies for payment in trust;
- recover excess money held by the trustee;
- compensate and indemnify the trustee; and
- appoint any successor trustee.

In order to exercise our rights to be discharged, we must deposit with the trustee money or government obligations sufficient to pay all the principal of, and any premium, if any, and interest on, the debt securities of the series on the dates payments are due.

Form, Exchange and Transfer

We will issue the debt securities of each series only in fully registered form without coupons and, unless we provide otherwise in the applicable prospectus supplement, in denominations of $1,000 and any integral multiple thereof. Unless we provide otherwise in the applicable prospectus supplement, the indenture will provide that we may issue debt securities of a series in temporary or permanent global form and as book-entry securities that will be deposited with, or on behalf of, The Depository Trust Company, New York, New York, known as DTC, or another depositary named by us and identified in the applicable prospectus supplement with respect to that series. To the extent the debt securities of a series are issued in global form and as book-entry, a description of terms relating to any book-entry securities will be set forth in the applicable prospectus supplement.

At the option of the holder, subject to the terms of the indenture and the limitations applicable to global securities described in the applicable prospectus supplement, the holder of the debt securities of any series can exchange the debt securities for other debt securities of the same series, in any authorized denomination and of like tenor and aggregate principal amount.

Subject to the terms of the indenture and the limitations applicable to global securities set forth in the applicable prospectus supplement, holders of the debt securities may present the debt securities for exchange or for registration of transfer, duly endorsed or with the form of transfer endorsed thereon duly executed if so required by us or the security registrar, at the office of the security registrar or at the office of any transfer agent designated by us for this purpose. Unless otherwise provided in the debt securities that the holder presents for transfer or exchange, we will impose no service charge for any registration of transfer or exchange, but we may require payment of any taxes or other governmental charges.

We will name in the applicable prospectus supplement the security registrar, and any transfer agent in addition to the security registrar, that we initially designate for any debt securities. We may at any time designate additional transfer agents or rescind the designation of any transfer agent or approve a change in the office through which any transfer agent acts, except that we will be required to maintain a transfer agent in each place of payment for the debt securities of each series.

Unless we provide otherwise in the applicable prospectus supplement, if we elect to redeem the debt securities of any series, we will not be required to:

- issue, register the transfer of, or exchange any debt securities of that series during a period beginning at the opening of business 15 days before the date of mailing of a notice of redemption of any debt securities that may be selected for redemption and ending at the close of business on the date of the mailing; or
- register the transfer of or exchange any debt securities so selected for redemption, in whole or in part, except for the unredeemed portion of any debt securities we are redeeming in part.

Information Concerning the Trustee

The trustee, other than during the occurrence and continuance of an event of default under an indenture, will undertake to perform only those duties as are specifically set forth in the applicable indenture. Upon an event of default under an indenture, the trustee must use the same degree of care as a prudent person would exercise or use in the conduct of his or her own affairs. Subject to this provision, the trustee will be under no obligation to exercise any of the powers given to it by the indenture at the request of any holder of debt securities unless it is offered reasonable security and indemnity against the costs, expenses and liabilities that it might incur.

Payment and Paying Agents

Unless we otherwise indicate in the applicable prospectus supplement, we will make payment of the interest on any debt securities on any interest payment date to the person in whose name the debt securities, or one or more predecessor securities, are registered at the close of business on the regular record date for the interest.

Unless we provide otherwise in the applicable prospectus supplement, we will pay principal of and any premium and interest on the debt securities of a particular series at the office of the paying agents designated by us, except that, unless we otherwise indicate in the applicable prospectus supplement, we will make interest payments by check that we will mail to the holder or by wire transfer to certain holders. Unless we otherwise indicate in the applicable prospectus supplement, we will designate the corporate trust office of the trustee as our sole paying agent for payments with respect to debt securities of each series. We will name in the applicable prospectus supplement any other paying agents that we initially designate for the debt securities of a particular series. We will maintain a paying agent in each place of payment for the debt securities of a particular series.

All money we pay to a paying agent or the trustee for the payment of the principal of, or any premium or interest on, any debt securities that remains unclaimed at the end of two years after such principal, premium or interest has become due and payable will be repaid to us, and the holder of the debt security thereafter may look only to us for payment thereof.

Governing Law

The indenture and the debt securities, and any claim, controversy or dispute arising under or related to the indenture or the debt securities, will be governed by and construed in accordance with the laws of the State of New York, except to the extent that the Trust Indenture Act is applicable.

