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DELTA REPORT

10-K

CAPR - CAPRICOR THERAPEUTICS, IN

10-K - DECEMBER 31, 2023 COMPARED TO 10-K - DECEMBER 31, 2022

The following comparison report has been automatically generated

TOTAL DELTAS	4152
CHANGES	323
DELETIONS	2320
ADDITIONS	1509

REFINITIV

UNITED STATES

SECURITIES AND EXCHANGE COMMISSION

WASHINGTON, D.C. 20549

FORM 10-K

þ **Annual Report Pursuant to Section 13 or 15(d) of the Securities Exchange Act of 1934**

for the fiscal year ended December 31, 2022 2023

or

□ **Transition Report Pursuant to Section 13 or 15(d) of the Securities Exchange Act of 1934**

for the transition period from to

Commission File Number: 001-34058

CAPRICOR THERAPEUTICS, INC.

(Exact Name Of Registrant As Specified In Its Charter)

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

10865 Road to the Cure, Suite 150, San Diego, California 92121

(Address of principal executive offices including zip code)

(858) 727-1755

(Registrant's telephone number, including area code)

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

Title of Each Class	**Trading Symbol(s)**	**Name of Each Exchange on Which Registered**
Common Stock, par value $0.001 per share	CAPR	The Nasdaq Capital Market

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

None

Indicate by check mark if the registrant is a well-known seasoned issuer, as defined in Rule 405 of the Securities Act. □ Yes þ No

Indicate by check mark if the registrant is not required to file reports pursuant to Section 13 or Section 15(d) of the Act. □ Yes þ No

Indicate by check mark whether the registrant (1) has filed all reports required to be filed by Section 13 or 15(d) of the Securities Exchange Act of 1934 during the preceding 12 months (or for such shorter period that the registrant was required to file such reports), and (2) has been subject to such filing requirements for the past 90 days. þ Yes □ No

Indicate by check mark whether the registrant has submitted electronically every Interactive Data File required to be submitted pursuant to Rule 405 of Regulation S-T (§232.405 of this chapter) during the preceding 12 months (or for such shorter period that the registrant was required to submit such files). Yes þ No □

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

Large accelerated filer	☐	Accelerated filer	☐
Non-accelerated filer	þ	Smaller reporting company	þ
		Emerging growth company	☐

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

Indicate by check mark whether the registrant has filed a report on and attestation to its management's assessment of the effectiveness of its internal control over financial reporting under Section 404(b) of the Sarbanes-Oxley Act (15 USC. 7262(b)) by the registered public accounting firm that prepared or issued its audit report. ☐

If securities are registered pursuant to Section 12(b) of the Act, indicate by check mark whether the financial statements of the registrant included in the filing reflect the correction of an error to previously issued financial statements. ☐

Indicate by check mark whether any of those error corrections are restatements that required a recovery analysis of incentive-based compensation received by any of the registrant's executive officers during the relevant recovery period pursuant to §240.10D-1(b). ☐

Indicate by check mark whether the registrant is a shell company (as defined in Rule 12b-2 of the Exchange Act). ☐ Yes þ No

The aggregate market value of the registrant's common stock held by non-affiliates of the registrant as of June 30, 2022 June 30, 2023 was approximately $82,668,886, $119,715,277, based on the last reported sale of the registrant's common stock on The Nasdaq Capital Market on June 30, 2022 June 30, 2023 of $3.49 $4.78 per share.

As of March 16, 2023 March 7, 2024, there were 25,255,154 31,399,667 shares of the registrant's common stock, par value $0.001 per share, issued and outstanding.

DOCUMENTS INCORPORATED BY REFERENCE

Part III of this Annual Report on Form 10-K incorporates information by reference from the definitive proxy statement for the registrant's 2023 2024 Annual Meeting of Stockholders.

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

FORWARD-LOOKING STATEMENTS

This Annual Report on Form 10-K contains "forward-looking statements" within the meaning of Section 27A of the Securities Act of 1933, or the Securities Act, and Section 21E of the Securities Exchange Act of 1934, or the Exchange Act. The forward-looking statements are only predictions and provide our current expectations or forecasts of future events and financial performance and may be identified by the use of forward-looking terminology, including the terms "believes," "estimates," "anticipates," "expects," "plans," "potential," "projects," "intends," "may," "will" or "should" or, in each case, their negative, or other variations or comparable terminology, though the absence of these words does not necessarily mean that a statement is not forward-looking. Forward-looking statements include all matters that are not historical facts and include, without limitation, statements about the development of our drug product candidates, including when we expect to undertake, initiate and complete clinical trials of our product candidates; expectation of or dates for commencement of clinical trials, trials; timing of study or trial results; manufacturing capabilities, investigational new drug filings, similar plans or projections; the regulatory approval of our drug candidates; candidates and dates for regulatory meetings; our ability to achieve product milestones and to receive milestone payments from commercial partners; our use of clinical research centers, third party third-party manufacturers and other contractors; our ability to find collaborative partners for research, development and commercialization of potential products; our or a designated third party's third-party's ability to manufacture products for clinical and commercial use; our ability to protect our patents and other intellectual property; our ability to market any of our products; our projected operating losses; losses and ability to operate as a going concern; the impact of taxes on our business, including our ability to utilize net operating losses; our ability to utilize our ability to compete against other companies and research institutions; the effect of potential strategic transactions on our business; acceptance of our products by doctors,

patients or payors and the availability of reimbursement for our product candidates; our ability to attract and retain key personnel; the volatility of our stock price; our ability to continue as a going concern; and other risks and uncertainties detailed in the section of this Annual Report on Form 10-K entitled "Risk Factors". These statements are subject to risks and uncertainties that could cause actual results and events to differ materially from those expressed or implied by such forward-looking statements. We caution the reader not to place undue reliance on these forward-looking statements, which reflect management's analysis only as of the date of this Annual Report on Form 10-K.

We intend that all forward-looking statements be subject to the safe-harbor provisions of the Private Securities Litigation Reform Act of 1995. Forward-looking statements are subject to many risks and uncertainties that could cause our actual results to differ materially from any future results expressed or implied by the forward-looking statements. Pharmaceutical and biotechnology companies have suffered significant setbacks in advanced clinical trials, even after obtaining promising earlier trial results and preclinical studies. Data obtained from such clinical trials are susceptible to varying interpretations, which could delay, limit or prevent regulatory approval. Readers are expressly advised to review and consider certain risk factors, which include risks associated with (1) our ability to successfully conduct clinical trials and preclinical studies for our product candidates, (2) our ability to obtain required regulatory approvals to develop, manufacture and market our product candidates, either on an accelerated basis or at all, (3) our ability to raise additional capital or to license our products on favorable terms, (4) our ability to execute our development plan on time and on budget, (5) our ability to identify and obtain additional product candidates, (6) our ability to raise enough capital to fund our operations, (7) our ability to protect our intellectual property rights, and (8) our compliance with legal and regulatory requirements as a public company. Although we believe that the assumptions underlying the forward-looking statements contained in this Annual Report on Form 10-K are reasonable, any of the assumptions could be inaccurate, and therefore there can be no assurance that such statements will be accurate. In light of the significant uncertainties inherent in the forward-looking statements included herein, the inclusion of such information should not be regarded as a representation by us or any other person that the results or conditions described in such statements or our objectives and plans will be achieved. Furthermore, past performance in operations and share price is not necessarily indicative of future performance. Except to the extent required by applicable laws or rules, we do not undertake to update any forward-looking statements or to announce publicly revisions to any of our forward-looking statements, whether resulting from new information, future events or otherwise.

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The following discussion should be read together with our consolidated financial statements and related consolidated notes contained in this Annual Report on Form 10-K. Results for the year ended December 31, 2022 December 31, 2023 are not necessarily indicative of results that may be attained in the future.

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PART I

ITEM 1. BUSINESS

Company Overview

Capricor Therapeutics, Inc. is a clinical-stage biotechnology company focused on the development of transformative cell and exosome-based therapeutics for treating Duchenne muscular dystrophy or DMD, ("DMD"), a rare form of muscular dystrophy which results in muscle degeneration and premature death, and other diseases with high unmet medical needs.

Our Programs Technology and Platforms

Cell Therapy (CAP-1002) for the Treatment of Duchenne Muscular Dystrophy (Phase III) Platform

Our core program is focused on the development and commercialization of a cell therapy (referred to herein as CAP-1002) comprised of cardiosphere-derived cells ("CDCs"), which are an endogenous a population of stromal cells isolated from donated cells of healthy human hearts currently being developed for the treatment of Duchenne muscular dystrophy ("DMD"). DMD. DMD is a rare, monogenic, X-linked muscle disease driven by the impaired production of functional dystrophin, which normally functions as a structural protein in muscle. The reduction of functional dystrophin in muscle cells leads to significant cell damage and ultimately causes muscle cell death and fibrotic replacement. CAP-1002 is designed to slow disease progression in DMD through the immunomodulatory, anti-inflammatory, and anti-fibrotic actions of CDCs, which are mediated by secreted exosomes laden with bioactive cargo. Among the cargo elements known to be bioactive in CDC-exosomes are microRNAs. Collectively, these non-coding RNA species alter gene expression in macrophages and other target cells, dialing down generalized inflammation and stimulating tissue regeneration in DMD (and in a variety of other inflammatory diseases). This mechanism of action, which is consistent with the changes observed in clinical studies to date in circulating inflammatory biomarkers, contrasts with that of exon-skipping oligonucleotides and gene therapy approaches which that aim to restore dystrophin expression. Our CAP-1002 cell therapy program for the treatment of DMD is a rare form of muscular dystrophy which results currently in muscle degeneration and premature death. Additionally, the absence of dystrophin in muscle cells leads to significant cell damage and ultimately causes muscle cell death and fibrotic replacement. The annual cost of care for patients with DMD is very high and increases with disease progression. We therefore believe that DMD represents a significant market opportunity for our product candidate, CAP-1002.

To date, we have completed two promising Phase 3 clinical trials investigating CAP-1002 for DMD. Data from the first trial, a Phase I/II trial named HOPE-Duchenne, suggested improvements in skeletal and cardiac endpoints. In HOPE-2, a Phase II clinical trial conducted development in the United States, CAP-1002 was used for which we expect to treat patients with late-stage DMD. In March 2022, we announced that the final one-year results from HOPE-2 were published in The Lancet showing that the trial met its primary efficacy endpoint of the mid-level dimension of the Performance of the Upper Limb ("PUL") v1.2 (p=0.01) and additional positive endpoints of full PUL v2.0 (p=0.04) and a cardiac endpoint of left ventricular ejection fraction (p=0.002). CAP-1002 was generally safe and well-tolerated throughout the studies. Additionally, we are conducting an open label extension ("OLE") study of the HOPE-2 trial in which 12 patients have elected to continue treatment of CAP-1002. We recently announced positive one-year and 18-month results from this ongoing OLE study. Data from the OLE study suggests disease modification with statistically significant differences in the PUL v2.0 scale in the CAP-1002 original treatment group when compared to the original placebo group from HOPE-2. In addition, disease progression was attenuated equally in both groups once patients began treatment in the OLE. CAP-1002 treatment during the OLE portion of the study continues to yield a consistent safety profile and has been well-tolerated throughout the study.

We are currently enrolling the HOPE-3, Phase III clinical study investigating CAP-1002 for the treatment of late-stage DMD patients for the potential approval of CAP-1002 in the United States. HOPE-3 is a multi-center, randomized, double-blind, placebo-controlled study currently designed to treat up to 68 subjects at approximately 15-20 investigative sites in the United States. The primary outcome measure will be the full PUL v2.0 at one-year. HOPE-3 will also measure various secondary endpoints including cardiac function assessments. We have currently treated over 30% of the patients in the currently designed study and have 11 active sites. At this time, our plans to conduct an interim analysis for sample size re-estimation and analysis of conditional power remain unchanged and we anticipate that these results will be top-line data available in the fourth quarter of this year.

Under our RMAT designation, we recently met with the FDA in a Type-B CMC meeting where we discussed our manufacturing plans in anticipation of a potential BLA application. In the meeting, we discussed our plans with respect to commercial manufacturing activities, including our potency assay and other product release criteria to support commercialization. We are awaiting the meeting minutes from the FDA, but at this time, we believe that we will need to

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add some patients to HOPE-3 who will be treated with product manufactured at our new San Diego facility, in order to support a potential BLA application. Our San Diego facility is designed to produce commercial-scale GMP CAP-1002 product and we believe that it will be available to manufacture CAP-1002 doses by the third quarter of 2023. We plan to request a follow-on Type B clinical meeting with FDA and expect to have further clarity following that meeting on this topic. Furthermore, at the request of the FDA, we have submitted the interim results from our HOPE-2 OLE for their review and we continue to discuss our pathway towards potential registration.

The regulatory pathway for CAP-1002 is supported by Regenerative Medicine Advanced Therapy ("RMAT") designation as well as orphan drug designation. If Capricor were to receive market approval for CAP-1002 by the U.S. Food and Drug Administration ("FDA"), Capricor would be eligible to receive a Priority Review Voucher based on its designation as a rare pediatric disease. Capricor has entered into two Commercialization and Distribution Agreements with Nippon Shinyaku, Co., Ltd. ("Nippon Shinyaku") appointing Nippon Shinyaku as its exclusive distributor of CAP-1002 in the United States and Japan. 2024.

Exosomes Platform (Preclinical)

Our exosome platform program consists of engineered Extracellular vesicles, including exosomes and microvesicles, are nano-scale, membrane-enclosed vesicles 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 the delivery of their cargo into the cytosol of target cells. Exosomes act as messengers to regulate the functions of neighboring or distant cells and have been shown to regulate functions such as cell survival, proliferation, inflammation and tissue regeneration. Their size, low or null immunogenicity and ability to communicate in native cellular language potentially make them an exciting new class of therapeutic agents with the potential to expand our ability to address complex biological responses. Because exosomes derived from CDCs (CAP-2003), both of which are cell-free substances, they can be stored, handled, reconstituted and administered in various stages of preclinical development. similar fashion to common biopharmaceutical products such as antibodies. Aspects of our exosomes exosome pipeline have been supported through collaborations and alliances. Our collaborations and research around exosomes include the National Institutes of Health ("NIH"), the National Institute of Allergy and Infectious Diseases ("NIAID"), Johns Hopkins University ("JHU"), the Department of Defense ("DoD"), the U.S. Army Institute of Surgical Research ("USAISR"), the National Institutes of Health ("NIH") and Cedars-Sinai Medical Center ("CSMC").

Engineered Exosome-Based Therapeutics Our platform builds on advances in fundamental RNA and Vaccines

We are focused on developing protein science, targeting technology and manufacturing, providing us the opportunity to potentially build a precision-engineered exosome platform technology that has the ability to deliver defined sets broad pipeline of effector molecules which exert their effects through defined mechanisms of action. We recently published new preclinical data on our StealthX™ platform showing the rapid development of a recombinant protein-based vaccine for immunization and prevention against SARS-CoV-2, the virus causing COVID-19. At this time, therapeutic candidates. Currently, we are developing exosome-based vaccines and therapeutics for infectious diseases, monogenic diseases and other potential indications. Our current strategy is focused on securing partners who will provide capital and additional resources to enable us to bring this program into the clinic, should we decide to do so. clinic.

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Objectives and Business Strategy

CDC-Derived Exosomes (CAP-2003) We believe that our cell therapy and exosome-based platforms can be used to develop novel therapeutics to treat a broad range of diseases. We intend to leverage our technology, collaborations and resources to develop therapeutics for diseases with high unmet needs. In pursuit of this objective, we intend to focus on the following activities:

CAP-2003 is the name of our exosomes product candidate which are derived from our CDCs. We have promising preclinical data in several indications from studies done utilizing CAP-2003 in our labs as well as in collaboration with other companies and academic institutions. In 2020, we filed an IND with the FDA to investigate the use of CAP-2003 in patients with DMD. The FDA has requested more

information related to manufacturing for this product candidate and we are evaluating the next steps for this program as we continue to further develop our exosome platform.

- continuing the development of our CAP-1002 program for the treatment of DMD in preparation for potential commercialization, which includes streamlining our manufacturing capabilities, furthering our commercial capabilities and securing additional partners in other markets around the world for the potential launch in the U.S., Japan and in other select territories;
- advancing our exosome technology for therapeutic development, focused on internal research, strategic partnerships and collaborations; and
- opportunistically evaluating strategic collaborations to accelerate development and commercialization timelines as well as potentially expand our pipeline within our core therapeutic areas.

Our Technologies History

Cardiosphere-Derived Cells (CAP-1002)

Capricor, Inc., a wholly-owned subsidiary of Capricor Therapeutics, was founded in 2005 as a Delaware corporation based on the innovative work of its founder, Eduardo Marbán, M.D., Ph.D. Our core cell therapy technology is based on cardiosphere-derived cells, a cardiac-derived cell therapy that was first identified in the academic laboratory of Capricor's scientific founder, Dr. Eduardo Marbán while he was Chief of Cardiology at JHU. Johns Hopkins. Since the its 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 We began 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-muscular and cardiac function. Preclinical and clinical data support explore the therapeutic concept potential of administering CDCs exosomes as a means to address conditions in which the skeletal or heart 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

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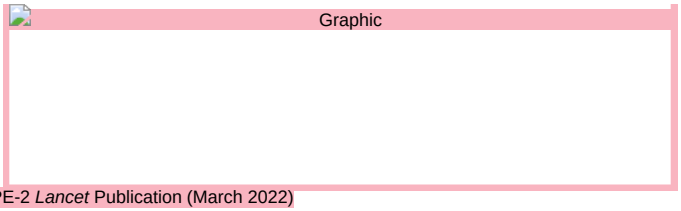
of CDCs to stimulate tissue repair and regeneration by first reducing inflammation, which then enables new healthy muscle to form, as was shown in the mouse model of DMD.

CDCs are derived from cardiospheres ("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 skeletal and heart muscles, with the goal of improving skeletal and cardiac 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.

Schematic summary of mechanism of action and clinical trials for CDCs (1)(2)



(1) Image adapted from HOPE-2 *Lancet* Publication (March 2022)
(2) The CADUCEUS, ALPHA and REGRESS studies were sponsored by academic investigators.

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 we learned that CDCs mediate most of their therapeutic activities through the secretion of extracellular vesicles. exosomes.

Exosomes act as messengers to regulate the functions We have assembled a scientific advisory board with cardiology and neurology experts, including DMD specialists. Our advisors include clinicians and researchers who are experts on DMD's skeletal and cardiac aspects. Moreover, some 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.

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The following table summarizes our active product development programs:

Product Candidate	Indication	Development Stage	Partner
CAP-1002 (allogeneic CDCs)	Duchenne muscular dystrophy*	HOPE-3 Phase III enrolling HOPE-2 Phase II completed**	Nippon Shinyaku Co., Ltd. (U.S. and Japan distribution rights)
Exosome protein-based vaccine (multivalent design)	SARS-CoV-2	Preclinical	
Engineered Exosomes (RNA, protein and small molecule delivery)	Evaluating	Preclinical	
CAP-2003 (CDC-exosomes)	Duchenne muscular dystrophy	IND submitted	

***** The FDA has granted orphan drug, RMAT, and Rare Pediatric Disease designations to CAP-1002 for the treatment of DMD.
**We are currently conducting an OLE study advisors lead clinical units at some of the HOPE-2 trial.

CAP-1002: Duchenne Muscular Dystrophy Program

Background on Duchenne Muscular Dystrophy

leading DMD is a rare form of muscular dystrophy which results in muscle degeneration and premature death. DMD affects approximately 1 in 3,600 male infants worldwide, and it is estimated that approximately 15,000 to 20,000 boys and young men are living with the disease centers in the United States and are actively involved in our drug development process and programs.

Capricor became public after the completion of a merger between Capricor and a subsidiary of Nile Therapeutics, Inc., a Delaware corporation ("Nile"), in 2013, where Capricor became a wholly-owned subsidiary of Nile and Nile formally changed its name to Capricor Therapeutics, Inc. Capricor Therapeutics was listed on the Nasdaq Capital Market shortly thereafter and currently trades under the symbol "CAPR". Capricor Therapeutics and Capricor have together raised approximately 200,000 worldwide. $145.0 million in equity capital (both privately and publicly) as well as approximately $90.0 million in non-dilutive funding from our partners including Nippon Shinyaku Co. Ltd., a Japanese corporation ("Nippon Shinyaku"), as well as government sources such as the NIH and the California Institute for Regenerative Medicine ("CIRM").

Core Therapeutic Areas

Duchenne muscular dystrophy (DMD): DMD results from is a rare, monogenic, X-linked muscle disease with mortality at a median age of approximately 30 years. There is no cure for DMD, and for the lack vast majority of patients, there are no satisfactory symptomatic or disease-modifying treatments. It is estimated that DMD occurs in approximately one in every 3,500 to 5,000 live male births and that the patient population is estimated to be approximately 15,000-20,000 in the United States. DMD pathophysiology is driven by the impaired production of functional dystrophin, which normally functions as a structural protein caused by a gene mutation. in muscle. The lack reduction of dystrophin, an important structural component of muscle cells, causes them to have increased susceptibility to damage and to progressively die. Additionally, the absence of functional dystrophin in muscle cells leads to significant cell damage and ultimately causes muscle cell death and fibrotic replacement. In DMD patients, heart muscle cells progressively die Due to reduced functional dystrophin protein, affected individuals generally experience the following symptoms, although disease severity and are replaced with scar tissue. This cardiomyopathy eventually leads to heart failure, which is currently the leading cause of death among those with DMD. life expectancy vary:

- muscle damage characterized by inflammation and fibrosis beginning at an early age;
- muscle weakness and progressive loss of muscle function beginning in the first few years of life;
- decline of ambulation and respiratory function after the age of seven;
- total loss of ambulation in the pre-teenage or early teenage years;
- progressive loss of upper extremity function during mid- to late-teens;
- respiratory and/or cardiac failure, resulting in death before the age of 30; and
- cardiomyopathy eventually leads to heart failure, which is currently the leading cause of death among those with DMD.

Patients with DMD experience progressive 5

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Glucocorticoid treatment, the current standard of care, has been shown to improve muscle weakness and degeneration starting at an early age. Generally, a loss strength temporarily, prolong the period of ambulation occurs after and slow the first decade progression of life DMD. However, glucocorticoid use is associated with well-known adverse side effects, including: severe weight gain, stunted growth, weakening of bone structure (osteoporosis) and eventually the patients suffer respiratory metabolic dysfunctions, among others. Despite recent therapeutic advances, DMD represents a significant societal and cardiac failure. Their lifespan is abbreviated and averages less than three decades. economic burden. The annual cost of care for patients with DMD is very high and increases with disease progression. The economic burden includes costs associated with hospital admissions, medications, frequent doctor visits, assistive devices, as well as indirect costs related to productivity losses for caregivers and costs due to pain, anxiety, social handicap as well as end-of-life care expenses. While there are many clinical initiatives in DMD, Capricor's program is one of the very few to focus on predominantly non-ambulant patients. These boys and young men are looking to maintain their function in their arms and hands and slow the progression of cardiomyopathy. We therefore believe that DMD represents a significant market opportunity for our product candidate, CAP-1002.

SARS-CoV-2: Coronaviruses are a large family of viruses that can cause illness in animals or humans. In humans, several known coronaviruses cause respiratory infections. These coronaviruses range from the common cold to more severe diseases such as severe acute respiratory syndrome ("SARS"), Middle East respiratory syndrome ("MERS") and COVID-19. SARS-CoV-2 is the novel coronavirus first identified in humans in 2019 and is the cause of COVID-19. The risk of mortality increases with age and the risk of severe disease and mortality increases for persons with certain pre-existing diseases or comorbid conditions (e.g. cardiovascular disease, diabetes, chronic lung disease, obesity). Since late 2021, infections have been dominated by subvariants of the Omicron strain which continue to displace previous circulating strains by evading immunity and spreading more efficiently resulting in an increased risk of breakthrough infection among the vaccinated. As the world pivots from the kinds of responses needed during the pandemic, vulnerable populations need a vaccine strategy to provide protective durable immunity against current and emerging variants of SARS-CoV-2 to reduce the infection and disease burden for both the public and the health care systems globally. We therefore believe that SARS-CoV-2 represents a potential market opportunity for our exosome-based vaccine program.

Our Pipeline – Key Programs

CAP-1002: Duchenne Muscular Dystrophy Program: CAP-1002 is designed to slow disease progression in DMD through the immunomodulatory, anti-inflammatory, and anti-fibrotic actions of CDCs, with the goal of improving skeletal and cardiac muscle function in patients with DMD.

Phase 3 (HOPE-3) Clinical Trial: HOPE-3 is a Phase 3, multi-center, randomized, double-blind, placebo-controlled clinical trial comprised of two cohorts evaluating the safety and efficacy of CAP-1002 in participants with DMD and impaired skeletal muscle function who are on a stable regimen of systemic glucocorticoids. Non-ambulatory and ambulatory boys who meet eligibility criteria are randomly assigned to receive either CAP-1002 or placebo every 3 months for a total of 4 doses during the first 12-months of the study. Approximately 102 eligible study subjects will participate in this dual-cohort study. Enrollment has been completed for Cohort A where 61 subjects were randomized to either CAP-1002 or placebo in a 1:1 ratio and is intended to support a Biologics License Application ("BLA") submission. In December 2023, we announced a positive outcome of the interim futility analysis for Cohort A of HOPE-3, which was reviewed by the Data Safety Monitoring Board ("DSMB"). This resulted in a favorable recommendation to continue the HOPE-3 trial as planned. At this time, we expect to have topline data available from Cohort A in the fourth quarter of 2024. Cohort A uses product manufactured at our Los Angeles facility.

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Performance of the Upper Limb (PUL entry items) (1)

(CAP-1002 current DMD target population)

Graphic

(1) Image adapted from HOPE-2 *Lancet* Publication (March 2022)

Phase III HOPE-3 Clinical Trial

HOPE-3 Enrollment is a multi-center, randomized, double-blind, placebo-controlled study currently designed to treat up to 68 subjects at approximately 15-20 investigative sites in the United States. The clinical trial underway for Cohort B, which is designed to evaluate the safety and efficacy of repeat, intravenous ("IV") doses of CAP-1002, in boys and young men with evidence of skeletal muscle impairment regardless of ambulatory status and who are on a stable regimen of systemic glucocorticoids. HOPE-3 enroll approximately 44 participants will be randomized to either CAP-1002 or placebo in a 1:1 ratio. The active arm A primary efficacy and safety analysis will be performed for each individual cohort at month 12, following 4 administrations of participants CAP-1002 or placebo. We plan to complete enrollment for Cohort B in the trial will receive 150 million cardiosphere-derived cells (CAP-1002) via intravenous infusion every 3 months for a total second quarter of 4 doses. 2024. Cohort B uses product manufactured at our San Diego facility.

The study's primary outcome measure of the HOPE-3 study will be the PUL Performance of the Upper Limb ("PUL") v2.0, a validated tool specifically designed for assessing high (shoulder), mid (elbow) and distal (wrist and hand) function, functions, with a conceptual framework reflecting weakness progression in upper limb function. HOPE-3 will also measure various secondary endpoints including cardiac function assessments. Enrollment is currently ongoing at 11 active clinical trial investigative sites

Under our RMAT designation, in the United States. third quarter of 2023, we met with the FDA in a Type-B meeting where we discussed our manufacturing plans in anticipation of potentially submitting a BLA application. In this meeting, we affirmed alignment with respect to our Phase 3, HOPE-3 program. Additionally, we discussed our plans with respect to commercial manufacturing activities, including our potency assay and other product release criteria to support commercialization. We plan to meet with FDA in the first quarter of 2024 to continue discussing our pathway to BLA. In the upcoming Type-B meeting, we intend to discuss our further CMC plans for commercial launch, if approved, with the aim of expediting our BLA submission pathway. Our ultimate goal is to file a BLA allowing for the use of CAP-1002 commercial product manufactured at our San Diego facility.

Phase II 2 HOPE-2 Clinical Trial Trial:

HOPE-2 was a randomized, double-blind, placebo-controlled clinical trial which was conducted at multiple sites located in the United States. We randomized 20 States and was completed in 2021. The clinical trial was designed to evaluate the safety and efficacy of repeated, intravenous doses of CAP-1002, in boys and young men with evidence of skeletal muscle impairment regardless of ambulatory status. Approximately 90% of the patients in our HOPE-2 clinical trial. Approximately 80% of the patients study were non-ambulant and all patients were on a stable regimen of steroids. Demographic and baseline characteristics were similar between the two treatment groups. The clinical final one-year results from HOPE-2 were published in *The Lancet* in March 2022, showing that the trial was designed to evaluate the safety and efficacy of repeat, IV, doses of CAP-1002, in boys and young men with evidence of skeletal muscle impairment regardless of ambulatory status and who were on a stable regimen of systemic glucocorticoids.

While there are many clinical initiatives in DMD, HOPE-2 was one of the very few to focus on predominantly non-ambulant patients. These boys and young men are looking to maintain what function they have in their arms and hands, and Capricor's previous Phase I/II (HOPE-Duchenne) study of a single intracoronary dose of CAP-1002 provided promising preliminary evidence on the retention or slowing of the loss of upper limb function.

The met its primary efficacy endpoint of the HOPE-2 trial was the relative change in patients' abilities to perform manual tasks that relate to activities of daily living and are important to their quality of life. These abilities were measured through the Performance mid-level dimension of the Upper Limb PUL test. In the HOPE-2 study, we have evaluated these through both the v1.2 (p=0.01) and additional positive endpoints of full PUL 1.2 and 2.0 versions. v2.0 (p=0.04). Although the PUL v1.2 for the mid-level was the primary endpoint established for the trial, we also conducted an analysis using the PUL v2.0 as the FDA suggested the use of the updated PUL v2.0 as the primary efficacy endpoint in support of a Biologics License Application ("BLA"). HOPE-2 assessed the mid-level dimension of the PUL which evaluates one's ability to use muscles extending from the elbow to the hand, which muscles are essential for operating wheelchairs and performing other daily functions. In HOPE-2, additional secondary and exploratory endpoints such as cardiac function, pulmonary function, quality of life and additional measures were included.

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

In September 2021, we reported the final 12-month results from the HOPE-2 study and subsequently, in March 2022, we announced that the results were published in *The Lancet*. The final data showed improvements in upper limb and cardiac function with p-values of less than p=0.05 in multiple measures. BLA. Left ventricular ejection fraction (LVEF), a global measure of cardiac pump function, decreased in the placebo group over time, but improved in the CAP-1002 group, showing a 107% slowing of the progression of cardiac disease (p=0.002). Additionally, the final data suggested global improvements in cardiac function as measured by indexed volumes (LVESV, LVEDV). These are surrogate measures of cardiac function and are considered significant in terms of relevance to long term long-term outcomes. Furthermore, the data showed a reduction in the biomarker CK-MB, an enzyme that is only released when there is cardiac muscle cell damage. In normal human subjects, there is typically no CK-MB measurable in the blood. It is well accepted that continuous muscle cell damage in DMD leads to pathologically high enzyme levels associated with cardiac muscle cell loss. In HOPE-2, treatment with CAP-1002 was associated with a reduction in CK-MB levels as compared to placebo. To our knowledge, this is the first clinical study in DMD that correlates cardiac functional stabilization with a reduction of a biomarker of cell damage. With the exception of steroids, preservation of function in DMD is uncommon. The results of the placebo patients were consistent with natural history, but in the treated group, most patients were stable or improved on these endpoints throughout the one-year treatment period.

CAP-1002 was generally safe and well tolerated throughout the study. With the exception of hypersensitivity

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reactions early in the clinical trial, which were mitigated with a common pre-medication regimen, there were no serious safety signals identified by the HOPE-2 DSMB.

HOPE-2 Study Results - 12-Month Final Efficacy Data

12-Month Difference in Change from Baseline†

	Δ, CAP-1002 vs. Placebo (n=8, n=12)	**p-value**
Skeletal-Muscle (Upper Limb Function)		
Mid-level PUL (v1.2)*	2.6	0.01
Shoulder + Mid + Distal PUL (v1.2)	3.2	0.02
Shoulder + Mid + Distal PUL (v2.0)	1.8	0.04
Cardiac Function		
LV Ejection Fraction %*	4.0	0.002
LV End-Diastolic Volume, Indexed mL/m2	-12.4‡	0.03
LV End-Systolic Volume, Indexed mL/m2	-4.2‡	0.01
Creatine Kinase-MB (% of total CK)	-2.2‡	0.02

ITT (intent to treat) population shown

† Non-parametric mixed model repeated measures analysis with percentile ranked baseline, treatment, visit, visit-by-treatment interaction, PUL entry-item score at stratification, and site as model effects. Percentile ranked change from baseline converted back to original scale

‡Negative value favors CAP-1002

*Graphed figures below

PUL v1.2 mid-level dimension (1)


Graphic

Left ventricular ejection fraction % (LVEF) (1)


Graphic

(1) Images adapted from HOPE-2 *Lancet* Publication (March 2022)

*Phase 2 HOPE-2-Open Label Extension ("OLE") Clinical Trial*Safety:

CAP-1002 was generally safe and well tolerated throughout the study. With the exception of hypersensitivity reactions early in the We are currently conducting an OLE clinical trial which were mitigated with a common pre-medication regimen, there were no serious safety signals identified by the HOPE-2 Data and Safety Monitoring Board ("DSMB").

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Open Label Extension (OLE) HOPE-2 Clinical Trial

We are conducting an open-label extension available to all patients who participated in the HOPE-2 study which includes those patients who received placebo. After the completion

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Table of the HOPE-2 study, all Contents

12 patients stopped treatment for approximately 392 days, which is referred elected to as the gap phase. Then all eligible patients who wished to remain on treatment re-entered the OLE study where they received CAP-1002 (150 million cells per infusion) every three months. Patients in the ongoing study are being evaluated using the PUL v2.0 as well as cardiac assessments at certain time-points.

continue treatment. We recently announced positive one-year and 18-month two-year results from this ongoing OLE study. Data from the OLE study continues to show evidence for suggests disease modification with statistically significant differences in the PUL v2.0 scale in the CAP-1002 original treatment group when compared to the original placebo group from HOPE-2. The HOPE-2-OLE study previously met its primary endpoint at the one-year timepoint on the PUL v2.0 scale (p=0.02). At the two-year timepoint, data showed statistically significant differences in the PUL v2.0 in the OLE treatment group when compared to the original rate of decline of the placebo group from HOPE-2 after one-year (p=0.021). LVEF was measured using cardiac magnetic resonance imaging (cMRI) and six of nine patients showed improvements in heart function with CAP-1002 treatment compared to their final assessment at the end of the HOPE-2 study. CAP-1002 treatment during the OLE portion of the study continues to yield a consistent safety profile and has been well-tolerated throughout the study. We plan At this time, we expect to report the 24-month have three-year data available from this OLE data study in the second quarter of this year. 2024.

Phase I/II 1/2 HOPE-Duchenne Clinical Trial

In 2017, we completed the: HOPE-Duchenne was a randomized, controlled, multi-center Phase I/II HOPE-Duchenne 1/2 clinical trial which was designed to evaluate the safety and exploratory efficacy of CAP-1002 in patients with cardiomyopathy associated with DMD. Twenty-five patients were randomized in a 1:1 ratio to receive either CAP-1002 on top of usual care or usual care only. In patients receiving CAP-1002, 25 million cells were infused into each of their three main coronary arteries for a total dose of 75 million cells. It was a one-time treatment, and the last patient was infused in September 2016. Patients were observed over the course of 12 months. Efficacy was evaluated according to several exploratory outcome measures. This study was funded in part through a grant award (the "CIRM Award") from the California Institute for Regenerative Medicine ("CIRM"). CIRM. In January 2019, this study was published in the online issue of *Neurology*, , the medical journal of the American Academy of Neurology.

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

CAP-1002 was generally safe and well-tolerated in the HOPE-Duchenne trial. There was no significant difference in the incidences of treatment-emergent adverse events in either group. There were no early study discontinuations due to adverse events.

CAP-1002 - Investigator Sponsored Clinical Trials: Capricor provided CAP-1002 for investigational purposes in two clinical trials sponsored by CSMC. These cells were developed as part of the Company's past research and development efforts. The first trial is known as "Regression of Fibrosis and Reversal of Diastolic Dysfunction in HFpEF Patients Treated with Allogeneic CDCs (the "REGRESS trial"). Dr. Eduardo Marbán is the named principal investigator under the study. The second trial is known as "Pulmonary Arterial Hypertension treated with Cardiosphere-derived Allogeneic Stem Cells (the "ALPHA trial"). Enrollment of the REGRESS and ALPHA trials have been completed. In December 2023, the results from the ALPHA study were published in the peer-reviewed journal, *eBioMedicine*, a *Lancet* journal. The Phase 1 results were shown to be safe, with no short-term clinical safety adverse events related to the investigational product, which was the primary outcome measure of the study. Although this study was only designed to assess the safety of the CAP-1002 infusions, investigators observed encouraging changes that might indicate the 16 patients who received CAP-1002 infusions had improved cardiopulmonary health.

Exosome Platform: Our exosome platform program consists of engineered exosomes and exosomes derived from CDCs (CAP-2003), both of which are in preclinical development.

Exosome Platform: Engineered Exosome-Based Vaccines: The StealthX™ vaccine is a proprietary vaccine developed internally by Capricor utilizing exosomes that were engineered to express either spike or nucleocapsid proteins on the surface. Preclinical results from murine and rabbit models published in the peer-reviewed journal, *Microbiology Spectrum*, showed the StealthX™ vaccine, resulted in robust antibody production, potent neutralizing antibodies, a strong T-cell response and a favorable safety profile. These effects were obtained with administration of only nanogram amounts of protein and without adjuvant or synthetic lipid nanoparticles. Exosomes offer a new antigen delivery system that could potentially be utilized to rapidly generate multivalent protein-based vaccines. Recently, we were selected to be part of Project NextGen, an initiative by the U.S. Department of Health and Human Services to advance a pipeline of new, innovative vaccines providing broader and more durable protection for COVID-19. As part of Project NextGen, the National Institute of Allergy and Infectious Diseases, part of the National Institutes of Health, will conduct a Phase 1 clinical study with our StealthX™ vaccine, subject to regulatory approval. At this time, we have submitted an Investigational New Drug Application ("IND") to the FDA for our StealthX™ vaccine, which is currently under review and we anticipate that if the IND is approved, that NIAID plans to initiate this trial in late 2024. NIAID's Division of

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Microbiology and Infectious Diseases (DMID) would oversee the study. If NIAID finds that our StealthX™ vaccine meets its criteria for safety and efficacy, they may consider our program for a funded Phase 2.

Exosome Platform: Engineered Exosome-Based Therapeutics: We are focused on developing a precision-engineered exosome platform technology that has the potential to deliver defined sets of effector molecules that exert their effects through defined mechanisms of action. At this time, we are exploring the use of our proprietary StealthX™ exosome platform for a broad range of therapeutic applications including targeted RNA, protein and small molecule therapeutics to treat or prevent a variety of diseases.

Exosome Platform: CDC-Derived Exosomes (CAP-2003): CAP-2003 is the name of our exosomes product candidate which are derived from CDCs. We have promising preclinical data in several indications from studies done utilizing CAP-2003 in our labs as well as in collaboration with other academic institutions. In 2020, we filed an IND with the FDA to investigate the use of CAP-2003 in patients with DMD. The FDA has requested more information related to manufacturing for this product candidate and we are evaluating the next steps for this program as we continue to further develop our exosome platform.

These programs represent our core technology and products.

*Regulatory Designations for CAP-1002 for the treatment of DMD***The following table summarizes our active product development programs:**
In April 2015, the

Product Candidate	Indication	Development Stage	Distributor/Partner/Collaborator
CAP-1002 (allogeneic CDCs)	Duchenne muscular dystrophy*	Phase 3 (HOPE-3) Cohort A: enrollment complete Cohort B: enrolling Phase 2 (HOPE-2) completed**	Nippon Shinyaku Co., Ltd. (U.S. and Japan rights)
Exosome protein-based vaccine (multivalent design)	SARS-CoV-2	IND submitted	Collaboration with National Institute of Allergy and Infectious Diseases
Engineered Exosomes (RNA, protein and small molecule delivery)	Evaluating	Preclinical	
CAP-2003 (CDC-exosomes)	Duchenne muscular dystrophy	IND submitted	

***** The FDA has granted orphan drug, designation Regenerative Medicine Advanced Therapy, and Rare Pediatric Disease designations to CAP-1002 for the treatment of DMD. Orphan drug designation
**We are currently conducting an OLE study of the HOPE-2 trial.