DESCRIPTION OF WARRANTS

The following description, together with the additional information we may include in any applicable prospectus supplements and free writing prospectuses we have authorized for use in connection with a specific offering, summarizes the material terms and provisions of the warrants that we may offer under this prospectus, which may consist of warrants to purchase common stock, preferred stock or debt securities and may be issued in one or more series.

Warrants may be issued independently or together with common stock, preferred stock or debt securities offered by any prospectus supplement, and may be attached to or separate from those securities. While the terms we have summarized below will apply generally to any warrants that we may offer under this prospectus, we will describe the particular terms of any series of warrants that we may offer in more detail in the applicable prospectus supplement and any applicable free writing prospectus we authorize for use in connection with the specific offering. The terms of any warrants offered under a prospectus supplement may differ from the terms described below.

We have filed forms of the warrant agreements as exhibits to the registration statement of which this prospectus is a part. We will file as exhibits to the registration statement of which this prospectus is a part, or will incorporate by reference from reports that we file with the SEC, the form of warrant agreement, if any, including a form of warrant certificate, that describes the terms of the particular series of warrants we are offering. The following summaries of material provisions of the warrants and the warrant agreements are subject to, and qualified in their entirety by reference to, all the provisions of the warrant agreement and warrant certificate applicable to the particular series of warrants that we may offer under this prospectus. We urge you to read the applicable prospectus supplements related to the particular series of warrants that we may offer under this prospectus, as well as any related free writing prospectuses we have authorized for use in connection with a specific offering, and the complete warrant agreements and warrant certificates that contain the terms of the warrants.

General Matters

We will describe in the applicable prospectus supplement the terms relating to a series of warrants being offered, including:

- the title of such securities;
- the offering price or prices and aggregate number of warrants offered;
- the currency or currencies for which the warrants may be purchased;
- if applicable, the designation and terms of the securities with which the warrants are issued and the number of warrants issued with each such security or each principal amount of such security;
- if applicable, the date on and after which the warrants and the related securities will be separately transferable;
- if applicable, the minimum or maximum amount of such warrants which may be exercised at any one time;
- in the case of warrants to purchase debt securities, the principal amount of debt securities purchasable upon exercise of one warrant and the price at which, and currency in which, this principal amount of debt securities may be purchased upon such exercise;
- in the case of warrants to purchase common stock or preferred stock, the number of shares of common stock or preferred stock, as the case may be, purchasable upon the exercise of one warrant and the price at which, and the currency in which, these shares may be purchased upon such exercise;
- the effect of any merger, consolidation, sale or other disposition of our business on the warrant agreements and the warrants;
- the terms of any rights to redeem or call the warrants;
- the terms of any rights to force the exercise of the warrants;
- any provisions for changes to or adjustments in the exercise price or number of securities issuable upon exercise of the warrants;
- the dates on which the right to exercise the warrants will commence and expire;
- the manner in which the warrant agreements and warrants may be modified;
- a discussion of any material or special United States federal income tax consequences of holding or exercising the warrants;
- the terms of the securities issuable upon exercise of the warrants; and
- any other specific terms, preferences, rights or limitations of or restrictions on the warrants.

Before exercising their warrants, holders of warrants will not have any of the rights of holders of the securities purchasable upon such exercise, including:

- in the case of warrants to purchase debt securities, the right to receive payments of principal of, or premium, if any, or interest on, the debt securities purchasable upon exercise or to enforce covenants in the applicable indenture; or
- in the case of warrants to purchase common stock or preferred stock, the right to receive dividends, if any, or payments upon our liquidation, dissolution or winding up or to exercise voting rights, if any.

Exercise of Warrants

Each warrant will entitle the holder to purchase the securities that we specify in the applicable prospectus supplement at the exercise price that we describe in the applicable prospectus supplement. Unless we otherwise specify in the applicable prospectus supplement, holders of the warrants may exercise the warrants at any time up to the specified time on the expiration date that we set forth in the applicable prospectus supplement. After the close of business on the expiration date, unexercised warrants will become void.

Unless we otherwise specify in the applicable prospectus supplement, holders of the warrants may exercise the warrants by delivering the warrant certificate representing the warrants to be exercised together with specified information, and paying the required amount to the warrant agent in immediately available funds, as provided in the applicable prospectus supplement. We will set forth on the reverse side of the warrant certificate and in the applicable prospectus supplement the information that the holder of the warrant will be required to deliver to the warrant agent in connection with the exercise of the warrant.