Manufacturing, Supply and Distribution

We have developed proprietary Chemistry, Manufacturing and Controls (“CMC”) and manufacturing capabilities that allow manufacturing and testing of our product candidates to support both clinical development as well as potential commercialization. Manufacturing is granted by subject to extensive regulations that impose procedural and documentation requirements. These regulations govern record keeping, manufacturing processes and controls, personnel, quality control and quality assurance. We continue to enhance, refine and optimize our manufacturing processes. We currently maintain two manufacturing facilities for the FDA's Office production of Orphan Drug Products CAP-1002. In 2022, we completed construction of our San Diego Research and Development Facility (GMP pilot manufacturing facility) as we prepare for potential commercial launch, subject to drugs intended FDA approval. This facility was designed to treat be compliant with U.S. and European Medicines Agency (“EMA”) standards. This facility is currently producing CAP-1002 product for clinical use in Cohort B of our HOPE-3 trial and supporting our OLE trials. We are preparing for a rare disease or condition affecting fewer than 200,000 people potential commercial launch, subject to FDA approval, from the San Diego facility. It is to be determined whether the

FDA will ultimately approve commercial manufacturing at this facility. Our second manufacturing facility is located within our laboratory, research and manufacturing facilities at CSMC in Los Angeles pursuant to a Facilities Lease. In that portion of the United States or a disease or condition leased premises where we manufacture CAP-1002 and may manufacture our exosome products for potential clinical use, we believe that affects more than 200,000 people in the United States and for which there is no reasonable expectation that the cost of developing and making available in the United States a drug for this type of disease or condition will be recovered from sales in the United States for that drug. This designation confers special incentives we follow, current good manufacturing practices to the drug developer, including tax credits on extent that they are applicable to the stage of our clinical development costs and prescription drug user fee waivers and may allow programs although our facility at CSMC is not current Good Manufacturing Practices ("cGMP") qualified for a seven-year period of market exclusivity in the United States upon FDA approval.

In July 2017, the FDA granted Rare Pediatric Disease Designation to commercial at this time. Capricor manufactured CAP-1002 for the treatment of DMD. The FDA defines a "rare pediatric disease" as a serious or life-threatening disease in which the serious or life-threatening manifestations primarily affect individuals aged from birth to 18 years and that affects fewer than 200,000 individuals in the United States, or a disease or condition that affects more than 200,000 people in the United States and for which there is no reasonable expectation that the cost of developing and making available in the United States a drug for this type of

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disease or condition will be recovered from sales in this facility for our current and previous studies including Cohort A of the United States HOPE-3 trial. Our Facilities Lease at CSMC has an expiration date of July 31, 2026.

In the third quarter of 2023, we met with the FDA, where we affirmed alignment with respect to our Phase 3, HOPE-3 program where the FDA agreed to allow us to submit a BLA supported by results using product manufactured at our Los Angeles manufacturing site. At this time, we are planning on utilizing such data for that drug. Under the FDA's Rare Pediatric Disease Priority Review Voucher program, upon the approval submission of a qualifying New BLA, but it is to be determined whether the FDA will ultimately approve commercial manufacturing at this facility. The sale of commercial product produced in our Los Angeles facility may require the consent of CSMC.

We are required to obtain and maintain certain other licenses in connection with our manufacturing facilities and activities. At this time, we have a Drug Application ("NDA") or BLA Manufacturing License issued from the State of California for the treatment of a rare pediatric disease, the sponsor of such application would be eligible both our San Diego and CSMC facilities. We are currently applying for a Rare Pediatric Disease Priority Review Voucher Tissue Bank License from the State of California for both of our facilities.

Additionally, in February 2024, we entered into a License and Services Agreement with Azzur Cleanrooms-on-Demand – San Diego, LLC (the "Azzur License Agreement") pursuant to which we have been granted an exclusive license to use certain space and the non-exclusive right to use certain equipment and property for our early phase clinical and/or pre-clinical manufacturing purposes. We are planning to use this facility to manufacture our exosome-based vaccine for potential clinical use to support our collaboration with NIAID.

Manufacturing Process for CAP-1002

The manufacturing process for CAP-1002 begins with material from an entire heart from a donor that was collected from an organ procurement organization ("OPO"). This tissue is then taken to the lab where the cells are isolated, expanded, and processed through a series of proprietary unit operations. After expanding, processing, release testing and quality review, the CAP-1002 product becomes available for administration to patients participating in clinical trials. CAP-1002 is cryo-preserved, enabling us to produce large lots that can be used frozen and then administered to obtain priority review for a subsequent NDA or BLA. The Priority Review Voucher may be sold or transferred an unlimited number of times. patients as needed.

In February 2018, we were notified by*Manufacturing Process for Engineered-Exosome Technologies*

We have also made significant progress planning the FDA Office of Tissues and Advanced Therapies, that we were granted the RMAT designation for CAP-1002 next steps for the treatment manufacturing process for our exosome product candidates. We believe these developments will enable us to scale up our manufacturing capabilities and allow us to manufacture enough material for early-stage clinical development, subject to FDA approval. We have explored the use of DMD. various cell sources to generate our exosomes for preclinical and potential clinical use.

Manufacturing Process for CDC-Exosomes (CAP-2003)

The FDA grants process for manufacturing CAP-2003 starts with the RMAT designation to regenerative medicine therapies intended to treat, modify, reverse, or cure proprietary process of creating a serious or life-threatening disease or condition and for which preliminary clinical evidence indicates a potential to address unmet medical needs for that condition. The RMAT designation makes therapies eligible for cell bank from donor heart tissue through the same actions to expedite the development and review expansion of a marketing application that CDCs. Afterwards, exosomes are available to drugs that receive fast track or breakthrough therapy designation – including increased meeting opportunities, early interactions to discuss any potential surrogate or intermediate endpoints and the potential to support accelerated approval. CAP-1002 is one of the few therapies currently in development to help late-stage patients with DMD. To receive the RMAT designation, we submitted data isolated from the HOPE-Duchenne Trial.

Collaboration Material Agreements, License Agreements & Collaborations

To accelerate the advancement of our technologies, we have entered into, and intend to seek other opportunities to form collaborations with a diverse group of strategic partners. We have forged productive collaborations with pharmaceutical and biotechnology companies, government agencies, academic laboratories, and research institutes with diverse area expertise and resources in as effort to advance our programs.

Commercialization and Distribution Agreement with Nippon Shinyaku (Territory: United States)

On January 24, 2022, Capricor entered into an Exclusive a Commercialization and Distribution Agreement (the "U.S. Distribution Agreement") with Nippon Shinyaku, a Japanese corporation. Under the terms of the U.S. Distribution Agreement, Capricor appointed Nippon Shinyaku as its exclusive distributor in the United States of CAP-1002 for the treatment of DMD.

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Under the terms of the U.S. Distribution Agreement, Capricor will be responsible for the conduct of the HOPE-3 trial as well as the manufacturing of CAP-1002. Nippon Shinyaku will be responsible for the distribution of CAP-1002 in the United States. Pursuant to the U.S Distribution Agreement, Capricor received an upfront payment of $30.0 million in the first quarter of 2022. The first milestone payment of $10.0 million was paid upon completion of the interim futility analysis of the HOPE-3 trial whereby the outcome was determined to be not futile. Additionally, there are potential milestones totaling up to $90.0 million leading up to and including the BLA approval. Further, there are various potential sales-based milestones, if commercialized, tied to the achievement of certain sales thresholds for annual net sales of CAP-1002 of up to $605.0 million. Further, pursuant to the U.S. Distribution Agreement, Capricor has the obligation to sell commercial product to Nippon Shinyaku, subject to regulatory approval, and in addition Capricor will have the right to receive a meaningful mid-range double-digit share of product revenue and additional development and sales-based milestone payments, if achieved. In the first quarter of 2022, Capricor received an upfront payment of $30.0 million. Pursuant to the terms of the U.S. Distribution Agreement, there are potential additional sales and development milestone payments of up to $705.0 million. revenue.

Commercialization and Distribution Agreement with Nippon Shinyaku (Territory: Japan)

On February 10, 2023, Capricor entered into an Exclusive a Commercialization and Distribution Agreement (the "Japan Distribution Agreement") with Nippon Shinyaku. Under the terms of the Japan Distribution Agreement, Capricor appointed Nippon Shinyaku as its exclusive distributor in Japan of CAP-1002 for the treatment of DMD.

Under the terms of the Japan Distribution Agreement, Capricor expects to receive received an upfront payment of $12 million $12.0 million in the first quarter of 2023 and in addition, Capricor will may potentially receive additional development and sales-based milestone payments of up to approximately $89 million $89.0 million, subject to foreign currency exchange rates, and a meaningful double-digit share of product revenue. Nippon Shinyaku will be responsible for the distribution of CAP-1002 in Japan. Capricor will be responsible for the conduct of clinical development in Japan, as may be required, as well as the manufacturing of CAP-1002. Subject to regulatory approval, Capricor will sell commercial product to Nippon Shinyaku. Shinyaku in Japan. In addition, Capricor or its designee will hold the Marketing Authorization in Japan if the product is approved in that territory.

Collaboration Agreement with NIH

In 2023, we were notified by the NIH that we had been selected to be part of Project NextGen, an initiative by the U.S. Department of Health and Human Services to advance a pipeline of new, innovative vaccines providing broader and more durable protection for COVID-19. As part of Project NextGen, the National Institute of Allergy and Infectious Diseases, part of the National Institutes of Health, will conduct a Phase 1 clinical study with our StealthX™ vaccine, subject to regulatory approval. NIAID's Division of Microbiology and Infectious Diseases (DMID) will oversee the study. Under the terms of the collaboration, Capricor will be responsible for supplying investigational product for the trial.

Cooperative Research and Development Agreement with the U.S. Army Institute of Surgical Research

In 2018, we entered into a Cooperative Research and Development Agreement with the USAISR, pursuant to which we agreed to cooperate in research and development on the evaluation of our CAP-2003 for the treatment of trauma

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related injuries and conditions. In 2021, in collaboration with the USAISR, we published a manuscript demonstrating CAP-2003 as a potential antishock therapeutic, if delivered early.

Other CAP-1002 Programs

CAP-1002 - Investigator Sponsored Clinical Trials

Capricor provided CAP-1002 for investigational purposes in two clinical trials sponsored by CSMC. These cells were developed as part of the Company's past research and development efforts. The first trial is known as "Regression of Fibrosis and Reversal of Diastolic Dysfunction in HFpEF Patients Treated with Allogeneic CDCs (the "REGRESS trial"). Dr. Eduardo Marbán is the named principal investigator under the study. The second trial is known as "Pulmonary Arterial Hypertension treated with Cardiosphere-derived Allogeneic Stem Cells (the "ALPHA trial"). In this trial, the investigational product was infused into the venous system via catheter into the right atrium. CSMC informed us that the enrollment of the REGRESS and ALPHA trials have been completed and as a result, we do not expect to receive any further material revenues from these trials.

CAP-1002 for the Treatment of Cardiac Conditions

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

Engineered Exosome Platform

StealthX™ Platform

We are focused on developing a precision-engineered exosome platform technology that has the ability to deliver defined sets of effector molecules which exert their effects through defined mechanisms of action. We recently published new preclinical data on our StealthX™ platform showing the rapid development of a recombinant protein-based vaccine for immunization and prevention against SARS-CoV-2, the virus causing COVID-19. The data explored the therapeutic potential of Capricor's proprietary StealthX™ platform, which generated two vaccine candidates (STX-S and STX-N), that independently, and in combination (STX-S+N), induced a strong immune response against two SARS-CoV-2 proteins, spike and nucleocapsid. Results showed that this multivalent, protein-based vaccine candidate has the potential to achieve potent, longer lasting immunization, broaden reactivity and improve T-cell response with only nanograms of protein without any adjuvant. The data from this study suggests that StealthX™ could potentially deliver a more potent vaccine with broader immunity than is currently available, by combining the advantages of both mRNA and recombinant protein vaccines into a potentially superior, rapidly generated, low-dose vaccine.

The current study used engineered exosomes to express either SARS-CoV-2 spike (StealthX-Spike, STX-S) or nucleocapsid (StealthX-Nucleocapsid, STX-N) protein on the exosome surface rapidly, a timeframe similar to mRNA vaccines. When administered as a single product, both STX-S and STX-N induced strong immunization with the production of a potent humoral and cellular immune response simultaneously. These effects were obtained with administration of only nanograms of protein without the use of any adjuvant or lipid nanoparticles which further supports the potential safety profile of this product candidate. The study also investigated the combination of STX-S and STX-N, namely STX-S+N, in two independent animal models. Administration of this multivalent, low dose protein-based vaccine resulted in increased, persistent antibody production, potent neutralizing antibodies with cross-reactivity to other variants of concern, and strong T-cell response. The results show efficacy of this multivalent protein-based vaccine for SARS-CoV-2 in model systems and suggests that other vaccines or therapeutics could potentially be rapidly developed using the same StealthX™ platform.

At this time, we are developing exosome-based vaccines and therapeutics for infectious diseases, monogenic diseases and other potential indications. Our platform builds on advances in fundamental RNA and protein science, targeting technology and manufacturing, providing us the opportunity to potentially build a broad pipeline of new therapeutic candidates. We plan to continue research investigating these vaccine candidates including conducting IND-enabling studies.

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These programs represent our core technology and products.

Intellectual Property and Proprietary Know-How

Our goal is to obtain, maintain and enforce patent rights for our products, formulations, processes, methods of use and other proprietary technologies, preserve our trade secrets, and operate without knowingly infringing on the valid and enforceable proprietary rights of other parties, both in the United States and abroad. Our policy is to actively seek to obtain, where appropriate, the broadest intellectual property protection possible for our current product candidates and any future product candidates, proprietary information and proprietary technology through a combination of contractual arrangements and patents, both in the United States and abroad. Even patent protection, however, may not always afford us with complete protection against competitors who seek to circumvent our patents. If we fail to adequately protect or enforce our intellectual property rights or secure rights to patents of others, the value of our intellectual property rights would diminish. To this end, we require all of our employees, consultants, advisors and other contractors to enter into confidentiality agreements that prohibit the disclosure and use of confidential information and, where applicable, require disclosure and assignment to us of the ideas, developments, discoveries and inventions relevant to our technologies and important to our business.

The development of complex biotechnology products such as ours typically includes the early discovery of a technology platform – often in an academic institution – followed by increasingly focused development around a product opportunity, including identification and definition of a specific product candidate and development of scalable manufacturing processes, formulations, patient selection and treatment regimes, and delivery and dosage regimens. As a result, biotechnology products are often protected by several families of patent filings that are made at different times in the development cycle and cover different aspects of the product. Earlier filed broad patent applications directed to the discovery of the platform technology thus usually expire ahead of patents covering later developments such as scalable manufacturing processes and dosing regimens. Patent expirations on products may therefore span several years and vary from country to country based on the scope of available coverage. Our patents, or patent applications, if issued and upon payment of patent maintenance fees, would expire as early as 2024 and as late as 2043 or beyond depending on any patent term adjustment or patent term extension. There are also limited opportunities to obtain extensions of patent terms in certain countries.

Intellectual Property Rights for Capricor's Technology - CAP-1002 and Exosomes

Capricor has entered into exclusive license agreements for intellectual property rights related to certain cardiac-derived cells with Università Degli Studi Di Roma La Sapienza (the "University of Rome"), JHU and CSMC. Capricor has also entered into an exclusive license agreement for intellectual property rights related to exosomes with CSMC and JHU. In addition, Capricor has filed patent applications related to the technology developed by its own scientists.

University of Rome License Agreement

Capricor and the University of Rome entered into a License Agreement, dated June 21, 2006 (the "Rome License Agreement"), which provides for the grant of an exclusive, world-wide, royalty-bearing license by the University of Rome to Capricor (with the right to sublicense) to develop and commercialize licensed products under the licensed patent rights in all fields.

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Pursuant to the Rome License Agreement, Capricor paid the University of Rome a license issue fee, is currently paying minimum annual royalties in the amount of 20,000 Euros per year, and is obligated to pay a lower-end of a mid-range double-digit percentage on all royalties received as a result of sublicenses granted, which are net of any royalties paid to third parties under a license agreement from such third party third-party to Capricor. The minimum annual royalties are creditable against future royalty payments.

The Rome License Agreement will, unless extended or sooner terminated, remain in effect until the later of the last claim of any patent or until any patent application comprising licensed patent rights has expired or been abandoned. Under the terms of the Rome License Agreement, either party may terminate the agreement should the other party become insolvent or file a petition in bankruptcy. Either party may terminate the agreement upon the other party's material breach, provided that the breaching party will have up to 90 days to cure its material breach. Capricor may also terminate for any reason upon 90 days' written notice to the University of Rome.

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The Johns Hopkins University License Agreements

License Agreement for CDCs

Capricor and JHU entered into an Exclusive License Agreement, effective June 22, 2006 (the "JHU License Agreement"), which provides for the grant of an exclusive, world-wide, royalty-bearing license by JHU to Capricor (with the right to sublicense) to develop and commercialize licensed products and licensed services under the licensed patent rights in all fields and a nonexclusive right to the know-how. Various amendments were entered into to revise certain provisions of the JHU License Agreement. Under the JHU License Agreement, Capricor is required to exercise commercially reasonable and diligent efforts to develop and commercialize licensed products covered by the licenses from JHU.

Pursuant to the JHU License Agreement, JHU was paid an initial license fee and, thereafter, Capricor is required to pay minimum annual royalties on the anniversary dates of the JHU License Agreement. The minimum annual royalties are creditable against a low single-digit running royalty on net sales of products and net service revenues, which Capricor is also required to pay under the JHU License Agreement, which running royalty may be subject to further reduction in the event that Capricor is required to pay royalties on any patent rights to third parties in order to make or sell a licensed product. In addition, Capricor is required to pay a low double-digit percentage of the consideration received by it from sublicenses granted and is required to pay JHU certain defined development milestone payments upon the successful completion of certain phases of its clinical studies and upon receiving approval from the FDA. The maximum aggregate amount of milestone payments payable under the JHU License Agreement, as amended, is $1,850,000. In March 2022, Capricor paid the $250,000 development milestone related to the Phase II 2 study pursuant to the terms of the JHU License Agreement. The next milestone is triggered upon successful completion of a full Phase III 3 study for which a payment of $500,000 will be due.

The JHU License Agreement will, unless sooner terminated, continue in effect in each applicable country until the date of expiration of the last to expire patent within the patent rights, or, if no patents are issued, then for twenty years from the effective date. Under the terms of the JHU License Agreement, either party may terminate the agreement should the other party become insolvent or file a petition in bankruptcy or fail to cure a material breach within 30 days after notice. In addition, Capricor may terminate for any reason upon 60 days' written notice.

License Agreement for Exosome-based Vaccines and Therapeutics

Capricor and JHU entered into an Exclusive License Agreement (the "JHU Exosome License Agreement"), effective April 28, 2021 for its co-owned interest in certain intellectual property rights related to exosome-mRNA vaccines and therapeutics. The JHU Exosome License Agreement provides provided for the grant of an exclusive, world-wide, worldwide, royalty-bearing license of JHU's co-owned rights by JHU to Capricor, with the right to sublicense, in order to conduct research using the patent rights and know-how and to develop and commercialize products in the field using the patent rights and know-how.

Pursuant to the JHU Exosome License Agreement, JHU was paid an upfront license fee of $10,000 and Capricor has agreed to reimburse JHU for certain fees and costs incurred in connection with the prosecution of certain patent rights.

Additionally, Capricor is required to meet certain development milestones for which a milestone payment fee shall be due and is obligated to pay low single-digit royalties on sales of royalty-bearing products as well as a double-digit percentage of any non-royalty consideration received from any sublicenses, subject to certain exclusions. The above-mentioned royalties are subject to reduction in the event Capricor becomes obligated to pay royalties on one or more third party patents as a requirement to make or sell a licensed product. In addition, Capricor will, beginning with the third year of the JHU Exosome License Agreement, be obligated to pay JHU a minimum annual royalty which is non-refundable but will be credited against royalties incurred by Capricor for the year in which the minimum annual royalty becomes due.

The JHU Exosome License Agreement will, unless sooner terminated, continue in each country until the date of expiration of the last to expire patent included within the patent rights in that country, or if no patents issue, then for 20 years. The JHU Exosome License Agreement may be was terminated by Capricor upon 90 days' written notice in its discretion and with 60 days' notice with respect to any particular patent or application or as to any particular licensed product. The JHU Exosome License Agreement may also be terminated by either party if the other party fails to perform or otherwise on December 15, 2023.

breaches any of its obligations and fails to cure such breach within a 60-day cure period commencing upon notice. A material breach by Capricor may include (a) a delinquency with respect to payment or reporting; (b) the failure by Capricor to timely achieve a specified milestone or otherwise failing to diligently develop, commercialize, and sell licensed products throughout the term of the JHU Exosome License Agreement; (c) non-compliance with record keeping or audit obligations; (d) voluntary bankruptcy or insolvency of Capricor; and (e) non-compliance with Capricor's insurance obligations.

Cedars-Sinai Medical Center License Agreements

License Agreement for CDCs

On January 4, 2010, Capricor entered into an Exclusive License Agreement with CSMC (the "Original CSMC License Agreement"), for certain intellectual property related to its CDC technology. In 2013, the Original CSMC License Agreement was amended twice resulting in, among other things, a reduction in the percentage of sublicense fees which would have been payable to CSMC. Effective December 30, 2013, Capricor entered into an Amended and Restated Exclusive License Agreement with CSMC (the "Amended CSMC License Agreement"), which amended, restated, and superseded the Original CSMC License Agreement, pursuant to which, among other things, certain definitions were added or amended, the timing of certain obligations was revised and other obligations of the parties were clarified.

The Amended CSMC License Agreement provides for the grant of an exclusive, world-wide, royalty-bearing license by CSMC to Capricor (with the right to sublicense) to conduct research using the patent rights and know-how and develop and commercialize products in the field using the patent rights and know-how. In addition, Capricor has the exclusive right to negotiate for an exclusive license to any future rights arising from related work conducted by or under the direction of Dr. Eduardo Marbán on behalf of CSMC. In the event the parties fail to agree upon the terms of an exclusive license for any future rights, Capricor will have a non-exclusive license to such future rights, subject to royalty obligations.

Pursuant to the Original CSMC License Agreement, CSMC was paid a license fee and Capricor was obligated to reimburse CSMC for certain fees and costs incurred in connection with the prosecution of certain patent rights. Additionally, Capricor is required to meet certain spending and development milestones.

Pursuant to the Amended CSMC License Agreement, Capricor remains obligated to pay low single-digit royalties on sales of royalty-bearing products as well as a low double-digit percentage of the consideration received from any sublicenses or other grant of rights. The above-mentioned royalties are subject to reduction in the event Capricor becomes obligated to obtain a license from a third party third-party for patent rights in connection with the royalty-bearing product.

The Amended CSMC License Agreement will, unless sooner terminated, continue in effect on a country by country basis until the last to expire of the patents covering the patent rights or future patent rights. Under the terms of the Amended CSMC License Agreement, unless waived by CSMC, the agreement shall automatically terminate: (i) if Capricor ceases, dissolves or winds up its business operations; (ii) in the event of the insolvency or bankruptcy of Capricor or if Capricor makes an assignment for the benefit of its creditors; (iii) if performance by either party jeopardizes the licensure, accreditation or tax exempt status of CSMC or the agreement is deemed illegal by a governmental body; (iv) within 30 days for non-payment of royalties; (v) after 90 days' notice from CSMC if Capricor fails to undertake commercially reasonable efforts to exploit the patent rights or future patent rights; (vi) if a material breach has not been cured within 90 days; or (vii) if Capricor challenges any of the CSMC patent rights. If Capricor fails to undertake commercially reasonable efforts to exploit the patent rights or future patent rights, and fails to cure that breach after 90 days' notice from CSMC, instead of terminating the license, CSMC has the option to convert any exclusive license to Capricor to a non-exclusive or co-exclusive license. Capricor may terminate the agreement if CSMC fails to cure any material breach within 90 days after notice.

On March 20, 2015, August 5, 2016, December 26, 2017, June 20, 2018, and July 27, 2021, Capricor and CSMC have entered into a number of several amendments to the Amended CSMC License Agreement, pursuant to which the parties agreed to add and delete certain patent applications from the list of scheduled patents and extend the timing of certain development milestones, among other things. Capricor reimbursed CSMC for certain attorneys' fees and filing fees incurred in connection with the additional patent applications.

We recently received a letter from CSMC alleging that pursuant to the Amended CSMC License Agreement between CSMC and Capricor, Capricor has certain overdue payment obligations to CSMC arising out of a milestone payment received by Capricor pursuant to the U.S. Distribution Agreement entered into between Capricor and Nippon Shinyaku. The notice letter requests that Capricor cure the alleged breaches of the Amended CSMC License Agreement, and reserves CMSC's purported right to terminate the Amended CSMC License

Agreement if such alleged breaches are not cured. We dispute the allegations in the letter from CSMC and intend to vigorously defend our position and pursue all available remedies, but there is no guarantee that any disputes that we have with CSMC will be resolved or if resolved, will not result in our incurring certain payment and other obligations.

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License Agreement for Exosomes

On May 5, 2014, Capricor entered into an Exclusive License Agreement with CSMC (the "Exosomes License Agreement"), for certain intellectual property rights related to CDC-derived exosomes technology. The Exosomes License

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

Pursuant to the Exosomes License Agreement, CSMC was paid a license fee and Capricor reimbursed CSMC for certain fees and costs incurred in connection with the preparation and prosecution of certain patent applications. Additionally, Capricor is required to meet certain non-monetary development milestones and is obligated to pay low single-digit royalties on sales of royalty-bearing products as well as a single-digit percentage of the consideration received from any sublicenses or other grant of rights. The above-mentioned royalties are subject to reduction in the event Capricor becomes obligated to obtain a license from a third party third-party for patent rights in connection with the royalty bearing product.

The Exosomes License Agreement will, unless sooner terminated, continue in effect on a country by country basis until the last to expire of the patents covering the patent rights or future patent rights. Under the terms of the Exosomes License Agreement, unless waived by CSMC, the agreement shall automatically terminate: (i) if Capricor ceases, dissolves or winds up its business operations; (ii) in the event of the insolvency or bankruptcy of Capricor or if Capricor makes an assignment for the benefit of its creditors; (iii) if performance by either party jeopardizes the licensure, accreditation or tax exempt status of CSMC or the agreement is deemed illegal by a governmental body; (iv) within 30 days for non-payment of royalties; (v) after 90 days if Capricor fails to undertake commercially reasonable efforts to exploit the patent rights or future patent rights; (vi) if a material breach has not been cured within 90 days; or (vii) if Capricor challenges any of the CSMC patent rights. If Capricor fails to undertake commercially reasonable efforts to exploit the patent rights or future patent rights and fails to cure that breach after 90 days' notice from CSMC, instead of terminating the license, CSMC has the option to convert any exclusive license to Capricor to a non-exclusive or co-exclusive license. Capricor may terminate the agreement if CSMC fails to cure any material breach within 90 days after notice.

On February 27, 2015, June 10, 2015, August 5, 2016, December 26, 2017, June 20, 2018, September 25, 2018, August 19, 2020, August 28, 2020, and March 19, 2021, Capricor and CSMC have entered into a number of several amendments to the Exosomes License Agreement. Collectively, these amendments added additional patent applications and patent families to the Exosomes License Agreement,

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

Sponsored Research Agreement with Johns Hopkins University

On April 1, 2020 we entered into a Sponsored Research Agreement (the "SRA") with JHU pursuant to which researchers in the lab of Dr. Stephen Gould performed certain research activities in connection with our engineered exosomes program. Pursuant to the SRA, we funded certain research activities. This SRA expired in accordance with its terms on March 31, 2022.

Cell Line License Agreement with Life Technologies

On March 7, 2022, Capricor entered into a non-exclusive cell line license agreement with Life Technologies Corporation, a subsidiary of Thermo Fisher Scientific, Inc., for the supply of certain cells which we will use in connection with the development of our exosomes platform. An initial license fee payment was made in the first quarter of 2022 and additional milestone fees may become due based on the progress of our development program.

Manufacturing Patents and Proprietary Rights

Capricor currently maintains two Our goal is to obtain, maintain and enforce patent rights for our products, formulations, manufacturing facilities. We recently completed construction processes, methods of use and other proprietary technologies, preserve our trade secrets, and operate without knowingly infringing on the valid and enforceable proprietary rights of other parties, both in the United States and abroad. Our policy is to actively seek to obtain, where appropriate, the broadest and focused intellectual property protection possible for our San Diego Research current product candidates and Development Facility any future product candidates, proprietary information and proprietary technology through a combination of contractual arrangements and patents, both in the United States and abroad. Even patent protection, however, may not always afford us with complete protection against competitors who seek to circumvent our patents. If we fail to adequately protect or enforce our intellectual property rights or secure rights to patents of others, the value of our intellectual property rights would diminish. To this end, we require all of our employees, consultants, advisors and

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other contractors to enter into confidentiality agreements that prohibit the disclosure and use of confidential information and, where applicable, require disclosure and assignment to us of the ideas, developments, discoveries and inventions relevant to our technologies and important to our business.

The development of complex biotechnology products such as ours typically includes the early discovery of a new GMP pilot technology platform – often in an academic institution – followed by increasingly focused development around a product opportunity, including identification and definition of a specific product candidate and development of manufacturing facility processes, formulations, patient selection and treatment regimes, and delivery and dosage regimens. As a result, biotechnology products are often protected by several families of patent filings that are made at different times in the development cycle and cover different aspects of the product. Earlier filed broad patent applications directed to the discovery of the platform technology thus usually expire ahead of patents covering later developments such as manufacturing processes, specific formulations, additional indications and dosing regimens. Patent expirations on products may therefore span several years and vary from country to country based on the scope of available coverage. Our patents, or patent applications, if issued and upon payment of patent maintenance fees, would expire as early as 2024 and as late as 2044 or beyond depending on any patent term adjustment or patent term extension. There are also limited opportunities to obtain extensions of patent terms in certain countries. The earlier expiring patents are generally directed to precursor cell populations or early non-DMD indications and administration methods. We have patents directed to CAP-1002 for the treatment of DMD that expire in 2038 unless otherwise extended

under Hatch-Waxman. We continue to file patents on processes, indications, dosage forms and formulations directed to extend the patent portfolio related to CAP-1002 and our exosome technologies as our technology progresses.

Our product candidates and our technologies are primarily protected by composition of matter and process (methods of use and methods of making) patents and patent applications as well as trade secrets. As of the date of this filing, we prepare have 46 granted patents and 15 pending patent applications covering processes and compositions of matter related to our CDC (CAP-1002) technology and 37 granted patents and 43 pending patent applications covering processes and compositions of matter related to our exosome technology.

Regulatory Designations

Regulatory Designations for CAP-1002 for the treatment of DMD

In 2015, the FDA granted orphan drug designation to CAP-1002 for the treatment of DMD. Orphan drug designation is granted by the FDA's Office of Orphan Drug Products to drugs intended to treat a rare disease or condition affecting fewer than 200,000 people in the United States or a disease or condition that affects more than 200,000 people in the United States and for which there is no reasonable expectation that the cost of developing and making available in the United States a drug for this type of disease or condition will be recovered from sales in the United States for that drug. This designation confers special incentives to the drug developer, including tax credits on the clinical development costs and prescription drug user fee waivers and may allow for a seven-year period of market exclusivity in the United States upon FDA approval.

In 2017, the FDA granted Rare Pediatric Disease Designation to CAP-1002 for the treatment of DMD. The FDA defines a "rare pediatric disease" as a serious or life-threatening disease in which the serious or life-threatening manifestations primarily affect individuals aged from birth to 18 years and that affects fewer than 200,000 individuals in the United States, or a disease or condition that affects more than 200,000 people in the United States and for which there is no reasonable expectation that the cost of developing and making available in the United States a drug for this type of disease or condition will be recovered from sales in the United States for that drug. Under the FDA's Rare Pediatric Disease Priority Review Voucher program, upon the approval of a qualifying New Drug Application ("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. If Capricor were to receive market approval for CAP-1002 by the FDA, Capricor would be eligible to receive a Priority Review Voucher based on its designation as a rare pediatric disease.

In 2018, we were granted the Regenerative Medicine Advanced Therapy ("RMAT") designation for CAP-1002 for the treatment of DMD. The FDA grants the RMAT designation to regenerative medicine therapies intended to treat, modify, reverse, or cure a serious or life-threatening disease or condition and for which preliminary clinical evidence indicates a potential commercial launch. This facility is being designed to be compliant with U.S., European Medicines Agency ("EMA"), and other address unmet medical needs for that condition. The RMAT designation makes therapies eligible

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international standards. This facility for the same actions to expedite the development and review of a marketing application that are available to drugs that receive fast track or breakthrough therapy designation – including increased meeting opportunities, early interactions to discuss any potential surrogate or intermediate endpoints and the potential to support accelerated approval. CAP-1002 is designed one of the few therapies currently in development to produce commercial-scale GMP CAP-1002 product for further clinical and potential commercial use. help late-stage patients with DMD. To receive the RMAT designation, we submitted data from the HOPE-Duchenne Trial.

Trademarks

Our second manufacturing facility is located within trademarks are generally filed to protect our laboratory corporate brand, our products and research our platform technologies. We typically file trademark applications and manufacturing facilities located at CSMC pursuant to a Facilities Lease. In that portion of pursue their registration in the leased premises where U.S., Europe and other markets in which we manufacture CAP-1002 and may manufacture our exosome products for potential clinical use, we believe that we follow, current

good manufacturing practices, to the extent that they are applicable to the stage of our clinical programs although our current facility does not meet commercial current Good Manufacturing Practices ("cGMP") standards. The CSMC manufacturing facility is licensed by the California Department of Public Health Food and Drug Branch to manufacture drugs. Capricor has been manufacturing CAP-1002 in this facility for our current and previous studies including the HOPE-3 trial, although we are planning to potentially use product from our San Diego facility to support the ongoing HOPE-3 trial. Our Facilities Lease has an expiration date of July 31, 2024. At this time, we are considering the possible extension of our current Facilities Lease.

anticipate using such trademarks. We are required the owner of several common law, and federal trademark registrations or applications in the U.S. including, but not limited to, obtain Capricor®, Capricor Therapeutics, STEALTHX™ and maintain the Capricor logo. Trademark protection varies in accordance with local law, and continues in some countries as long as the trademark is used and in other certain licenses in connection with our manufacturing facilities and activities. We have also been issued a Manufacturing License and a Tissue Bank License from countries as long as the State of California.

Additionally, we initiated a technology transfer with Lonza Houston, Inc., a leading global contract manufacturing organization to prepare trademark is registered. Trademark registrations generally are for the possibility of commercial launch to support product demand, as needed, for manufacturing of CAP-1002. Process development and cGMP readiness have been the focus of the work done by Lonza to date. We are evaluating whether it would be in our best interests to have Lonza move forward to complete the technology transfer process at this time. The next steps will be based on many factors, including our ability to produce GMP CAP-1002 product from our facility in San Diego as well as our discussions with regulatory agencies.

Manufacturing Process for CAP-1002

The manufacturing process for CAP-1002 begins with material from an entire heart from a donor that was collected from an organ procurement organization ("OPO"). This tissue is then taken to the lab where the cells are isolated, expanded, and processed through a series of proprietary unit operations. After expanding, processing, release testing and quality review, the CAP-1002 product becomes available for administration to patients participating in clinical trials. CAP-1002 is cryo-preserved, enabling us to produce large lots that can be frozen and then administered to patients as needed.

Manufacturing Process for Engineered-Exosome Technologies

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

Manufacturing Process for CDC-Exosomes (CAP-2003)

The process for manufacturing CAP-2003 starts with the proprietary process of creating a cell bank from donor heart tissue through the expansion of CDCs. Afterwards, exosomes are isolated from the expanded CDCs. After these exosomes are prepared, formulated, filled, tested, and validated, the exosomes product becomes available for clinical investigation, subject to regulatory approval.**fixed but renewable terms.**

Research and Development

Capricor's research and development program has been advanced in part through federal and state grants and loan awards totaling approximately $28 million $28.0 million to date. Our ongoing research and development activities primarily concern CDCs and exosomes and are focused on the characterization of their composition and actions, the evaluation of their therapeutic potential in selected disease settings, the development of next generation product candidates, and the identification of new technologies and indications.

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Competition

We are engaged in fields that are characterized by extensive worldwide research and competition by pharmaceutical companies, medical device companies, specialized biotechnology companies, hospitals, physicians, and academic institutions, government agencies and research organizations both in the United States and abroad. This There are many pharmaceutical companies, biotechnology companies, public and private universities, government agencies and research organizations that compete with us in developing various approaches to the treatment of DMD, which includes competitors both in the United States and internationally. With CAP-1002, we expect to face competition from existing products and products in development. In addition, at this time, there are four FDA conditionally approved exon skipping drugs: EXONDYS 51 (eteplirsen), AMONDYS 45 (casimersen) and VYONDYS 53 (golodirsen), which are phosphorodiamidate Morpholino oligomers (PMOs) approved for the treatment of DMD patients amenable to Exon 51, Exon 45 and Exon 53 skipping, respectively, and are marketed by Sarepta Therapeutics, Inc., and VILTEPSO (vitolarsen), a PMO approved for the treatment of DMD patients amenable to Exon 53 skipping, which is marketed by Nippon Shinyaku (U.S. subsidiary: NS Pharma, Inc.). In June 2023, the FDA approved Sarepta's BLA application seeking accelerated approval of Elevidys (delandistrogene moxeparvovec), its microdystrophin gene therapy, for the treatment of ambulant individuals with Duchenne. There are multiple other companies focused on developing genetic based therapies that target dystrophin mechanisms and non-dystrophin mechanisms for the treatment of DMD. Additionally, competition is particularly intense for products involving the treatment or prevention of diseases associated with COVID-19. The pharmaceutical industry is highly competitive, with a number of established, large pharmaceutical companies, as well as many smaller companies. companies being involved. Many of the organizations competing with us have substantially greater financial resources, larger research and development staffs and facilities, longer drug development history in obtaining regulatory approvals, and greater manufacturing and marketing capabilities than we do. There are many pharmaceutical companies, biotechnology companies, public and private universities, government agencies, and research organizations actively engaged in research and development of products which may target the same indications as our product candidates. We expect any future products and product candidates we develop to compete on the basis of, among other things, product efficacy and safety, time to market, price, extent of adverse side effects, and convenience of treatment procedures. The biotechnology and pharmaceutical industries are subject to rapid and significant technological change. The drugs that we are attempting to develop will have to compete with existing and future therapies. Our future success will depend in part on our ability to maintain a competitive position with respect to evolving cell therapy and exosome technologies. There can be no assurance that existing or future therapies developed by others will not render our potential products obsolete or noncompetitive. In addition, companies pursuing

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different but related fields represent substantial competition. These organizations also compete with us to attract patients for clinical trials, qualified personnel and parties for acquisitions, joint ventures, or other collaborations.

Government Regulation

The research, development, testing, manufacture, quality control, approval, labeling, packaging, storage, recordkeeping, serialization and tracking, promotion, advertising, distribution and marketing, post-approval monitoring and reporting, and export and import, among other things, of our product candidates are extensively regulated by governmental authorities in the United States and other countries. In the United States, the FDA regulates drugs under the Federal Food, Drug, and Cosmetic Act (the "FDCA"), and its implementing regulations. Failure to comply with the applicable U.S. requirements may subject us to administrative or judicial sanctions, such as the FDA's refusal to approve a pending NDA or a pending BLA, warning letters, product recalls, product seizures, total or partial suspension of production or distribution, injunctions and/or criminal prosecution. We would also be facing additional regulations and requirements from regulatory authorities in other countries outside the U.S. if we seek approval of our product candidates for sale or distribution within such countries.

FDA Approval Process for Drugs and Biologics

Pharmaceutical products, including biological products such as ours, may not be commercially marketed without prior approval from the FDA and comparable regulatory agencies in other countries. In the United States, the process for receiving such approval is long, expensive and risky, and includes the following steps:

- preclinical laboratory tests, animal studies, and formulation studies;
- submission to the FDA of an IND for human clinical testing, which must become effective before human clinical trials may begin;
- approval by an IRB at each clinical site before each trial may be initiated;
- adequate and well-controlled human clinical trials to establish the safety and efficacy of the drug for each indication;
- submission to the FDA of an NDA, for a drug, or BLA, for a biological product;
- satisfactory completion of an FDA advisory committee review, if applicable;
- satisfactory completion of an FDA inspection of the manufacturing facility or facilities at which the drug is produced to assess compliance with cGMP;
- a potential FDA audit of the preclinical pre-clinical and clinical trial sites that generated the data in support of the NDA or BLA;
- the ability to obtain clearance or approval of companion diagnostic tests, if required, on a timely basis, or at all;
- FDA review and approval of the NDA or BLA prior to any commercial marketing or sale of the drug in the United States; and

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- compliance with any post-approval requirements, including the potential requirement to implement a Risk Evaluation and Mitigation Strategy ("REMS"), and the potential requirement to conduct post-approval studies.