Upon receipt of the required payment and the warrant certificate properly completed and duly executed at the corporate trust office of the warrant agent or any other office indicated in the applicable prospectus supplement, we will issue and deliver the securities purchasable upon such exercise. If fewer than all of the warrants represented by the warrant certificate are exercised, then we will issue a new warrant certificate for the remaining amount of warrants. If we so indicate in the applicable prospectus supplement, holders of the warrants may surrender securities as all or part of the exercise price for warrants.

Governing Law

Unless we provide otherwise in the applicable prospectus supplement, the warrants and warrant agreements, and any claim, controversy or dispute arising under or related to the warrants or warrant agreements, will be governed by and construed in accordance with the laws of the State of New York.

Enforceability of Rights by Holders of Warrants

Each warrant agent will act solely as our agent under the applicable warrant agreement and will not assume any obligation or relationship of agency or trust with any holder of any warrant. A single bank or trust company may act as warrant agent for more than one issue of warrants. A warrant agent will have no duty or responsibility in case of any default by us under the applicable warrant agreement or warrant, including any duty or responsibility to initiate any proceedings at law or otherwise, or to make any demand upon us. Any holder of a warrant may, without the consent of the related warrant agent or the holder of any other warrant, enforce by appropriate legal action its right to exercise, and receive the securities purchasable upon exercise of, its warrants.

Outstanding Warrants

As of June 11, 2021, the Company has 126,173 warrants for the Company's common stock outstanding. These warrants are not related to the warrants which are described in this prospectus.

DESCRIPTION OF UNITS

We may issue units consisting of any combination of the other types of securities offered under this prospectus in one or more series. We may evidence each series of units by unit certificates that we will issue under a separate agreement. We may enter into unit agreements with a unit agent. Each unit agent will be a bank or trust company that we select. We will indicate the name and address of the unit agent in the applicable prospectus supplement relating to a particular series of units.

The following description, together with the additional information included in any applicable prospectus supplement, summarizes the general features of the units that we may offer under this prospectus. You should read any prospectus supplement and any free writing prospectus we authorize for use in connection with a specific offering of units, as well as the complete unit agreements that contain the terms of the units. Specific unit agreements will contain additional important terms and provisions and we will file as an exhibit to the registration statement of which this prospectus is a part, or will incorporate by reference from another report that we file with the SEC, the form of each unit agreement relating to units offered under this prospectus. If we offer any units, certain terms of that series of units will be described in the applicable prospectus supplement, including, without limitation, the following, as applicable:

- the title of the series of units;
- identification and description of the separate constituent securities comprising the units;
- the price or prices at which the units will be issued;
- the date, if any, on and after which the constituent securities comprising the units will be separately transferable;
- a discussion of certain U.S. federal income tax considerations applicable to the units; and
- any other terms of the units and their constituent securities.

LEGAL OWNERSHIP OF SECURITIES

We can issue securities in registered form or in the form of one or more global securities. We describe global securities in greater detail below. We refer to those persons who have securities registered in their own names on the books that we or any applicable trustee or depositary maintain for this purpose as the "holders" of those securities. These persons are the legal holders of the securities. We refer to those persons who, indirectly through others, own beneficial interests in securities that are not registered in their own names, as "indirect holders" of those securities. As we discuss below, indirect holders are not legal holders, and investors in securities issued in book-

entry form or in street name will be indirect holders.

Book-Entry Holders

We may issue securities in book-entry form only, as we will specify in the applicable prospectus supplement. This means securities may be represented by one or more global securities registered in the name of a financial institution that holds them as depositary on behalf of other financial institutions that participate in the depositary's book-entry system. These participating institutions, which are referred to as participants, in turn, hold beneficial interests in the securities on behalf of themselves or their customers.

Only the person in whose name a security is registered is recognized as the holder of that security. Global securities will be registered in the name of the depositary or its participants. Consequently, for global securities, we will recognize only the depositary as the holder of the securities, and we will make all payments on the securities to the depositary. The depositary passes along the payments it receives to its participants, which in turn pass the payments along to their customers who are the beneficial owners. The depositary and its participants do so under agreements they have made with one another or with their customers; they are not obligated to do so under the terms of the securities.