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

Regulation by U.S. and foreign governmental authorities is a significant factor affecting our ability to commercialize any of our products, as well as the timing of such commercialization and our ongoing research and development activities. The commercialization of drug products requires regulatory approval by governmental agencies prior to commercialization. Various laws and regulations govern or influence the research and development, non-clinical and clinical testing, manufacturing, processing, packaging, validation, safety, labeling, storage, record keeping, registration, listing, distribution, advertising, sale, marketing and post-marketing commitments of our products. The lengthy process of seeking these approvals, and the subsequent compliance with applicable laws and regulations, require expending substantial resources.

The results of preclinical testing, which include laboratory evaluation of product chemistry, formulation, toxicity and carcinogenicity animal studies to assess the potential safety and efficacy of the product and its formulations, details

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concerning the drug manufacturing process and its controls, and a proposed clinical trial protocol and other information must be submitted to the FDA as part of an IND that must be reviewed and become effective before clinical testing can begin. The study protocol and informed consent information for patients in clinical trials must also be submitted to an independent Institutional Review Board ("IRB") for approval covering each institution at which the clinical trial will be conducted. Once a sponsor submits an IND, the sponsor must wait 30 calendar days before initiating any clinical trials. If the FDA has comments or questions within this 30-day period, the issue(s) must be resolved to the satisfaction of the FDA before a clinical trial can begin. In addition, the FDA or IRB may impose a clinical hold on ongoing clinical trials if, among other things, it believes that a clinical trial either is not being conducted in accordance with FDA requirements or presents an unacceptable and significant risk to clinical trial patients. If the FDA imposes a clinical hold, clinical trials can only proceed under terms authorized by the FDA. If applicable, our preclinical and clinical studies must conform to the FDA's Good Laboratory Practice ("GLP"), and Good Clinical Practice ("GCP") requirements, respectively, which are designed to ensure the quality and integrity of submitted data and

protect the rights and well-being of study patients. Information for certain clinical trials also must be publicly disclosed within certain time limits on the clinical trial registry and results databank maintained by the NIH.

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

- Phase I 1 clinical trials typically are conducted in a small number of volunteers or patients to assess the early tolerability and safety profile, the pattern of drug absorption, distribution and metabolism, the mechanism of action in humans, and may include studies where investigational drugs are used as research to explore biological phenomena or disease processes;
- Phase II 2 clinical trials typically are conducted in a limited patient population with a specific disease in order to assess appropriate dosages and dose regimens, expand evidence of the safety profile and evaluate preliminary efficacy; and
- Phase III 3 clinical trials typically are larger scale, multicenter, well-controlled trials conducted on patients with a specific disease to generate enough data to statistically evaluate the efficacy and safety of the product, to establish the overall benefit-risk relationship of the drug and to provide adequate information for the labeling of the drug.

A therapeutic product candidate being studied in clinical trials may be made available for treatment of individual patients, intermediate-size patient populations, or for widespread treatment use under an expanded access protocol, under certain circumstances. Pursuant to the 21st Century Cures Act (the “Cures Act”), which was signed into law in December 2016, the manufacturer of one or more investigational products for the diagnosis, monitoring, or treatment of one or more serious diseases or conditions is required to make available, such as by posting on its website, its policy on evaluating and responding to requests for individual patient access to such investigational product.

Additionally, on May 30, 2018, the Trickett Wendler, Frank Mongiello, Jordan McLinn, and Matthew Bellina Right to Try Act of 2017 was signed into law. The law, among other things, provides a federal framework for certain patients to access certain investigational new drug products that have completed a Phase 1 clinical trial and that are

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undergoing investigation for FDA approval. Under certain circumstances, eligible patients can seek treatment without enrolling in clinical trials and without obtaining FDA authorization under an FDA expanded access program; however, manufacturers are not obligated to provide investigational new drug products under the current federal right to try law.

The results of the preclinical and clinical testing, chemistry, manufacturing and control information, proposed labeling and other information are then submitted to the FDA in the form of either an NDA or BLA for review and potential approval to begin commercial sales. Within 60 days following submission of the application, the FDA reviews an application submission to determine if it is substantially complete before the agency accepts it for filing. The FDA may refuse to file any application that it deems incomplete or not properly reviewable at the time of submission and may request additional information. In this event, the application must be resubmitted with the additional information. The resubmitted application also is subject to review before the FDA accepts it for filing. Once the submission is accepted for filing, the FDA begins an in-depth substantive review of the application. In responding to an NDA or BLA, the FDA may grant marketing approval, or issue a Complete Response Letter (“CRL”). A CRL generally contains a statement of specific conditions that must be met in order to secure final approval of an NDA or BLA and may require substantial additional testing or information. If and when those conditions have been met to the FDA's satisfaction, the FDA will typically issue an approval letter, which authorizes commercial marketing of the product with specific prescribing information for specific indications, and sometimes with specified post-marketing commitments and/or distribution and use restrictions imposed

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under a Risk Evaluation and Mitigation Strategy program. Any approval required from the FDA might not be obtained on a timely basis, if at all.

Disclosure of Clinical Trial Information

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

Orphan Drugs

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

If a therapeutic candidate with orphan drug designation subsequently receives the first FDA approval for such drug for the disease for which it has such designation, the therapeutic candidate is entitled to orphan product exclusivity, which means that the FDA may not approve any other applications to market the same therapeutic candidate for the same indication, for seven years, unless the sponsor of the subsequent application demonstrates clinical superiority, in the form of a greater efficacy, greater safety, or a major contribution to patient care. Orphan drug exclusivity, however, could also block the approval of one of our therapeutic candidates for seven years if a competitor obtains orphan drug designation and FDA approval of the same therapeutic candidate for the same condition or disease as our orphan-designated drug. For macromolecules, FDA considers a drug to be the same drug as an orphan-designated macromolecule if it contains the same principal molecular structural features, but not necessarily all of the same structural features.

In addition, as the FDA has interpreted the Orphan Drug Act, even if a previously approved same drug does not have unexpired orphan exclusivity, a demonstration of clinical superiority is required for a subsequent marketing application for the same orphan-designated drug for the same disease or condition to be awarded a 7-year period of orphan exclusivity upon marketing approval. In recent years, there have been multiple legal challenges to this FDA interpretation,

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and in August 2017, Congress amended the orphan drug provisions of the FDCA through enactment of the FDA Reauthorization Act of 2017 to codify FDA's longstanding interpretation. Section 527 of the FDCA now expressly provides that if a sponsor of an orphan-designated drug that is otherwise the same as an already approved drug for the same rare disease or condition is seeking orphan exclusivity, FDA shall require such sponsor to demonstrate that such drug is clinically superior to any already approved or licensed drug that is the same drug in order to obtain orphan drug exclusivity. Orphan drug exclusivity does not prevent the FDA from approving a different drug for the same disease or condition, or the same drug for a different disease or condition.

Expedited Development and Review Programs

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

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complete application is submitted, if the sponsor provides a schedule for the submission of the sections of the application, the FDA agrees to accept sections of the application and determines that the schedule is acceptable, and the sponsor pays any required user fees upon fees. Upon submission of the first section of the application FDA may revoke the Fast Track designation if it believes that the designation is no longer supported by data emerging in the clinical trial process.

Products may also be eligible for other types of FDA programs intended to expedite development and review, such as Breakthrough Therapy designation, priority review and accelerated approval. Under the Breakthrough Therapy program, products intended to treat a serious or life-threatening disease or condition may be eligible for the benefits of the Fast Track program when preliminary clinical evidence demonstrates that such product may have substantial improvement on one or more clinically significant endpoints over existing therapies. Additionally, FDA will seek to ensure the sponsor of a breakthrough therapy product receives timely advice and interactive communications to help the sponsor design and conduct a development program as efficiently as possible.

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

Additionally, a product may be eligible for accelerated approval if it is intended to treat a serious or life-threatening disease or condition and would provide meaningful therapeutic benefit over existing treatments. Eligible products may receive accelerated approval on the basis of adequate and well-controlled clinical studies establishing that the product has an effect on a surrogate endpoint that is reasonably likely to predict a clinical benefit, or on a clinical endpoint that can be measured earlier than irreversible morbidity or mortality and is reasonably likely to predict an effect on irreversible morbidity, mortality, or other clinical benefit. As a condition of approval, the FDA may require that a sponsor of a drug or biological product receiving accelerated approval diligently perform adequate and well-controlled post-marketing clinical studies demonstrating clinical benefit. In addition, the FDA requires as a condition for accelerated approval the submission of promotional materials, which could adversely impact the timing of the commercial launch of the product. Fast Track designation, Breakthrough Therapy designation, priority review and accelerated approval do not change the standards for full approval but may expedite the development or approval process.

Regenerative Medicine Advanced Therapies (RMAT) Designation

The FDA has established a Regenerative Medicine Advanced Therapy (“RMAT”) RMAT designation as part of its implementation of the Cures Act. The RMAT designation program is intended to fulfill the Cures Act requirement that the FDA facilitate an efficient development program for, and expedite review of, any drug that meets the following criteria: (1) it qualifies as a an RMAT, which is defined as a cell therapy, therapeutic tissue engineering product, human cell and tissue product, or any combination product using such therapies or products, with limited exceptions; (2) it is intended to treat, modify, reverse, or cure a serious or life-threatening disease or condition; and (3) preliminary clinical evidence indicates that the drug has the potential to address unmet medical needs for such a disease or condition. Like breakthrough therapy designation, RMAT designation provides potential benefits that include more frequent meetings with FDA to discuss the development plan for the product candidate, and eligibility for rolling review and priority review. Products granted RMAT

designation may also be eligible for accelerated approval on the basis of a surrogate or intermediate endpoint reasonably likely to predict long-term clinical benefit, or reliance upon data obtained from a meaningful number of sites, including through expansion to additional sites. RMAT-designated products that receive accelerated approval may, as appropriate, fulfill their post-approval requirements through the submission of clinical evidence, clinical studies, patient registries, or other sources of real-world evidence (such as electronic health records); through the collection of larger confirmatory data sets; or via post-approval monitoring of all patients treated with such therapy prior to approval of the therapy.

Rare Pediatric Disease Priority Review Voucher

The FDA generally defines a “rare pediatric disease” as a serious or life-threatening disease that affects fewer than 200,000 individuals in the U.S. primarily under the age of 18 years old. Under the FDA's Rare Pediatric Disease Priority Review Voucher (PRV) program, upon the approval of an application for a product for the treatment of a rare pediatric disease, the sponsor of such application is eligible for a Rare Pediatric Disease Priority Review Voucher. Currently, the Priority Review Voucher can be used to obtain priority review for any subsequent application and may be sold or transferred an unlimited number of times. Congress has only authorized the rare pediatric disease priority review voucher program until September 30, 2024. However, if a drug candidate receives Rare Pediatric Disease designation before September 30, 2024, it is eligible to receive a voucher if it is approved before September 30, 2026.

Post-Approval Requirements

FDA Requirements

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

Oftentimes, even after a drug has been approved by the FDA for sale, the FDA may require that certain post-approval requirements be satisfied, including the conduct of additional clinical studies. If such post-approval requirements are not satisfied, the FDA may withdraw its approval of the drug. In addition, holders of an approved NDA or BLA are required to report certain adverse reactions to the FDA, comply with certain requirements concerning advertising and promotional labeling for their products, and continue to have quality control and manufacturing procedures conform to cGMP after approval. In addition, drug manufacturers and other entities involved in the manufacture and distribution of approved drugs are required to register their establishments with the FDA and state agencies and are subject to periodic unannounced inspections by the FDA and these state agencies for compliance with cGMP requirements. Changes to the manufacturing process are strictly regulated and often require prior FDA approval before being implemented. FDA regulations also require investigation and correction of any deviations from cGMP and impose reporting and documentation requirements upon the sponsor and any third-party manufacturers that the sponsor may decide to use. Accordingly, manufacturers must continue to expend time, money, and effort in the area of production and quality control to maintain cGMP compliance.

Among the conditions for an NDA or BLA approval is the requirement that the manufacturing operations conform on an ongoing basis with cGMP. In complying with cGMP, we must expend time, money and effort in the areas of training, production and quality control within our

own organization and at our contract manufacturing facilities. A successful inspection of the manufacturing facility by the FDA is usually a prerequisite for final approval of a pharmaceutical product. Following approval of the NDA or BLA, we and our manufacturers will remain subject to periodic inspections by the FDA to assess compliance with cGMP requirements and the conditions of approval. We will also face similar inspections coordinated by foreign regulatory authorities. authorities if we are selling or manufacturing in foreign countries. The FDA periodically inspects the sponsor's records related to safety reporting and/or manufacturing facilities; this latter effort includes assessment of compliance with cGMP. Accordingly, manufacturers must continue to expend time, money, and effort in the area of production and quality control to maintain cGMP compliance.

Once an approval is granted, the FDA may withdraw the approval if compliance with regulatory requirements and standards is not maintained or if problems occur after the product reaches the market. Later discovery of previously unknown problems with a product, including adverse events of unanticipated severity or frequency, or with manufacturing

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processes, or failure to comply with regulatory requirements, may result in revisions to the approved labeling to add new safety information; imposition of post-market studies or clinical trials to assess new safety risks; or imposition of distribution or other restrictions under an REMS program. Other potential consequences include, among other things:

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

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

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In addition, the distribution of prescription drug products is subject to the Prescription Drug Marketing Act (the "PDMA") which regulates the distribution of drugs and drug samples at the federal level and sets minimum standards for the registration and regulation of drug distributors by the states. Both the PDMA and state laws limit the distribution of prescription drug product samples and impose requirements to ensure accountability in distribution.

Pricing, Coverage and Reimbursement

Significant uncertainty exists as to the coverage and reimbursement status of any of our products, if and when approved. Sales of pharmaceutical products depend, in part, on the availability of sufficient coverage and adequate reimbursement from third-party payors, which

include government health programs, such as Medicare, Medicaid, TRICARE, and the Veterans Administration, as well as commercial insurance, and managed healthcare organizations. Prices at which we or our customers seek reimbursement for our therapeutic product candidates may be subject to challenge, reduction, or denial by payors. Third-party payors may limit coverage to specific products on an approved list or formulary, which might not include all of the FDA-approved products for a particular indication. Also, third-party payors may refuse to include a particular branded drug on their formularies or otherwise restrict patient access to a branded drug when a less costly generic equivalent or another alternative is available. Third-party payors are increasingly challenging the prices charged for medical products and services.

The process for determining whether a payor will provide coverage for a product is typically separate from the process for setting the reimbursement rate that the payor will pay for the product. A payor's decision to provide coverage for a product does not imply reimbursement will be available at a rate that covers our costs, including research, development, manufacture, and sales and distribution costs. Additionally, in the United States there is no uniform policy among payors for determining coverage or reimbursement. Many third-party payors often rely upon Medicare coverage policy and payment limitations in setting their own coverage and reimbursement policies, but also have their own methods and approval processes. Therefore, coverage and reimbursement for products can differ significantly from payor to payor. One third-party payor's decision to cover a particular medical product or service does not ensure that other payors will also provide coverage for the medical product or service or will provide coverage at an adequate reimbursement rate. As a result, the coverage determination process will require us to provide scientific and clinical support for the use of our products to each payor separately and will likely be a time-consuming process. If coverage and adequate reimbursement are not available, or are available only at limited levels, successful commercialization of, and obtaining a satisfactory financial return on, any product we develop may not be possible.

Third-party payors are increasingly challenging the prices and examining the medical necessity and cost-effectiveness of medical products and services, in addition to their safety and efficacy. In order to obtain coverage and reimbursement for any product that might be approved for marketing, we may need to conduct expensive studies in order to demonstrate the medical necessity and cost-effectiveness of any products, which would be in addition to the costs expended to obtain regulatory approvals. Third-party payors may not consider our product candidates to be medically necessary or cost-effective compared to other available therapies, or payor negotiations may not enable us to maintain price levels sufficient to realize an appropriate return on our investment in drug development. If these third-party payors do not consider our products to be cost-effective compared to other therapies, they may not cover our products once

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approved as a benefit under their plans or, if they do, the level of reimbursement may not be sufficient to allow us to sell our products on a profitable basis. Decreases in third-party reimbursement for our products once approved or a decision by a third-party payor to not cover our products could reduce or eliminate utilization of our products and have an adverse effect on our sales, results of operations, and financial condition.

Additionally, efforts to contain healthcare costs (including drug prices) have become a priority of federal and state governments. The U.S. government, state legislatures, and foreign governments have shown significant interest in implementing cost-containment programs, including price controls, restrictions on reimbursement, and requirements for substitution by generic products. There has also been heightened governmental scrutiny recently over the manner in which drug manufacturers set prices for their marketed products, which has resulted in several Congressional inquiries and proposed and enacted federal and state legislation designed to, among other things, bring more transparency to product pricing, review the relationship between pricing and manufacturer patient programs, and reform government program reimbursement methodologies for drug products. Several federal healthcare reform efforts have been adopted in recent years which aim to restrict drug product pricing and limit reimbursement. For further details, See Part I, Item 1- Healthcare Reform. We anticipate additional state and federal healthcare reform measures will be adopted in the future. These may include price controls and cost-containment measures, or more restrictive policies in jurisdictions with existing controls and measures, any of which could limit the amounts that federal and state governments will pay for healthcare products

and services, and potentially could reduce demand for our products once approved, create additional pricing pressures, or ultimately limit our net revenue and results.

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

In Japan, almost all medical-use drugs that have been approved (i.e., whose efficacy and safety have been confirmed) under the Pharmaceuticals and Medical Devices Act may be covered by the National Health Insurance ("NHI"). In order to be covered by the NHI, a drug must be listed on the NHI drug price standard within 60 or 90 days after approval for marketing. After the NHI drug price is listed, the NHI price, which is the official price of drugs, will be reviewed and updated on a regular basis. In principle, NHI price revisions are conducted once every two years in conjunction with the April revision of medical fees. When NHI drug prices are revised, most drugs will be priced lower than before the revision. The reason for this is that between pharmaceutical wholesalers and medical institutions and pharmacies, drugs are sold at prices lower than the NHI price, and the basic principle of NHI price revision is to reduce the NHI price in line with the prevailing market price. Accordingly, the NHI drug price revisions every two years may lead to the cut of the drug price in Japan.

Other Healthcare Fraud and Abuse Laws

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

The U.S. federal Anti-Kickback Statute prohibits, among other things, any person or entity, including a prescription drug manufacturer or a party acting on its behalf, from knowingly and willfully offering, paying, soliciting or receiving any remuneration, directly or indirectly, overtly or covertly, in cash or in kind, to induce or in return for purchasing, leasing, ordering or arranging for the purchase, lease or order of any item or service that may be reimbursable, in whole or in part, under Medicare, Medicaid or other federal healthcare programs. The term "remuneration" has been interpreted broadly to include anything of value. The Anti-Kickback Statute has been interpreted to apply to arrangements between therapeutic product manufacturers on one hand and prescribers, purchasers, and formulary managers, among others, on the other. There other, including, for example, arrangements relating to consulting/speaking arrangements, discount and rebate offers, grants, charitable contributions, and patient support offerings. Although there are a number of statutory exceptions and regulatory safe harbors protecting some common business activities from prosecution under the Anti-Kickback Statute. The exceptions and safe harbors are drawn narrowly and practices that involve remuneration that may be alleged to be intended to induce prescribing, purchasing or recommending of products or services reimbursable under federal healthcare programs may be subject to scrutiny if they do not qualify for an exception or safe harbor. Failure to meet all of the requirements of a particular applicable statutory exception or regulatory safe harbor does not make the conduct per se illegal under the Anti-Kickback Statute. Instead, the legality of the arrangement will be evaluated on a case-by-case basis based on a cumulative review of all of its facts and circumstances. Several courts have interpreted the statute's intent requirement to mean that if any one purpose of an arrangement involving remuneration is to induce referrals of federal healthcare covered business, the Anti-Kickback Statute has been violated. Additionally, the intent standard under the Anti-Kickback Statute was amended by the Patient Protection and Affordable Care Act, as amended by the Health Care and Education Reconciliation Act of 2010 (collectively, the "Affordable Care Act" or the "ACA"), to a stricter standard such that a person or entity no longer needs to have actual knowledge of the statute or specific intent to violate it in order to have committed a violation. In addition,

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the ACA codified case law that a claim including items or services resulting from a violation of the federal Anti-Kickback Statute constitutes a false or fraudulent claim for purposes of the federal False Claims Act. Violations A violation of the federal Anti-Kickback Statute may result in Statue includes per violation civil monetary penalties up to $100,000 (adjusted for inflation) for each violation, plus up to three times the total amount of remuneration between the parties to the arrangement. Civil penalties for such conduct can further be assessed and significant criminal fines under the federal statute, additional civil penalties and treble damages under the False Claims Act. Violations can also result Act, as discussed in criminal penalties, including criminal fines of up to $100,000 (adjusted for inflation) more detail below, possible imprisonment, and imprisonment of up to 10 years. Similarly, violations can result in mandatory exclusion from participation or suspension from future participation in the federal and state healthcare programs, including Medicare and Medicaid. meaning that federal healthcare programs would no longer reimburse (directly or indirectly) for products or services furnished by the excluded entity or individuals.

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The U.S. federal civil False Claims Act, prohibits, among other things, any person or entity from knowingly presenting, or causing to be presented, for payment to, or approval by, federal programs, including Medicare and Medicaid, claims for items or services, including drugs, that are false or fraudulent or not provided as claimed. Persons and entities can be held liable under these laws if they are deemed to "cause" the submission of false or fraudulent claims by, for example, providing inaccurate billing or coding information to customers or promoting a product off-label. In addition, certain of our future activities relating to the reporting of wholesaler or estimated retail prices for our products, the reporting of prices used to calculate Medicaid rebate information, and other information affecting federal, state, and third-party reimbursement for our products, and the sale and marketing of our products, are subject to scrutiny under this law. Penalties for federal civil False Claims Act violations may include up to three times the actual damages sustained by the government, plus mandatory civil penalties of between $13,508 $13,946 and $27,018 for each separate false claim $27,894 per false claim or statement for penalties assessed after January 30, 2023 January 15, 2024 with respect to violations occurring after November 2, 2015 (and penalties of between $5,500 and $11,000 per claim or statement with respect to violations occurring before that date). Other penalties include the potential for exclusion from participation in federal healthcare programs. Additionally, although the federal False Claims Act is a civil statute, False Claims Act violations may also implicate various federal criminal statutes.

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

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

The federal Health Insurance Portability and Accountability Act of 1996 (“HIPAA”) created additional federal criminal statutes that prohibit, among other things, knowingly and willfully executing, or attempting to execute, a scheme to defraud or to obtain, by means of false or fraudulent pretenses, representations or promises, any money or property owned by, or under the control or custody of, any healthcare benefit program, including private third-party payors, willfully obstructing a criminal investigation of a healthcare offense, and knowingly and willfully falsifying, concealing or covering up by trick, scheme or device, a material fact or making any materially false, fictitious or fraudulent statement in connection with the delivery of or payment for healthcare benefits, items or services. Like the Anti-Kickback Statute, the ACA amended the intent standard for certain healthcare fraud statutes under HIPAA such that a person or entity no longer needs to have actual knowledge of the statute or specific intent to violate it in order to have committed a violation.

We may be subject to data privacy and security regulations by both the federal government and the states in which we conduct our business. HIPAA, as amended by the Health Information Technology for Economic and Clinical Health Act (“HITECH”), and its implementing regulations, imposes requirements relating to the privacy, security and transmission of individually identifiable health information. Among other things, HITECH makes HIPAA’s privacy and security standards directly applicable to business associates, independent contractors, or agents of covered entities that receive or obtain protected health information in connection with providing a service on behalf of a covered entity. HITECH also created four new tiers of civil monetary penalties, amended HIPAA to make civil and criminal penalties directly applicable to business associates, and gave state attorneys general new authority to file civil actions for damages

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or injunctions in federal courts to enforce HIPAA and seek attorneys’ fees and costs associated with pursuing federal civil actions. Regulatory guidance and obligations continue to evolve. For example, on December 10, 2020, the Office for Civil Rights (“OCR”) issued a proposed rule aimed at reducing regulatory burdens that may exist in discouraging coordination of care, among other changes. Finally, pursuant to legislation passed in 2021, OCR recently issued guidance on recognized security practices for covered entities and business associates. OCR indicated that recognized security practices will not be an aggravating factor in OCR investigations, but that implementation of recognized security practices strengthen an organization’s cybersecurity and regulatory posture, as well as possibly lessening enforcement penalties in a potential regulatory enforcement. As HIPAA and HITECH requirements evolve, we may be required to update our compliance strategies or modify our business processes to comply.

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The Federal Trade Commission (“FTC”) and many state attorneys general are interpreting existing federal and state consumer protection laws to impose evolving standards for the collection, use, dissemination and security of health-related and other personal information. Privacy laws require us to publish statements that describe how we handle personal information and choices individuals may have about the way we handle their personal information. Violating individuals’ privacy rights, publishing false or misleading information about security practices, or failing to take appropriate steps to keep individuals’ personal information secure may constitute unfair or deceptive acts or practices in violation of Section 5 of the FTC Act. Additionally, the FTC recently published an advance notice of proposed rule making on “commercial surveillance” and data security, and is seeking comment on whether it should implement new trade regulation rules or other regulatory alternatives concerning the ways in which companies (1) collect, aggregate, protect, use, analyze, and retain consumer data, as well as (2) transfer, share, sell, or otherwise monetize that data in ways that are unfair or deceptive. Federal regulators, state attorneys

general and plaintiffs' attorneys have been and will likely continue to be active in this space, and if we do not comply with existing or new laws and regulations related to patient health information, we could be subject to criminal or civil sanctions.

In addition, many state laws govern the privacy and security of health information in specified circumstances, many of which differ from each other in significant ways, are often not pre-empted by HIPAA, and may have a more prohibitive effect than HIPAA, thus complicating compliance efforts. For instance, the California Consumer Privacy Act ("CCPA") became effective on January 1, 2020, giving California residents expanded privacy rights, and requiring businesses to provide detailed information about their data practices. The CCPA provides for civil penalties for violations, as well as a private right of action for data breaches that is expected to increase data breach litigation. Although there are limited exemptions for PHI and certain clinical trial data, the CCPA's implementation standards and enforcement practices may increase our compliance costs and legal risks. Additionally, the California Privacy Rights Act ("CPRA") was passed in November 2020 and amended the CCPA beginning in 2023. The CPRA imposes additional data protection obligations on companies doing business in California, including additional consumer rights processes, limitations on data uses, new audit requirements for higher risk data, and opt outs for certain uses of sensitive data. It also created a new California data protection agency authorized to issue substantive regulations and could result in increased privacy and information security enforcement. Similar laws have been adopted in other states or proposed in other states and at the federal level, and if passed, such laws may have potentially conflicting requirements that would make compliance challenging. For example, the Nevada Privacy of Information Collected on the Internet from Consumers Act went into effect on October 1, 2021, the Virginia Consumer Data Protection Act went into effect on January 1, 2023, the Colorado Privacy Act goes into effect on July 1, 2023, the Connecticut Data Privacy Act goes into effect July 1, 2023, and the Utah Consumer Privacy Act goes into effect December 31, 2023. Additional compliance investment and potential business process changes may be required to respond to these this rapidly changing privacy law landscape. If we fail to comply with existing or new privacy laws and regulations, we could face legal liability from regulatory actions or litigation, as well as reputational damage.

Additionally, the U.S. federal Physician Payments Sunshine Act (the "Sunshine Act"), created under the ACA, and its implementing regulations, require that certain manufacturers of drugs, devices, biological and medical supplies for which payment is available under Medicare, Medicaid or the Children's Health Insurance Program (with certain exceptions) report annually to CMS Centers for Medicare and Medicaid Services ("CMS") information related to certain payments or other transfers of value made or distributed to physicians (defined to include doctors, dentists, optometrists, podiatrists, and teaching hospitals, or to entities or individuals at the request of, or designated on behalf of, the physicians, licensed chiropractors), physician assistants, nurse practitioners, clinical nurse specialists, anesthesiologist assistants, certified nurse anesthetists, certified nurse-midwives and U.S. teaching hospitals and to report annually certain ownership and investment interests held by physicians and their immediate family members. Failure to submit timely, accurately and completely the required information for all payments, transfers of value and ownership or investment interests may result in civil monetary penalties of up to an aggregate of $150,000 (adjusted annually for inflation) per year and up to an aggregate of $1,000,000 (adjusted annually for inflation) per year for "knowing failures." Covered manufacturers are required to submit reports on aggregate payment data to the Secretary of the U.S. Department of Health and Human Services on an annual basis.

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Many states have similar statutes or regulations to the above federal laws that may be broader in scope and may apply regardless of payor. We may also be subject to state laws that require pharmaceutical companies to comply with the pharmaceutical industry's voluntary compliance guidelines and the relevant compliance guidance promulgated by the federal government, and/or state laws that require drug manufacturers to report information related to payments and other transfers of value to physicians and other healthcare providers, drug pricing or marketing expenditures. These laws may differ from each other in significant ways and may not have the same effect, further complicating compliance efforts. Additionally, to the extent that we have business operations in foreign countries or sell any of our products in foreign countries and jurisdictions, including Japan or the European Union, we may be subject to additional regulations.

Although we do not currently have any products on the market, once our product candidates or clinical trials are covered by federal health care programs, we will be subject to additional healthcare statutory and regulatory requirements

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and enforcement by the federal and state governments of the jurisdictions in which we conduct our business. Because we intend to commercialize products that could be reimbursed under a federal healthcare program and other governmental healthcare programs, we intend to develop a comprehensive compliance program that establishes internal controls to facilitate adherence to the rules and program requirements to which we will or may become subject. Although the development and implementation of compliance programs can mitigate the risk of violating these laws, and the subsequent investigation, prosecution, and penalties assessed for violations of these laws, the risks cannot be entirely eliminated.

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

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

Healthcare Reform

In the United States and foreign jurisdictions, there have been, and we expect there will continue to be, a number of legislative and regulatory changes to healthcare systems that could affect our future results of operations.

In the United States, the pharmaceutical industry has been a particular focus of healthcare reform efforts and has been significantly affected by major legislative and regulatory initiatives, including the ACA, which has had, and is expected to continue to have, a significant impact on the healthcare industry. This law was designed to expand access to health insurance coverage for uninsured and underinsured individuals while at the same time containing overall healthcare costs. With regard to pharmaceutical products, among other things, the ACA contains provisions that may potentially affect the profitability of our products, including, for example, subjecting biologics potential competition by lower-cost biosimilars, increased rebates for products sold to Medicaid programs, extension of Medicaid rebates to Medicaid managed care plans, mandatory discounts for certain products under Medicare Part D, expansion of entities eligible for discounts under the Public Health Service's pharmaceutical pricing program, and a significant annual fee on companies that manufacture or import certain branded prescription drug products. Substantial new provisions affecting compliance have also been enacted, which may affect our business practices with healthcare providers and entities.

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Additionally, there have been executive, judicial, and legislative challenges to certain aspects of the ACA. For example, while Congress has not passed legislation to comprehensively repeal the ACA, the Tax Cuts and Jobs Act included a provision that, effective January 1, 2019, changed to $0 the tax-based shared responsibility payment imposed by ACA on certain individuals who fail to maintain qualifying health coverage for all or part of a year, which is commonly referred to as the "individual mandate." Additionally, in March 2021, Congress enacted the American Rescue Plan Act of 2021, which included among its provisions a temporary increase in premium tax credit assistance for individuals eligible to receive qualified health plan premium subsidies for 2021 and 2022 and temporarily removed the 400% federal poverty level limit that otherwise applies for purposes of eligibility to receive premium such tax credits. The Inflation Reduction Act of 2022 ("IRA") extended this increased tax credit assistance and removal of the 400% federal poverty limit through 2025. Moreover, on June 17, 2021, the U.S. Supreme Court dismissed the most recent judicial challenge to the ACA brought by several states without specifically ruling on the constitutionality of the ACA. Prior to the Supreme Court's decision, President Biden had issued an executive order that instructed certain governmental agencies to review and

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reconsider their existing policies and rules that limit access to healthcare, including among others, policies that create barriers to obtaining access to health insurance coverage through the ACA marketplaces.

We cannot predict what effect the healthcare reform measures of the Biden administration or other efforts, if any, to challenge, repeal, amend or replace the ACA would have on our business.

Other legislative changes have been proposed and adopted since the ACA was enacted. For example, the Budget Control Act of 2011 included reductions to Medicare payments to providers of up to 2% per fiscal year, which went into effect on April 1, 2013 and, due to subsequent legislation, will stay in effect into 2031 through the first six months of the fiscal year 2032 sequestration order (with the exception of a temporary suspension due to the COVID-19 pandemic from May 1, 2020 through March 31, 2022 and a subsequent reduction to 1% from April 1, 2022 until June 30, 2022). To offset the temporary suspension during the COVID-19 pandemic, in 2030, reductions in Medicare payments will be 2.25% for the first half of the year, and 3% in the second half of the year. Additionally, the American Taxpayer Relief Act of 2012, among other things, further reduced Medicare payments to several providers and increased the statute of limitations period for the government to recover overpayments to providers from three to five years. In the future, there may be additional challenges and/or amendments to the ACA. It remains to be seen precisely what any new legislation will provide, when or if it will be enacted, and what impact it may have on the availability and cost of healthcare items and services, including drug products.

In addition, in recent years the pricing and costs of prescription pharmaceuticals has been the subject of considerable discussion in the United States. A number of federal reports and inquiries have focused on these issues, and various legislative and regulatory provisions have been proposed and enacted at the federal and state level that seek to, among other things, bring more transparency to drug pricing, review the relationship between pricing and manufacturer patient programs, reduce the out-of-pocket cost of prescription drugs, and reform government program reimbursement methodologies for drugs. Additionally, on December 21, 2020, Congress passed a $900 billion U.S. coronavirus relief and government appropriations legislation, the Consolidated Appropriations Act of 2021, 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 (the "PDP") sponsors and Medicare Advantage organizations ("MAOs") to implement tools to display Medicare Part D prescription drug benefit information in real time and provisions requiring group and health insurance issuers offering health insurance coverage to report information on certain pharmacy benefit and drug costs to the Secretaries of HHS, Labor, and the Treasury.

Further, the Biden Administration and Congress have each indicated that it will continue to pursue new legislative and administrative measures to control drug costs. For example, the American Rescue Plan Act of 2021 included among its provisions a sunset of the ACA's cap on pharmaceutical manufacturers' rebate liability under the Medicaid Drug Rebate Program. Under the ACA, manufacturers' rebate liability was capped at 100% of the average manufacturer price for a covered outpatient drug. However, effective January 1, 2024, manufacturers'

Medicaid Drug Rebate Program rebate liability will is no longer be capped, potentially resulting in a manufacturer paying more in Medicaid Drug Rebate Program rebates than it receives on the sale of certain covered outpatient drugs. Further, in August 2022, President Biden signed into law IRA, which implements substantial changes to the Medicare program, including drug pricing reforms and the creation of new Medicare inflation rebates. Namely, the IRA imposes inflation rebates on drug manufacturers for products reimbursed under Medicare Parts B and D if the prices of those products increase faster than inflation; implements changes to the Medicare Part D benefit that, beginning in 2025, will cap beneficiary annual out-of-pocket spending at $2,000, while imposing new discount obligations for pharmaceutical manufacturers; and, beginning in 2026, establishes a "maximum fair price" for a fixed number of high expenditure pharmaceutical and biological products covered under Medicare Parts B and D following a price negotiation process with the CMS. Since its enactment, CMS has taken steps to implement various drug pricing provisions of the IRA. This includes, without limitation, issuing guidance on June 30, 2023 detailing the requirements and parameters of the first round of price negotiations, to take place during 2023 and 2024, for products subject to the "maximum fair price" provision that would become effective in 2026; on August 29, 2023, releasing the initial list of 10 drugs subject to price negotiations; and on December 14, 2023 releasing a list of 48 Medicare Part B products that had adjusted coinsurance rates based on the inflationary rebate provisions of the IRA for the time period of January 1, 2024 to March 31, 2024. Several pharmaceutical manufacturers and other industry stakeholders have challenged the law, including through lawsuits brought against the Department of Health and Human Services, the Secretary of the Department of Health and Human Services, CMS, and the CMS Administrator challenging the constitutionality and administrative implementation of the IRA's drug price negotiation provisions. We cannot predict whether the IRA, or any of its component parts, will be overturned, repealed, replaced, or amended nor can we predict the likelihood, nature, or extent of other health reform initiatives that may arise from future legislation, administrative, or other action. However, we expect these initiatives to increase pressure on drug pricing.

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Medicare Parts B and D following a price negotiation process with the Centers for Medicare and Medicaid Services. Furthermore, the Biden administration continues to direct the Department of Health and Human Services HHS to consider new healthcare payment and delivery models that would lower drug costs and promote access to innovative therapies for beneficiaries enrolled in the Medicare and Medicaid programs. For example, on October 14, 2022 President Biden issued an Executive Order on Lowering Prescription Drug Costs for Americans, which instructed the Secretary of the Department of Health and Human Services to consider whether to select for testing by the CMS Innovation Center new health care payment and delivery models that would lower drug costs and promote access to innovative drug therapies for beneficiaries enrolled in the Medicare and Medicaid programs. On February 14, 2023, the Department of Health and Human Services issued a report in response to the October 14, 2022 Executive Order, which, among other things, selects three potential drug affordability and accessibility models to be tested by the CMS Innovation Center. Specifically, the report addresses: (1) a model that would allow Part D Sponsors to establish a "high-value drug list" setting the maximum co-payment amount for certain common generic drugs at $2; (2) a Medicaid-focused model that would establish a partnership between CMS, manufacturers, and state Medicaid agencies that would result in multi-state outcomes-based agreements for certain cell and gene therapy drugs; and (3) a model that would adjust Medicare Part B payment amounts for Accelerated Approval Program drugs to advance the developments of novel treatments. We cannot predict how, or to what extent, the Biden administration's drug pricing policies will affect our products. We cannot predict what other healthcare reforms will ultimately be implemented at the federal or state level or the effect of any future legislation or regulation. Accordingly, we face uncertainties that might result from additional reforms.

At the state level, legislatures are increasingly passing legislation and implementing regulations designed to control biopharmaceutical and biologic product pricing, including price or patient reimbursement constraints, discounts, restrictions on certain product access and marketing cost disclosure and transparency measures, and, in some cases, designed to encourage importation from other countries and bulk purchasing. The implementation of cost containment measures or other healthcare reforms may prevent us from being able to generate revenue, attain profitability, or commercialize any product that is ultimately approved, if approved. In addition, several recently passed state laws require disclosures related to state agencies and/or commercial purchasers with respect to certain price increases that exceed a certain level as identified in the relevant statutes. Another emerging trend at the state level is the establishment of prescription drug affordability boards, some of which will prospectively permit certain states to establish upper payment limits for drugs that the state has determined to be "high-cost." Some of these laws and regulations contain ambiguous requirements that government officials have not yet

clarified. Given the lack of clarity in the laws and their implementation, our future reporting actions could be subject to the penalty provisions of the pertinent federal and state laws and regulations.

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

Corporate Information

Our corporate and research headquarters are located at 10865 Road to the Cure, Suite 150, San Diego, California 92121. Our telephone number is (858) 727-1755 and our internet address is *www.capricor.com*. The information on, or accessible through, our website is not part of incorporated into this Annual Report on Form 10-K. 10-K or any other filings we make with the U.S. Securities and Exchange Commission (the "SEC"). We have included our website address in this Annual Report on Form 10-K solely as an inactive textual reference.

Employees

Currently, As of December 31, 2023, we have 74 had 102 employees, of whom 101 are full-time employees. employees with 34 holding advanced degrees. None of our employees are covered by a collective bargaining agreement. We believe that our relations with our employees are satisfactory. We have also retained several consultants to perform various operational and administrative functions. Certain officers of Capricor are also serving as officers of the Company.

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ITEM 1A. RISK FACTORS

Investment in our common stock involves significant risk. You should carefully consider the information described in the following risk factors, together with the other information appearing elsewhere in this Annual Report on Form 10-K, before making an investment decision regarding our common stock. If any of the events or circumstances described in these risks actually occur, our business, financial condition, results of operations and future growth prospects would likely be materially and adversely affected. In these circumstances, the market price of our common stock could decline, and you may lose all or a part of your investment in our common stock. Moreover, the risks described below are not the only ones that we face.