As a result, investors in a global security will not own securities directly. Instead, they will own beneficial interests in a global security, through a bank, broker or other financial institution that participates in the depositary's book-entry system or holds an interest through a participant. As long as the securities are issued in global form, investors will be indirect holders, and not legal holders, of the securities.

Street Name Holders

We may terminate a global security in certain situations, as described under "—Special Situations When a Global Security Will Be Terminated", or issue securities that are not issued in global form. In these cases, investors may choose to hold their securities in their own names or in "street name". Securities held by an investor in street name would be registered in the name of a bank, broker or other financial institution that the investor chooses, and the investor would hold only a beneficial interest in those securities through an account he or she maintains at that institution.

For securities held in street name, we or any applicable trustee or depositary will recognize only the intermediary banks, brokers and other financial institutions in whose names the securities are registered as the holders of those securities, and we or any such trustee or depositary will make all payments on those securities to them. These institutions pass along the payments they receive to their customers who are the beneficial owners, but only because they agree to do so in their customer agreements or because they are legally required to do so. Investors who hold securities in street name will be indirect holders, and not legal holders, of those securities.

Legal Holders

Our obligations, as well as the obligations of any applicable trustee or third party employed by us or a trustee, run only to the legal holders of the securities. We do not have obligations to investors who hold beneficial interests in global securities, in street name or by any other indirect means. This will be the case whether an investor chooses to be an indirect holder of a security or has no choice because we are issuing the securities only in global form.

For example, once we make a payment or give a notice to the legal holder, we have no further responsibility for the payment or notice even if that legal holder is required, under agreements with its participants or customers or by law, to pass the payment or notice along to the indirect holders but does not do so. Similarly, we may want to obtain the approval of the holders to amend an indenture, to relieve us of the consequences of a default or of our obligation to comply with a particular provision of an indenture, or for other purposes. In such an event, we would seek approval only from the legal holders, and not the indirect holders, of the securities. Whether and how the legal holders contact the indirect holders is up to the legal holders.

Special Considerations for Indirect Holders

If you hold securities through a bank, broker or other financial institution, either in book-entry form because the securities are represented by one or more global securities or in street name, you should check with your own institution to find out:

- how it handles securities payments and notices;
- whether it imposes fees or charges;
- how it would handle a request for the holders' consent, if ever required;
- whether and how you can instruct it to send you securities registered in your own name so you can be a holder, if that is permitted in the future;
- how it would exercise rights under the securities if there were a default or other event triggering the need for holders to act to protect their interests; and
- if the securities are in book-entry form, how the depositary's rules and procedures will affect these matters.

Global Securities

A global security is a security that represents one or any other number of individual securities held by a depositary. Generally, all securities represented by the same global securities will have the same terms.

Each security issued in book-entry form will be represented by a global security that we issue to, deposit with and register in the name of a financial institution or its nominee that we select. The financial institution that we select for this purpose is called the depositary. Unless we specify otherwise in the applicable prospectus supplement, The Depository Trust Company, New York, New York, known as DTC, will be the depositary for all securities issued in book-entry form.

A global security may not be transferred to or registered in the name of anyone other than the depositary, its nominee or a successor depositary, unless special termination situations arise. We describe those situations below under "—Special Situations When a Global Security Will Be Terminated". As a result of these arrangements, the depositary, or its nominee, will be the sole registered owner and legal holder of all securities represented by a global security, and investors will be permitted to own only beneficial interests in a global security. Beneficial interests must be held by means of an account with a broker, bank or other financial institution that in turn has an account with the depositary or with another institution that does. Thus, an investor whose security is represented by a global security will not be a legal holder of the security, but only an indirect holder of a beneficial interest in the global security.

If the prospectus supplement for a particular security indicates that the security will be issued as a global security, then the security will be represented by a global security at all times unless and until the global security is terminated. If termination occurs, we may issue the securities through another book-entry clearing system or decide that the securities may no longer be held through any book-entry clearing system.

Special Considerations for Global Securities

As an indirect holder, an investor's rights relating to a global security will be governed by the account rules of the investor's financial institution and of the depositary, as well as general laws relating to securities transfers. We do not recognize an indirect holder as a holder of securities and instead deal only with the depositary that holds the global security.

If securities are issued only as global securities, an investor should be aware of the following:

- an investor cannot cause the securities to be registered in his or her name, and cannot obtain non-global certificates for his or her interest in the securities, except in the special situations described below;
- an investor will be an indirect holder and must look to his or her own bank or broker for payments on the securities and protection of his or her legal rights relating to the securities, as described above;
- an investor may not be able to sell interests in the securities to some insurance companies and to other institutions that are required by law to own their securities in non-book-entry form;
- an investor may not be able to pledge his or her interest in the global security in circumstances where certificates representing the securities must be delivered to the lender or other beneficiary of the pledge in order for the pledge to be effective;
- the depositary's policies, which may change from time to time, will govern payments, transfers, exchanges and other matters relating to an investor's interest in the global security;
- we and any applicable trustee have no responsibility for any aspect of the depositary's actions or for its records of ownership interests in the global security, nor will we or any applicable trustee supervise the depositary in any way;
- the depositary may, and we understand that DTC will, require that those who purchase and sell interests in the global security within its book-entry system use immediately available funds, and your broker or bank may require you to do the same; and
- financial institutions that participate in the depositary's book-entry system, and through which an investor holds its interest in the global security, may also have their own policies affecting payments, notices and other matters relating to the securities.

There may be more than one financial intermediary in the chain of ownership for an investor. We do not monitor and are not responsible for the actions of any of those intermediaries.

Special Situations When a Global Security Will Be Terminated

In a few special situations described below, a global security will terminate and interests in it will be exchanged for physical certificates representing those interests. After that exchange, the choice of whether to hold securities directly or in street name will be up to the investor. Investors must consult their own banks or brokers to find out how to have their interests in securities transferred to their own names, so that they will be direct holders. The rights of holders and street name investors are described above.

A global security will terminate when the following special situations occur:

- if the depositary notifies us that it is unwilling, unable or no longer qualified to continue as depositary for that global security and we do not appoint another institution to act as depositary within 90 days;
- if we notify any applicable trustee that we wish to terminate that global security; or
- if an event of default has occurred with regard to securities represented by that global security and has not been cured or waived.

The applicable prospectus supplement may also list additional situations for terminating a global security that would apply only to the particular series of securities covered by the prospectus supplement. When a global security terminates, the depositary, and neither we nor any applicable trustee, is responsible for deciding the names of the institutions that will be the initial direct holders.

PLAN OF DISTRIBUTION

We may sell the securities in and outside the United States from time to time pursuant to underwritten public offerings, "at the market" offerings, negotiated transactions, block trades or a combination of these methods. We may sell the securities to or through underwriters or dealers, directly to one or more purchasers, including to a limited number of institutional purchasers, to a single purchaser or to our affiliates and stockholders, through agents or through a combination of these methods.

We may distribute securities from time to time in one or more transactions, including:

- at a fixed price or prices, which may be changed from time to time;
- in "at the market" offerings, within the meaning of Rule 415(a)(4) of the Securities Act;
- through a market maker or into an existing trading market on an exchange or otherwise;
- at prices related to such prevailing market prices; or
- at negotiated prices.

A prospectus supplement or supplements (and any related free writing prospectus that we may have authorized for use in connection with a specific offering) will describe the following information to the extent applicable:

- the terms of the offering of the securities;
- the name or names of the underwriters, dealers or agents, if any;
- the name or names of any managing underwriter or underwriters;
- the purchase price of the securities or other consideration therefor;
- the net proceeds, if any, we will receive from the sale;
- any delayed delivery arrangements;
- any over-allotment options under which underwriters may purchase additional securities from us;
- any underwriting discounts, commissions and other items constituting underwriters' compensation;
- any agency fees, commissions and other items constituting agents' compensation;
- any public offering price;
- any discounts or concessions allowed or re-allowed or paid to dealers; and
- any securities exchange or market on which the securities may be listed.

Only underwriters named in the prospectus supplement will be underwriters of the securities offered by the prospectus supplement.

Sale through Underwriters or Dealers

If any securities are offered through underwriters, the underwriters will acquire the securities for their own account and may resell them from time to time in one or more transactions, including negotiated transactions, at a fixed public offering price or at varying prices determined at the time of sale. Underwriters may offer and sell securities to the public either through underwriting syndicates represented by one or more managing underwriters or directly by one or more firms acting as underwriters without a syndicate. Unless otherwise provided in the applicable prospectus supplement, the obligations of the underwriters to purchase the securities will be subject to certain conditions set forth in the applicable underwriting agreement, and the underwriters will be obligated to purchase all of the securities offered by the prospectus supplement, other than securities covered by any over-allotment option, if they purchase any of them. In connection with the sale of securities, underwriters may be deemed to have received

compensation from us in the form of underwriting discounts or commissions and dealers may receive compensation from the underwriters in the form of discounts or concessions. The underwriters may change from time to time any public offering price and any discounts or concessions allowed or reallowed or paid to dealers. We may use underwriters with whom we have a material relationship. We will describe in the prospectus supplement, naming the underwriter, the nature of any such relationship.