Summary Risk Factors

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

Risks Related to Our Business

- 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 third-party vendor's systems and data; and
- we may not have adequate personnel and may not be able to attract or retain personnel needed to develop our products;
- the COVID-19 pandemic, including its impact on our business and operations; 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;
- we may not be able to use our facilities to manufacture CAP-1002 product for use in our Phase III trial of CAP-1002 for DMD; commercial purposes;
- we may be required to obtain consent from CSMC in order to sell commercial product from our Los Angeles facility;
- we may not be able to satisfy clinical and/or regulatory requirements necessary for the approval of our product in the U.S. or Japan;
- we may not be able to reach the milestones set forth in our distribution agreements therefore preventing us from receiving the financial benefits of those agreements; and
- our partners may not perform as expected and therefore deny us the financial benefits of those agreements; agreements.

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 donor hearts and other raw materials that are critical for the manufacturing of our product candidates;
- we may need to rely upon third party 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;
- we may not be able to replicate our manufacturing processes;
- we may not be able to comply with cGMP regulations;

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- we may not be able to identify or retain necessary manufacturing personnel;
- the FDA may not accept the viability or comparability of our manufacturing processes; and
- the FDA may not approve our manufacturing facilities for the manufacture of commercial products.

Risks Related to Our Intellectual Property

- our ability we may not be able to obtain, maintain, protect, and enforce our intellectual property rights;
- we may face potential challenges to the validity, enforceability, or scope of our intellectual property;
- potential we may experience claims from third parties that we are infringing their patents or other intellectual property rights; and
- our ability we may not be able to satisfy our obligations under our licensing agreements; agreements.

Risks Related to Our Relationships with Third Parties

- we depend on our relationships with our licensors, collaborators, and other third parties and there is no guarantee that such relationships will continue; and
- we will depend on the ability of Nippon Shinyaku to perform according to the terms of the U.S. Distribution and Japan Distribution Agreements and all applicable laws, and to successfully commercialize our lead product CAP-1002 in DMD; DMD.

Risks Related to Competitive Factors

- our products will likely face intense competition; and
- 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; any.

Risks Related to Product and Environmental Liability

- our products may expose us to potential product liability; liability.

Risks Related to Our Common Stock

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

Risks Related to Our Business

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

Developing biopharmaceutical products, including conducting preclinical studies and clinical trials and establishing manufacturing capabilities, is expensive. As of December 31, 2022 December 31, 2023, we had cash, cash equivalents, and marketable securities totaling approximately $41.4 million $39.5 million. Additionally, we received a milestone payment of $10.0 million in the first quarter of 2024 under the terms of our Japan U.S. Distribution Agreement with Nippon Shinyaku and we expect to receive an upfront payment of $12.0 million in the first quarter of 2023 and may potentially receive other additional development and sales-based milestones. 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 private and public sales of our equity securities, government grants and payments from distribution agreements and collaboration partners. As we have not generated any revenue from the commercial sale of our products to date, and we do not expect to generate revenue for several years, if ever, we will need to raise substantial additional capital in order to fund our general corporate activities and to fund our research and development, including our long-term plans for clinical trials and new product development.

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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

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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 DMD program, which includes our HOPE-3 clinical trial for our CAP-1002 product candidate for DMD;
- the availability of funding from government programs including the NIH, DoD, and CIRM, 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;
- our ability to manufacture commercial-scale GMP CAP-1002 product at our San Diego manufacturing facility;
- 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, as applicable, for any product candidates for which we may receive regulatory approval.

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

Our audited financial statements include a statement that there is substantial doubt about our ability to continue as a going concern. We have historically incurred substantial losses to fund our business operations including our research and development activities and more recently manufacturing scale-up 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. While we have historically been able to adjust the timing associated with our R&D efforts, as well as reducing headcount and implementing certain budget restrictions, to alleviate

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uncertainties surrounding our ability to continue as a going concern, if ultimately we cannot continue as a going concern, our stockholders may lose their entire investment in us.

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

We have a history of net losses, expect to continue to incur substantial net losses for the foreseeable future, and may never achieve or maintain profitability. Our operations to date have been primarily limited to organizing and staffing our company, developing our technology, and undertaking 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 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;

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- 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, as necessary or to establish partnerships with other companies who have greater sales and marketing capabilities;
- the ability of our distribution partner, Nippon Shinyaku, to successfully market and sell our CAP-1002 product if and to the extent it is approved;
- our ability to establish or maintain collaborations, licensing or other arrangements, including strategic partnerships for CAP-1002 outside of DMD 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 product candidates;
- 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, as necessary;
- our ability to maintain and staff our current manufacturing facilities;
- our ability to build or secure new manufacturing facilities, if necessary, and achieve and maintain cGMP and obtain required certifications as necessary; required;
- 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 adequate reimbursement levels 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 to manage our business and operations.

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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 our ongoing Phase III 3 trial of our CAP-1002 product candidate for 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 additional strategic partners, 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.

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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 or some other infectious disease outbreak 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 marketing approval;
- timely receipt of 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; third-party;
- the performance of our current and future distributors or 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-parties for raw materials and drug product supplies and potential manufacturers who are able to manufacture clinical trial and commercial quantities of drug substance and drug products products;
- our ability to develop, validate and maintain a commercially viable manufacturing process that is compliant with cGMP at a scale sufficient to meet anticipated demand;
- establishment of arrangements with potential manufacturers who are able to develop, validate and maintain a commercially viable manufacturing process that is compliant with cGMP at a scale sufficient to meet anticipated demand and over time enable us to reduce our cost of manufacturing, if necessary;
- 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 marketing approval;
- a continued acceptable safety profile following marketing approval;
- commercial acceptance by patients, the medical community and third-party payors;

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- 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. therapies; and
- our ability to conduct post-marketing surveillance and comply with requirements of FDA and other comparable regulatory authorities after product approval.

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 or geopolitical conflicts could seriously harm our future revenues and financial condition and increase our costs and expenses.

Our corporate headquarters and our manufacturing and research facilities are located in San Diego and 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 in the California region, or geopolitical conflicts, such as the Russia-Ukraine conflict and the conflicts in the Middle East, 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 COVID-19, could severely disrupt our operations or the operations of third parties that we depend on, including any third-party contract manufacturer, our CROs, clinical data

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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 COVID-19, in China. COVID-19 has since spread globally and while cases and hospitalizations 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 measures to slow the spread of COVID-19.

If COVID-19 continues to spread and further variants emerge, 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.

Additionally, disruptions at the at FDA, the EMA and other regulatory agencies, 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. Regulatory authorities outside the United States may adopt similar restrictions or other policy measures in response to the COVID-19 pandemic. It is unclear how FDA's and other health agencies' policies and guidance will impact any inspections of our facilities, including our clinical trial sites. It is also unclear whether, when, and how FDA and other health agencies will change their policies for facility inspections.

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 or other outbreak could severely impact our business.

A breakdown, corruption or breach of our information technology systems or computer systems, or those used or hosted by our CROs, contractors, consultants or third-party vendors could subject us to liability or interrupt the operation of our business.

We are increasingly dependent upon information technology systems, computer systems and data, as well as the information technology systems, computer systems and data of our current and future clinical research organizations ("CROs"), contractors, consultants and third-party vendors, especially if we expand our clinical trials and therefore our databases of patient information.

Our or our third-party vendors' information technology systems, computer systems and data (and those of our current and future CROs, contractors, consultants and third-party vendors) are potentially vulnerable to breakdown, corruption, deliberate attacks, malicious intrusion and random attack. or software, as well as unintentional cybersecurity incidents, such as system misconfigurations, misuses or human error. 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 third parties that their systems and services are compliant with HIPAA and other applicable privacy and cybersecurity laws, there can

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be no assurance that such third parties will comply with applicable laws or regulations. Non-compliance by such vendors third parties or weaknesses in their information security cybersecurity 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 information technology systems and computer systems, and those of our current and future clinical research organizations (CROs") CROs, contractors, consultants and other contractors and consultants third parties are potentially vulnerable to damage from computer viruses breakdown, corruption, disruption or cybersecurity incidents. Cyber-attacks are increasing in their frequency, sophistication and unauthorized access. intensity and are becoming increasingly difficult to detect. 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

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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 significantly delayed.

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, information technology systems and computer systems, and we intend to defend against and respond to data security incidents. 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, which could result in a material disruption of our development programs and business operations, and our business, financial condition, results of operations and prospects could be adversely impacted.

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 an NDA 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 and other foreign regulatory agencies have 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.

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

We have limited late-stage clinical trial experience with respect to its product candidates. The clinical testing process is governed by stringent regulations 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.

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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.

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.

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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 2, Phase III 3 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 2 or Phase III 3 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 the probability 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, and to the best of our knowledge, no products based on exosomes have been approved in the United States or the European Union. for therapeutic use. 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 our exosome technologies and we cannot predict whether the application of our 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. We may also decide to discontinue exosome development programs if we believe that there is excessive competition in a disease target. 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.

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The clinical trial requirements of the FDA, the 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 therapeutics and vaccines 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

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

- to our knowledge, obtaining marketing approval 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 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, having sufficient processes in place in connection with the manufacturing of the exosomes and the availability of necessary funding for any potential clinical trial.

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. The FDA may also impose clinical holds at any time before or during clinical trials due to unacceptable and significant risks to clinical trial subjects or non-compliance with FDA requirements. 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 regulations 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, there is no assurance that it will not revert to prior critical levels. A Additionally, 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 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 site personnel availability, patient screening and patient enrollment;
- competition from other companies operating in the same disease setting;
- 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 by us;
- 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

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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. In August 2023, the FDA published a guidance document, Informed Consent, Guidance for IRBs, Clinical Investigators, and Sponsors, which supersedes past guidance and finalizes draft guidance on informed consent. The FDA's new guidance presents evolving requirements for informed consent which may affect recruitment and retention of patients in clinical trials. Further, in December 2023, the FDA published a final rule, Institutional Review Board Waiver or Alteration of Informed Consent for Minimal Risk Clinical Investigations, which allows exceptions from informed consent requirements when a clinical investigation poses no more than minimal risk to the human subject and includes appropriate safeguards to protect the rights, safety, and welfare of human subjects. Modifications to informed consent or other clinical trial requirements may affect enrollment or retention of patients, require modifications to trial documents and may cause delays to the trial.

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.

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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;

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- 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 late-stage 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.

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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

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other adverse finding in a clinical trial conducted by a third party 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 III 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 approval 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. approval in our target markets, including the United States and Japan.

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

The speed at which select parties are acting have acted to create and test many therapeutics and vaccines for COVID-19 or other infection diseases is atypical. Further, changing plans or priorities within the FDA or the regulatory authorities in other jurisdictions, including changes based on new knowledge of COVID-19 or other infectious diseases, and new variants of the virus, may significantly affect the regulatory timeline for further authorizations or approvals. We cannot anticipate or predict with certainty the timelines or regulatory processes that may be required for the development of our potential COVID-19 vaccine that may be developed to fight against variants of the SARS-CoV-2 virus. We may also decide to discontinue exosome development programs if we believe that there is excessive competition in a disease target.

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

Our research programs may initially show promise in identifying potential product candidates or potential additional indications for existing product candidates, yet fail to lead to successful 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.

For example, we previously initiated the INSPIRE trial 42

Table of our lead product candidate, CAP-1002, in patients with severe COVID-19, but we ultimately decided not to pursue further clinical evaluation in that indication. Contents

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.

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If any of our product candidates receives marketing approval 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 distributors or 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 sufficient revenues from sales of drugs to cover our costs 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;
- the performance of third-party distributors, such as our exclusive distributor for our lead product candidate, CAP-1002;

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- 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.

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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.

There are many pharmaceutical companies, biotechnology companies, public and private universities, government agencies and research organizations that compete with us in developing various approaches to the treatment of DMD which includes competitors both in the United States and internationally. We have competitors both in the United States and internationally. With CAP-1002, we expect to face competition from existing products and products in development. In addition, at this time, there are four FDA conditionally approved exon skipping drugs: EXONDYS 51 (eteplirsen), AMONDYS 45 (casimersen) and VYONDYS 53 (golodirsen), which are PMOs approved for the treatment of DMD patients amenable to Exon 51, Exon 45 and Exon 53 skipping, respectively, and are marketed by Sarepta Therapeutics, Inc., and VILTEPSO (vitolarsen), a PMO approved for the treatment of DMD patients amenable to Exon 53 skipping, which is marketed by Nippon Shinyaku (U.S. subsidiary: NS Pharma, Inc.). In June 2023, the FDA approved Sarepta's BLA application seeking accelerated approval of Elevidys (delandistrogene moxeparvovec), its microdystrophin gene therapy, for the treatment of ambulant individuals with Duchenne. There are multiple other companies focused on developing genetic based therapies that target dystrophin mechanisms and non-dystrophin mechanisms for the treatment of DMD.

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 an 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 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.

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We have received orphan drug status for CAP-1002 for the treatment of DMD. Even though we have received orphan drug designation (ODD) as described above, we may not be the first to obtain marketing approval for the orphan-designated indication due to the uncertainties associated with developing pharmaceutical products. For any product candidate for which we have been or will be granted ODD in a particular indication, it is possible that another company also holding ODD for the same product candidate will receive marketing approval for the same indication before we do. If that were to happen, our applications for that indication may not be approved until the competing company's period of exclusivity expires.

In addition, our exclusive marketing rights in the United States, if obtained, 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.

In addition, Congress is considering updates to the orphan drug provisions of the FDCA in response to a recent 11th Circuit decision. Any changes to the orphan drug provisions could change our opportunities for, or likelihood of

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success in obtaining, orphan drug exclusivity and would materially adversely affect our business, financial condition, results of operations, cash flows and prospects.

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, as long as the sponsor making the transfer has not yet submitted the application. Also, although Priority Review Vouchers may be sold or transferred to third parties, there is no guaranty that we will be able to realize any value if we were to sell a Priority Review Voucher. The FDA may also revoke any priority review voucher if the rare pediatric disease drug for which the voucher was awarded is not marketed in the U.S. within one year following the date of approval.

Congress has only authorized the rare pediatric disease priority review voucher program until September 30, 2024. However, if a drug candidate receives Rare Pediatric Disease designation before September 30, 2024, it is eligible to receive a voucher if it is approved before September 30, 2026. 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.

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

In addition to manufacturing CAP-1002 for its own clinical trials, Capricor provided CAP-1002 for investigational purposes in two clinical trials sponsored by CSMC. The first trial is known as “Regression Additionally, we recently were selected to be part of Fibrosis Project NextGen, an initiative by the U.S. Department of Health and Reversal Human Services to advance a pipeline of Diastolic Dysfunction in HFpEF Patients Treated new, innovative vaccines for COVID-19. As part of Project NextGen, the National Institute of Allergy and Infectious Diseases, part of the National Institutes of Health, will conduct a Phase 1 clinical study with Allogeneic CDCs.” The second trial is known as “Pulmonary Arterial Hypertension treated with Cardiosphere-derived Allogeneic Stem Cells.” In both studies, Capricor provided doses our StealthX™ vaccine, subject to regulatory approval. NIAID's Division of CAP-1002 Microbiology and received a negotiated amount of monetary compensation in exchange for doing so. Infectious Diseases (DMID) would oversee the study.

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. Similarly, providing product for compassionate use can pose risks for the Company as its use will not be subject to the same protocol and procedures established in our clinical trials. 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. We have

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been informed by CSMC that both of these the CAP-1002 (REGRESS and ALPHA) trials have ceased enrollment and that the trials have been concluded. Notwithstanding their cessation, there is a risk that injuries could result from the use of the product or other claims may arise.

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

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

Our research and development activities, 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 including determinations that our manufacturing processes being utilized in the United States are not compliant with the regulations adopted in those 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

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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 will be required to manufacture on our own behalf or retain the services of a commercial manufacturer to develop product suitable for commercial sale in compliance with cGMP requirements;
- we may have limitations on how we or our distributor promote our products; and
- we may be subject to litigation or product liability claims. claims; and
- the products we manufacture may experience failures in the manufacturing process.

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There are additional risks involved in conducting clinical trials internationally.

If we decide to expand or conduct one or more of our clinical trials to investigative sites in Europe, Japan, 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 may have to 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, enter into an agreement with a domestic manufacturer who maintains an acceptable cGMP facility or ensure that our facility meets Japanese, European or other foreign specifications. 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.

Further, we have entered into the Japanese Distribution Agreement with Nippon Shinyaku for the distribution of CAP-1002 in Japan. In order for us to be able to sell CAP-1002 in Japan, we will be required to satisfy the requirements of and get approval from the PMDA. At this time, we are uncertain as to the type or types of trials that may be required, whether the PMDA in Japan will accept product manufactured at our facilities, if approved, the price at which our product may be sold and market acceptance.

To the extent we conduct business in the European Union (“EU”), or receive information about EU residents, we will also have to comply with the EU General Data Protection Regulation (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 (“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.

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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.

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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 or untitled 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,

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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 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 Some of our pre-commercial activities also may be subject to some of these laws. For more information on potentially applicable federal and state healthcare laws and regulations, include, but are not limited to, the following: See Part I, Item 1 – Other Healthcare Fraud and Abuse Laws.

- 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 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

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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;
- HIPAA includes a fraud and abuse provision referred to as the HIPAA All-Payor Fraud Law, which imposes criminal and civil liability for executing a scheme to defraud any healthcare benefit program, or knowingly and willfully falsifying, concealing or covering up a material fact or making any materially false statement in connection with the delivery of or payment for healthcare benefits, items or services. Similar to the federal Anti-Kickback Statute, a person or entity does not need to have actual knowledge of the statute or specific intent to violate it in order to have committed a violation;
- HIPAA, as amended by HITECH, and its implementing regulations, which impose obligations on certain covered entity healthcare providers, health plans, and healthcare clearinghouses as well as their business associates that perform certain services involving the use or disclosure of individually identifiable health information, including mandatory contractual terms, with respect to safeguarding, the privacy, security, and transmission of individually identifiable health information, and require notification to affected individuals and regulatory authorities of certain breaches of security of individually identifiable health information;
- the FDCA, which prohibits the adulteration and misbranding of drugs, including therapeutic biological products;
- 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,"

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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 non-governmental third party payors, including private insurers; and some state laws requiring 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. reform. Federal and state enforcement bodies have 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 healthcare 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 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

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authorities, private health insurers and other organizations. However, there may be significant delays in obtaining coverage

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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 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 of care and/or expanding access to care and

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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. See Part I, Item 1 – Healthcare Reform for additional detail on recent legislative and regulatory changes that could affect our operations.

Our risk mitigation measures cannot guarantee that we effectively manage all operational risks and that we are in compliance with all potentially applicable U.S. federal and state regulations and all potentially applicable foreign regulations and/or and 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 (“BBA”), and the Coronavirus Aid, Relief, and Economic Security Act (the “CARES Act”), an annual 2% reduction to Medicare payments took effect on April 1, 2013, and has been extended into 2031 through the first six months of the

fiscal year 2032 sequestration order (with the exception of a temporary suspension from May 1, 2020 through March 31, 2022 and a subsequent reduction to 1% from April 1, 2022 until June 30, 2022). To offset the temporary suspension during the COVID-19 pandemic, in 2030, reductions in Medicare payments will be 2.25% for the first half of the year, and 3% in the second half of the year. The U.S. federal budget remains in flux, which could, among other things, result in additional cuts 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

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of President Biden's administration and the U.S. Congress may have on the federal budget. If federal spending is reduced, anticipated budgetary shortfalls may also impact the ability of relevant agencies, such as the FDA or the National Institutes of Health, to continue to function at current levels. Amounts allocated to federal grants and contracts may be reduced or

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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 planning to potentially develop 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, Japan and the EU, could result in restricted access to, or the 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, PMDA 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.

Our In 2022, we completed construction of our new primary research and new manufacturing facility is located in San Diego, California. We recently completed construction in within our San Diego Research and Development Facility of a new GMP pilot manufacturing facility in San Diego, California as we prepare for potential commercial launch. This facility is designed to produce commercial-scale GMP CAP-1002 product for further clinical and potential commercial use. use, subject to FDA approval.

Additionally, we also maintain a portion of our laboratories, research and manufacturing facilities in leased premises at CSMC in Los Angeles, California. Currently, in the area of our leased premises at CSMC where we manufacture CAP-1002 and may potentially manufacture our exosome technologies, we believe that we follow good manufacturing practices sufficient for an investigational stage product. Capricor has been manufacturing CAP-1002 in this facility for our current and previous studies including Cohort A of the HOPE-3 trial, although we trial. We are planning to potentially use (and, as discussed further below, we may be required by the FDA to use) using product manufactured from our San Diego facility to support Cohort B of the ongoing HOPE-3 trial. trial and supporting our OLE trials. Furthermore, it is to be determined whether the FDA will ultimately approve commercial manufacturing at this facility. Our plans to use the CSMC facility for future trials could change 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, if necessary. Currently, our CSMC Facilities Lease is scheduled to expire on July 31, 2024 July 31, 2026. There can be no assurance that the Facilities Lease for the manufacturing space will be continued beyond July 31, 2024. July 31, 2026 or whether the facility will be approved by the FDA for commercial manufacturing following approval of the BLA.

In the third quarter of 2023, we met with the FDA, where we affirmed alignment with respect to our Phase 3, HOPE-3 program where the FDA agreed to allow us to submit a BLA supported by results using product manufactured at our Los Angeles manufacturing site. At this time, we are considering can provide no assurance that the possible extension of our current Facilities Lease.

The FDA has informed will ultimately approve this facility for commercial use, or that CMSC will allow us that we will need to use cGMP CAP-1002 market commercial product in connection with the ongoing HOPE-3 trial from this facility. Should this facility ultimately not be approved to support a potential BLA filing. Such change manufacture commercial product, this may result in delays and significant expenses which would have a negative materially impact on our business and product development.

In addition, FDA may disagree with our position consider the data we provide are insufficient to prove that the drug used in Cohort B of our prior clinical studies HOPE-3 study is sufficiently comparable to the drug to be produced in our Los Angeles facility and used in our HOPE-3 study. prior clinical studies. This could result in us being required to conduct further comparability testing and may result in us being required to conduct

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additional clinical and/or nonclinical studies before we are able to submit a BLA for approval. Additional testing or clinical

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trial requirements could lead us not to pursue an application for approval. Conducting a clinical trial may prove too difficult or too expensive, and the process of designing a clinical trial, enrolling enough patients, and completing treatment and data collection under the protocol could take a significant amount of time, effort, and resources. Even if we do complete the clinical trial, the study may not meet its prespecified

endpoints, and even if it does, the FDA may still disagree with our determination that the trial is sufficient to support the submission and approval of a marketing BLA application.

We obtain the donor hearts from which our CDCs are manufactured from organ procurement organizations ("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 CDC-exosomes and the development of our lead product candidate would be significantly impaired and possibly terminated. Additionally, we initiated a technology transfer with Lonza Houston, Inc., a leading global contract manufacturing organization OPOs are subject to prepare 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 possibility of commercial launch OPOs to support product demand, as needed, for manufacturing of CAP-1002. Process development and cGMP readiness have been continue to supply us with the focus of the work done by Lonza to date. We are evaluating whether it would be in our best interests to have Lonza move forward to complete the technology transfer process. The next steps will be based on many factors, including our ability hearts we need to produce GMP CAP-1002 our product from our facility in San Diego as well as our discussions with regulatory agencies. candidates.

We may be are required to obtain and maintain certain licenses in connection with our manufacturing facilities and activities. For example, we have recently entered into Azzur License Agreement with Azzur Cleanrooms-on-Demand – San Diego, LLC pursuant to which we have been granted an exclusive license to use certain space and the non-exclusive right to use certain equipment and property for our early phase clinical and/or pre-clinical manufacturing purposes. We are planning to use this facility to manufacture our exosome-based vaccine for potential clinical use. There is no guarantee that any licenses issued to us will not expire, be revoked, 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 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, late-stage clinical trials or commercial use.

To date, our manufacturing experience has been limited to manufacturing CAP-1002 for clinical use in multiple clinical 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 for large scale, late-stage (Phase III) clinical trials or for commercial use. Our product candidates have not previously been tested in any large trials to show safety or efficacy, nor are they available for commercial use. We face risks of manufacturing failures and risks of making products that are not proven to be safe or effective.

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

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

We may need to rely exclusively on third parties to formulate and manufacture our product candidates and provide us with the devices and other products necessary to administer such a product.

Our resources and expertise to formulate or manufacture our product candidates on a large or commercial scale basis are still very limited. If we need to secure an additional manufacturer of our product candidates, demand for third-

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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 products. If CAP-1002 or any of our exosome technologies receives FDA approval, we may need to ultimately rely on one or more third-party contractors to manufacture supplies of these drug products which may cause delays in our ability to sell commercially. Our current and anticipated future reliance on a limited number of third-party manufacturers exposes us to the following risks:

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

The process of manufacturing our products is complex and we may encounter difficulties in production, particularly with respect to process development or scaling-up of our manufacturing capabilities.

We are currently producing doses of CAP-1002 in order to conduct our ongoing HOPE-3 Phase III clinical trial. trials at both of our facilities. The process of manufacturing our products is complex, highly regulated and subject to multiple risks. The complex processes associated with the manufacture of our product candidates expose us to various manufacturing challenges and risks, which may include

delays in manufacturing adequate supply of our product candidates, limits on our ability to increase manufacturing capacity, and the potential for product failure and product variation that may interfere with preclinical and clinical trials, along with additional costs. We also may make changes to our manufacturing process at various points during development, and even after commercialization, for various reasons, such as controlling costs,

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achieving scale, decreasing processing time, increasing manufacturing success rate, or other reasons. Such changes carry the risk that they will not achieve their intended objectives, and any of these changes could cause our product candidates to perform differently and affect the results of current or future clinical trials, or the performance of the product, once commercialized. In some circumstances, changes in the manufacturing process may require us to perform ex vivo comparability studies and to collect additional data from patients prior to undertaking more advanced clinical trials. For instance, changes in our process during the course of clinical development may require us to show the comparability of the product used in earlier clinical trials or at earlier portions of a trial to the product used in later clinical trials or later portions of the trial. We may also make further changes to our manufacturing process before or after commercialization, and such changes may require us to show the comparability of the resulting product to the product used in the clinical trials using earlier processes. We may be required to collect additional clinical data from any modified process prior to obtaining marketing approval for the product candidate produced with such modified process. If clinical data are not ultimately comparable to that seen in the earlier trials in terms of safety or efficacy, we may be required to make further changes to our process and/or undertake additional clinical and/or nonclinical testing, which could significantly delay the clinical development or commercialization of the associated product candidate.

Although we continue to build on our experience in manufacturing our products, product candidates, we have no experience, as a company, manufacturing product candidates for commercial supply. We may never be successful in manufacturing product candidates in sufficient quantities or with sufficient quality for commercial use. Our manufacturing capabilities could be affected by cost-overruns, unexpected delays, equipment failures, labor shortages, operator error,

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natural disasters, unavailability of qualified personnel, difficulties with logistics and shipping, problems regarding yields or stability of product, contamination or other quality control issues, power failures, and numerous other factors that could prevent us from realizing the intended benefits of our manufacturing strategy and have a material adverse effect on our business.

Furthermore, compliance with cGMP requirements and other quality issues may arise during our internal efforts to scale-up manufacturing, and with our current suppliers, or any future CMOs. If contaminants are discovered in our supply of our product candidates or in our manufacturing facilities or those of our CMOs, such manufacturing facilities may need to be closed for an extended period of time to investigate and remedy the contamination. We cannot assure that any stability failures or other issues relating to the manufacture of our product candidates will not occur in the future. Additionally, we and our CMOs may experience manufacturing difficulties due to resource constraints or as a result of labor disputes or unstable political environments. If we or our CMOs were to encounter any of these difficulties, our ability to provide our product candidate to patients in clinical trials, or to provide product for treatment of patients once approved, would be jeopardized.

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.

We may need to rely exclusively on third parties to formulate and manufacture our product candidates and provide us with the devices and other products necessary to administer such a product.

Our resources and expertise to formulate or manufacture our product candidates on a large or commercial scale basis are still very limited. If we need to secure an additional manufacturer of our product candidates, 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 products. If CAP-1002 or any of our exosome technologies receives FDA approval, we may need to ultimately rely on one or more third-party contractors to manufacture supplies of these products which may cause delays in our ability to sell commercially. Our current and anticipated future reliance on a limited number of third-party manufacturers exposes us to the following risks:

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

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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.

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

Our product candidates, if approved, 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. In addition, approved products, manufacturers and manufacturers' facilities are subject to continual review and periodic inspections. If a regulatory agency discovers previously unknown problems with a product, such as adverse events of unanticipated severity or frequency or problems with the

facility where the product is manufactured, a regulatory agency may impose restrictions on that product or us, including requiring withdrawal of the product from the market. If our product candidates fail to comply with applicable regulatory requirements, such as cGMPs, a regulatory agency may:

- issue warning letters or untitled 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 non-compliance;
- 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.

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 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 valid and enforceable 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 Company-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 enforce against 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

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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 valid and enforeceable enforceable 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.

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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 may 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 (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 ("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 and product candidates 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 the University of Rome, JHU, and CSMC. We have also licensed certain patent and other intellectual property rights from CSMC and JHU that cover extracellular vesicles, such as exosomes and microvesicles. 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

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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.

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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 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 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. third-party. These lawsuits are expensive and would consume time and other resources, even if we were successful in

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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

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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 third-party may claim that we or our manufacturing or commercialization partners are using inventions covered by the third party's 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 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

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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.

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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 will depend on our exclusive distributor, Nippon Shinyaku, for the commercial sale of our lead product CAP-1002 in DMD in the United States and Japan, if we receive regulatory approval in those territories.

We believe that a substantial portion of our revenue for the foreseeable future will depend on milestones and other payments received from our distributor, Nippon Shinyaku. Nippon Shinyaku has exclusive distribution rights for CAP-1002 in the United States and Japan for a significant period of time, with only limited rights of either party to terminate these Agreements. agreements.

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. 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. By way of example, we recently received a letter from CSMC alleging that pursuant to the Amended CSMC License Agreement between CSMC and Capricor, Capricor has certain overdue payment obligations to CSMC arising out of a milestone payment received by Capricor pursuant to the U.S. Distribution Agreement entered into between Capricor and Nippon Shinyaku. The notice letter requests that Capricor cure the alleged breaches of the Amended CSMC License Agreement, and reserves CMSC's purported right to terminate the Amended CSMC License Agreement if such alleged breaches are not cured. We dispute the allegations in the letter from CSMC and intend to vigorously defend our position and pursue all available remedies, but there is no guarantee that any disputes that we have with CSMC will be resolved or if resolved, will not result in our incurring certain payment and other obligations.

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

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Marbán, who is the Director of the Smidt Heart Institute at CSMC) are under no obligation to conduct, continue, or conclude either current or future studies utilizing our cell therapy or exosomes technology, and they are not compelled to license any further technologies or intellectual

property rights to us except as may be stated in the applicable licensing agreements 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.

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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.

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 additional strategic partnerships for our product candidates, particularly for CAP-1002 in additional territories outside the United States and Japan and our 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;

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- 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.

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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 ("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. Further, GCP requirements may evolve. In June 2023, the FDA published a draft guidance, E6(R3) Good Clinical Practice (GCP), which seeks to unify standards for clinical trial data for ICH member countries and regions. Changes to data requirements may cause the FDA or comparable foreign regulatory authorities to disagree with data from preclinical studies or clinical trials, and may require further studies.

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 third-party commences work. As a result, delays occur, which can materially impact our ability to meet our desired clinical development timelines.

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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

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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.

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 from time to time have contributed 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 also developed a working relationship between the academic lab 62

Table of Dr. Stephen Gould at JHU and our research and development team where employees and consultants of both entities contributed 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. This SRA expired in accordance with its terms on March 31, 2022. Contents

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 and manufacturing 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 having access to 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 entered into the U.S. Distribution Agreement and the Japan Distribution Agreement with Nippon Shinyaku for the exclusive commercialization and distribution rights in the United States and Japan of CAP-1002 for DMD. We continue to evaluate additional potential partners for this program in other territories outside of these territories, subject to any rights of Nippon Shinyaku.

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. As we entered into the U.S. Distribution Agreement and the Japan Distribution Agreement with Nippon Shinyaku, we will depend upon Nippon Shinyaku's strategic interest in our CAP-1002 product candidate and Nippon Shinyaku's ability to successfully market and sell any such products, if and when approved. If any of our other product candidates are cleared for commercialization, we intend to pursue collaborative arrangements regarding the sales and marketing of such 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, such as our partnership with Nippon Shinyaku, 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, 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;

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- 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;

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- 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 or other indications is at an early stage and is subject to significant risks.

Our development of a vaccine is in early stages and we may be unable to produce a vaccine that successfully treats a particular virus in a timely manner, if at all. Even if we were able to successfully develop and obtain regulatory approval for a 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 and visibility than us are developing COVID-19 vaccines. Even if we were 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 products sell for inadequate prices or patients are unable to obtain adequate levels of reimbursement.

Our or our collaborators' 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 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

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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

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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 is 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, biologics, 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,

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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.

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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 provisions requiring us to maintain certain levels of insurance extending for multiple years beyond the termination or expiration of the agreement as well as 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.

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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;

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- developments in establishing and maintaining new strategic alliances or with existing alliances or collaborators;
- failure to meet milestone requirements under distribution agreements, including the U.S. Distribution Agreement and Japan Distribution Agreement with Nippon Shinyaku;
- 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.

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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.

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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 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, 2022 December 31, 2023, there were approximately 25.2 million 31.1 million shares of common stock outstanding and approximately 0.1 million 5.0 million common warrants outstanding, as well as outstanding awards to purchase approximately 5.8 million 8.2 million shares of common stock under various incentive stock plans of the Company. Additionally, as of December 31, 2022 December 31, 2023, there were approximately 2.6 million 1.2 million shares of common stock available for future issuance under various our incentive plans. This number of shares available for future issuance under those plans was subsequently increased by 1,557,416 shares in accordance with the terms of our 2021 equity incentive plan which include an automatic increase previously approved by our Board and stockholders. 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.

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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 ("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 (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 U.S. Internal Revenue Service ("IRS")

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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. ("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 of 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 (the "Exchange Act"), and other applicable securities rules and regulations, and are subject to the listing requirements of The Nasdaq Stock Market LLC ("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 ("Sarbanes-Oxley"), as well as rules implemented by the Securities and Exchange Commission ("SEC"), SEC, 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 ("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

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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

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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 subject to 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 Additionally, we face such may be subject to litigation it and business challenges in the operation of our company due to actions instituted by activist stockholders. Perceived uncertainties as to our future direction as a result of stockholder activism may lead to the perception of a change in the direction of the business or other instability and may affect our relationships with vendors, distributors, collaborators, prospective and current employees and others. Responding to legal and/or business challenges related to securities class action litigation, or litigation initiated by individual stockholders, including activist stockholders, could result in substantial costs be costly and a diversion of time-consuming, may not align with our business strategies, and could divert management's attention and resources from the pursuit of our business strategies, any of 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 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.

ITEM 1B. UNRESOLVED STAFF COMMENTS

None.

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ITEM 1B. UNRESOLVED STAFF COMMENTS

None.

ITEM 1C. CYBERSECURITY

We operate in the biotechnology sector, which is subject to various cybersecurity risks that could adversely affect our business, financial condition, and results of operations, including intellectual property theft; fraud; extortion; harm to employees; violation of privacy laws and other litigation and legal risk; and reputational risk. We have implemented a risk-based approach to identify and assess the cybersecurity threats that could affect our business and information systems. We use various tools and methodologies to manage cybersecurity risk that are tested on a regular cadence to the best of our ability. We also monitor and evaluate our cybersecurity posture and performance on an ongoing basis through regular vulnerability scans and penetration tests.

Our business depends on the availability, reliability, and security of our information systems, networks, data, and intellectual property. Any disruption, compromise, or breach of our systems or data due to a cybersecurity threat or incident could adversely affect our operations, research, product development, and competitive position. They may also result in a breach of our contractual obligations or legal duties to protect the privacy and confidentiality of our stakeholders. Such a breach could expose us to business interruption, future lost revenue, ransom payments, remediation costs, liabilities to affected parties, cybersecurity protection costs, lost assets, litigation, regulatory scrutiny and actions, reputational harm, and harm to our vendor relationships.

The company is currently in the process of implementing a more formalized cybersecurity program.

ITEM 2. PROPERTIES

We do not own any real property. Our primary operations are conducted at the leased facilities summarized in the below table. We believe our facilities are adequate and suitable for our current needs and that we will be able to obtain new or additional leased space in the future, if necessary.

Location of Property	Lease Expiration Date (1)	Purpose	Square Footage (approximate)
10865 Road to the Cure, Suite 150, San Diego, California	September 30, 2026	Corporate Headquarters: Laboratory, manufacturing and office space	9,605 12,161
10865 Road to the Cure, Room 7, San Diego, California	October 31, 2023 2024	Laboratory space	234
8840 Wilshire Blvd., 2nd Floor, Beverly Hills, California	Month-to-Month, terminable on 90-day notice	Office space	1,627
8700 Beverly Blvd., Davis Building, Los Angeles, California	July 31, 2024 2026	Laboratory, manufacturing and office space	1,892

(1) Certain leases have specific options for potential renewal or extensions.

ITEM 3. LEGAL PROCEEDINGS

We are not involved in any material pending legal proceedings and are not aware of any material threatened legal proceedings against us. us by any governmental authority. We draw your attention to the disclosure in Item 1A. above under “Risk Factors -- Risks Related to Our Relationships with Third Parties -- We are dependent on our relationships with our licensors and collaborators and there is no guarantee that such relationships will be maintained or continued.”

ITEM 4. MINE SAFETY DISCLOSURES

Not applicable.

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PART II

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

Market for Common Stock

Our common stock is traded on the Nasdaq Capital Market under the symbol “CAPR”. The following table lists the high and low closing sales prices of our common stock as quoted, in U.S. dollars, by Nasdaq for the periods indicated. The quotations reflect inter-dealer

prices, without retail markup, markdown or commission, and may not represent actual transactions. Consequently, the information provided below may not be indicative of our common stock price under different conditions.

	High	Low
Year ended December 31, 2021		
First Quarter	$ 7.93	$ 3.63
Second Quarter	5.72	3.16
Third Quarter	5.23	3.80
Fourth Quarter	4.16	2.89
Year ended December 31, 2022		
First Quarter	$ 5.68	$ 2.83
Second Quarter	4.51	2.89
Third Quarter	6.08	3.61
Fourth Quarter	6.55	3.36

Holders

According to the records of our transfer agent, American Stock Transfer & Equiniti Trust Company LLC, as of March 16, 2023 March 7, 2024, we had 134 126 holders of record of common stock, which does not including include holders who held in "street name." name" or beneficial holders, whose shares are held of record by banks, brokers and other financial institutions.

Dividends

We have never declared or paid a dividend on our common stock and do not anticipate paying any cash dividends in the foreseeable future. The ability of our Board of Directors to declare a dividend is subject to limits imposed by Delaware corporate law.

Securities Authorized for Issuance Under Equity Compensation Plans

The information required by this item is set forth in the section entitled "Securities Authorized for Issuance Under Equity Compensation Plans" in our Definitive Proxy Statement for our 2023 2024 Annual Meeting of Stockholders, to be filed with the SEC within 120 days after the end of the fiscal year ended December 31, 2022 December 31, 2023, and is incorporated herein by reference.

Performance Graph

We are a smaller reporting company, as defined by Rule 12b-2 of the Securities Exchange Act of 1934, as amended, and are not required to provide a performance graph.

Recent Sales of Unregistered Securities and Use of Proceeds

Not applicable.

Issuer Purchases of Equity Securities

None.

ITEM 6. RESERVED

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ITEM 7. MANAGEMENT'S DISCUSSION AND ANALYSIS OF FINANCIAL CONDITION AND RESULTS OF OPERATIONS

The following discussion of our financial condition and results of operations should be read in conjunction with the audited consolidated financial statements and the related audited consolidated notes to those statements included elsewhere in this Annual Report on Form 10-K. This discussion includes forward-looking statements that involve risks and uncertainties. As a result of many factors, including those set forth under Item 1A., "Risk Factors" or elsewhere in this annual report, our actual results may differ materially from those anticipated in these forward-looking statements.

Company Overview

Capricor Therapeutics, Inc. is a clinical-stage biotechnology company focused on the development of transformative cell and exosome-based therapeutics for treating Duchenne muscular dystrophy or DMD, ("DMD"), a rare form of muscular dystrophy which results in muscle degeneration and premature death, and other diseases with high unmet medical needs.