In order to facilitate the offering of securities, the underwriters may engage in transactions that stabilize, maintain or otherwise affect the price of the securities. Any underwriter may engage in over-allotment, stabilizing transactions, short-covering transactions and penalty bids in accordance with Regulation M under the Securities Exchange Act of 1934, as amended, or the Exchange Act. Specifically, the underwriters may overallot in connection with the offering, creating a short position in the securities for their account. In addition, to cover overallotments or to stabilize the price of the shares, the underwriters may bid for, and purchase, shares in the open market. Stabilizing transactions permit bids to purchase the underlying security so long as the stabilizing bids do not exceed a specified maximum price. Syndicate-covering or other short-covering transactions involve purchases of the securities, either through exercise of the over-allotment option or in the open market after the distribution is completed, to cover short positions. Penalty bids permit the underwriters to reclaim a selling concession from a dealer when the securities originally sold by the dealer are purchased in a stabilizing or covering transaction to cover short positions. Any of these activities may stabilize or maintain the market price of the offered securities above independent market levels. The underwriters are not required to engage in these activities, and may discontinue any of these activities at any time.

Some or all of the securities that we offer through this prospectus may be new issues of securities with no established trading market. Any underwriters to whom we sell securities for public offering and sale may make a market in those securities, but they will not be obligated to do so and they may discontinue any market making at any time without notice. Accordingly, we cannot assure you of the liquidity of, or continued trading markets for, any securities offered pursuant to this prospectus.

If any securities are offered through dealers, we will sell the securities to them as principals. They may then resell those securities to the public at varying prices determined by the dealers at the time of resale.

Direct Sales and Sales through Agents

We may sell the securities directly to purchasers. If the securities are sold directly to institutional investors or others who may be deemed to be underwriters within the meaning of the Securities Act with respect to any sale of those securities, we will describe the terms of any such sales in the applicable prospectus supplement. We may also sell the securities through agents designated from time to time. Sales may be made by means of ordinary brokers' transactions on The NASDAQ Capital Market at market prices, in block transactions and such other transactions as agreed by us and any agent. In the applicable prospectus supplement, we will name any agent involved in the offer or sale of the offered securities, and we will describe any commissions payable to the agent. Unless otherwise provided in the applicable prospectus supplement, any agent will agree to use its reasonable best efforts to solicit purchases for the period of its appointment.

At-the-Market Offerings

To the extent that we make sales through one or more underwriters or agents in at-the-market offerings, we will do so pursuant to the terms of a sales agency financing agreement or other at-the-market offering arrangement between us, on one hand, and the underwriters or agents, on the other. If we engage in at-the-market sales pursuant to any such agreement, we will issue and sell our securities through one or more underwriters or agents, which may act on an agency basis or a principal basis. During the term of any such agreement, we may sell securities on a daily basis in exchange transactions or otherwise as we agree with the underwriters or agents. Any such agreement will provide that any securities sold will be sold at prices related to the then prevailing market prices for our securities. Therefore, exact figures regarding proceeds that will be raised or commissions to be paid cannot be determined at this time. Pursuant to the terms of the applicable agreement, we may agree to sell, and the relevant underwriters or agents may agree to solicit offers to purchase, blocks of our common stock or other securities. The terms of any such agreement will be set forth in more detail in the applicable prospectus supplement.

Remarketing Arrangements

Offered securities may also be offered and sold, if we so indicate in the applicable prospectus supplement, in connection with a remarketing upon their purchase, in accordance with a redemption or repayment pursuant to their terms, or otherwise, by one or more remarketing firms, acting as principals for their own accounts or as our agents. Any remarketing firm will be identified and the terms of its agreements, if any, with us and its compensation will be described in the applicable prospectus supplement. Remarketing firms may be deemed to be underwriters of the offered securities under the Securities Act.