Since our inception, we have devoted substantial resources to developing CAP-1002 and our other product candidates including our exosomes platform, developing our manufacturing processes, staffing our company and providing general and administrative support for these operations. We do not have any products approved for sale. Our ability to eventually generate any product revenue sufficient to achieve profitability will depend on the successful development, approval and eventual commercialization of CAP-1002 for the treatment of DMD and our other product candidates. If successfully developed and approved, we intend to commercialize CAP-1002 in the United States and Japan with our partner, Nippon Shinyaku Co., Ltd., a Japanese corporation ("Nippon Shinyaku"), and may enter into additional licensing agreements or strategic collaborations in other markets. If we generate product sales or enter into licensing agreements or strategic collaborations, or further distribution relationships, we expect that any revenue we generate will fluctuate from quarter-to-quarter and year-to-year as a result of the timing and amount of any product sales, license fees, milestone payments and other payments. If we fail to complete the development of our product candidates in a timely manner, our ability to generate future revenue, and our results of operations and financial position, would be materially adversely affected.

A summary description of our key product candidates, is as follows:

- **CAP-1002 for the treatment of DMD (Phase III) 3):** Our core program is focused on the development and commercialization of a cell therapy technology (referred herein as CAP-1002) comprised of CDCs, which are an endogenous a population of stromal cells isolated from donated cells of healthy human hearts, for the treatment of DMD. CAP-1002 is designed to slow disease progression in DMD through the immunomodulatory, anti-inflammatory, and anti-fibrotic actions of CDCs, which are mediated by secreted exosomes laden with bioactive cargo. Among the cargo elements known to be bioactive in CDC-exosomes CDC exosomes are microRNAs. Collectively, these non-coding RNA species alter gene expression in macrophages and other target cells, dialing down generalized inflammation and stimulating tissue regeneration in DMD (and in a variety of other inflammatory diseases). This mechanism of action, which is consistent with the changes observed in clinical studies to date in circulating inflammatory biomarkers, contrasts with that of exon-skipping oligonucleotides and gene therapy approaches, which aim to restore dystrophin expression. DMD is a rare form of muscular dystrophy which results in muscle degeneration and premature death. Additionally, DMD pathophysiology is driven by the absence impaired production of functional dystrophin which normally functions as a structural protein in muscle. The reduction of functional dystrophin in muscle cells leads to significant cell damage and ultimately causes muscle cell death and fibrotic replacement. The annual cost of care for patients with DMD is very high and increases with disease progression. We therefore believe that DMD represents a significant market opportunity for our product candidate, CAP-1002. Our CAP-1002 cell therapy program for the treatment of DMD is currently in Phase 3 clinical development in the United States, for which we expect to have top-line data available in the fourth quarter of 2024.

  To date, we have completed two promising clinical trials investigating CAP-1002 for DMD. Data from the first trial, a Phase I/II trial named HOPE-Duchenne, suggested improvements in skeletal and cardiac endpoints. In HOPE-2, a Phase II clinical trial conducted in the United States, CAP-1002 was used to treat patients with late-stage DMD. In March 2022, we announced that the final one-year results from HOPE-2 were published in *The Lancet* showing that the trial met its primary efficacy endpoint of the mid-level dimension of the PUL Performance of the Upper Limb ("PUL") v1.2 (p=0.01) and additional positive endpoints

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of full PUL v2.0 (p=0.04) and a cardiac endpoint of left ventricular ejection fraction (p=0.002). CAP-1002 was generally safe and well-tolerated throughout the studies.

Additionally, we are currently conducting an OLE open label extension ("OLE") study of the HOPE-2 trial in which 12 patients have elected to continue treatment of CAP-1002. We recently announced positive one-year and 18-month two-year results from this ongoing OLE study. Data from The HOPE-2-OLE study previously met its primary endpoint at the OLE study suggests disease modification with one-year timepoint on the PUL v2.0 scale (p=0.02). At the two-year timepoint, data showed statistically significant differences in the PUL v2.0 scale in the CAP-1002 original OLE treatment group when compared to the original rate of decline of the placebo group from HOPE-2. In addition, disease progression was attenuated equally in both

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groups once patients began treatment in the OLE. HOPE-2 after one-year (p=0.021). CAP-1002 treatment during the OLE portion of the study continues to yield a consistent safety profile and has been well-tolerated throughout the study. At this time, we expect to have three-year data available from this OLE study in the second quarter of 2024.

We are currently enrolling*Phase 3 (HOPE-3) Clinical Trial:* HOPE-3 is a Phase 3, multi-center, randomized, double-blind, placebo-controlled clinical trial comprised of two cohorts evaluating the HOPE-3, Phase III clinical study investigating CAP-1002 for the treatment of late-stage DMD patients for the potential approval safety and efficacy of CAP-1002 in participants with DMD and impaired skeletal muscle function who are on a stable regimen of systemic glucocorticoids. Non-ambulatory and ambulatory boys who meet eligibility criteria are randomly assigned to receive either CAP-1002 or placebo every 3 months for 4 doses during the United States. first 12-months of the study. Approximately 102 eligible study subjects will participate in this dual-cohort study. Enrollment has been completed for Cohort A where 61 subjects were randomized to either CAP-1002 or placebo in a 1:1 ratio and is intended to support a Biologics License Application ("BLA") submission. In December 2023, we announced a positive outcome of the interim futility analysis for Cohort A of HOPE-3, which was reviewed by the Data Safety Monitoring Board ("DSMB"). This resulted in a favorable recommendation to continue the HOPE-3 trial as planned. At this time, we expect to have topline data available from Cohort A in the fourth quarter of 2024. Cohort A uses product manufactured at our Los Angeles facility.

Enrollment is a muti-center, randomized, double-blind, placebo-controlled study currently underway for Cohort B which is designed to treat up enroll approximately 44 participants randomized to 68 subjects either CAP-1002 or placebo in a 1:1 ratio. A primary efficacy and safety analysis will be performed for each individual cohort at approximately 15-20 investigative sites month 12, following 4 administrations of CAP-1002 or placebo. We plan to complete enrollment for Cohort B in the United States. second quarter of 2024. Cohort B uses product manufactured at our San Diego facility.

The primary outcome measure of the HOPE-3 study will be the full PUL Performance of the Upper Limb ("PUL") v2.0, at one-year. a validated tool specifically designed for assessing high (shoulder), mid (elbow) and distal (wrist and hand) functions, with a conceptual framework reflecting weakness progression in upper limb function. HOPE-3 will also measure various secondary endpoints including cardiac function assessments. We have currently treated over 30% of the patients in the currently designed study and have 11 active sites. At this time, our plans to conduct an interim analysis for sample size re-estimation and analysis of conditional power remain unchanged and we anticipate that these results will be available in the fourth quarter of this year.

Under our RMAT designation, in the third quarter of 2023, we recently met with the FDA in a Type-B CMC meeting where we discussed our manufacturing plans in anticipation of potentially submitting a potential BLA application. In the this meeting, we affirmed alignment with respect to our Phase 3, HOPE-3 program. Additionally, we discussed our plans with respect to commercial manufacturing activities, including our potency assay and other product release criteria to support commercialization. We are awaiting plan to meet with FDA in the first quarter of 2024 to continue discussing our pathway to BLA. In the upcoming Type-B meeting, minutes from we intend to discuss our further CMC plans for commercial launch, if approved, with the FDA, but at this time, we believe that we will need aim of expediting our BLA submission pathway. Our ultimate goal is to add some patients to HOPE-3 who will be treated with file a BLA allowing for the use of CAP-1002 commercial product manufactured at our

new San Diego facility, in order to support a potential BLA application. Our San Diego facility is designed to produce commercial-scale GMP CAP-1002 product and we believe that it will be available to manufacture CAP-1002 doses by the third quarter of 2023. We plan to request a follow-on Type B clinical meeting with FDA and expect to have further clarity following that meeting on this topic. Furthermore, at the request of the FDA, we have submitted the interim results from our HOPE-2 OLE for their review and we continue to discuss our pathway towards potential registration. facility.

The regulatory pathway for CAP-1002 is supported by RMAT designation as well as orphan drug designation. If In addition, if Capricor were to receive market FDA marketing approval for CAP-1002 by for the FDA, treatment of DMD, Capricor would be eligible to receive a Priority Review Voucher ("PRV") based on its designation as previous receipt of a rare pediatric disease. disease designation. Capricor retains full rights to the PRV, if received. Further, Capricor has entered into two Commercialization and Distribution Agreements with Nippon Shinyaku appointing Nippon Shinyaku as its exclusive distributor of CAP-1002 in the United States and Japan.

- **Exosome-Based Therapeutics Platform (Preclinical):** Extracellular vesicles, including exosomes and Vaccines (Preclinical):We microvesicles, are focused on developing a precision-engineered exosome platform technology that has 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 the delivery of their cargo into the cytosol of target cells. Exosomes act

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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. Their size, low or null immunogenicity and ability to deliver defined sets communicate in native cellular language potentially make them an exciting new class of effector molecules which exert their effects through defined mechanisms of action. We recently presented new preclinical data on therapeutic agents with the potential to expand our StealthX™ platform showing the rapid development of a recombinant protein-based vaccine for immunization ability to address complex biological responses. Because exosomes are cell-free substances, they can be stored, handled, reconstituted and prevention against SARS-CoV-2, the virus causing COVID-19. At this time, we are developing vaccines and therapeutics for infectious diseases, monogenic diseases and other potential indications. Our platform builds on advances administered in fundamental RNA and protein science, targeting technology and manufacturing, providing us the opportunity similar fashion to potentially build a broad pipeline of new therapeutic candidates. common biopharmaceutical products such as antibodies.

We are focused on developing a precision-engineered exosome platform technology that has the ability to deliver defined sets of effector molecules that exert their effects through defined mechanisms of action. Aspects of our exosome pipeline have been supported through collaborations and alliances. Our collaborations and research around exosomes include the National Institutes of Health ("NIH"), the National Institute of Allergy and Infectious Diseases ("NIAID"), Johns Hopkins University ("JHU"), the Department of Defense ("DoD"), the U.S. Army Institute of Surgical Research ("USAISR"), and Cedars-Sinai Medical Center ("CSMC"). We have published preclinical data on our StealthX™ platform showing the rapid development of a recombinant protein-based vaccine for immunization and prevention against SARS-CoV-2, the virus causing COVID-19. Our platform builds on advances in fundamental RNA and protein science, targeting technology and manufacturing, providing us the opportunity to potentially build a broad pipeline of new therapeutic candidates. Recently, we were selected to be part of Project NextGen, an initiative by the U.S. Department of Health and Human Services to advance a pipeline of new, innovative vaccines providing broader and more durable protection for COVID-19. As part of Project NextGen, the National Institute of Allergy and Infectious Diseases, part of the National Institutes of Health, will conduct a Phase 1 clinical study with our StealthX™ vaccine, subject to regulatory approval. At this time, we have submitted an Investigational New Drug Application ("IND") to the FDA for our StealthX™ vaccine, which is currently under review and we anticipate that once the IND is approved, that NIAID plans to initiate this trial in late 2024. Furthermore, If NIAID finds that our StealthX™ vaccine meets its criteria for safety and efficacy, they may consider our program for a funded Phase 2. At this time, we are developing exosome-based vaccines and therapeutics for infectious diseases, monogenic diseases and other potential indications. Our current strategy is focused on securing partners who will provide capital and additional resources to enable us to bring this program into the clinic.

As of December 31, 2022 December 31, 2023, we had cash, cash equivalents, and marketable securities totaling approximately $41.4 million $39.5 million. Additionally, under In the terms fourth quarter of 2023, we announced a positive outcome of the interim futility analysis for HOPE-3, which was reviewed by the Data Safety Monitoring Board. This resulted in a favorable recommendation to continue the HOPE-3 trial as planned, and in accordance with our Japan U.S. Distribution Agreement with Nippon Shinyaku we expect to receive an upfront, triggered a milestone payment of $12.0 million $10.0 million which was received in the first quarter of 2023 January 2024. We estimate this will fund our operating expenses and capital expenditure requirements into the fourth first quarter of 2024. 2025. This expectation includes the $10.0 million milestone payment but excludes any additional potential additional milestone payments under our commercialization Commercialization and distribution Distribution agreements with Nippon Shinyaku. 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.

Due to our significant research and development expenditures, and general administrative costs associated with our operations, we have generated substantial operating losses in each period since our inception. Our net losses were $29.0 million $22.3 million and $20.0 million $29.0 million, for the years ended December 31, 2022 December 31, 2023 and 2021, 2022, respectively. As of December 31, 2022 December 31, 2023, we had an accumulated deficit of $137.1 million $159.4 million. We expect to incur significant expenses and operating losses for the foreseeable future.

During the year ended December 31, 2022 December 31, 2023, we sold 830,858 877,821 shares of common stock at an average price of approximately $5.97 $4.78 per share pursuant to a sales agreement by and between us and H.C. Wainwright & Co. LLC ("Wainwright"), under our at-the-market offering, resulting in net proceeds of $4.8 million $4.1 million. Additionally, in October 2023, we completed a registered direct offering for gross proceeds of approximately $23.0 million.

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Recent Operational Developments

CAP-1002 DMD Program Updates

- Enrollment has been completed for Cohort A in our Phase 3 trial which enrolled 61 subjects randomized to either CAP-1002 or placebo in a 1:1 ratio.

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- Reported a positive outcome from the interim futility analysis for Cohort A which triggered the first milestone payment of $10.0 million under our U.S. Commercialization Agreement with Nippon Shinyaku. There is an additional $90.0 million in potential milestone payments up to the time of approval which are triggered upon certain regulatory-based achievements. Following potential approval, there is an additional $605.0 million in potential milestones payments which may be payable to Capricor based on various sales-based targets being met.
- Next steps for Cohort A: plan to readout top-line data in the fourth quarter of 2024.
- Enrollment is underway for Cohort B designed to enroll approximately 44 subjects randomized to either CAP-1002 or placebo in a 1:1 ratio.
- Next steps for Cohort B: expect to complete enrollment in the second quarter of 2024.

- Announced the scale-up to expand the manufacturing capacity of CAP-1002 to our new San Diego facility, intended for commercial use, subject to regulatory approval. This facility was designed to be a versatile and cost-effective way to bring CAP-1002 to market efficiently and it is expected that our enhanced manufacturing capacity will increase our supply capabilities and improve our margins on ultimate product sales, if any. We are currently producing CAP-1002 doses at our San Diego facility for use in Cohort B.
- Announced a positive outcome from a Type-B meeting held with FDA in the third quarter of 2023. In the meeting, the FDA affirmed alignment on the current HOPE-3 clinical trial design comprised of two cohorts and our plan to submit a BLA supported by results from Cohort A which uses product manufactured from our Los Angeles manufacturing facility.
- We recently completed construction plan to meet with FDA in the first quarter of 2024 to continue discussing our pathway to BLA. In the upcoming Type-B meeting, we intend to discuss our further CMC plans for commercial launch, if approved, with an aim to expedite the approval pathway to our BLA filing. Our ultimate goal is to transition to our San Diego Research and Development Facility of a new GMP pilot manufacturing facility for commercial manufacturing as we prepare for potential commercial launch. This facility is being designed to be compliant with U.S., European Medicines Agency ("EMA"), and other international standards. This facility is designed to produce commercial-scale GMP CAP-1002 product for further clinical and potential commercial use. quickly as possible.
- In February 2023 we entered into Hosted a Commercialization and Distribution Agreement (the "Japan Distribution Agreement") webinar in conjunction with Nippon Shinyaku Parent Project Muscular Dystrophy (PPMD) where key updates on our DMD program were outlined.
- Presented a late-breaking poster at the 28th International Annual Congress of the World Muscle Society (WMS). Highlights from the poster included data from the HOPE-2 OLE trial measured by the Performance of the Upper Limb (PUL 2.0) showing a delta change=4.9 points, p=0.021 after 24-months of treatment, compared with the placebo patient group.

Exosome Program

- Announced that our proprietary StealthX™ exosome-based multivalent vaccine (StealthX™ vaccine) for the exclusive commercialization prevention of SARS-CoV-2 was selected to be part of Project NextGen, an initiative by the U.S. Department of Health and distribution Human Services to advance a pipeline of CAP-1002 new, innovative vaccines providing broader and more durable protection for DMD in Japan. COVID-19. As part of Project NextGen, NIAID, part of the National Institutes of Health, will conduct and fund a Phase 1 clinical trial with our StealthX™ vaccine, subject to regulatory approval. Under the terms of the Japan Distribution Agreement, we collaboration, Capricor will be responsible supply the investigational product and NIAID's Division of Microbiology and Infectious Diseases (DMID) will oversee the trial.
- Next steps for this project: NIAID plans to initiate the development of the Phase 1 clinical program trial in Japan required to obtain manufacturing and marketing approval for CAP-1002 as well as for the manufacturing of CAP-1002. Pursuant to the Japan Distribution Agreement, we have the obligation to sell commercial product to Nippon Shinyaku, late 2024, subject to regulatory approval, and in addition, Capricor will have the right to receive a meaningful, double-digit share of product revenue and additional development and sales-based milestone payments, if achieved. We are entitled to receive an upfront payment of $12.0 million which is expected to be received in the first quarter of 2023 and have the potential to receive additional milestone payments of up to approximately $89 million, subject to foreign currency exchange rates. approval.
- We Currently, in collaboration with an undisclosed pharmaceutical company, we are conducting an OLE study also investigating the therapeutic application of the HOPE-2 trial in which 12 patients have elected to continue treatment of CAP-1002. In June 2022, we announced positive one-year results from this ongoing OLE study. In February 2023, we announced positive 18-month results from this ongoing OLE Study. The one year and 18-month data from this OLE study showed statistically significant improvements on the PUL v2.0 for patients on CAP-1002 testing three different hypotheses of treatment benefit during the open label extension. We plan to report the 24-month OLE data in the second quarter of this year. our StealthX™ exosome platform.
- In March 2022, we announced that Presented a late-breaking poster at the final one-year results WMS on the application of our StealthX™ exosome platform for the delivery of antisense oligonucleotides (ASO). Highlights from our HOPE-2, Phase II clinical trial were published in The Lancet the poster included data showing that the trial met its primary efficacy endpoint presence of mid-level PUL v1.2 (p=0.01) and additional positive endpoints of full PUL v2.0 (p=0.04) and cardiac endpoint of ejection fraction (p=0.002). CAP-1002 was generally safe and well-tolerated throughout the study. With the exception of hypersensitivity reactions early exosomes loaded with a labeled ASO in the clinical trial, which lower limbs of mice 24 hours post-intravenous (IV) injection. Notably, the exosomes carrying the muscle-targeting moiety were mitigated not detected in any other tissues except for the expected clearance pathways (kidney and liver) with a common pre-medication regimen, there were no serious safety signals identified by the HOPE-2 DSMB. single dose.

Corporate Updates

- Announced receipt of our first milestone payment of $10.0 million under our U.S. Exclusive Distribution and Commercialization Agreement with Nippon Shinyaku.

- In January 2022 we entered into the U.S. Distribution Agreement Announced completion of a registered direct offering with participation from Nippon Shinyaku for the exclusive commercialization and distribution gross proceeds of CAP-1002 for DMD in the United States. Under the terms of the U.S. Distribution Agreement, we will be responsible for the conduct of the HOPE-3 trial as well as for the manufacturing of CAP-1002. NS Pharma, Inc., a subsidiary of Nippon Shinyaku, will be responsible for the distribution of CAP-1002 in the United States. Pursuant to the U.S. Distribution Agreement, we have the obligation to sell commercial product to Nippon Shinyaku, subject to regulatory approval, and in addition, Capricor will have the right to receive a meaningful, double-digit share of product revenue and additional development and sales-based milestone payments, if achieved. We received an upfront payment of $30.0 million in the first quarter of 2022 and have the potential to receive additional milestone payments of up to $705.0 million approximately $23.0 million.

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As we seek to develop and commercialize CAP-1002 or any other product candidates including those related to our exosomes program, we anticipate that our expenses will increase significantly and that we will need substantial additional funding to support our continuing operations. Until such time when we can generate significant revenue from product sales, if ever, we expect to finance our operations through a combination of public or private equity financings, debt financings or other sources, which may include licensing agreements or strategic collaborations or other distribution agreements. We may be unable to raise additional funds or enter into such agreements or arrangements when needed on favorable terms, if at all. If we fail to raise capital or other potential funding or enter into such agreements as and when needed, we may have to significantly delay, scale back or discontinue the development or commercialization of CAP-1002 or our other product candidates.

The COVID-19 pandemic has presented a substantial public health and economic challenge around the world. Our business operations and financial condition and results have been impacted to varying degrees, and we expect the impact will continue in future quarters particularly in connection with supply chain constraints. For additional information on the various risks posed by the COVID-19 pandemic, refer to Part I, Item 1A. Risk Factors of this Annual Report on Form 10-K.

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Financial Operations Overview

We have no commercial product sales to date and will not have the ability to generate any commercial product revenue until after we have received approval from the FDA or equivalent foreign regulatory bodies to begin selling our pharmaceutical product candidates. Developing pharmaceutical biological products is a lengthy and very expensive process. Even if we obtain the capital necessary to continue the development of our product candidates, whether through a strategic transaction or otherwise, we do not expect to complete the development of a product candidate for several years, if ever. To date, most of our development expenses have related to our product candidates, consisting of CAP-1002 and our exosome technologies. As we proceed with the clinical development of CAP-1002, and as we further develop our exosome technologies, our expenses will further increase. Accordingly, our success depends not only on the safety and efficacy of our product candidates, but also on our ability to finance the development of our products and our clinical programs. Our recent major sources of working capital have been primarily proceeds from public equity sales of securities and an upfront payment payments pursuant to our U.S. and Japan Distribution Agreement Agreements with Nippon Shinyaku. While we pursue our preclinical and clinical programs, we continue to explore potential partnerships for the development of one or more of our product candidates in the US and in other territories across the world.

Our results have included non-cash compensation expense due to the issuance of stock options and warrants, as applicable. We expense the fair value of stock options and warrants over their vesting period as applicable. When more precise pricing data is unavailable, we determine the fair value of stock options using the Black-Scholes option-pricing model. The terms and vesting schedules for share-based awards vary by type of grant and the employment status of the grantee. Generally, the awards vest based upon time-based conditions. Stock-based compensation expense is included in the consolidated statements of operations under general and administrative ("G&A&A") or research and development ("R&D&D") expenses, as applicable. We expect to record additional non-cash compensation expense in the future, which may be significant.

Results of Operations for the fiscal years ended December 31, 2022December 31, 2023 and 20212022

Revenue

Clinical Development Income. Clinical development income for the years ended December 31, 2022December 31, 2023 and 20212022 was approximately $2.6 million$25.2 million and zero,$2.6 million, respectively. The Company started recognizingbegan to recognize the $30.0 million upfront payment received from Nippon Shinyaku related to an Exclusive Commercialization and Distribution Agreement (the "U.S. Distribution Agreement") with Nippon Shinyaku in the third quarter of 2022. The Company began to recognize the $10.0 million milestone payment in connection with the U.S. Distribution Agreement in the fourth quarter of 2023. Revenue is ratably recognized using a proportional performance method in relation to the completion of the HOPE-3 clinical study.trial (Cohort A).

Miscellaneous Income. Miscellaneous income for the years ended December 31, 2022 and 2021 was zero and $0.2 million, respectively. The miscellaneous income was related to providing CAP-1002 for investigational purposes for clinical trials sponsored by CSMC. The decrease in miscellaneous income is due to the clinical trials sponsored by CSMC completing or ceasing enrollment in 2021.

Operating Expenses

Research and Development Expenses. Research and development ("R&D")&D expenses consist primarily of compensation and other related personnel costs, supplies, clinical trial costs, patient treatment costs, rent for laboratories and manufacturing facilities, consulting fees, costs of personnel and supplies for manufacturing, costs of service providers for preclinical, clinical and manufacturing, certain legal expenses resulting from intellectual property prosecution, stock-based compensation expense and other expenses relating to the design, development, testing and enhancement of our product candidates.

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The following table summarizes our R&D expenses by category for each of the periods indicated:

	Year ended December 31,				Year ended December 31,			
	2022	2021	Change ($)	Change (%)	2023	2022	Change ($)	Chang
Compensation and other personnel expenses	$ 7,450,879	$ 3,016,745	$ 4,434,134	147 %	$11,272,356	$ 7,450,879	$ 3,821,477	
Duchenne muscular dystrophy (CAP-1002)	7,470,558	4,003,854	3,466,704	87 %	18,667,993	7,470,558	11,197,435	
Exosomes platform research	3,600,916	3,446,950	153,966	4 %	2,090,999	3,600,916	(1,509,917)	
Facility expenses	1,070,598	410,279	660,319	161 %	1,457,097	1,070,598	386,499	
Stock-based compensation	805,089	398,809	406,280	102 %	1,916,245	805,089	1,111,156	
Depreciation	420,581	241,593	178,988	74 %	626,514	420,581	205,933	
Research and other projects	998,328	2,052,815	(1,054,487)	(51)%				
Research and other					416,835	998,328	(581,493)	
Total research and development expenses	$21,816,949	$13,571,045	$ 8,245,904	61 %	$36,448,039	$21,816,949	$14,631,090	

R&D expenses for 2022 2023 increased by approximately $8.2 million $14.6 million, or 61% 67%, compared to 2021. 2022. The increase was primarily driven by the following:

- $4.4 3.8 million increase in compensation and other personnel expenses primarily due to increases in headcount;
- $3.5 11.2 million increase in DMD (CAP-1002) program primarily due to the commencement enrollment of our HOPE-3 clinical trial in 2022, continuation of program, our HOPE-2 OLE clinical program, trial and our expanded manufacturing production efforts for CAP-1002;
- $0.2 million increase in exosomes platform research primarily due to our continued development efforts;
- $0.7 0.4 million increase in facility expenses primarily related to increased lease expenses due to our expansion efforts of our research and manufacturing facility in San Diego expansion efforts; Diego;
- $0.4 1.1 million increase in stock-based compensation expense primarily due to increases in headcount and stock price; risk-free rate, which resulted in an increase in fair value of option issued; and
- $0.2 million increase in depreciation expense primarily related to increased equipment purchases and capital improvements primarily due related to the San Diego manufacturing cleanroom buildout; and
- $1.1 million decrease in expansion efforts of our research and other projects primarily due to the close-out of our INSPIRE program. manufacturing facility in San Diego.

This increase was partially offset by a $1.5 million decrease in exosomes research primarily due to reduced expenses related to completion of certain research projects and a $0.6 million decrease in research and other primarily due to the completion of activities related to our INSPIRE clinical program in 2022.

General and Administrative Expenses. General and administrative ("G&A") &A expenses consist primarily of compensation and other related personnel expenses for executive, finance and other administrative personnel, stock-based compensation expense, accounting, legal and other professional fees, consulting expenses, rent for corporate offices, business insurance and other corporate expenses.

The following table summarizes our G&A expenses by category for each of the periods indicated:

	Year ended December 31,				Year ended December 31,			
	2022	2021	Change ($)	Change (%)	2023	2022	Change ($)	Change (%
Stock-based compensation	$ 3,653,489	$2,566,883	$1,086,606	42 %	$ 5,476,151	$ 3,653,489	$1,822,662	50
Compensation and other personnel expenses	3,283,964	2,316,675	967,289	42 %	3,702,469	3,283,964	418,505	13
Professional services	1,958,666	1,698,424	260,242	15 %	1,700,852	1,958,666	(257,814)	(13)
Facility expenses	355,318	175,042	180,276	103 %	294,841	355,318	(60,477)	(17)
Depreciation					442,368	112,550	329,818	293
Other corporate expenses	1,180,466	855,271	325,195	38 %	1,191,205	1,067,916	123,289	12
Total general and administrative expenses	$10,431,903	$7,612,295	$2,819,608	37 %	$12,807,886	$10,431,903	$2,375,983	23

G&A expenses for 2022 2023 increased by approximately $2.8 million $2.4 million, or 37% 23%, compared to 2021. 2022. The increase was primarily driven by the following:

- $1.1 1.8 million increase in stock-based compensation expense primarily due to increases in headcount;
- $1.0 0.4 million increase in compensation and other personnel expenses primarily due to increases in headcount; headcount and recruiting costs;
- $0.3 million increase in professional service expenses primarily due depreciation related to an increase in business insurance and investor relations expenses;
- $0.2 million increase in facility related expenses primarily due leasehold improvements to our continuing expansion efforts; San Diego corporate headquarters; and
- $0.3 million increase in other corporate expenses primarily related to accounting fees and other general corporate expenses related to increases in headcount.

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- $0.1 million increase in other corporate expenses primarily related to increased travel and payroll processing costs due to increased headcount.

This increase was partially offset by a $0.3 million decrease in professional service expenses primarily due to a decrease in business development related expenses.

Other Income

Other Income. Other income for the years ended December 31, 2022 December 31, 2023 and 2021 2022 was approximately $0.2 million $0.1 million and $0.5 million $0.2 million, respectively. Other income in 2022 was related to the Employer Retention Credit under the CARES Act.

Investment Income. Investment income for the years ended December 31, 2022 December 31, 2023 and 2021 2022 was approximately $0.5 million $1.7 million and $57,460, $0.5 million, respectively. The increase in investment income in 2022 2023 as compared to 2021 2022 is due to increased interest rates and the higher principal balance in our marketable securities, savings and money market fund accounts.

Products Under Active Development

CAP-1002 for the treatment of DMD – We are currently conducting our HOPE-3, Phase III 3 study for DMD and our ongoing OLE study of the HOPE-2 trial for which we expect to spend approximately $12.5 million $25.0 million to $17.5 million $35.0 million in 2023. 2024. The expenses for our DMD program will include costs for personnel, clinical, regulatory and manufacturing-related expenses, including expenses related to the scale-up for potential commercial scale manufacturing. manufacturing if our CAP-1002 product is approved.

Exosome-Based Therapeutics and Vaccines – Our exosome platform is in early-stage preclinical development. We expect to spend approximately $4.0 million $3.0 million to $6.0 million $5.0 million during 2023 2024 on development expenses related to our exosomes program, which includes personnel, preclinical studies and manufacturing related expenses for these technologies. Our expenses for this program are primarily focused on the expansion of our engineered exosomes platform including the conduct manufacturing of IND-enabling studies. our StealthX™ vaccine to be used in connection with our collaboration with NIAID.

Our expenditures on current and future clinical development programs, particularly our CAP-1002 and exosomes programs, cannot be predicted with any significant degree of certainty as they are dependent on the results of our current trials and our ability to secure additional funding and a strategic partner. Further, we cannot predict with any significant degree of certainty the amount of time which will be required to complete our clinical trials, the costs of completing research and development projects or whether, when and to what extent we will generate revenues from the commercialization and sale of any of our product candidates. The duration and cost of clinical trials may vary significantly over the life of a project as a result of unanticipated events arising during manufacturing and clinical development and as a result of a variety of other factors, including:

- the number of trials and studies in a clinical program;
- the number of patients who participate in the trials;
- the number of sites included in the trials;
- the rates of patient recruitment and enrollment;
- the duration of patient treatment and follow-up;
- the costs of manufacturing our product candidates;
- the availability of necessary materials required to make our product candidates; and
- the costs, requirements and timing of, and the ability to secure, regulatory approvals; and approvals.
- additional delays caused by the COVID-19 pandemic.

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Liquidity and Capital Resources for the fiscal years ended December 31, 2022 December 31, 2023 and 2021 2022

The following table summarizes our liquidity and capital resources as of and for each of our last two fiscal years, and our net increase (decrease) in cash, cash equivalents, and marketable securities as of and for each of our last two fiscal years and is intended to supplement the more detailed discussion that follows. The amounts stated in the tables below are expressed in thousands.

Liquidity and capital resources	December 31, 2022	December 31, 2021	As of December 31, 2023	As of December 31, 2022
Cash and cash equivalents	$ 9,603	$ 34,885	$14,695	$ 9,603
Marketable securities	$ 31,818	$ -	$24,793	$31,818
Working capital	$ 19,302	$ 32,304	$19,586	$19,302
Stockholders' equity	$ 11,786	$ 31,368	$22,601	$11,786

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Cash flow data	Year ended December 31, 2022	Year ended December 31, 2021	Year ended December 31, 2023	Year ended December 31, 2022
Cash provided by (used in):				
Operating activities	$ 4,917	$ (16,809)	$ (25,596)	$ 4,917
Investing activities	(35,073)	(1,196)	5,108	(35,073)
Financing activities	4,874	20,225	25,580	4,874
Net increase (decrease) in cash and cash equivalents	$ (25,282)	$ 2,220	$ 5,092	$ (25,282)

Our total cash, cash equivalents, and marketable securities as of December 31, 2022 was December 31, 2023 were approximately $41.4 million $39.5 million compared to approximately $34.9 million $41.4 million as of December 31, 2021 December 31, 2022. The increase decrease in cash, cash equivalents and marketable securities from December 31, 2022 December 31, 2023 as compared to December 31, 2021 December 31, 2022 is primarily due to a net loss of approximately $22.3 million for the upfront payment year ended December 31, 2023, receipt of $30.0 million $12.0 million upfront from Nippon Shinyaku. Shinyaku related to the Japan Distribution Agreement in the first quarter of 2023, and approximately $23.0 million raised in October 2023 through a registered direct offering. The net loss of approximately $22.3 million for the year ended December 31, 2023 was driven by the increased R&D expenses in connection with our clinical program in DMD. As of December 31, 2022 December 31, 2023, we had approximately $38.3 million $36.1 million in total liabilities, of which approximately $27.4 million $24.3 million relates to deferred revenue and approximately $2.6 million $2.2 million related to lease liabilities in connection with our operating lease right-of-use assets. As of December 31, 2022 December 31, 2023, we had approximately $19.3 million $19.6 million in net working capital. We had a net loss of

Cash used in operating activities was approximately $29.0 million $25.6 million for the year ended December 31, 2022.

Cash December 31, 2023 and cash provided by operating activities was approximately $4.9 million and cash used in operating activities was approximately $16.8 million for the years year ended December 31, 2022 and 2021, respectively. . The difference net change of approximately $21.7 million $30.5 million in cash from operating activities is primarily due to the upfront milestone payment of $30.0 million $10.0 million from Nippon Shinyaku. Shinyaku and deferred revenue. Furthermore, there was an increase of approximately $1.5 million $2.9 million in stock-based compensation and an increase a decrease in net loss of approximately $9.0 million $6.7 million for the year ended December 31, 2022 December 31, 2023 as compared to the same period in 2021. 2022. Furthermore, there was a net change of approximately $0.2 million $0.1 million in accounts payable and accrued expenses, which includes related party accounts payable and accrued expenses, and a change of approximately $0.2 million in receivables for the year ended December 31, 2022 as compared to the same period in 2021. expenses. To the extent we obtain sufficient capital and/or long-term debt funding and are able to continue developing our product candidates, including if we expand our platform technology portfolio, engage in further research and development activities, and, in particular, conduct preclinical studies and clinical trials, we expect to continue incurring substantial losses, which will generate negative net cash flows from operating activities.

We had cash flow provided by investing activity of approximately $5.1 million for the year ended December 31, 2023 and cash flow used in investing activities of approximately $(35.1) million and $(1.2) million $35.1 million for the years year ended December 31, 2022 and 2021, respectively. . The change in cash flow by investing activities for the year ended December 31, 2022 December 31, 2023 as compared to the same period of 2021 2022 is primarily due to the net effect from purchases, sales, and maturities of marketable securities as well as purchases of property and equipment and leasehold improvements.

We had cash flow provided by financing activities of approximately $4.9 million $25.6 million and $20.2 million $4.9 million for the years ended December 31, 2022 December 31, 2023 and 2021, 2022, respectively. The decrease increase in cash provided by financing activities for the year ended December 31, 2022 December 31, 2023 as compared to the same period of 2021 2022 is primarily due to the net proceeds from the sale of common stock. During 2022 2023 we received net proceeds from the sale of stock of approximately $4.8 million $25.5 million compared to approximately $20.2 million $4.8 million over the same period of 2021. 2022.

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From inception through December 31, 2022 December 31, 2023, we financed our operations primarily through private and public sales of our equity securities, government grants, and payments from distribution agreements and collaboration partners. As we have not generated any revenue from the commercial sale of our products to date, and we do not expect to generate revenue for several years, if ever, we will need to raise substantial additional capital to fund our research and development, including our long-term plans for clinical trials and new product development. We may seek to raise additional funds through various potential sources, such as equity and debt financings, government grants, or through strategic collaborations and license agreements or other distribution agreements. We can give no assurances that we will be able to secure such additional sources of funds to support our operations, complete our clinical trials or if such funds become available to us, that such additional financing will be sufficient to meet our needs. Moreover, to the extent that we raise additional funds by issuing equity securities, our stockholders may experience significant dilution, and debt financing, if available, may involve restrictive covenants. To the extent that we raise additional funds through collaboration and licensing arrangements, it may be necessary to relinquish some rights to our technologies or our product candidates or grant licenses on terms that may not be favorable to us.

Our estimates regarding the sufficiency of our financial resources are based on assumptions that may prove to be wrong. We may need to obtain additional funds sooner than planned or in greater amounts than we currently anticipate. At this time, we believe our cash resources are sufficient to fund our operations for at least the next twelve months. The

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actual amount of funds we will need to operate is subject to many factors, some of which are beyond our control. These factors include the following:

- the progress of our clinical and research activities;
- the number and scope of our clinical and research programs;
- the progress and success of our preclinical and clinical development activities;
- the progress of the development efforts of parties with whom we have entered into research and development agreements;
- our ability to successfully manufacture product for our clinical trials; trials and potential commercial use;
- the availability of materials necessary to manufacture our product candidates;

- the costs of manufacturing our product candidates, and the progress of efforts with parties with whom we may enter into commercial manufacturing agreements, if necessary;
- our ability to maintain current research and development programs and to establish new research and development and licensing arrangements;
- additional costs associated with maintaining licenses and insurance;
- the costs involved in prosecuting and enforcing patent claims and other intellectual property rights; and
- the costs and timing of regulatory approvals.

As a result of the spread of the COVID-19 coronavirus, uncertainties have arisen that have impacted enrollment of clinical trials, deliverables related to contract performance, payments from trial sponsors, workforce stability, supply chain disruptions or delays, timing of grant disbursements as well as other potential business operations. While the disruption is currently expected to be temporary, there is considerable uncertainty around its expected duration. In addition to potential impact on grant availability, there may be risks to the Company's ability to obtain financing from other sources, due to the impact of the coronavirus. There could be other financial impacts on our business from the coronavirus, the specifics of which are unknown at this time.

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Collaborations

Commercialization and Distribution Agreement with Nippon Shinyaku (Territory: United States)

On January 24, 2022, Capricor entered into an Exclusive a Commercialization and Distribution Agreement (the "U.S. Distribution Agreement") with Nippon Shinyaku, a Japanese corporation. Under the terms of the U.S. Distribution Agreement, Capricor appointed Nippon Shinyaku as its exclusive distributor in the United States of CAP-1002 for the treatment of DMD.

Under the terms of the U.S. Distribution Agreement, Capricor will be responsible for the conduct of the HOPE-3 trial as well as the manufacturing of CAP-1002. Nippon Shinyaku will be responsible for the distribution of CAP-1002 in the United States. Pursuant to the U.S Distribution Agreement, Capricor received an upfront payment of $30.0 million in the first quarter of 2022. The first milestone payment of $10.0 million was paid upon completion of the interim futility analysis of the HOPE-3 trial whereby the outcome was determined to be not futile. Capricor received this milestone payment from Nippon Shinyaku in January 2024. Additionally, there are potential milestones totaling up to $90.0 million leading up to and including the BLA approval. Further, there are various potential sales-based milestones, if commercialized, tied to the achievement of certain sales thresholds for annual net sales of CAP-1002 of up to $605.0 million. Further, pursuant to the U.S. Distribution Agreement, Capricor has the obligation to sell commercial product to Nippon Shinyaku, subject to regulatory approval, and in addition Capricor will have the right to receive a meaningful mid-range double-digit share of product revenue and additional development and sales-based milestone payments, if achieved. In the first quarter revenue.

Table of 2022, Capricor received an upfront payment of $30.0 million. Pursuant to the terms of the U.S. Distribution Agreement, there are potential additional sales and development milestone payments of up to $705.0 million. Contents

Commercialization and Distribution Agreement with Nippon Shinyaku (Territory: Japan)

On February 10, 2023, Capricor entered into an Exclusive a Commercialization and Distribution Agreement (the "Japan Distribution Agreement") with Nippon Shinyaku. Under the terms of the Japan Distribution Agreement, Capricor appointed Nippon Shinyaku as its

exclusive distributor in Japan of CAP-1002 for the treatment of DMD.