Delayed Delivery Contracts

If we so indicate in the applicable prospectus supplement, we may authorize agents, underwriters or dealers to solicit offers by certain institutions to purchase securities from us pursuant to contracts providing for payment and delivery on a specified future date. The applicable prospectus supplement will describe the conditions to those contracts and the commission payable for solicitation of those contracts.

General Information

We may have agreements with the agents, dealers, underwriters and remarketing firms to indemnify them against certain civil liabilities, including liabilities under the Securities Act, or to contribute with respect to payments that the agents, dealers or underwriters may be required to make. Agents, dealers, underwriters and remarketing firms may be customers of, engage in transactions with or perform services for us in the ordinary course of their businesses.

Each underwriter, dealer and agent participating in the distribution of any of the securities that are issuable in bearer form will agree that it will not offer, sell or deliver, directly or indirectly, securities in bearer form in the United States or to United States persons, other than qualifying financial institutions, during the restricted period, as defined in United States Treasury Regulations Section 1.163-5(c)(2)(i)(D)(7).

Any underwriters that are qualified market makers on the NASDAQ Capital Market may engage in passive market making transactions in the common stock on the NASDAQ Capital Market in accordance with Regulation M under the Exchange Act, during the business day prior to the pricing of the offering, before the commencement of offers or sales of the common stock. Passive market makers must comply with applicable volume and price limitations and must be identified as passive market makers. In general, a passive market maker must display its bid at a price not in excess of the highest independent bid for such security; if all independent bids are lowered below the passive market maker's bid, however, the passive market maker's bid must then be lowered when certain purchase limits are exceeded. Passive market making may stabilize the market price of the securities at a level above that which might otherwise prevail in the open market and, if commenced, may be discontinued at any time.

In compliance with guidelines of the Financial Industry Regulatory Authority, or FINRA, the maximum consideration or discount to be received by any FINRA member or independent broker dealer may not exceed 8% of the aggregate amount of the securities offered pursuant to this prospectus and the applicable prospectus supplement.

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.

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, 2020 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 MORE 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 on Form S-3 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.

INFORMATION INCORPORATED 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, 2020, filed with the SEC on March 15, 2021;
- our Quarterly Report on Form 10-Q for the fiscal quarter ended March 31, 2021, filed with the SEC on May 14, 2021;
- our Definitive Proxy Statement on Schedule 14A, filed with the SEC on April 20, 2021;
- our Current Report on Form 8-K, filed with the SEC on April 30, 2021; and
- the description of our common stock contained in Exhibit 4.1 to our Annual Report on Form 10-K for the fiscal year ended December 31, 2020, filed with the SEC on March 15, 2021, 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 prior to effectiveness of such registration statement, until we file a post-effective amendment that indicates 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. Any statement contained herein or in a document incorporated or deemed to be incorporated by reference herein shall be deemed to be modified or superseded for purposes hereof or of the related prospectus supplement to the extent that a statement contained herein or in any other subsequently filed document which is also incorporated or deemed to be incorporated herein modifies or supersedes such statement. Any such statement so modified or superseded shall not be deemed, except as so modified or superseded, to constitute a part of this prospectus.

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.

PART II

INFORMATION NOT REQUIRED IN PROSPECTUS

ITEM 14. OTHER EXPENSES OF ISSUANCE AND DISTRIBUTION.

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

SEC registration fee	$	16,365
NASDAQ Capital Market listing fee		(1)
FINRA filing fee		(1)
Legal fees and expenses		(1)
Accounting fees and expenses		(1)
Transfer agent and registrar fees and expenses		(1)
Miscellaneous fees and expenses		(1)
Total	$	(1)

(1) These fees are calculated based on the securities offered and the number of issuances and accordingly cannot be estimated at this time.

ITEM 15. 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 16. EXHIBITS AND FINANCIAL STATEMENT SCHEDULES.

(a) Exhibits.

1.1	Form(s) of underwriting agreement(s).+
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).
3.1	Certificate of Incorporation of the Company (incorporated by reference to Exhibit 3.1 to the Company's Current Report on Form 8-K, filed with the Commission on February 9, 2007).
3.2	Certificate of Amendment of Certificate of Incorporation of the Company (incorporated by reference to Exhibit 3.1 to the Company's Current Report on Form 8-K, filed with the Commission on November 26, 2013).
3.3	Certificate of Amendment of Certificate of Incorporation of the Company (incorporated by reference to Exhibit 3.1 to the Company's Current Report on Form 8-K, filed with the SEC on June 4, 2019).
3.4	Bylaws of the Company (incorporated by reference to Exhibit 3.2 to the Company's Current Report on Form 8-K, filed with the Commission on February 9, 2007).
3.5	Certificate of Amendment of the Bylaws of the Company (incorporated by reference to Exhibit 3.1 to the Company's Current Report on Form 8-K, filed with the Commission on August 25, 2020).
4.1	Form of Indenture, between the Registrant and one or more trustees to be named (incorporated by reference to Exhibit 4.8 to the Company's Registration Statement on Form S-3, Registration No. 333-207149).

4.2	Form of Common Stock Warrant Agreement and Warrant Certificate (incorporated by reference to Exhibit 4.9 to the Company's Registration Statement on Form S-3, Registration No. 333-207149).
4.3	Form of Preferred Stock Warrant Agreement and Warrant Certificate (incorporated by reference to Exhibit 4.10 to the Company's Registration Statement on Form S-3, Registration No. 333-207149).
4.4	Form of Debt Securities Warrant Agreement and Warrant Certificate (incorporated by reference to Exhibit 4.11 to the Company's Registration Statement on Form S-3, Registration No. 333-207149).
4.5	Description of the Company's Common Stock, par value $0.001 per share (incorporated by reference to Exhibit 4.1 to the Company's Annual Report on Form 10-K, filed with the Commission on March 15, 2021).
4.6	Form of Debt Securities.+
4.7	Specimen Preferred Stock Certificate and Form of Certificate of Designation of Preferred Stock.+
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).++

* 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.

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 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 under the Securities Act of 1933 to any purchaser:

(i) Each prospectus filed by the registrant pursuant to Rule 424(b)(3) shall be deemed to be part of the registration statement as of the date the filed prospectus was deemed part of and included in the registration statement; and

(ii) Each prospectus required to be filed pursuant to Rule 424(b)(2), (b)(5), or (b)(7) as part of a registration statement in reliance on Rule 430B relating to an offering made pursuant to Rule 415(a)(1)(i), (vii), or (x) for the purpose of providing the information required by section 10(a) of the Securities Act of 1933 shall be deemed to be part of and included in the registration statement as of the earlier of the date such form of prospectus is first used after effectiveness or the date of the first contract of sale of securities in the offering described in the prospectus. As provided in Rule 430B, for liability purposes of the issuer and any person that is at that date an underwriter, such date shall be deemed to be a new effective date of the registration statement relating to the securities in the registration statement to which that prospectus relates, and the offering of such securities at that time shall be deemed to be the initial bona fide offering thereof. Provided, however, that no statement made in a registration statement or prospectus that is part of the registration statement or made in a document incorporated or deemed incorporated by reference into the registration statement or prospectus that is part of the registration statement will, as to a purchaser with a time of contract of sale prior to such effective date, supersede or modify any statement that was made in the registration statement or prospectus that was part of the registration statement or made in any such document immediately prior to such effective date.

(5) 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.

(6) 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.

(7) 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.

(8) To file an application for the purpose of determining the eligibility of the trustee to act under subsection (a) of Section 310 of the Trust Indenture Act in accordance with the rules and regulations prescribed by the Commission under Section 305(b)(2) of the Trust Indenture Act.

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.

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-3 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 June 14, 2021.

CAPRICOR THERAPEUTICS, INC.

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

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, Ph.D. Linda Marbán, Ph.D.	Chief Executive Officer and Director *(Principal Executive Officer)*	June 14, 2021
/s/ Anthony J. Bergmann Anthony J. Bergmann	Chief Financial Officer *(Principal Financial and Accounting Officer)*	June 14, 2021
/s/ Frank Litvack, M.D. Frank Litvack, M.D.	Executive Chairman and Director	June 14, 2021
/s/ Earl M. Collier, Jr. Earl M. Collier, Jr.	Director	June 14, 2021
/s/ Louis V. Manzo Louis V. Manzo	Director	June 14, 2021
/s/ George W. Dunbar, Jr. George W. Dunbar, Jr.	Director	June 14, 2021
/s/ David B. Musket David B. Musket	Director	June 14, 2021

Exhibit 23.1

CONSENT OF INDEPENDENT REGISTERED PUBLIC ACCOUNTING FIRM

We hereby consent to the incorporation by reference, in this Amendment Number 1 to the Registration Statement on Form S-3 of our report dated March 15, 2021, 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, 2020.

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
June 14, 2021