Under the terms of the Japan Distribution Agreement, Capricor expects to receive received an upfront payment of $12 million $12.0 million in the first quarter of 2023 and in addition, Capricor will potentially receive additional development and sales-based milestone payments of up to approximately $89 million $89.0 million, subject to foreign currency exchange rates, and a meaningful double-digit share of product revenue. Nippon Shinyaku will be responsible for the distribution of CAP-1002 in Japan. Capricor will be responsible for the conduct of clinical development in Japan, as may be required, as well as the manufacturing of CAP-1002. Subject to regulatory approval, Capricor will sell commercial product to Nippon Shinyaku. Shinyaku in Japan. In addition, Capricor or its designee will hold the Marketing Authorization in Japan if the product is approved in that territory.

Financing Activities by the Company

June 2021 October 2023 Financing

On October 3, 2023, the Company entered into Securities Purchase Agreements with its commercial partner, Nippon Shinyaku and funds associated with Highbridge Capital Management, LLC (the "Investors"), pursuant to which the Company agreed to issue and sell to the Investors, in a registered direct offering (the "Registered Direct Offering"), an aggregate of 4,935,621 shares of its common stock, par value $0.001 per share, at a price per share of $4.66 for an aggregate purchase price of approximately $23.0 million. Each share of common stock offered was sold with a warrant to purchase one share of common stock at an exercise price of $5.70 per share. Each warrant will be exercisable beginning six months after issuance and will expire seven years from the date of issuance. As part of the Registered Direct Offering, the Company agreed not to issue or sell shares (subject to customary exceptions for employee stock option issuances and other customary exceptions) for a period of 30 days following the date of the prospectus supplement that was used in the Registered Direct Offering. That prospectus was dated September 29, 2023, and the Company "lock-up" expired on October 29, 2023. The Company's directors and executive officers also entered into "lock-up" agreements with the placement agent in the Registered Direct Offering, which agreements expired on the 60th day following the date of the Securities Purchase Agreements, or December 2, 2023.

ATM Program

On June 21, 2021, the Company initiated an at-the-market offering under a prospectus supplement for aggregate sales proceeds of up to $75.0 million (the "June 2021 ATM "ATM Program"), with the common stock to be distributed at the market prices prevailing at the time of sale. The June 2021 ATM Program was established under a Common Stock Sales Agreement (the "Sales Agreement" Agreement,"), with Wainwright, under which we may, from time to time, issue and sell shares of our common stock through Wainwright as sales agent. The Sales Agreement provides that Wainwright will be entitled to compensation for its services at a commission rate of 3.0% of the gross sales price per share of common stock sold. All shares issued pursuant to the June 2021 ATM Program were issued pursuant to our shelf registration statement on Form S-3 (File No. 333-254363), which was initially filed with the SEC on March 16, 2021, amended on June 15, 2021 and declared effective by the SEC on June 16, 2021. From June 21, 2021 through December 31, 2022 March 7, 2024, the Company has sold an aggregate of 2,098,333 3,227,501 shares of common stock under the June 2021 ATM Program at an average price of approximately $5.93 $5.50 per share for gross proceeds of approximately $12.4 million $17.8 million. Approximately $62.6 million $57.2 million of common stock may still be sold pursuant to the June 2021 ATM Program. The Company paid cash commissions on the gross proceeds, plus reimbursement of expenses to Wainwright, as well as legal and accounting fees in the aggregate amount of approximately $0.4 million $0.6 million. Subsequent to December 31, 2022 and through the date of this filing, no additional shares have been sold under the June 2021 ATM Program.

May 2020 ATM Program

On May 4, 2020, the Company initiated an at-the-market offering under a prospectus supplement for aggregate sales proceeds of up to $40.0 million (the "May 2020 ATM Program"), with the common stock to be distributed at the market prices prevailing at the time of sale. The May 2020 ATM Program was established under the Sales Agreement. All shares issued pursuant to the May 2020 ATM Program were issued pursuant to our shelf registration statement on Form

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S-3 (File No. 333-227955), which was initially filed with the SEC on October 24, 2018, amended on July 17, 2019 and declared effective by the SEC on July 18, 2019. From May 4, 2020 through June 21, 2021, the Company sold an aggregate of 6,027,852 shares of common stock under the May 2020 ATM Program at an average price of approximately $6.15 per share for gross proceeds of approximately $37.1 million. The Company paid cash commissions on the gross proceeds, plus reimbursement of expenses to Wainwright, as well as legal and accounting fees in the aggregate amount of approximately $1.2 million. As of June 21, 2021, the May 2020 ATM Program expired and was replaced with the June 2021 ATM Program.

CIRM Grant Award

On June 16, 2016, Capricor entered into an award (the "CIRM Award") with the California Institute for Regenerative Medicine ("CIRM") in the amount of approximately $3.4 million to fund, in part, Capricor's Phase I/II 1/2 HOPE-Duchenne clinical trial investigating CAP-1002 for the treatment of Duchenne muscular dystrophy-associated cardiomyopathy. Pursuant to terms of the CIRM Award, the disbursements were tied to the achievement of specified operational milestones. In addition, the terms of the CIRM Award included a co-funding requirement pursuant to which Capricor was required to spend approximately $2.3 million of its own capital to fund the CIRM funded research project. The CIRM Award is further subject to the conditions and requirements set forth in the CIRM Grants Administration Policy

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for Clinical Stage Projects. Such requirements include, without limitation, the filing of quarterly and annual reports with CIRM, the sharing of intellectual property pursuant to Title 17, California Code of Regulations (CCR) Sections 100600-100612, and the sharing with the State of California of a fraction of licensing revenue received from a CIRM funded research project and net commercial revenue from a commercialized product which resulted from the CIRM funded research as set forth in Title 17, CCR Section 100608. The maximum royalty on net commercial revenue that Capricor may be required to pay to CIRM is equal to nine times the total amount awarded and paid to Capricor.

After completing the CIRM funded research project and at any time after the award period end date (but no later than the ten-year anniversary of the date of the award), Capricor has the right to convert the CIRM Award into a loan, the terms of which will be determined based on various factors, including the stage of the research and development of the program at the time the election is made. On June 20, 2016, Capricor entered into a Loan Election Agreement with CIRM whereby, among other things, CIRM and Capricor agreed that if Capricor elects to convert the grant into a loan, the term of the loan could be up to five years from the date of execution of the applicable loan agreement; provided that the maturity date of the loan will not surpass the ten-year anniversary of the grant date of the CIRM Award. Beginning on the date of the loan, the loan shall bear interest on the unpaid principal balance, plus the interest that has accrued prior to the election point according to the terms set forth in CIRM's the CIRM Loan Policy and CIRM Grants Administration Policy for Clinical Stage Projects (the "New Loan Balance"), at a per annum rate equal to the LIBOR rate for a three-month deposit in U.S. dollars, as published by the Wall Street Journal on the loan date, plus one percent. Interest shall be compounded annually on the outstanding New Loan Balance commencing with the loan date and the interest shall be payable, together with the New Loan Balance, upon the due date of the loan. Depending on the timing of our election, additional funds may be owed. If Capricor elects to convert the CIRM Award into a loan, certain requirements of the CIRM Award will no longer be applicable, including the revenue sharing requirements. Capricor has not yet made its decision as to whether it will elect to convert the CIRM Award into a loan. If we elect to do so, Capricor would be required to repay some or all of the amounts awarded by CIRM, therefore the Company accounts for this award as a liability rather than income.

In 2019, Capricor completed all milestones and close-out activities associated with the CIRM Award and expended all funds received. As of December 31, 2022 December 31, 2023, Capricor's liability balance for the CIRM Award was approximately $3.4 million.

Off-Balance Sheet Arrangements

During the periods presented, we did not have, nor do we currently have, any off-balance sheet arrangements, as defined in the rules and regulations of the SEC.

Critical Accounting Policies and Estimates

Our financial statements are prepared in accordance with generally accepted accounting principles. The preparation of these financial statements requires us to make estimates and assumptions that affect the reported amounts of assets, liabilities, revenues, expenses and related disclosures. We evaluate our estimates and assumptions on an ongoing basis, including research and development and clinical trial accruals, and stock-based compensation estimates. Our estimates are based on historical experience and various other assumptions that we believe to be reasonable under the

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circumstances. Our actual results could differ from these estimates. We believe the following critical accounting policies reflect the more significant judgments and estimates used in the preparation of our financial statements and accompanying notes.

Leases

ASC Topic 842,*Leases* ("ASC 842"), requires lessees to recognize most leases on the balance sheet with a corresponding right-to-use ("ROU") asset. ROU assets represent the Company's right to use an underlying asset for the lease term and lease liabilities represent the Company's obligation to make lease payments arising from the lease. The assets and lease liabilities are recognized at the lease commencement date based on the estimated present value of fixed lease payments over the lease term. ROU assets are evaluated for impairment using the long-lived assets impairment guidance.

Leases will be classified as financing or operating, which will drive the expense recognition pattern. The Company elects to exclude short-term leases if and when the Company has them.

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The Company leases office and laboratory space, all of which are operating leases. Most leases include the option to renew and the exercise of the renewal options is at the Company's sole discretion. Options to renew a lease are not included in the Company's assessment unless there is reasonable certainty that the Company will renew. In addition, the Company's lease agreements generally do not contain any residual value guarantees or restrictive covenants.

The interest rate implicit in lease contracts is typically not readily determinable. As a result, the Company utilizes its incremental borrowing rate, which reflects the fixed rate at which the Company could borrow on a collateralized basis the amount of the lease payments in the same currency, for a similar term, in a similar economic environment.

For real estate leases, the Company has elected the practical expedient under ASC 842 to account for the lease and non-lease components together for existing classes of underlying assets and allocates the contract consideration to the lease component only. This practical expedient is not elected for manufacturing facilities and equipment embedded in product supply arrangements.

Revenue Recognition

The Company applies ASU 606, *Revenue for Contracts from Customers*, which amended revenue recognition principles and provides a single, comprehensive set of criteria for revenue recognition within and across all industries. The Company has not yet achieved commercial sales of its drug candidates to date, however, the new standard is applicable to its distribution agreements.

The revenue standard provides a five-step framework for recognizing revenue as control of promised goods or services is transferred to a customer at an amount that reflects the consideration to which the entity expects to be entitled in exchange for those goods or services. To determine revenue recognition for arrangements that it determines are within the scope of the revenue standard, the Company performs the following five steps: (i) identify the contract; (ii) identify the performance obligations; (iii) determine the transaction price; (iv) allocate the transaction price to the performance obligations in the contract; and (v) recognize revenue when (or as) the Company satisfies a performance obligation. At contract inception, the Company assesses whether the goods or services promised within each contract are distinct and, therefore, represent a separate performance obligation, or whether they are not distinct and are combined with other goods and services until a distinct bundle is identified. The Company then determines the transaction price, which typically includes upfront payments and any variable consideration that the Company determines is probable to not cause a significant reversal in the amount of cumulative revenue recognized when the uncertainty associated with the variable consideration is resolved. The Company then allocates the transaction price to each performance obligation and recognizes the associated revenue when, or as, each performance obligation is satisfied.

The Company's distribution agreements may entitle it to additional payments upon the achievement of milestones or royalties on sales. shares of product revenue. The milestones are generally categorized into three types: development milestones, regulatory milestones and sales-based milestones. The Company evaluates whether it is probable that the consideration associated with each milestone or royalty shared revenue payments will not be subject to a significant reversal in the cumulative amount of revenue recognized. Amounts that meet this threshold are included in the transaction price using the most likely amount method, whereas amounts that do not meet this threshold are excluded from the transaction price until they meet this threshold. At the end of each subsequent reporting period, the Company re-evaluates the probability of a significant reversal of the cumulative

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revenue recognized for its milestones and royalties, shared revenue payments, and, if necessary, adjusts its estimate of the overall transaction price. Any such adjustments are recorded on a cumulative catch-up basis, which would affect revenues and net income (loss) in the Company's consolidated statements of operation and comprehensive loss. Typically, milestone payments and royalties shared revenue payments are achieved after the Company's performance obligations associated with the distribution agreements have been completed and after the customer has assumed responsibility for the respective clinical program. Milestones or royalties shared revenue payments achieved after the Company's performance obligations have been completed are recognized as revenue in the period the milestone or royalty shared revenue payments was achieved. If a milestone payment is achieved during the performance period, the milestone payment would be recognized as revenue to the extent performance had been completed at that point, and the remaining balance would be recorded as deferred revenue.

The revenue standard requires the Company to assess whether a significant financing component exists in determining the transaction price. The Company performs this assessment at the onset of its distribution agreements. Typically, a significant financing component does not exist because the customer is paying for services in advance with

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an upfront payment. Additionally, future royalty shared revenue payments are not substantially within the control of the Company or the customer.

Whenever the Company determines that goods or services promised in a contract should be accounted for as a combined performance obligation over time, the Company determines the period over which the performance obligations will be performed and revenue will be recognized. Revenue is recognized using either the proportional performance method or on a straight-line basis if efforts will be expended evenly over time. Percentage of completion of patient visits in clinical trials are used as the measure of performance. The Company feels this method of measurement to be the best depiction of the transfer of services and recognition of revenue. Significant management judgment is required in determining the level of effort required under an arrangement and the period over which the Company is expected to complete its performance obligations. If the Company determines that the performance obligation is satisfied over time, any upfront payment received is initially recorded as deferred revenue on its consolidated balance sheets.

Certain judgments affect the application of the Company's revenue recognition policy. For example, the Company records short-term (less than one year) and long-term (over one year) deferred revenue based on its best estimate of when such revenue will be recognized. This estimate is based on the Company's current operating plan and, the Company may recognize a different amount of deferred revenue over the next 12-month period if its plan changes in the future.

Grant Income

The determination as to when income is earned is dependent on the language in each specific grant. Generally, we recognize grant income in the period in which the expense is incurred for those expenses that are deemed reimbursable under the terms of the grant. Grant income is due upon submission of reimbursement request. The transaction price varies for grant income based on the expenses incurred under the awards.

Miscellaneous Income

Revenue is recognized in connection with the delivery of doses which were developed as part of our past R&D efforts. Income is recorded when the Company has satisfied the obligations as identified in the contracts with the customer. Miscellaneous income is due upon billing. Miscellaneous income is based on contracts with fixed transaction prices.

CIRM Grant Award

Capricor accounts for the disbursements under its CIRM Award as long-term liabilities. Capricor recognizes the CIRM grant disbursements as a liability as the principal is disbursed rather than recognizing the full amount of the grant award. After completing the CIRM funded research project and after the award period end date, Capricor has the right to convert the CIRM Award into a loan, the terms of which will be determined based on various factors, including the stage of the research and the stage of development at the time the election is made. In June, 2016, Capricor entered into a Loan Election Agreement with CIRM whereby, among other things, CIRM and Capricor agreed that if Capricor elects to convert the grant into a loan, the term of the loan could be up to five years from the date of execution of the applicable loan agreement; provided that the maturity date of the loan will not surpass the ten-year anniversary of the grant date of the CIRM Award. Since Capricor may be required to repay some or all of the amounts awarded by CIRM, the Company accounts for this award as a liability rather than income.

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Research and Development Expenses and Accruals

R&D expenses consist primarily of salaries and related personnel costs, supplies, clinical trial costs, patient treatment costs, rent for laboratories and manufacturing facilities, consulting fees, costs of personnel and supplies for manufacturing, costs of service providers for preclinical, clinical and manufacturing, and certain legal expenses resulting from intellectual property prosecution, stock compensation

expense and other expenses relating to the design, development, testing and enhancement of our product candidates. Except for certain capitalized intangible assets, R&D costs are expensed as incurred.

Our cost accruals for clinical trials and other R&D activities are based on estimates of the services received and efforts expended pursuant to contracts with numerous clinical trial centers and contract research organizations ("CROs"), clinical study sites, laboratories, consultants or other clinical trial vendors that perform activities in connection with a trial. Related contracts vary significantly in length and may be for a fixed amount, a variable amount based on actual costs incurred, capped at a certain limit, or for a combination of fixed, variable and capped amounts. Activity levels are monitored through close communication with the CROs and other clinical trial vendors, including detailed invoice and task completion review, analysis of expenses against budgeted amounts, analysis of work performed against approved contract budgets and payment schedules, and recognition of any changes in scope of the services to be performed. Certain CRO and significant clinical trial vendors provide an estimate of costs incurred but not invoiced at the end of each quarter

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for each individual trial. These estimates are reviewed and discussed with the CRO or vendor as necessary, and are included in R&D expenses for the related period. For clinical study sites which are paid periodically on a per-subject basis to the institutions performing the clinical study, we accrue an estimated amount based on subject screening and enrollment in each quarter. All estimates may differ significantly from the actual amount subsequently invoiced, which may occur several months after the related services were performed.

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

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

Stock-Based Compensation

Our results include non-cash compensation expense as a result of the issuance of stock, stock options and warrants, as applicable. We have issued stock options to employees, directors and consultants under our five stock option plans: (i) the 2006 Stock Option Plan, (ii) the 2012 Restated Equity Incentive Plan (which superseded the 2006 Stock Option Plan) (the "2012 Plan"), (iii) the 2012 Non-Employee Director Stock Option Plan (the "2012 Non-Employee Director Plan"), (iv) the 2020 Equity Incentive Plan (the "2020 Plan"), and (v) the 2021 Equity Incentive Plan. Plan (the "2021 Plan"). At this time, the Company only issues options under the 2020 Plan and the 2021 Plan and no longer issues options under the 2006 Stock Option Plan, the 2012 Plan, or the 2012 Non-Employee Director Plan.

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

Stock options or other equity instruments to non-employees (including consultants) issued as consideration for goods or services received by us are accounted for based on the fair value of the equity instruments issued. The fair value of stock options is determined using the Black-Scholes option-pricing model. The Company calculates the fair value for non-qualified options as of the date of grant and expenses over the applicable vesting periods.

The terms and vesting schedules for share-based awards vary by type of grant and the employment status of the grantee. Generally, the awards vest based upon time-based conditions. Stock-based compensation expense is included in general and administrative expense or

research and development expense, as applicable, in the Statements of Operations

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and Comprehensive Income (Loss). We expect to record additional non-cash compensation expense in the future, which may be significant.

Clinical Trial Expense

As part of the process of preparing our consolidated financial statements, we are required to estimate our accrued expenses. Our clinical trial accrual process is designed to account for expenses resulting from our obligations under contracts with vendors, consultants, CROs and clinical site agreements in connection with conducting clinical trials. The financial terms of these contracts are subject to negotiations, which vary from contract to contract and may result in payment flows that do not match the periods over which materials or services are provided to us under such contracts. Our objective is to reflect the appropriate clinical trial expenses in our consolidated financial statements by matching the appropriate expenses with the period in which services are provided and efforts are expended. We account for these expenses according to the progress of the trial as measured by patient progression and the timing of various aspects of the trial. We determine accrual estimates through financial models that take into account discussions with applicable personnel and outside service providers as to the progress or state of completion of trials, or the services completed. During the course of a clinical trial, we adjust our clinical expense recognition if actual results differ from our estimates. We make

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estimates of our accrued expenses as of each balance sheet date in our consolidated financial statements based on the facts and circumstances known to us at that time. Our clinical trial accrual and prepaid assets are dependent, in part, upon the receipt of timely and accurate reporting from CROs and other third-party vendors. Although we do not expect our estimates to be materially different from amounts actually incurred, our understanding of the status and timing of services performed relative to the actual status and timing of services performed may vary and may result in us reporting amounts that are too high or too low for any particular period.

Recently Issued or Newly Adopted Accounting Pronouncements

In November 2021, October 2023, the Financial Accounting Standards Board (“FASB”) issued ASU 2021-10, 2023-06, *Government Assistance (Topic 832)* *Disclosure Improvements: Codification Amendments in Response to the SEC’s Disclosure Update and Simplification Initiative*, . This standard was issued in response to the SEC’s disclosure update and simplification initiative, which requires business affects a variety of topics within the Accounting Standards Codification. The amendments apply to all reporting entities to disclose information about transactions with a government entity that are accounted for by applying a grant or contribution model by analogy. For transactions within scope, the new standard requires the disclosure of information about the nature scope of the transaction, including significant terms and conditions, as well as affected topics unless otherwise indicated. The effective date for each amendment will be the amounts and specific date on which the SEC’s removal of that related disclosure from Regulation S-X or Regulation S-K becomes effective, with early adoption prohibited. The Company is currently evaluating the impact this guidance will have on its financial statement line items affected by the transaction. The new guidance is effective for annual reporting periods beginning after December 15, 2021. The Company adopted ASU 2021-10 in the first quarter of 2022. The adoption of this update did not have a material impact on the Company’s financial statements and footnote disclosures.

Other recent accounting pronouncements issued by the FASB, Financial Accounting Standards Board, including its Emerging Issues Task Force, the American Institute of Certified Public Accountants, and the SEC, did not or are not believed by management to have a material impact on the Company's present or future consolidated financial statement presentation or disclosures.

ITEM 7A. QUANTITATIVE AND QUALITATIVE DISCLOSURES ABOUT MARKET RISK

Interest Rate Sensitivity

Our exposure to market risk for changes in interest rates relates primarily to our marketable securities and cash and cash equivalents. As of December 31, 2022 December 31, 2023, the fair value of our cash, cash equivalents, and marketable securities was approximately $41.4 million $39.5 million. Additionally, as of December 31, 2022 December 31, 2023, Capricor's investment portfolio was classified as cash, cash equivalents and marketable securities which consisted primarily of money market funds and bank money market accounts, which included short term U.S. treasuries, bank savings and checking accounts.

The goal of our investment policy is to place our investments with highly rated credit issuers and limit the amount of credit exposure. We seek to improve the safety and likelihood of preservation of our invested funds by limiting default risk and market risk. Our investments may be exposed to market risk due to fluctuation in interest rates, which may affect our interest income and the fair market value of our investments, if any. We will manage this exposure by performing ongoing evaluations of our investments. Due to the short-term maturities, if any, of our investments to date, their carrying value has always approximated their fair value. Our policy is to mitigate default risk by investing in high credit quality securities, and we currently do not hedge interest rate exposure. Due to our policy of making investments in U.S. treasury securities with primarily short-term maturities, we believe that the fair value of our investment portfolio would not be significantly materially impacted by a hypothetical 100 basis point increase or decrease in interest rates.

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ITEM 8. FINANCIAL STATEMENTS AND SUPPLEMENTARY DATA

CAPRICOR THERAPEUTICS, INC.
INDEX TO FINANCIAL STATEMENTS

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REPORT OF INDEPENDENT REGISTERED PUBLIC ACCOUNTING FIRM

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

Opinion on the Consolidated Financial Statements

We have audited the accompanying consolidated balance sheets of Capricor Therapeutics, Inc. and Subsidiary (the Company) as of December 31, 2022 December 31, 2023 and 2021, 2022, and the related consolidated statements of operations and comprehensive loss, stockholders' equity, and cash flows for each of the years in the two-year period ended December 31, 2022 December 31, 2023, and the related notes (collectively referred to as the consolidated financial statements). In our opinion, the consolidated financial statements present fairly, in all material respects, the consolidated financial position of the Company as of December 31, 2022 December 31, 2023 and 2021, 2022, and the consolidated results of its operations and its cash flows for each of the years in the two-year period ended December 31, 2022 December 31, 2023, in conformity with accounting principles generally accepted in the United States of America.

Explanatory Paragraph – Going Concern

The accompanying consolidated financial statements have been prepared assuming that the Company will continue as a going concern. As discussed in Note 1 to the consolidated financial statements, the Company has continued to incur significant operating losses and negative cash flows from operations, during the year ended December 31, 2023. These conditions raise substantial doubt about the Company's ability to continue as a going concern. Management's plans in regard to these matters are also described in Note 1. The consolidated financial statements do not include any adjustments that might result from the outcome of this uncertainty.

Basis for Opinion

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

We conducted our audits in accordance with the standards of the PCAOB. Those standards require that we plan and perform the audit to obtain reasonable assurance about whether the consolidated financial statements are free of material misstatement, whether due to error or fraud. The Company is not required to have, nor were we engaged to perform, an audit of its internal control over financial reporting. As part of our audits, we are required to obtain an understanding of internal control over financial reporting, but not for the purpose of expressing an opinion on the effectiveness of the Company's internal control over financial reporting. Accordingly, we express no such opinion.

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

Critical Audit Matters

The critical audit matters communicated below are matters arising from the current period audit of the consolidated financial statements that were communicated or required to be communicated to the audit committee and that: (1) relate to accounts or disclosures that are material to the financial statements and (2) involved our especially challenging, subjective, or complex judgments. The communication of critical audit matters does not alter in any way our opinion on the consolidated financial statements, taken as a whole, and we are not, by communicating the critical audit matters below, providing separate opinions on the critical audit matters or on the accounts or disclosures to which they relate.

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Revenue Recognition – Revenue Recognized Over Tim Timee

Description of the Matter

As discussed in Note 1 and Note 8 7 to the Consolidated Financial Statements, the Company earns its revenue through an exclusive commercialization and distribution agreement. For performance obligations related to services that are required to be recognized over time, the Company generally measures its progress to completion using an input measure of total costs for patient visits incurred divided by total costs expected to be incurred for all patient visits.

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Auditing revenue recognition is complex and highly judgmental due to the variability and uncertainty associated with the Company's assessment of measure of progress. Changes in these estimates would have a significant effect on the amount of revenue recognized.

How We Addressed the Matter in Our Audit

To test the measures of progress used for performance obligations related to services that are required to be recognized over time, our audit procedures included, among others, evaluating the appropriateness of the Company's accounting policy for each type of arrangement, testing the identified measure of performance by reading contracts with customers, including all amendments, and reviewing the contract analyses prepared by management. We evaluated whether the selected measures of progress towards satisfaction of performance obligations were applied consistently. We also tested the completeness and accuracy of the underlying data used for the measure of progress by testing and or analyzing the underlying data and conducting interviews of project personnel.

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

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

Encino, California
March 17, 2023 8, 2024

CAPRICOR THERAPEUTICS, INC.
CONSOLIDATED BALANCE SHEETS
DECEMBER 31, 2022 2023 AND 2021 2022

ASSETS

	December 31, 2022	December 31, 2021	December 31, 2023	December 31, 2022
CURRENT ASSETS				
Cash and cash equivalents	$ 9,603,242	$ 34,885,274	$ 14,694,857	$ 9,603,242
Marketable securities	31,818,020	—	24,792,846	31,818,020
Receivables	547,580	391,750	10,371,993	547,580
Prepaid expenses and other current assets	919,892	1,159,937	995,776	919,892
TOTAL CURRENT ASSETS	42,888,734	36,436,961	50,855,472	42,888,734
PROPERTY AND EQUIPMENT, net	4,588,030	1,795,696	5,560,641	4,588,030
OTHER ASSETS				
Lease right-of-use assets, net	2,349,974	2,821,944	2,050,042	2,349,974
Other assets	268,172	275,722	268,172	268,172
TOTAL ASSETS	$ 50,094,910	$ 41,330,323	$ 58,734,327	$ 50,094,910
LIABILITIES AND STOCKHOLDERS' EQUITY				
CURRENT LIABILITIES				
Accounts payable and accrued expenses	$ 4,834,683	$ 3,116,371	$ 6,222,762	$ 4,834,683
Accounts payable and accrued expenses, related party	89,234	599,388	27,479	89,234
Lease liabilities, current	682,039	417,632	749,112	682,039
Deferred revenue, current	17,980,599	—	24,270,465	17,980,599
TOTAL CURRENT LIABILITIES	23,586,555	4,133,391	31,269,818	23,586,555
LONG-TERM LIABILITIES				
CIRM liability	3,376,259	3,376,259	3,376,259	3,376,259
Lease liabilities, net of current	1,878,070	2,452,707	1,486,783	1,878,070
Deferred revenue, net of current	9,467,932	—	—	9,467,932
TOTAL LONG-TERM LIABILITIES	14,722,261	5,828,966	4,863,042	14,722,261
TOTAL LIABILITIES	38,308,816	9,962,357	36,132,860	38,308,816
COMMITMENTS AND CONTINGENCIES (NOTE 7)				
COMMITMENTS AND CONTINGENCIES (NOTE 6)				

STOCKHOLDERS' EQUITY				
Preferred stock, $0.001 par value, 5,000,000 shares authorized, none issued and outstanding	—	—	—	—
Common stock, $0.001 par value, 50,000,000 shares authorized, 25,241,402 and 24,185,001 shares issued and outstanding, respectively	25,241	24,185		
Common stock, $0.001 par value, 50,000,000 shares authorized, 31,148,320 and 25,241,402 shares issued and outstanding, respectively			31,148	25,241
Additional paid-in capital	148,735,420	139,404,060	181,701,859	148,735,420
Accumulated other comprehensive income	105,244	—	235,813	105,244
Accumulated deficit	(137,079,811)	(108,060,279)	(159,367,353)	(137,079,811)
TOTAL STOCKHOLDERS' EQUITY	11,786,094	31,367,966	22,601,467	11,786,094
TOTAL LIABILITIES AND STOCKHOLDERS' EQUITY	$ 50,094,910	$ 41,330,323	$ 58,734,327	$ 50,094,910

See accompanying notes to the audited consolidated financial statements.

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CAPRICOR THERAPEUTICS, INC.
CONSOLIDATED STATEMENTS OF OPERATIONS AND COMPREHENSIVE LOSS
FOR THE YEARS ENDED DECEMBER 31, 2022 2023 AND 2021 2022

	Years ended December 31,		Years ended December 31,	
	2022	2021	2023	2022
REVENUE				
Revenue	$ 2,551,469	$ 244,898	$ 25,178,066	$ 2,551,469
TOTAL REVENUE	2,551,469	244,898	25,178,066	2,551,469
OPERATING EXPENSES				
Research and development	21,816,949	13,571,045	36,448,039	21,816,949
General and administrative	10,431,903	7,612,295	12,807,886	10,431,903
TOTAL OPERATING EXPENSES	32,248,852	21,183,340	49,255,925	32,248,852
LOSS FROM OPERATIONS	(29,697,383)	(20,938,442)	(24,077,859)	(29,697,383)
OTHER INCOME (EXPENSE)				
Other income	190,582	548,207	67,657	190,582
Investment income	521,535	57,460	1,728,701	521,535

Forgiveness of debt	—	318,160		
Loss on disposal of fixed assets	(34,266)	(7,905)	(6,041)	(34,266)
TOTAL OTHER INCOME (EXPENSE)	677,851	915,922	1,790,317	677,851
NET LOSS	(29,019,532)	(20,022,520)	(22,287,542)	(29,019,532)
OTHER COMPREHENSIVE INCOME (LOSS)				
Net unrealized gain on marketable securities	105,244	—	130,569	105,244
COMPREHENSIVE INCOME (LOSS)	$ (28,914,288)	$ (20,022,520)		
COMPREHENSIVE LOSS			$ (22,156,973)	$ (28,914,288)
Net loss per share, basic and diluted	$ (1.18)	$ (0.87)	$ (0.83)	$ (1.18)
Weighted average number of shares, basic and diluted	24,552,688	23,089,323	26,778,360	24,552,688

See accompanying notes to the audited consolidated financial statements.

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CAPRICOR THERAPEUTICS, INC.
CONSOLIDATED STATEMENTS OF CHANGES IN STOCKHOLDERS' EQUITY
FOR THE PERIOD FROM DECEMBER 31, 2020 2021 THROUGH DECEMBER 31, 2022 2023

	COMMON STOCK		ADDITIONAL PAID-IN CAPITAL	OTHER COMPREHENSIVE INCOME	ACCUMULATED DEFICIT	TOTAL STOCKHOLDERS' EQUITY
	SHARES	AMOUNT				
Balance at December 31, 2020	20,577,123	$ 20,577	$ 116,216,966	$ —	$ (88,037,759)	$ 28,199,784
Issuance of common stock, net of fees	3,566,349	3,566	20,170,882	—	—	20,174,448
Exercise of common warrants	20,391	20	22,410	—	—	22,430
Stock-based compensation	—	—	2,965,692	—	—	2,965,692
Stock options exercised	21,138	22	28,110	—	—	28,132
Net loss	—	—	—	—	(20,022,520)	(20,022,520)
Balance at December 31, 2021	24,185,001	$ 24,185	$ 139,404,060	$ —	$ (108,060,279)	$ 31,367,966
Issuance of common stock, net of fees	830,858	831	4,802,703	—	—	4,803,534

Stock-based compensation	—	—	4,458,578	—	—	4,458,578
Stock options exercised	225,543	225	70,079	—	—	70,304
Unrealized gain on marketable securities	—	—	—	105,244	—	105,244
Net loss	—	—	—	—	(29,019,532)	$ (29,019,532)
Balance at December 31, 2022	25,241,402	$ 25,241	$ 148,735,420	$ 105,244	$ (137,079,811)	$ 11,786,094

	COMMON STOCK		ADDITIONAL PAID-IN CAPITAL	OTHER COMPREHENSIVE INCOME	ACCUMULATED DEFICIT	TOTAL STOCKHOLDERS' EQUITY
	SHARES	AMOUNT				
Balance at December 31, 2021	24,185,001	$ 24,185	$ 139,404,060	$ —	$ (108,060,279)	$ 31,367,966
Issuance of common stock, net of fees	830,858	831	4,802,703	—	—	4,803,534
Stock-based compensation	—	—	4,458,578	—	—	4,458,578
Stock options exercised	225,543	225	70,079	—	—	70,304
Unrealized gain on marketable securities	—	—	—	105,244	—	105,244
Net loss	—	—	—	—	(29,019,532)	(29,019,532)
Balance at December 31, 2022	25,241,402	$ 25,241	$ 148,735,420	$ 105,244	$ (137,079,811)	$ 11,786,094
Issuance of common stock, net of fees	5,813,442	5,813	25,509,536	—	—	25,515,349
Stock-based compensation	—	—	7,392,396	—	—	7,392,396
Stock options exercised	93,476	94	64,507	—	—	64,601
Unrealized gain on marketable securities	—	—	—	130,569	—	130,569
Net loss	—	—	—	—	(22,287,542)	$ (22,287,542)
Balance at December 31, 2023	31,148,320	$ 31,148	$ 181,701,859	$ 235,813	$ (159,367,353)	$ 22,601,467

See accompanying notes to the audited consolidated financial statements.

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CAPRICOR THERAPEUTICS, INC.
CONSOLIDATED STATEMENTS OF CASH FLOWS

FOR THE YEARS ENDED DECEMBER 31, 2022 2023 AND 2021 2022

	Years ended December 31,		Years ended December 31,	
	2022	2021	2023	2022
Cash flows from operating activities:				
Net loss	$ (29,019,532)	$ (20,022,520)	$ (22,287,542)	$ (29,019,532)
Adjustments to reconcile net loss to net cash provided by (used in) operating activities:				
Loss on disposal of fixed assets	34,266	7,905	6,041	34,266
Depreciation and amortization	533,131	245,697	1,068,882	533,131
Stock-based compensation	4,458,578	2,965,692	7,392,396	4,458,578
Forgiveness of debt	—	(318,160)		
Changes in lease liabilities	161,740	48,395	(24,282)	161,740
Changes in operating assets and liabilities:				
Receivables	(155,830)	(391,750)	(9,824,413)	(155,830)
Prepaid expenses and other current assets	240,045	(148,728)	(75,884)	240,045
Other assets	7,550	(187,021)	—	7,550
Accounts payable and accrued expenses	1,718,312	400,750	1,388,078	1,718,312
Accounts payable and accrued expenses, related party	(510,154)	590,416	(61,755)	(510,154)
Deferred revenue	27,448,531	—	(3,178,066)	27,448,531
Net cash provided by (used in) operating activities	4,916,637	(16,809,324)	(25,596,545)	4,916,637
Cash flows from investing activities:				
Purchase of marketable securities	(114,218,737)	—	(97,441,506)	(114,218,737)
Proceeds from sales and maturities of marketable securities	82,505,961	—	104,597,249	82,505,961
Purchases of property and equipment	(2,000,243)	(1,196,286)	(1,311,660)	(2,000,243)
Payments for leasehold improvements	(1,359,488)	—	(735,873)	(1,359,488)
Net cash used in investing activities	(35,072,507)	(1,196,286)		
Net cash provided by (used in) investing activities			5,108,210	(35,072,507)
Cash flows from financing activities:				
Net proceeds from sale of common stock	4,803,534	20,174,448	25,515,349	4,803,534
Proceeds from exercise of stock awards	70,304	50,562	64,601	70,304
Net cash provided by financing activities	4,873,838	20,225,010	25,579,950	4,873,838
Net increase (decrease) in cash and cash equivalents	(25,282,032)	2,219,400	5,091,615	(25,282,032)
Cash and cash equivalents balance at beginning of period	34,885,274	32,665,874	9,603,242	34,885,274
Cash and cash equivalents balance at end of period	$ 9,603,242	$ 34,885,274	$ 14,694,857	$ 9,603,242
Supplemental disclosures of cash flow information:				
Interest paid in cash	$ —	$ —	$ —	$ —
Income taxes paid in cash	$ —	$ —	$ —	$ —

See accompanying notes to the audited consolidated financial statements.

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CAPRICOR THERAPEUTICS, INC.
NOTES TO CONSOLIDATED FINANCIAL STATEMENTS
DECEMBER 31, 2022 2023 AND 2021 2022

1. ORGANIZATION AND SUMMARY OF SIGNIFICANT ACCOUNTING POLICIES

Description of Business

Capricor Therapeutics, Inc., a Delaware corporation (referred to herein as "Capricor Therapeutics" or the "Company" "Company," "we," "us" or "we" "our"), is a clinical-stage biotechnology company focused on the development of transformative cell and exosome-based therapeutics for treating Duchenne muscular dystrophy ("DMD"), a rare form of muscular dystrophy which results in muscle degeneration and premature death, and other diseases with high unmet medical needs. Capricor, Inc. ("Capricor"), a wholly-owned subsidiary of Capricor Therapeutics, was founded in 2005 as a Delaware corporation based on the innovative work of its founder, Eduardo Marbán, M.D., Ph.D. After completion of a merger between Capricor and a subsidiary of Nile Therapeutics, Inc., a Delaware corporation ("Nile"), on November 20, 2013, Capricor became a wholly-owned subsidiary of Nile and Nile formally changed its name to Capricor Therapeutics, Inc. Capricor Therapeutics, together with its subsidiary, Capricor, has multiple therapeutic drug and vaccine candidates in various stages of development.

Basis of Consolidation

Our consolidated financial statements include the accounts of the Company and our wholly-owned subsidiary. All intercompany transactions have been eliminated in consolidation.

Reclassification

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

Liquidity and Going Concern

The Company has historically financed its research and development activities as well as operational expenses primarily from equity financings, government grants, and payments from distribution agreements and collaboration partners.

Cash, cash equivalents, and marketable securities as of December 31, 2022 December 31, 2023 were approximately $41.4 million $39.5 million, compared to approximately $34.9 million $41.4 million as of December 31, 2021 December 31, 2022. In the first quarter of 2023, the Company expects to receive received an upfront payment of $12.0 million from Nippon Shinyaku Co., Ltd., a Japanese corporation, ("Nippon Shinyaku"), in accordance with its Japan Exclusive Commercialization and Distribution Agreement (see Note 10 7 – "Subsequent Events" "License and Distribution Agreements"). In October 2023, the Company completed a registered direct offering for gross proceeds of approximately $23.0 million (see Note 2 – "Stockholder's Equity"). We received our first milestone payment of $10.0 million in the first quarter of 2024, which was triggered upon completion of the interim futility analysis of the HOPE-3 trial whereby the outcome was determined to be not futile. Additionally, the Company has a Common Stock Sales Agreement in place with H.C. Wainwright & Co. LLC ("Wainwright") to create at-the-market equity programs under which the Company, from time to time, sells shares of its common stock (see Note 3 2 - "Stockholders' Equity").

The Company's principal uses of cash are for research and development expenses, general and administrative expenses, capital expenditures and other working capital requirements.

The Company's future expenditures and capital requirements may be substantial and will depend on many factors, including, but not limited to, the following:

- the timing and costs associated with its our research and development activities, clinical trials and preclinical studies, including the enrollment and progress of our ongoing HOPE-3 Phase III 3 clinical study trial of CAP-1002 in DMD;
- the timing and costs associated with the manufacturing of our product candidates, including the expansion of our manufacturing capacity to support the potential commercialization of CAP-1002 for DMD;
- the timing and costs associated with potential commercialization of its our product candidates;
- the number and scope of its our research programs, including the expansion of our exosomes program; and
- the costs involved in prosecuting and enforcing patent claims and other intellectual property rights.

CAPRICOR THERAPEUTICS, INC.
NOTES TO CONSOLIDATED FINANCIAL STATEMENTS
DECEMBER 31, 2023 AND 2022

The Company's options for raising additional capital include potentially seeking additional financing primarily from, but not limited to, the sale and issuance of equity or debt securities, the licensing or sale of its technology and other assets, potential distribution and other partnering opportunities, and from government grants.

Table The Company has incurred significant operating losses and negative cash flows from operations. Based on the Company's available cash resources and based upon the Company's projections for its operations, the Company does not have sufficient cash on hand to support current operations for at least the next twelve months from the date of Contentsfiling this Annual Report on Form 10-K. Therefore, there is a substantial doubt about the Company's ability to continue as a going concern.

CAPRICOR THERAPEUTICS, INC. The Company's plan to address its financial position may include potentially seeking additional financing primarily from, but not limited to, the sale and issuance of equity or debt securities, the licensing or sale of its technology and from government grants. The accompanying consolidated financial statements have been prepared on a going concern basis, which contemplates the realization of assets and satisfaction of liabilities in the ordinary course of business. The consolidated financial statements do not include any adjustments relating to the recoverability and classification of recorded asset amounts or the amounts and classification of liabilities that might result from the outcome of this uncertainty.

NOTES TO CONSOLIDATED FINANCIAL STATEMENTS
DECEMBER 31, 2022 AND 2021

The Company will require substantial additional capital to fund its operations. The Company cannot provide assurances that financing will be available when and as needed or that, if available, financing will be available on favorable or acceptable terms. If the Company is unable to obtain additional financing when and if required, it would have a material adverse effect on the Company's business and results of operations. The Company would likely need to delay, curtail or terminate portions of its clinical trial and research and development programs. To the extent the Company issues additional equity securities, its existing stockholders would experience substantial dilution.

Business Uncertainty Related to the Coronavirus

The COVID-19 pandemic has presented a substantial public health and economic challenge challenges around the world. Our business operations and financial condition and results have been impacted to varying degrees, and the impact may continue in future periods as we conduct our HOPE-3 trial and expand our exosomes-based research and development programs.

We are continuing to assess and plan our development for the ongoing and potential impact of COVID-19 on our business, operations and financial condition and results. Despite careful tracking and planning, however, we are unable to accurately predict the extent of the impact of the pandemic on our business, results of operations and financial condition due to the uncertainty of future developments involving the pandemic and its impact on our employees and operations. The full extent to which the COVID-19 pandemic will directly or indirectly impact our business, results of operations and financial condition will depend on future developments that are highly uncertain and cannot be accurately predicted, including new information that may emerge concerning COVID-19, the actions taken to contain it or treat its impact and the economic impact on local, regional, national and international markets. degrees.

In light of past uncertainties due to COVID-19 and its economic and other impacts and to uncertainties around the timing and availability of grant disbursements, the loss of revenue from the REGRESS and ALPHA trials as well as any potential equity and debt financings, the Company submitted for the Employee Retention Credit ("ERC"), a credit against certain payroll taxes allowed to an eligible employer for qualifying wages, which was established by the CARES Act. The Company has submitted $738,778 in ERC for applicable 2020 and 2021 periods, receiving $191,199 in 2021. 2021 and $191,463 in 2023. As of December 31, 2022 December 31, 2023, the Company has recorded a receivable for $547,580 $366,551 for the remainder of funds due. expected to be received.

Use of Estimates

The preparation of financial statements in conformity with U.S. GAAP requires management to make estimates and assumptions that affect the reported amounts of assets and liabilities and disclosure of contingent assets and liabilities at the date of the consolidated financial statements. Estimates also affect the reported amounts of revenues and expenses during the reporting period. Management uses its historical records and knowledge of its business in making these estimates. Accordingly, actual results may differ from these estimates.

Cash and Cash Equivalents

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

Marketable Securities

The Company determines the appropriate classification of its marketable securities at the time of purchase and reevaluates such designation at each balance sheet date. All of the Company's marketable securities are considered as available-for-sale and carried at estimated fair values. Realized gains and losses on the sale of debt and equity securities are determined using the specific identification method. Unrealized gains and losses on available-for-sale securities are excluded from net income (loss) and reported in accumulated other comprehensive income (loss) as a separate component of stockholders' equity. As of December 31, 2022, marketable securities consist primarily of short-term United States treasuries.

presented as accumulated other comprehensive income (loss) as a separate component of stockholders' equity. As of December 31, 2023, marketable securities consist primarily of short-term United States treasuries.

Property and Equipment

Property and equipment are stated at cost. Repairs and maintenance costs are expensed in the period incurred. Depreciation is computed using the straight-line method over the related estimated useful life of the asset, which such estimated useful lives range from five to seven years. Leasehold improvements are depreciated on a straight-line basis over the shorter of the useful life of the asset or the lease term. Depreciation was $533,131 $1,068,882 and $243,532 $533,131 for the years ended December 31, 2022 December 31, 2023 and 2021, 2022, respectively.

Property and equipment, net consisted of the following:

	December 31, 2022	December 31, 2021	December 31, 2023	December 31, 2022
Furniture and fixtures	$ 139,336	$ 43,123	$ 187,997	$ 139,336
Laboratory equipment	4,237,089	2,475,543	5,449,597	4,237,089
Leasehold improvements	1,393,230	33,742	2,129,102	1,393,230
	5,769,655	2,552,408	7,766,696	5,769,655
Less accumulated depreciation	(1,181,625)	(756,712)	(2,206,055)	(1,181,625)
Property and equipment, net	$ 4,588,030	$ 1,795,696	$ 5,560,641	$ 4,588,030

Intangible Assets

Amounts attributable to intellectual property consist primarily of the costs associated with the acquisition of certain technologies, patents, pending patents and related intangible assets with respect to research and development activities. Certain intellectual property

assets are stated at cost and amortized on a straight-line basis over the respective estimated useful lives of the assets ranging from five to fifteen years. Other intellectual property is expensed as incurred. Total amortization expense was zero and $2,165 for the years ended December 31, 2022 and 2021, respectively. All capitalized intellectual property has been fully amortized as of September 30, 2021.

The Company reviews goodwill and intangible assets at least annually for possible impairment. Goodwill and intangible assets are reviewed for possible impairment between annual tests if an event occurs or circumstances change that would more likely than not reduce the fair value of the reporting unit below its carrying value. No impairment was recorded for the years ended December 31, 2022 and 2021.

Long-Lived Assets

The Company accounts for the impairment and disposition of long-lived long-live assets in accordance with guidance issued by the FASB. Financial Accounting Standards Board ("FASB"). Long-lived assets to be held and used are reviewed for events or changes in circumstances that indicate that their carrying value may not be recoverable, or annually. No impairment related to long-lived assets was recorded for the years ended December 31, 2022 December 31, 2023 and 2021. 2022.

Leases

ASC Topic 842, "Leases"*Leases* ("ASC 842"), requires lessees to recognize most leases on the balance sheet with a corresponding right-to-use asset ("ROU asset"). ROU assets represent the Company's right to use an underlying asset for the lease term and lease liabilities represent the Company's obligation to make lease payments arising from the lease. The assets and lease liabilities are recognized at the lease commencement date based on the estimated present value of fixed lease payments over the lease term. ROU assets are evaluated for impairment using the long-lived assets impairment guidance.

Leases will be classified as financing or operating, which will drive the expense recognition pattern. The Company elects to exclude short-term leases if and when the Company has them.

The Company leases office and laboratory space, all of which are operating leases (see Note 76 - "Commitments and Contingencies"). Most leases include the option to renew and the exercise of the renewal options is at the Company's sole discretion. Options to renew a lease are not included in the Company's assessment unless there is reasonable certainty

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that the Company will renew. In addition, the Company's lease agreements generally do not contain any residual value guarantees or restrictive covenants.

The interest rate implicit in lease contracts is typically not readily determinable. As a result, the Company utilizes its incremental borrowing rate, which reflects the fixed rate at which the Company could borrow on a collateralized basis the amount of the lease payments in the same currency, for a similar term, in a similar economic environment.

For real estate leases, the Company has elected the practical expedient under ASC 842 to account for the lease and non-lease components together for existing classes of underlying assets and allocates the contract consideration to the lease component only. This practical expedient is not elected for manufacturing facilities and equipment embedded in product supply arrangements.

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Revenue Recognition

The Company adopted ASU 606, *Revenue for Contracts from Customers* ("ASU 606"), which amended revenue recognition principles and provides a single, comprehensive set of criteria for revenue recognition within and across all industries. The Company has not yet achieved commercial sales of its drug candidates to date, however, the new standard is applicable to its distribution agreements industries (see Note 8 7 – "License and Distribution Agreements").

The revenue standard provides a five-step framework for recognizing revenue as control of promised goods or services is transferred to a customer at an amount that reflects the consideration to which the entity expects to be entitled in exchange for those goods or services. To determine revenue recognition for arrangements that it determines are within the scope of the revenue standard, the Company performs the following five steps: (i) identify the contract; (ii) identify the performance obligations; (iii) determine the transaction price; (iv) allocate the transaction price to the performance obligations in the contract; and (v) recognize revenue when (or as) the Company satisfies a performance obligation. At contract inception, the Company assesses whether the goods or services promised within each contract are distinct and, therefore, represent a separate performance obligation, or whether they are not distinct and are combined with other goods and services until a distinct bundle is identified. The Company then determines the transaction price, which typically includes upfront payments and any variable consideration that the Company determines is probable to not cause a significant reversal in the amount of cumulative revenue recognized when the uncertainty associated with the variable consideration is resolved. The Company then allocates the transaction price to each performance obligation and recognizes the associated revenue when, or as, each performance obligation is satisfied.

The Company's distribution agreements may entitle it to additional payments upon the achievement of milestones or royalties shares of product revenue on sales. The milestones are generally categorized into three types: development milestones, regulatory milestones and sales-based milestones. The Company evaluates whether it is probable that the consideration associated with each milestone or royalty shared revenue payments will not be subject to a significant reversal in the cumulative amount of revenue recognized. Amounts that meet this threshold are included in the transaction price using the most likely amount method, whereas amounts that do not meet this threshold are excluded from the transaction price until they meet this threshold. At the end of each subsequent reporting period, the Company re-evaluates the probability of a significant reversal of the cumulative revenue recognized for its milestones and royalties, and, if necessary, adjusts its estimate of the overall transaction price. Any such adjustments are recorded on a cumulative catch-up basis, which would affect revenues and net income (loss) in the Company's consolidated statements of operation and comprehensive loss. Typically, milestone payments and royalties shared revenue payments are achieved after the Company's performance obligations associated with the distribution agreements have been completed and after the customer has assumed responsibility for the respective clinical commercialization program. Milestones or royalties shared revenue payments achieved after the Company's performance obligations have been completed are recognized as revenue in the period the milestone or royalty was shared revenue payments were achieved. If a milestone payment is achieved during the performance period, the milestone payment would be recognized as revenue to the extent performance had been completed at that point, and the remaining balance would be recorded as deferred revenue.

The revenue standard requires the Company to assess whether a significant financing component exists in determining the transaction price. The Company performs this assessment at the onset of its distribution agreements. Typically, a significant financing component does not exist because the customer is paying for services in advance with an upfront payment. Additionally, future royalty shared revenue payments are not substantially within the control of the Company or the customer.

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Whenever the Company determines that goods or services promised in a contract should be accounted for as a combined performance obligation over time, the Company determines the period over which the performance obligations will be performed and revenue will be recognized. Revenue is recognized using either the proportional performance method or on a straight-line basis if efforts will be expended evenly over time. Percentage of completion of patient visits in clinical trials are used as the measure of performance. The Company feels this method of measurement to be the best depiction of the transfer of services and recognition of revenue. Significant management judgment is required in determining the level of effort required under an arrangement and the period over which the Company is expected to

complete its performance obligations. If the Company determines that the performance obligation is satisfied over time, any upfront payment received is initially recorded as deferred revenue on its consolidated balance sheets.

Certain judgments affect the application of the Company's revenue recognition policy. For example, the Company records short-term (less than one year) and long-term (over one year) deferred revenue based on its best estimate of when such revenue will be recognized. This estimate is based on the Company's current operating plan and the Company may recognize a different amount of deferred revenue over the next 12-month period if its plan changes in the future.

The Under the U.S. Commercialization and Distribution Agreement (the "US Distribution Agreement") with Nippon Shinyaku, the transaction price consists of variable sales-based royalties shared revenue payments and fixed components in the form of an upfront payment and milestones. The timing of the fixed component of the transaction price is upfront, however, the performance obligation is satisfied over a period of time, which is the estimated duration of the HOPE-3 clinical trial. trial, Cohort A arm. Therefore, upon receipt of the upfront payment and achievement of milestones, a contract liability is recorded which represents deferred revenue. The Company evaluates the measure of progress each reporting period and, if necessary, adjusts the related revenue recognition.

Grant Income

Generally, government research grants that provide funding for research and development activities are recognized as income when the related expenses are incurred, as applicable. Because the terms of the grant award (the "CIRM Award") from the California Institute for Regenerative Medicine ("CIRM") allow Capricor to elect to convert the grant into a loan after the end of the project period, the CIRM Award is being classified as a liability rather than income (see Note 65 - "Government Grant Awards"). Grant income is due upon submission of a reimbursement request. The transaction price varies for grant income based on the expenses incurred under the awards. No grant income was recognized during the years ended December 31, 2022 December 31, 2023 and 2021.

Miscellaneous Income

Revenue is recognized in connection with the delivery of doses which were developed as part of our past research and development ("R&D") efforts. Income is recorded when the Company has satisfied the obligations as identified in the contracts with the customer (see Note 9 – "Related Party Transactions"). Miscellaneous income is due upon billing. Miscellaneous income is based on contracts with fixed transaction prices. Miscellaneous income for the years ended December 31, 2022 and 2021 was zero and approximately $0.2 million, respectively. 2022.

Income Taxes

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

The Company uses guidance issued by the FASB that clarifies the accounting for uncertainty in income taxes recognized in an enterprise's financial statements and prescribes a recognition threshold of more likely than not and a measurement process for financial

statement recognition and measurement of a tax position taken or expected to be taken in a tax return. In making this assessment, a company must determine whether it is more likely than not that a tax position will be sustained upon examination, based solely on the technical merits of the position, and must assume that the tax position will be examined by taxing authorities.

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As of December 31, 2022 December 31, 2023, the Company had federal net operating loss carryforwards of approximately $129.6 million $106.9 million, available to reduce future taxable income, of which $73.7 million approximately $50.7 million will begin to expire in 2027. The post December 31, 2017 net operating losses generated of $55.9 million approximately $56.2 million will carryforward indefinitely, but may be subject to an 80% limitation upon utilization. As of December 31, 2022 December 31, 2023, the Company had state net operating loss carryforwards of approximately $143.8 million $147.3 million, available to reduce future taxable income, which will begin to expire in 2028. Utilization of these net operating losses could be limited under Section 382 of the Internal Revenue Code of 1986, as amended (the "Code"), and similar state laws based on ownership changes and the value of the Company's stock. Additionally, currently, the Company has approximately $5.6 million $6.2 million of federal research and development credits and approximately $2.5 million $3.7 million of federal orphan drug credits, available to offset future taxable income. These federal research and development and orphan drug credits begin to expire in 2033 2027 and 2035, respectively. Additionally, the Company currently has approximately $1.7 million $2.2 million of California research and development credits available to offset future taxable income which will carryforward indefinitely. Utilization of these credits could be limited under Section 383 of the Code and similar state laws based on ownership changes and the value of the Company's stock.

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

The Company's policy is to include interest and penalties related to unrecognized tax benefits in income tax expense. The Company incurred no interest or penalties for the years ended December 31, 2022 December 31, 2023 and 2021. 2022. The Company files income tax returns with the IRS and the California Franchise Tax Board.

Research and Development

Costs relating to the design and development of new products are expensed as research and development as incurred in accordance with Financial Accounting Standards Board ("FASB") FASB ASC 730-10, *Research and Development*. Research and development costs

amounted to approximately $21.8 million $36.4 million and $13.6 million $21.8 million for the years ended December 31, 2022 December 31, 2023 and 2021, 2022, respectively.

Comprehensive Income (Loss)

Comprehensive income (loss) generally represents all changes in stockholders' equity during the period except those resulting from investments by, or distributions to, stockholders. The Company's comprehensive loss was approximately $28.9 million $22.2 million and $20.0 million $28.9 million for the years ended December 31, 2022 December 31, 2023 and 2021, 2022, respectively. The Company's other comprehensive income (loss) is related to a net unrealized gain (loss) on marketable securities. For the years ended December 31, 2022 December 31, 2023 and 2021, 2022, the Company's other comprehensive income was $105,244 $130,569 and zero, $105,244, respectively.

Clinical Trial Expense

As part of the process of preparing our consolidated financial statements, we are required to estimate our accrued expenses. Our clinical trial accrual process is designed to account for expenses resulting from our obligations under contracts with vendors, consultants, contract research organizations ("CROs"), and clinical site agreements in connection with conducting clinical trials. The financial terms of these contracts are subject to negotiations, which vary from contract to contract and may result in payment flows that do not match the periods over which materials or services are provided to us under such contracts. Our objective is to reflect the appropriate clinical trial expenses in our consolidated financial statements by matching the appropriate expenses with the period in which services are provided and efforts are expended.

We account for these expenses according to the progress of the trial as measured by patient progression and the timing of various aspects of the trial. We determine accrual estimates through financial models that take into account discussions with applicable personnel and outside service providers as to the progress or state of completion of trials, or the services completed. During the course of a clinical trial, we adjust our clinical expense recognition if actual results differ from our estimates. We make estimates of our accrued expenses as of each balance sheet date in our consolidated financial statements based on the facts and circumstances known to us at that time. Our clinical trial accrual and prepaid assets are dependent, in part, upon the receipt of timely and accurate reporting from CROs and other third-party vendors. Although we do not expect our estimates to be materially different from amounts actually incurred, our understanding of the status and timing of services performed relative to the actual status and timing of services performed may vary and may result in us reporting amounts that are too high or too low for any particular period.

Stock-Based Compensation

The Company accounts for stock-based employee compensation arrangements in accordance with guidance issued by the FASB, which requires the measurement and recognition of compensation expense for all share-based payment awards made to employees,

consultants, and directors based on estimated fair values.

The Company estimates the fair value of stock-based compensation awards on the date of grant using an option-pricing model. The value of the portion of the award that is ultimately expected to vest is recognized as an expense over the requisite service periods in the Company's statements of operations and comprehensive loss. The Company estimates the fair value of stock-based compensation awards using the Black-Scholes model. This model requires the Company to estimate the expected volatility and value of its common stock and the expected term of the stock options, all of which are highly complex and subjective variables. The variables take into consideration, among other things, actual and projected stock option exercise behavior. For employees and directors, the expected life was calculated based on the simplified method as described by the SEC Staff Accounting Bulletin No. 110, Share-Based Payment. For other service providers, the expected life was calculated using the contractual term of the award. The Company's estimate of expected volatility was based on the historical stock price of the Company. The Company has selected a risk-free rate based on the implied yield available on U.S. Treasury securities with a maturity equivalent to the expected term of the options.

Basic and Diluted Loss per Share

The Company reports earnings per share in accordance with FASB ASC 260-10, *Earnings per Share.* Basic earnings (loss) per share is computed by dividing income (loss) available to common stockholders by the weighted-average number of shares of common stock outstanding during the period. Diluted earnings (loss) per share is computed similarly to basic earnings (loss) per share except that the denominator is increased to include the number of additional shares of common stock that would have been outstanding if the potential shares of common stock had been issued and if the additional shares of common stock were dilutive.

For the years ended December 31, 2022 December 31, 2023 and 2021, 2022, warrants and options to purchase 5,882,621 13,268,807 and 3,899,606 5,882,621 shares of common stock, respectively, have been excluded from the computation of potentially dilutive securities. Potentially dilutive shares of common shares, stock, which primarily consist of stock options issued to employees, consultants, and directors as well as warrants issued, have been excluded from the diluted loss per share calculation because their effect is anti-dilutive. Because the impact of these items is anti-dilutive during periods of net loss, there was no difference between basic and diluted loss per share for the years ended December 31, 2022 December 31, 2023 and 2021. 2022.

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Fair Value Measurements

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

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

The following table summarizes the fair value measurements by level at December 31, 2022 December 31, 2023 and 2022 for assets and liabilities measured at fair value on a recurring basis:

	December 31, 2022			
	Level I	Level II	Level III	Total

Marketable Securities	$ 31,818,020	$ —	$ —	$ 31,818,020

	December 31, 2023			
	Level I	Level II	Level III	Total
Marketable Securities	$ 24,792,846	$ —	$ —	$ 24,792,846

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	December 31, 2022			
	Level I	Level II	Level III	Total
Marketable Securities	$ 31,818,020	$ —	$ —	$ 31,818,020

Carrying amounts reported in the balance sheet of cash and cash equivalents, receivables, accounts payable and accrued expenses approximate fair value due to their relatively short maturity. The carrying amounts of the Company's marketable securities are based on market quotations from national exchanges at the balance sheet date. Interest and dividend income are recognized separately on the income statement based on classifications provided by the brokerage firm holding the investments. The fair value of borrowings is not considered to be significantly different from its carrying amount because the stated rates for such debt reflect current market rates and conditions.

Recent Accounting Pronouncements

In November 2021, October 2023, the FASB issued ASU 2021-10, 2023-06, *Government Assistance (Topic 832)* *Disclosure Improvements: Codification Amendments in Response to the SEC's Disclosure Update and Simplification Initiative*, . This standard was issued in response to the SEC's disclosure update and simplification initiative, which requires business affects a variety of topics within the Accounting Standards Codification. The amendments apply to all reporting entities to disclose information about transactions with a government entity that are accounted for by applying a grant or contribution model by analogy. For transactions within scope, the new standard requires the disclosure of information about the nature scope of the transaction, including significant terms and conditions, as well as affected topics unless otherwise indicated. The effective date for each amendment will be the amounts and specific date on which the SEC's removal of that related disclosure from Regulation S-X or Regulation S-K becomes effective, with early adoption prohibited. The Company is currently evaluating the impact this guidance will have on its financial statement line items affected by the transaction. The new guidance is effective for annual reporting periods beginning after December 15, 2021. The Company adopted ASU 2021-10 in the first quarter of 2022. The adoption of this update did not have a material impact on the Company's financial statements and footnote disclosures.

Other recent accounting pronouncements issued by the FASB, including its Emerging Issues Task Force, the American Institute of Certified Public Accountants, and the SEC, did not or are not believed by management to have a material impact on the Company's present or future consolidated financial statement presentation or disclosures.

2. NOTE PAYABLE

Paycheck Protection Program Loan

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

In the second quarter of 2021, the Loan was forgiven, and the Company recognized a gain of $318,160 on the forgiveness.

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3. STOCKHOLDERS' EQUITY

ATM Programs and Other Offerings Program

The Company has established multiple an "at-the-market" ("ATM" program (the "ATM Program") on June 21, 2021, programs with an aggregate offering price of up to $75.0 million, pursuant to a Common Stock Sales Agreement with Wainwright by which Wainwright has sold and may continue to sell our common stock at the market prices prevailing at the time of sale. Wainwright is entitled to compensation for its services at a commission rate of 3.0% of the gross sales price per share of common stock sold plus reimbursement of certain expenses. These programs are referred to below as the "May 2020 ATM Program" and the "June 2021 ATM Program" based on when each program was initiated.

May 2020 ATM Program

On May 4, 2020, the Company initiated the May 2020 ATM Program. The Company established the May 2020 ATM Program with an aggregate offering price of up to $40.0 million. From May 4, 2020 June 21, 2021 through June 21, 2021 December 31, 2023, the Company sold an aggregate of 6,027,852 2,976,154 shares of common stock under the May 2020 ATM Program at an average price of approximately $6.15 $5.59 per share for gross proceeds of approximately $37.1 million $16.6 million. The Company paid cash commissions on the gross proceeds, plus reimbursement of expenses to Wainwright, as well as legal and accounting fees in the aggregate amount of approximately $1.2 million $0.6 million. As of June 21, 2021, the May 2020 ATM Program expired and was replaced with the June 2021 ATM Program described below.

June 2021 ATM Program

On June 21, 2021, the Company initiated the June 2021 ATM Program. The Company established the June 2021 ATM Program with an aggregate offering price of up to $75.0 million. From June 21, 2021 through December 31, 2022, the Company sold an aggregate of 2,098,333 shares of common stock under the June 2021 ATM Program at an average price of approximately $5.93 per share for gross proceeds of approximately $12.4 million. The Company paid cash commissions on the gross proceeds, plus reimbursement of expenses to Wainwright, as well as legal and accounting fees in the aggregate amount of approximately $0.4 million. Subsequent to December 31, 2022 and through the date of this filing, no additional approximately $57.2 million of common stock may still be sold pursuant to the ATM Program. Additionally, subsequent to December 31, 2023, the Company sold shares have been sold under the June 2021 ATM Program. Program (see Note 9 – "Subsequent Events").

October 2023 Financing

On October 3, 2023, the Company entered into Securities Purchase Agreements with its commercial partner, Nippon Shinyaku and funds associated with Highbridge Capital Management, LLC (the "Investors"), pursuant to which the Company agreed to issue and sell to the Investors, in a registered direct offering (the "Registered Direct Offering"), an aggregate of 4,935,621 shares of its common stock, par value $0.001 per share, at a price per share of $4.66 for an aggregate purchase price of approximately $23.0 million. Each share of common stock offered was sold with a warrant to purchase one share of common stock at an exercise price of $5.70 per share. Each warrant will be exercisable beginning six months after issuance and will expire seven years from the date of issuance. As part of the Registered Direct Offering, the Company agreed not to issue or sell shares (subject to customary exceptions for employee stock option issuances and other customary exceptions) for a period of 30 days following the date of the prospectus supplement that was used in the Registered Direct Offering. That prospectus was dated September 29, 2023, and the Company "lock-up" expired on October 29, 2023. The Company's directors and executive officers also entered into "lock-up" agreements with the

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placement agent in the Registered Direct Offering, which agreements expired on the 60th day following the date of the Securities Purchase Agreements, or December 2, 2023.

Outstanding Shares

At December 31, 2022 December 31, 2023, the Company had 25,241,402 31,148,320 shares of common stock issued and outstanding.

4. 3. STOCK AWARDS, WARRANTS AND OPTIONS

Warrants

The following table summarizes all warrant activity for the years ended December 31, 2022 December 31, 2023 and 2021: 2022:

	Warrants	Weighted Average Exercise Price	Warrants	Weighted Average Exercise Price
Outstanding at January 1, 2021	126,173	$ 1.32		
Granted	—	—		
Exercised	(20,391)	1.10		
Outstanding at December 31, 2021	105,782	$ 1.37		
Outstanding at January 1, 2022			105,782	$ 1.37
Granted	—	—	—	—
Exercised	—	—	—	—
Outstanding at December 31, 2022	105,782	$ 1.37	105,782	$ 1.37
Granted			4,935,621	5.70
Exercised			—	—
Outstanding at December 31, 2023			5,041,403	$ 5.61

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

		Warrants Outstanding					Warrants Outstanding			
Type	Grant Date	December 31, 2022	December 31, 2021	Exercise Price per Share	Expiration Date	Grant Date	December 31, 2023	December 31, 2022	Exercise Price per Share	Expiration Date

Common Warrants	12/19/2019	40,782	40,782	$	1.10	12/19/2024	12/19/2019	40,782	40,782	$	1.10	12/19/2024
Common Warrants	3/27/2020	65,000	65,000	$	1.5313	3/27/2025	3/27/2020	65,000	65,000	$	1.5313	3/27/2025
Common Warrants							10/3/2023	4,935,621	—	$	5.70	10/3/2030
		105,782	105,782									
								5,041,403	105,782			

Stock Options

The Company's Board of Directors (the "Board") has approved five stock option plans: (i) the 2006 Stock Option Plan, (ii) the 2012 Restated Equity Incentive Plan (which superseded the 2006 Stock Option Plan) (the "2012 Plan"), (iii) the 2012 Non-Employee Director Stock Option Plan (the "2012 Non-Employee Director Plan"), (iv) the 2020 Equity Incentive Plan (the "2020 Plan"), and (v) the 2021 Equity Incentive Plan (the "2021 Plan"). At this time, the Company only issues options under the 2020 Plan and the 2021 Plan.

In September Plan and no longer issues options under the 2006 Stock Option Plan, the 2012 the Board approved Plan, or the 2012 Non-Employee Director Plan, which authorized 269,731 shares of common stock, reserved for issuance of non-qualified options to members of the Board who are not employees of the Company. The 2012 Non-Employee Director Plan expired in September 2022, therefore, no additional stock option awards may be granted from the 2012 Non-Employee Director Plan.

In November 2012, the Board approved the 2012 Plan, which superseded the 2006 Stock Option Plan. Under the 2012 Plan, the Company may grant stock options, stock appreciation rights, restricted stock awards, and performance/unit share awards to employees, consultants and other service providers. Pursuant to the 2012 Plan, inclusive of annual evergreen provisions and amendments, the Company is authorized to issue 710,142 shares of common stock. The 2012 Plan expired in November 2022.

In June 2020, the Company's stockholders approved the 2020 Equity Incentive Plan (the "2020 Plan"), which authorized 2,500,000 shares of common stock to be issued and allows for the grant of stock options as well as other forms of equity-based compensation. Pursuant to the "evergreen" provision, on January 1, 2021, 823,084 shares were added under the 2020 Plan. Once the 2021 Plan was approved on June 11, 2021, no new shares have been or will be were added to the share reserve under the 2020 Plan pursuant to its "evergreen" provisions.

In June 2021, the Company's stockholders approved the 2021 Plan, which authorized 3,500,000 shares of common stock reserved under the 2021 Plan for the issuance of stock awards. The number of shares available for issuance under the 2021 Plan shall be automatically increased on January 1 of each year, commencing with January 1, 2022, by an amount equal to the lesser of 5% of the outstanding shares of Common Stock as of the last day of the immediately preceding

fiscal year. year or such number of shares determined by the compensation committee of the Board. On January 1, 2023 January 1, 2024 and 2022, 2023, 1,557,416 and 1,262,070 and 1,209,250 shares were added under the 2021 Plan, respectively.

As of December 31, 2022 December 31, 2023, 2,603,218 1,232,318 options remain available for issuance under the respective stock option plans.

Each of the The Company's stock option plans are administered by the Board, or in conjunction with the compensation committee of the Board, which determines the recipients and types of awards to be granted, as well as the number of shares subject to the awards, the exercise price and the vesting schedule. Each stock option granted will be designated in the award agreement as either an incentive stock option or a nonstatutory stock option. Notwithstanding such designation, however, to the extent that the aggregate fair market value of the

shares with respect to which incentive stock options are exercisable for the first time by the participant during any calendar year (under all plans of the Company and any parent or subsidiary) exceeds $100,000, such options will be treated as nonstatutory stock options. Stock options are granted with an exercise price not less than equal to the closing price of the Company's common stock on the date of grant, and generally vest over a period of one to four years. The term of stock options granted under each of the plans cannot exceed ten years.

The estimated weighted average fair value of the options granted during 2022 2023 and 2021 2022 were approximately $3.04 $3.85 and $3.45 $3.04 per share, respectively.

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The Company estimates the fair value of each option award using the Black-Scholes option-pricing model, with model. The company used the following assumptions: assumptions to estimate the fair value of stock options issued during the year ended December 31, 2023 and 2022:

	Year ended December 31,		Year ended December 31,	
	2022	2021	2023	2022
Expected volatility	123 - 124 %	123 - 124 %	111 - 121 %	123 - 124 %
Expected term	6 - 7 years	6 years	5 - 7 years	6 - 7 years
Dividend yield	0 %	0 %	0 %	0 %
Risk-free interest rates	1.5 - 3.9 %	0.5 - 1.1 %	3.5 - 4.5 %	1.5 - 3.9 %

Employee and non-employee stock-based compensation expense was as follows:

	Year ended December 31,		Year ended December 31,	
	2022	2021	2023	2022
General and administrative	$ 3,653,489	$ 2,566,883	$5,476,151	$3,653,489
Research and development	805,089	398,809	1,916,245	805,089
Total	$ 4,458,578	$ 2,965,692	$7,392,396	$4,458,578

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

Common stock, stock options or other equity instruments issued to non-employees (including consultants) as consideration for goods or services received by the Company are accounted for based on the fair value of the equity instruments issued. The fair value of stock options is determined using the Black-Scholes option-pricing model. The Company calculates the fair value for non-qualified options as of the date of grant and expenses over the applicable vesting periods. We account The Company accounts for forfeitures upon occurrence.

The following table summarizes information about stock options outstanding and exercisable at December 31, 2022:

Options Outstanding			
Range of Ex. Prices	Options Outstanding	Weighted Average Term (yrs.)	Weighted Average Exercise Price
$1.39	1,682,707	6.40	$ 1.39
$2.54 - $3.74	3,539,132	8.70	$ 3.40
$4.37 - $6.30	555,000	8.82	$ 5.04

	5,776,839		$ 2.97

Options Exercisable			
Range of Ex. Prices	Options Exercisable	Weighted Average Term (yrs.)	Weighted Average Exercise Price
$1.39	1,283,217	6.18	$ 1.39
$2.54 - $3.74	1,058,536	8.43	$ 3.51
$4.37 - $6.30	142,534	8.26	$ 5.15
	2,484,287		$ 2.51

As of December 31, 2022, the total unrecognized fair value compensation cost related to non-vested stock options was approximately $10.1 million, which is expected to be recognized over a weighted average period of approximately 1.3 years.

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The following table summarizes information about stock options outstanding and exercisable at December 31, 2023:

Options Outstanding			
Range of Ex. Prices	Options Outstanding	Weighted Average Term (yrs.)	Weighted Average Exercise Price
$1.39	1,600,054	5.71	$ 1.39
$2.54 - $3.41	1,889,562	8.14	3.19
$3.61 - $3.85	3,004,621	8.17	3.80
$4.11 - $7.14	1,733,167	9.02	5.08
	8,227,404		$ 3.46

Options Exercisable			
Range of Ex. Prices	Options Exercisable	Weighted Average Term (yrs.)	Weighted Average Exercise Price
$1.39	1,544,732	5.69	$ 1.39
$2.54 - $3.41	845,993	8.00	3.18
$3.61 - $3.85	1,601,850	7.85	3.79
$4.11 - $7.14	255,561	7.49	5.16
	4,248,136		$ 2.88

As of December 31, 2023, the total unrecognized fair value compensation cost related to non-vested stock options was approximately $13.5 million, which is expected to be recognized over a weighted average period of approximately 1.5 years.

The following is a schedule summarizing employee and non-employee stock option activity for the years ended December 31, 2022 December 31, 2023 and 2021: 2022:

	Number of Options	Weighted Average Exercise Price	Aggregate Intrinsic Value	Number of Options	Weighted Average Exercise Price	Aggregate Intrinsic Value
Outstanding at January 1, 2021	2,361,873	$ 1.89				
Granted	1,636,324	3.95				
Exercised	(21,338)	1.39	$ 51,044			

Expired/Cancelled	(183,035)	3.84				
Outstanding at December 31, 2021	3,793,824	$ 2.68				
Outstanding at January 1, 2022				3,793,824	$ 2.68	
Granted	2,817,370	3.46		2,817,370	3.46	
Exercised	(325,667)	1.37	$ 867,854	(325,667)	1.37	$ 867,854
Expired/Cancelled	(508,688)	4.55		(508,688)	4.55	
Outstanding at December 31, 2022	5,776,839	$ 2.97	$ 5,773,788	5,776,839	$ 2.97	
Exercisable at December 31, 2022	2,484,287	$ 2.51	$ 3,540,034			
Granted				3,420,979	4.32	
Exercised				(182,405)	2.55	$ 367,422
Expired/Cancelled				(788,009)	3.82	
Outstanding at December 31, 2023				8,227,404	$ 3.46	$12,493,414
Exercisable at December 31, 2023				4,248,136	$ 2.88	$ 8,636,326

The aggregate intrinsic value represents the difference between the exercise price of the options and the estimated fair value of the Company's common stock for each of the respective periods.

5. 4. CONCENTRATIONS

Concentration of Risk

Financial instruments, which potentially subject the Company to concentrations of credit risk, principally consist of cash, cash equivalents, and marketable securities. The Company has historically maintained maintains accounts at two three financial institutions. These accounts are each insured by the Federal Deposit Insurance Corporation (the "FDIC") for up to $250,000. $250,000 and/or the Securities Investor Protection Corporation, as applicable. The Company's cash, cash equivalents, and marketable securities in excess of the FDIC insured limits as of December 31, 2022 December 31, 2023, were approximately $41.1 million $39.2 million. The Company monitors the financial stability of the financial institutions with which it maintains accounts and believes it is not exposed to any significant credit risk in cash and cash equivalents. Historically, the Company has not experienced any significant losses

in such accounts and does not believe it is exposed to any significant credit risk due to the quality nature of the financial instruments in which the money is held.

6. 5. GOVERNMENT GRANT AWARDS

CIRM Grant Award (HOPE)

On June 16, 2016, Capricor entered into the CIRM Award with CIRM in the amount of approximately $3.4 million to fund, in part, Capricor's Phase I/II 1/2 HOPE-Duchenne clinical trial investigating CAP-1002 for the treatment of Duchenne muscular dystrophy-associated DMD-associated cardiomyopathy. Pursuant to terms of the CIRM Award, the disbursements were tied to the achievement of specified operational milestones. In addition, the terms of the CIRM Award included a co-funding requirement pursuant to which Capricor was required to spend approximately $2.3 million of its own capital to fund the CIRM funded research project. The CIRM Award is further subject to the conditions and requirements set forth in the CIRM Grants Administration Policy for Clinical Stage Projects. Such requirements include, without limitation, the filing of quarterly and annual reports with CIRM, the sharing of intellectual property pursuant to Title 17, California Code of Regulations (CCR) Sections 100600-100612, and the sharing with the State of California of a fraction of licensing revenue received from a CIRM funded research project and net commercial revenue from a commercialized product which resulted from the CIRM funded research as

set forth in Title 17, CCR Section 100608. The maximum royalty on net commercial revenue that Capricor may be required to pay to CIRM is equal to nine times the total amount awarded and paid to Capricor.

After completing the CIRM funded research project and at any time after the award period end date (but no later than the ten-year anniversary of the date of the award), Capricor has the right to convert the CIRM Award into a loan, the terms of which will be determined based on various factors, including the stage of the research and development of the program at the time the election is made. On June 20, 2016, Capricor entered into a Loan Election Agreement with CIRM whereby, among other things, CIRM and Capricor agreed that if Capricor elects to convert the grant into a loan, the term of the loan could be up to five years from the date of execution of the applicable loan agreement; provided that the maturity

date of the loan will not surpass the ten-year anniversary of the grant date of the CIRM Award. Beginning on the date of the loan, the loan shall bear interest on the unpaid principal balance, plus the interest that has accrued prior to the election point according to the terms set forth in CIRM's the CIRM Loan Policy and CIRM Grants Administration Policy for Clinical Stage Projects (the "New Loan Balance"), at a per annum rate equal to the LIBOR rate for a three-month deposit in U.S. dollars, as published by the Wall Street Journal on the loan date, plus one percent. Interest shall be compounded annually on the outstanding New Loan Balance commencing with the loan date and the interest shall be payable, together with the New Loan Balance, upon the due date of the loan. If Capricor elects to convert the CIRM Award into a loan, certain requirements of the CIRM Award will no longer be applicable, including the revenue sharing requirements. Capricor has not yet made its decision as to whether it will elect to convert the CIRM Award into a loan. Depending on the timing of our election, additional funds may be owed. If we elect to do so, Capricor would be required to repay some or all of the amounts awarded by CIRM; therefore, the Company accounts for this award as a liability rather than income.

In 2019, Capricor completed all milestones and close-out activities associated with the CIRM Award and expended all funds received. As of December 31, 2022 and 2021, December 31, 2023, Capricor's liability balance for the CIRM Award was approximately $3.4 million.

7. 6. COMMITMENTS AND CONTINGENCIES

Short-Term Operating Leases

Capricor leases office space in Beverly Hills, California from The Bubble Real Estate Company, LLC ("Bubble Real Estate") pursuant to a lease beginning in 2013. Capricor subsequently entered into several amendments modifying certain terms of the lease. Effective January 1, 2021, we entered into a month-to-month lease amendment with the Bubble Real Estate. The monthly lease payment was $13,073. In November 2021, Capricor entered into an amendment to the lease pursuant to Estate, which the square footage of the premises was reduced with a monthly lease payment of $5,548 per month commencing November 1, 2021. In July 2022, Capricor added additional office space increasing the monthly lease payment to $7,869 per month. The lease is terminable by either party upon 90 days' written notice to the other party. Commencing in July 2022, the monthly lease payment was $7,869 per month. Effective July 1, 2023, the monthly lease payment was reduced to $7,619 per month.

Expenses incurred under short-term operating leases for the years ended December 31, 2022 December 31, 2023 and 2021 2022 were $92,928 and $81,735, and $141,923, respectively.

Long-Term Operating Leases

Capricor leases facilities in Los Angeles, California from Cedars-Sinai Medical Center ("CSMC"), a related party (see Note 9 8 – "Related Party Transactions"), pursuant to a lease (the "Facilities Lease") beginning entered into in 2014. Capricor has subsequently entered into several amendments modifying certain terms of the lease. In July 2020, Capricor exercised its option to extend the term of the Facilities Lease for an additional 12-month period through July 31, 2021 with a monthly lease payment of $15,805. In July 2021, Capricor exercised its option to extend the term of the Facilities Lease for an additional 12-month period through July 31, 2022 with a monthly lease payment of $10,707. In July 2022, we entered into an amendment for an additional 24-month period extending the term through July 31, 2024 with a monthly lease payment of $10,707. Additionally, in September 2023, we entered into an amendment pursuant to which Capricor was granted an option to extend the lease for an additional 24-month period extending the term through July 31, 2026 with a monthly lease payment of $11,028 commencing on August 1, 2024.

The Company entered into a lease agreement commencing October 1, 2021 with Altman Investment Co, LLC ("Altman") for 9,396 square feet of office and laboratory space located at 10865 Road to the Cure, Suite 150, in San Diego, California. Under the terms of the lease, the base rent will be $48,859 per month, for which the Company received certain rent abatements during the initial year. Additionally, the California (the "San Diego Lease"). The rent is subject to a 3.0% annual rent increase during the initial lease term of five years, plus certain operating expenses and taxes. The lease San Diego Lease contains an option for Capricor to renew it for an additional term of five years. Effective July 1, 2022 the The Company has subsequently entered into an amendment several amendments to the lease San Diego Lease increasing the square footage to 9,485 square feet with a of the premises and effective July 1, 2022, the monthly lease payment of was increased to $49,322 per month. In November 2022, we entered into an amendment increasing Effective December 1, 2022, the square footage to 9,605 square feet with a new monthly lease payment of was increased to $51,444 per month effective December 1, 2022. month. Effective October 1, 2023, the monthly lease payment was increased to $58,409 per month.

Effective November 1, 2021, the Company entered into a vivarium agreement with Explora BioLabs, Inc. ("Explora"), a Charles River Company, for vivarium space and services. Under the terms of the agreement, the Company is obligated to pay a base rent will be of $4,021 per month for an exclusive large vivarium room located in San Diego, California. The lease term is for one-year and will automatically renew for additional successive one-year renewal terms unless either party provides the other

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party with 60-day written notice of its election not to renew prior to the end of the then-current term. In December 2022, we were notified by Explora of a monthly rent escalation of 4.5% for a bringing the base rent of to approximately $4,202 per month effective January 1, 2023. For ASC 842 purposes, we applied a lease term of five years.

The long-term real estate operating leases are included in "lease right-of-use assets, net" on the Company's Consolidated Balance Sheet and represent the Company's right-to-use the underlying assets for the lease term. The Company's obligation to make lease payments are included in "lease liabilities, current" and "lease liabilities, net of current" on the Company's Consolidated Balance Sheet.

The table below excludes short-term operating leases. The following table summarizes maturities of lease liabilities and the reconciliation of lease liabilities as of December 31, 2022 December 31, 2023:

2023	$ 798,688	
2024	763,814	$ 886,672
2025	708,087	910,106

2026	546,138	676,908
2027		—
2028		—
Total minimum lease payments	2,816,727	2,473,686
Less: imputed interest	(256,618)	(237,791)
Total operating lease liabilities	$ 2,560,109	$ 2,235,895
Included in the consolidated balance sheet:		
Current portion of lease liabilities	$ 682,039	$ 749,112
Lease liabilities, net of current	1,878,070	1,486,783
Total operating lease liabilities	$ 2,560,109	$ 2,235,895
Other Information:		
Weighted average remaining lease term	3.59 years	2.73 years
Weighted average discount rate	5.18%	7.24%

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As of December 31, 2022 December 31, 2023, ROU assets for operating leases were approximately $2.3 million $2.1 million and operating lease liabilities were approximately $2.6 million $2.2 million. The following table contains a summary of the lease costs recognized and lease payments pertaining to the Company's operating leases under ASC 842 for the period indicated:

	Year ended December 31,		Year ended December 31,	
	2022	2021	2023	2022
Lease costs, unrelated parties	$ 632,689	$ 129,726	$663,684	$632,689
Lease costs, related parties	128,478	—	129,158	128,478
Lease payments, unrelated parties	470,950	81,331	684,444	470,950
Lease payments, related parties	128,478	—	117,772	128,478

Legal Contingencies

The Company is not a party to any material legal proceedings at this time. From time to time, the Company may become involved in various legal proceedings that arise in the ordinary course of its business or otherwise. The Company records a loss contingency reserve for a legal proceeding when it considers the potential loss probable and it can reasonably estimate the amount of the loss or determine a probable range of loss. The Company has not recorded any material accruals for loss contingencies as of December 31, 2023. The Company has received a letter from CSMC alleging certain overdue payment obligations and alleged breaches (see Note 7 – "License and Distribution Agreements").

Accounts Payable

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

Other Funding Commitments

The Company is a party to various agreements, principally relating to licensed technology, that require future payments relating to milestones that may be met in subsequent periods or royalties on future sales of specific products (see Note 8 7 - "License and Distribution

Agreements").

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

Employee Severances

The Board of Directors approved approves severance packages for specific full-time employees based on their length of service and position ranging up to six months of their base salaries, in the event of termination of their employment, subject to certain conditions. No liability under these severance packages has been recorded as of December 31, 2022 December 31, 2023.

8. 7. LICENSE AND DISTRIBUTION AGREEMENTS

Intellectual Property Rights for Capricor's Technology - CAP-1002 and Exosomes

Capricor has entered into exclusive license agreements for intellectual property rights related to certain cardiac-derived cells with Università Degli Studi Di Roma La Sapienza (the "University of Rome"), JHU and CSMC. Capricor has also entered into an exclusive license agreement for intellectual property rights related to exosomes with CSMC and JHU. In addition, Capricor has filed patent applications related to the technology developed by its own scientists.

University of Rome License Agreement

Capricor and the University of Rome entered into a License Agreement, dated June 21, 2006 (the "Rome License Agreement"), which provides for the grant of an exclusive, world-wide, royalty-bearing license by the University of Rome

to Capricor (with the right to sublicense) to develop and commercialize licensed products under the licensed patent rights in all fields.

Pursuant to the Rome License Agreement, Capricor paid the University of Rome a license issue fee, is currently paying minimum annual royalties in the amount of 20,000 Euros per year, and is obligated to pay a lower-end of a mid-range double-digit percentage on all royalties received as a result of sublicenses granted, which are net of any royalties paid to third parties under a license agreement from such third party third-party to Capricor. The minimum annual royalties are creditable against future royalty payments.

The Rome License Agreement will, unless extended or sooner terminated, remain in effect until the later of the last claim of any patent or until any patent application comprising licensed patent rights has expired or been abandoned. Under the terms of the Rome License Agreement, either party may terminate the agreement should the other party become insolvent or file a petition in bankruptcy. Either party

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

The Johns Hopkins University License Agreements

License Agreement for CDCs

Capricor and JHU entered into an Exclusive License Agreement, effective June 22, 2006 (the "JHU License Agreement"), which provides for the grant of an exclusive, world-wide, royalty-bearing license by JHU to Capricor (with the right to sublicense) to develop and commercialize licensed products and licensed services under the licensed patent rights in all fields and a nonexclusive right to the know-how. Various amendments were entered into to revise certain provisions of the JHU License Agreement. Under the JHU License Agreement, Capricor is required to exercise commercially reasonable and diligent efforts to develop and commercialize licensed products covered by the licenses from JHU.

Pursuant to the JHU License Agreement, JHU was paid an initial license fee and, thereafter, Capricor is required to pay minimum annual royalties on the anniversary dates of the JHU License Agreement. The minimum annual royalties are creditable against a low single-digit running royalty on net sales of products and net service revenues, which Capricor is also required to pay under the JHU License Agreement, which running royalty may be subject to further reduction in

the event that Capricor is required to pay royalties on any patent rights to third parties in order to make or sell a licensed product. In addition, Capricor is required to pay a low double-digit percentage of the consideration received by it from sublicenses granted and is required to pay JHU certain defined development milestone payments upon the successful completion of certain phases of its clinical studies and upon receiving approval from the FDA. The maximum aggregate amount of milestone payments payable under the JHU License Agreement, as amended, is $1,850,000. In March 2022, Capricor paid the $250,000 development milestone related to the Phase II 2 study pursuant to the terms of the JHU License Agreement. The next milestone is triggered upon successful completion of a full Phase III 3 study for which a payment of $500,000 will be due.

The JHU License Agreement will, unless sooner terminated, continue in effect in each applicable country until the date of expiration of the last to expire patent within the patent rights, or, if no patents are issued, then for twenty years from the effective date. Under the terms of the JHU License Agreement, either party may terminate the agreement should the other party become insolvent or file a petition in bankruptcy or fail to cure a material breach within 30 days after notice. In addition, Capricor may terminate for any reason upon 60 days' written notice.

License Agreement for Exosome-based Vaccines and Therapeutics

Capricor and JHU entered into an Exclusive License Agreement (the "JHU Exosome License Agreement"), effective April 28, 2021 for its co-owned interest in certain intellectual property rights related to exosome-mRNA vaccines and therapeutics. The JHU Exosome License Agreement provides provided for the grant of an exclusive, world-wide, royalty-bearing license of JHU's co-owned rights by JHU to Capricor, with the right to sublicense, in order to conduct research using the patent rights and know-how and to develop and commercialize products in the field using the patent rights and know-how.

Pursuant to the JHU Exosome License Agreement, JHU was paid an upfront license fee of $10,000 and Capricor has agreed to reimburse JHU for certain fees and costs incurred in connection with the prosecution of certain patent rights.

Additionally, Capricor is required to meet certain development milestones for which a milestone payment fee shall be due and is obligated to pay low single-digit royalties on sales of royalty-bearing products as well as a double-digit percentage of any non-royalty consideration received from any sublicenses, subject to certain exclusions. The above-mentioned royalties are subject to reduction in the

event Capricor becomes obligated to pay royalties on one or more third party patents as a requirement to make or sell a licensed product. In addition, Capricor will, beginning with the third year of the JHU Exosome License Agreement, be obligated to pay JHU a minimum annual royalty which is non-refundable but will be credited against royalties incurred by Capricor for the year in which the minimum annual royalty becomes due.

The JHU Exosome License Agreement will, unless sooner terminated, continue in each country until the date of expiration of the last to expire patent included within the patent rights in that country, or if no patents issue, then for 20 years. The JHU Exosome License Agreement may be was terminated by Capricor upon 90 days' written notice in its discretion and with 60 days' notice with respect to any particular patent or application or as to any particular licensed product. The JHU Exosome License Agreement may also be terminated by either party if the other party fails to perform or otherwise breaches any on December 15, 2023.

Table of its obligations and fails to cure such breach within a 60-day cure period commencing upon notice. A material breach by Capricor may include (a) a delinquency with respect to payment or reporting; (b) the failure by Capricor to timely achieve a specified milestone or otherwise failing to diligently develop, commercialize, and sell licensed products throughout the term of the JHU Exosome License Agreement; (c) non-compliance with record keeping or audit obligations; (d) voluntary bankruptcy or insolvency of Capricor; and (e) non-compliance with Capricor's insurance obligations. Contents

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Cedars-Sinai Medical Center License Agreements

License Agreement for CDCs

On January 4, 2010, Capricor entered into an Exclusive License Agreement with CSMC (the "Original CSMC License Agreement"), for certain intellectual property related to its CDC technology. In 2013, the Original CSMC License Agreement was amended twice resulting in, among other things, a reduction in the percentage of sublicense fees which would have been payable to CSMC. Effective December 30, 2013, Capricor entered into an Amended and Restated Exclusive License Agreement with CSMC (the "Amended CSMC License Agreement"), which amended, restated, and

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superseded the Original CSMC License Agreement, pursuant to which, among other things, certain definitions were added or amended, the timing of certain obligations was revised and other obligations of the parties were clarified.

The Amended CSMC License Agreement provides for the grant of an exclusive, world-wide, royalty-bearing license by CSMC to Capricor (with the right to sublicense) to conduct research using the patent rights and know-how and develop and commercialize products in the field using the patent rights and know-how. In addition, Capricor has the exclusive right to negotiate for an exclusive license to any future rights arising from related work conducted by or under the direction of Dr. Eduardo Marbán on behalf of CSMC. In the event the parties fail to agree upon the terms of an exclusive license for any future rights, Capricor will have a non-exclusive license to such future rights, subject to royalty obligations.

Pursuant to the Original CSMC License Agreement, CSMC was paid a license fee and Capricor was obligated to reimburse CSMC for certain fees and costs incurred in connection with the prosecution of certain patent rights. Additionally, Capricor is required to meet certain spending and development milestones.

Pursuant to the Amended CSMC License Agreement, Capricor remains obligated to pay low single-digit royalties on sales of royalty-bearing products as well as a low double-digit percentage of the consideration received from any sublicenses or other grant of rights. The above-mentioned royalties are subject to reduction in the event Capricor becomes obligated to obtain a license from a third party third-party for patent rights in connection with the royalty-bearing product.

The Amended CSMC License Agreement will, unless sooner terminated, continue in effect on a country by country basis until the last to expire of the patents covering the patent rights or future patent rights. Under the terms of the Amended CSMC License Agreement, unless waived by CSMC, the agreement shall automatically terminate: (i) if Capricor ceases, dissolves or winds up its business operations; (ii) in the event of the insolvency or bankruptcy of Capricor or if Capricor makes an assignment for the benefit of its creditors; (iii) if performance by either party jeopardizes the licensure, accreditation or tax exempt status of CSMC or the agreement is deemed illegal by a governmental body; (iv) within 30 days for non-payment of royalties; (v) after 90 days' notice from CSMC if Capricor fails to undertake commercially reasonable efforts to exploit the patent rights or future patent rights; (vi) if a material breach has not been cured within 90 days; or (vii) if Capricor challenges any of the CSMC patent rights. If Capricor fails to undertake commercially reasonable efforts to exploit the patent rights or future patent rights, and fails to cure that breach after 90 days' notice from CSMC, instead of terminating the license, CSMC has the option to convert any exclusive license to Capricor to a non-exclusive or co-exclusive license. Capricor may terminate the agreement if CSMC fails to cure any material breach within 90 days after notice.

On March 20, 2015, August 5, 2016, December 26, 2017, June 20, 2018, and July 27, 2021, Capricor and CSMC have entered into a number of several amendments to the Amended CSMC License Agreement, pursuant to which the parties agreed to add and delete certain patent applications from the list of scheduled patents and extend the timing of certain development milestones, among other things. Capricor reimbursed CSMC for certain attorneys' fees and filing fees incurred in connection with the additional patent applications.

We recently received a letter from CSMC alleging that pursuant to the Amended CSMC License Agreement between CSMC and Capricor, Capricor has certain overdue payment obligations to CSMC arising out of a milestone payment received by Capricor pursuant to the U.S. Distribution Agreement entered into between Capricor and Nippon Shinyaku. Capricor has received a milestone payment of $10.0 million under its U.S. Distribution Agreement with Nippon Shinyaku, which CSMC is claiming 10% of this milestone payment is owed to them. The notice letter requests that Capricor cure the alleged breaches of the Amended CSMC License Agreement, and reserves CMSC's purported right to terminate the Amended CSMC License Agreement if such alleged breaches are not cured. We dispute the allegations in

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the letter from CSMC and intend to vigorously defend our position and pursue all available remedies, but there is no guarantee that any disputes that we have with CSMC will be resolved or if resolved, will not result in our incurring certain payment and other obligations.

License Agreement for Exosomes

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

Pursuant to the Exosomes License Agreement, CSMC was paid a license fee and Capricor reimbursed CSMC for certain fees and costs incurred in connection with the preparation and prosecution of certain patent applications. Additionally, Capricor is required to meet certain non-monetary development milestones and is obligated to pay low single-digit royalties on sales of royalty-bearing products as well as a single-digit percentage of the consideration received from any sublicenses or other grant of rights. The above-mentioned royalties are subject to reduction in the event Capricor becomes obligated to obtain a license from a third party third-party for patent rights in connection with the royalty bearing product.

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The Exosomes License Agreement will, unless sooner terminated, continue in effect on a country by country basis until the last to expire of the patents covering the patent rights or future patent rights. Under the terms of the Exosomes License Agreement, unless waived by CSMC, the agreement shall automatically terminate: (i) if Capricor ceases, dissolves or winds up its business operations; (ii) in the event of the insolvency or bankruptcy of Capricor or if Capricor makes an assignment for the benefit of its creditors; (iii) if performance by either party jeopardizes the licensure, accreditation or tax exempt status of CSMC or the agreement is deemed illegal by a governmental body; (iv) within 30 days for non-payment of royalties; (v) after 90 days if Capricor fails to undertake commercially reasonable efforts to exploit the patent rights or future patent rights; (vi) if a material breach has not been cured within 90 days; or (vii) if Capricor challenges any of the CSMC patent rights. If Capricor fails to undertake commercially reasonable efforts to exploit the patent rights or future patent rights and fails to cure that breach after 90 days' notice from CSMC, instead of terminating the license, CSMC has the option to convert any exclusive license to Capricor to a non-exclusive or co-exclusive license. Capricor may terminate the agreement if CSMC fails to cure any material breach within 90 days after notice.

On February 27, 2015, June 10, 2015, August 5, 2016, December 26, 2017, June 20, 2018, September 25, 2018, August 19, 2020, August 28, 2020, and March 19, 2021, Capricor and CSMC have entered into a number of several amendments to the Exosomes License Agreement. Collectively, these amendments added additional patent applications and patent families to the Exosomes License Agreement, added certain defined product development milestone payments, modified certain milestone deadlines, and added certain performance milestones with respect to product candidates covered by certain future patent rights in order to maintain an exclusive license to those future patent rights; failure rights, and converted certain exclusive rights to meet those milestones would cause CSMC to have the right to convert the license from exclusive to non-exclusive or co-exclusive or to terminate the license, subject to Capricor's right to license such patent rights for internal research purposes on a non-exclusive basis. rights. These amendments also obligated Capricor to reimburse CSMC for certain attorneys' fees and filing fees in connection with the additional patent applications and patent families.

Sponsored Research Agreement with Johns Hopkins University

On April 1, 2020 we entered into a Sponsored Research Agreement (the "SRA") with JHU pursuant to which researchers in the lab of Dr. Stephen Gould performed certain research activities in connection with our engineered exosomes program. Pursuant to the SRA, we funded certain research activities. This SRA expired in accordance with its terms on March 31, 2022.

Cell Line License Agreement with Life Technologies

On March 7, 2022, Capricor entered into a non-exclusive cell line license agreement with Life Technologies Corporation, a subsidiary of Thermo Fisher Scientific, Inc., for the supply of certain cells which we will use in connection with the development of our exosomes platform. An initial license fee payment was made in the first quarter of 2022 and additional milestone fees may become due based on the progress of our development program.

Commercialization and Distribution Agreement with Nippon Shinyaku (Territory: United States)

On January 24, 2022, Capricor entered into an Exclusive a Commercialization and Distribution Agreement (the "U.S. Distribution Agreement") with Nippon Shinyaku, a Japanese corporation. Under the terms of the U.S. Distribution

Agreement, Capricor appointed Nippon Shinyaku as its exclusive distributor in the United States of CAP-1002 for the treatment of DMD.

Under the terms of the U.S. Distribution Agreement, Capricor will be responsible for the conduct of the HOPE-3 trial as well as the manufacturing of CAP-1002. Nippon Shinyaku will be responsible for the distribution of CAP-1002 in the United States. Pursuant to the U.S Distribution Agreement, Capricor received an upfront payment of $30.0 million in the first quarter of 2022. The first milestone payment of $10.0 million was paid upon completion of the interim futility analysis of the HOPE-3 trial whereby the outcome was determined to be not futile. Additionally, there are potential milestones totaling up to $90.0 million leading up to and including the BLA approval. Further, there are various potential sales-based milestones, if commercialized, tied to the achievement of certain sales thresholds for annual net sales of CAP-1002 of up to $605.0 million. Further, pursuant to the U.S. Distribution Agreement, Capricor has the obligation to sell commercial product to Nippon Shinyaku, subject to regulatory approval, and in addition Capricor will have the right to receive a meaningful mid-range double-digit share of product revenue and additional development and sales-based milestone payments, if achieved. In the first quarter of 2022, Capricor received an upfront payment of $30.0 million. Pursuant to the terms of the U.S. Distribution Agreement, there are potential additional sales and development milestone payments of up to $705.0 million. revenue.

The Company has evaluated the U.S. Distribution Agreement in accordance with ASU 606, *Revenue for Contracts from Customers*. At the inception, the Company identified one distinct performance obligation. The Company determined that the performance obligation is the conduct of the HOPE-3, Phase III 3 clinical study.

The Company determined the initial transaction price totaled $30.0 million, $40.0 million, which was the upfront payment fee. of $30.0 million and $10.0 million milestone payment. The Company has excluded any future milestones milestone or royalties shared revenue payments from this transaction price to date based on probability. The Company has allocated the total $30.0 million initial $40.0 million transaction price to its one distinct performance obligation. Revenue will be recognized using a proportional performance method in relation to the completion of the HOPE-3 clinical study, Cohort A arm, to determine the extent of progress towards completion. Under this method, the transaction price is recognized over the contract's entire performance period using a cost percentage per patient visit relative to the total estimated costs cost of patient visits.

For the year ended December 31, 2022 December 31, 2023, the Company recognized approximately $2.6 million $25.2 million as revenue.

At revenue compared to approximately $2.6 million for the time year ended December 31, 2022. In relation to the U.S. Distribution Agreement, as of receipt of the upfront fee in March 2022, December 31, 2023, the Company recorded approximately $12.3 million as a contract liability, which represent current deferred revenue. revenue on the Company's consolidated balance sheets. As of December 31, 2022 December 31, 2023, there were approximately $27.4 million the Company recorded a receivable of contract liabilities recorded as deferred revenue. $10.0 million in connection with the interim futility milestone, which payment was received in January 2024.

The Company had no opening or closing contract asset balances recognized. The difference between the opening and closing balances of the Company's contract liability results from the Company performance of services in connection to its performance obligation.

Transaction The transaction price allocated to remaining performance obligations represents contracted revenue that has not yet been recognized. As of December 31, 2022 December 31, 2023, remaining performance obligations related to the U.S. Distribution

Agreement were approximately $27.4 million $12.3 million. 66% At this time, we estimate 100% of the remaining performance obligations are expected to be recognized over the next 12 months, with the remainder recognized thereafter. months. Remaining performance obligations estimates are subject to change.

Commercialization and Distribution Agreement with Nippon Shinyaku (Territory: Japan)

On February 10, 2023, Capricor entered into a Commercialization and Distribution Agreement (the "Japan Distribution Agreement") with Nippon Shinyaku. Under the terms of the Japan Distribution Agreement, Capricor appointed Nippon Shinyaku as its exclusive distributor in Japan of CAP-1002 for the treatment of DMD.

Under the terms of the Japan Distribution Agreement, Capricor received an upfront payment of $12.0 million in the first quarter of 2023 and in addition, Capricor may potentially receive additional development and sales-based milestone payments of up to approximately $89.0 million, subject to foreign currency exchange rates, and a meaningful double-digit share of product revenue. Nippon Shinyaku will be responsible for the distribution of CAP-1002 in Japan. Capricor will be responsible for the conduct of clinical development in Japan, as may be required, as well as the manufacturing of CAP-1002. Subject to regulatory approval, Capricor will sell commercial product to Nippon Shinyaku in Japan. In addition, Capricor or its designee will hold the Marketing Authorization in Japan if the product is approved in that territory.

The Company has evaluated the Japan Distribution Agreement in accordance with ASU 606, *Revenue for Contracts from Customers*. The Company determined the initial transaction price totaled $12.0 million, which was the upfront payment fee. The Company has excluded any future milestone or shared revenue payments from this transaction price to date based on probability. At this time, the Company is evaluating the regulatory pathway to achieve potential product approval in this territory. Until such time, the Company cannot identify any distinct performance obligation. As such, the Company has recorded the entire upfront payment fee of $12.0 million as current deferred revenue on the Company's consolidated balance sheets as of December 31, 2023.

9. 8. RELATED PARTY TRANSACTIONS

Lease and Sub-Lease Agreement

As noted above, Capricor is a party to lease agreements with CSMC (see Note 7 6 – "Commitments and Contingencies"), and CSMC has served as an investigative site in Capricor's clinical trials. Additionally, Dr. Eduardo Marbán, who is a stockholder of Capricor Therapeutics and has participated from time to time as an observer at the Company's meetings of the Board of Directors, is the Director of the Cedars-Sinai Smidt Heart Institute, and co-founder of Capricor.

Consulting Agreements

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

In July 2020, Capricor entered into an Advisory Services Agreement with Dr. Eduardo Marbán whereby he was granted an option to purchase 50,000 shares of the Company's common stock. Additionally, in January 2022, Dr. Eduardo Marbán was granted an additional option grant to purchase 50,000 shares of the Company's common stock.

In January 2024, Capricor entered into a Consulting Agreement with Michael Kelliher, a member of its Board of Directors, related to business development services whereby he was granted an option to purchase 30,000 shares of the Company's common stock.

Payables to Related Party

As of December 31, 2022 December 31, 2023 and 2021, 2022, the Company had accounts payable and accrued expenses to related parties totaling $89,234 $27,479 and $599,388, $89,234, respectively. CSMC accounts for $79,234 $17,479 and $589,388 $79,234 of the total accounts payable and accrued expenses to related parties as of December 31, 2022 December 31, 2023 and December 31, 2021 December 31, 2022, respectively. CSMC expenses relate to clinical trial costs, research and development costs, clinical trial costs, license and patent fees, and facilities rent. During the years ended December 31, 2022 December 31, 2023 and 2021, 2022, the Company paid CSMC approximately $794,000 $226,400 and approximately $341,000, $794,000, respectively, for such costs.

9. SUBSEQUENT EVENTS

Additional Sales under ATM Program

Subsequent to December 31, 2023 and through March 7, 2024, the Company sold an aggregate of 251,347 shares of common stock under the ATM Program at an average price of approximate $4.50 per share for gross proceeds of approximately $1.1 million. The Company paid cash commissions on the gross proceeds, plus reimbursement of expenses to the placement agent in the aggregate amount of approximately $35,900.

Stock Option Grants

In January 2024, the Company granted a total of 2,203,726 stock options to its employees, certain non-employee consultants, and directors.

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Related Party Clinical Trials License and Service Agreement

Capricor provided CAP-1002 In February 2024, we entered into a License and Services Agreement with Azzur Cleanrooms-on-Demand – San Diego, LLC (the "Azzur License Agreement") pursuant to which we have been granted an exclusive license to use certain space and the non-exclusive right to use certain equipment and property for investigational purposes in two our early phase clinical trials sponsored by CSMC. This product was developed as part of the Company's past research and development efforts. The first trial and/or pre-clinical manufacturing purposes. Our estimated license fee is known as "Regression of Fibrosis and Reversal of Diastolic Dysfunction in HFpEF Patients Treated with Allogeneic CDCs", or REGRESS. Dr. Eduardo Marbán is the named principal investigator under the study. The second trial is known as "Pulmonary Arterial Hypertension treated with Cardiosphere-derived Allogeneic Stem Cells" or ALPHA. In both studies, Capricor provided the necessary number of doses of cells and received approximately $120,500 per month for a total term of approximately $1.7 million of monetary compensation. For the year ended December 31, 2021, the Company recognized approximately $245,000 as revenue. No revenue was recognized in 2022 as the Company received the requisite funds in connection with these trials in 2021.

10. SUBSEQUENT EVENTS

Stock Option Grants

In January 2023, the Company granted a total of 2,061,979 stock options to its employees, certain non-employee consultants, and directors.

Commercialization and Distribution Agreement with Nippon Shinyaku (Territory: Japan)

On February 10, 2023, Capricor entered into an Exclusive Commercialization and Distribution Agreement (the "Japan Distribution Agreement") with Nippon Shinyaku. Under the terms of the Japan Distribution Agreement, Capricor appointed Nippon Shinyaku as its exclusive distributor in Japan of CAP-1002 for the treatment of DMD.

Under the terms of the Japan Distribution Agreement, Capricor expects to receive an upfront payment of $12.0 million and in addition, Capricor will potentially receive additional development and sales-based milestone payments of up to approximately $89 million, subject to foreign currency exchange rates, and a meaningful double-digit share of product revenue. Nippon Shinyaku will be responsible for the distribution of CAP-1002 in Japan. Capricor will be responsible for the conduct of clinical development in Japan, as may be required, as well as the manufacturing of CAP-1002. Capricor will sell commercial product to Nippon Shinyaku. In addition, Capricor or its designee will hold the Marketing Authorization in Japan if the product is approved in that territory.

6 months.

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ITEM 9. CHANGES IN AND DISAGREEMENTS WITH ACCOUNTANTS ON ACCOUNTING AND FINANCIAL DISCLOSURE

None.

ITEM 9A. CONTROLS AND PROCEDURES

Evaluation of Disclosure Controls and Procedures

We have adopted and maintain disclosure controls and procedures that are designed to ensure that information required to be disclosed in our reports under the Securities Exchange Act of 1934, as amended, is recorded, processed, summarized and reported within the time periods specified in the SEC's rules and forms and that such information is accumulated and communicated to our management, including our Chief Executive Officer and Chief Financial Officer, as appropriate, to allow for timely decisions regarding required disclosures. In designing and evaluating the disclosure controls and procedures, management recognizes that controls and procedures, no matter how well designed and operated, cannot provide absolute assurance of achieving the desired control objectives.

As required by Rule 13a-15(b), under the Securities Exchange Act of 1934, as amended, we carried out an evaluation, under the supervision and with the participation of management, including our Chief Executive Officer and Chief Financial Officer, of the effectiveness of the design and operation of our disclosure controls and procedures as of the end of the period covered by this report. Based on the foregoing, our Chief Executive Officer and Chief Financial Officer concluded that as of December 31, 2022 December 31, 2023, our disclosure controls and procedures were effective at the reasonable assurance level.

Management's Report on Internal Control over Financial Reporting

Our management is responsible for establishing and maintaining adequate internal control over financial reporting as defined in Rule 13a-15(f) and 15d-15(f) of the Securities Exchange Act of 1934, as amended. Our internal control over financial reporting is a process designed to provide reasonable assurance to our management and Board of Directors regarding the reliability of financial reporting and the preparation of financial statements for external purposes in accordance with generally accepted accounting principles and includes policies and procedures that: (1) pertain to the maintenance of records that, in reasonable detail, accurately and fairly reflect the transactions and dispositions of our assets; (2) provide reasonable assurance that transactions are recorded as necessary to permit preparation of financial statements in accordance with generally accepted accounting principles, and that our receipts and expenditures are being made only in accordance with authorizations of our management and directors; and (3) provide reasonable assurance regarding prevention or timely detection of unauthorized acquisition, use or disposition of our assets that could have a material effect on the financial statements.

Because of its inherent limitations, internal control over financial reporting may not prevent or detect misstatements, errors or fraud. Also, projections of any evaluations of effectiveness to future periods are subject to the risk that controls may become inadequate because of changes in conditions, or that the degree of compliance with the policies or procedures may deteriorate.

Management assessed the effectiveness of our internal control over financial reporting as of December 31, 2022 December 31, 2023 based on the framework set forth by the Committee of Sponsoring Organizations of the Treadway Commissions in Internal Control-Integrated

Framework. Based on that assessment, management has concluded that our internal control over financial reporting was effective as of December 31, 2022 December 31, 2023.

This Annual Report on Form 10-K does not include an attestation report of our registered public accounting firm regarding internal control over financial reporting. Management's report was not subject to attestation by our registered public accounting firm pursuant to rules of the SEC that permit smaller reporting companies to provide only management's report in this Annual Report on Form 10-K.

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Changes in Internal Controls over Financial Reporting

There have been no changes in our internal control over financial reporting (as defined in Rules 13a-15(f) and 15d-15(f) under the Securities Exchange Act of 1934, as amended) during the fiscal year ended December 31, 2022 December 31, 2023 that have materially affected, or are reasonably likely to materially affect, our internal control over financial reporting.

ITEM 9B. OTHER INFORMATION

None.

PART III

ITEM 10. DIRECTORS, EXECUTIVE OFFICERS AND CORPORATE GOVERNANCE.

The information required by this item will be set forth in the sections entitled "Information Regarding the Board of Directors and Corporate Governance," "Information Regarding Executive Officers" and "Section "Delinquent Section 16(a) Beneficial Ownership Reporting Compliance" Reports" in our Definitive Proxy Statement for our 2023 2024 Annual Meeting of Stockholders (our "2023 "2024 Proxy Statement"), to be filed with the SEC within 120 days after the end of the fiscal year ended December 31, 2022 December 31, 2023, and is incorporated herein by reference.

ITEM 11. EXECUTIVE COMPENSATION.

The information required by this item will be set forth in the section entitled "2022 "2023 Executive Compensation" and "Compensation of Directors" in our 2023 2024 Proxy Statement and is incorporated herein by reference.

ITEM 12. SECURITY OWNERSHIP OF CERTAIN BENEFICIAL OWNERS AND MANAGEMENT AND RELATED STOCKHOLDER MATTERS.

The information required by this item will be set forth in the sections entitled "Securities Authorized for Issuance Under Equity Compensation Plans" and "Security Ownership of Certain Beneficial Owners and Management" in our 2023 2024 Proxy Statement and is incorporated herein by reference.

ITEM 13. CERTAIN RELATIONSHIPS AND RELATED TRANSACTIONS, AND DIRECTOR INDEPENDENCE.

The information required by this item will be set forth in the sections entitled "Certain Relationships and Related Party Transactions" and "Information Regarding the Board of Directors and Corporate Governance" in our 2023 2024 Proxy Statement and is incorporated herein by reference.

ITEM 14. PRINCIPAL ACCOUNTING FEES AND SERVICES.

The information required by this item will be set forth in the section entitled “Principal Accountant Fees and Services” in our 2023 Proxy Statement and is incorporated herein by reference.

PART IV

ITEM 15. EXHIBITS AND FINANCIAL STATEMENT SCHEDULES

(a)(1) Financial Statements

The financial statements required by this item are included in a separate section of this Annual Report on Form 10-K beginning on page 88.

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(a)(2) Financial Statement Schedules

Financial Statement Schedules have been omitted because they are either not applicable or the required information is included in the consolidated financial statements or notes thereto listed in (a)(1) above.

(a)(3) Exhibits

The following exhibits are filed herewith or incorporated herein by reference:

3.1	Certificate of Incorporation of the Company (incorporated by reference to Exhibit 3.1 to the Company's Current Report on Form 8-K, filed with the SEC on February 9, 2007).
3.2	Certificate of Amendment of Certificate of Incorporation of the Company (incorporated by reference to Exhibit 3.1 to the Company's Current Report on Form 8-K, filed with the SEC on November 26, 2013).
3.3	Certificate of Amendment of Certificate of Incorporation of the Company (incorporated by reference to Exhibit 3.1 to the Company's Current Report on Form 8-K, filed with the SEC on June 4, 2019).
3.4	Bylaws of the Company (incorporated by reference to Exhibit 3.2 to the Company's Current Report on Form 8-K, filed with the SEC on February 9, 2007).
3.5	Certificate of Amendment of the Bylaws of the Company (incorporated by reference to Exhibit 3.1 to the Company's Current Report on Form 8-K, filed with the Commission on August 25, 2020).
4.1	Description of the Company's Common Stock, par value $0.001 per share.*
4.2	Form of Common Warrant (incorporated by reference to Exhibit 4.4 to the Company's Amendment No. 1 to Registration Statement on Form S-1/A, filed with the Commission on December 13, 2019).
4.3	Form of Common Stock Purchase Warrant #2 (incorporated by reference to Exhibit 4.2 to the Company's Quarterly Report on Form 10-Q, filed with the Commission on May 15, 2020).
10.1	Consulting Agreement between Capricor, Inc. and Frank Litvack, dated March 24, 2014 (incorporated by reference to Exhibit 10.9 to the Company's Annual Report on Form 10-K, filed with the Commission on March 31, 2014). †

10.2	Form of Indemnification Agreement (incorporated by reference to Exhibit 10.11 to the Company's Annual Report on Form 10-K, filed with the Commission on March 31, 2014). †
10.3	Capricor, Inc. 2006 Stock Option Plan (incorporated by reference to Exhibit 4.4 to the Company's Registration Statement on Form S-8, filed with the Commission on March 4, 2014). †
10.4	Capricor, Inc. 2012 Restated Equity Incentive Plan (incorporated by reference to Exhibit 4.5 to the Company's Registration Statement on Form S-8, filed with the Commission on March 4, 2014). †
10.5 10.4	Capricor, Inc. 2012 Non-Employee Director Stock Option Plan (incorporated by reference to Exhibit 4.6 to the Company's Registration Statement on Form S-8, filed with the Commission on March 4, 2014). †
10.6	First Amendment to Capricor, Inc. 2006 Stock Option Plan (incorporated by reference to Exhibit 4.11 to the Company's Registration Statement on Form S-8, filed with the Commission on March 4, 2014). †
10.7	First Amendment to Capricor, Inc. 2012 Restated Equity Incentive Plan (incorporated by reference to Exhibit 4.12 to the Company's Registration Statement on Form S-8, filed with the Commission on March 4, 2014). †
10.8 10.5	First Amendment to Capricor, Inc. 2012 Non-Employee Director Stock Option Plan (incorporated by reference to Exhibit 4.13 to the Company's Registration Statement on Form S-8, filed with the Commission on March 4, 2014). †

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10.9	Form of Incentive Stock Option Agreement for the Capricor, Inc. 2006 Stock Option Plan (incorporated by reference to Exhibit 4.7 to the Company's Registration Statement on Form S-8, filed with the Commission on March 4, 2014). †
10.10	Form of Non-Qualified Stock Option Agreement for the Capricor, Inc. 2006 Stock Option Plan (incorporated by reference to Exhibit 4.8 to the Company's Registration Statement on Form S-8, filed with the Commission on March 4, 2014). †
10.11	Form of Stock Option Agreement for the Capricor, Inc. 2012 Restated Equity Incentive Plan (incorporated by reference to Exhibit 4.9 to the Company's Registration Statement on Form S-8, filed with the Commission on March 4, 2014). †
10.12 10.6	Form of Stock Option Agreement for the Capricor, Inc. 2012 Non-Employee Director Stock Option Plan (incorporated by reference to Exhibit 4.10 to the Company's Registration Statement on Form S-8, filed with the Commission on March 4, 2014). †
10.13	Exclusive License Agreement, dated June 21, 2006, between Capricor, Inc. and the Universita Degli Studi Di Roma "La Sapienza" (incorporated by reference to Exhibit 10.31 to the Company's Annual Report on Form 10-K, filed with the Commission on March 31, 2014). +
10.14 10.7	Exclusive License Agreement, dated June 22, 2006, between Capricor, Inc. and the Johns Hopkins University (incorporated by reference to Exhibit 10.32 to the Company's Annual Report on Form 10-K, filed with the Commission on March 31, 2014). +
10.15 10.8	First Amendment to the Exclusive License Agreement, dated May 13, 2009, between Capricor, Inc. and the Johns Hopkins University (incorporated by reference to Exhibit 10.33 to the Company's Annual Report on Form 10-K, filed with the Commission on March 31, 2014). +

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10.16	10.9	Second Amendment to the Exclusive License Agreement, dated December 20, 2013, between Capricor, Inc. and the Johns Hopkins University (incorporated by reference to Exhibit 10.34 to the Company's Annual Report on Form 10-K, filed with the Commission on March 31, 2014). +
10.17	10.10	Amended and Restated Exclusive License Agreement, dated December 30, 2013, between Capricor, Inc. and Cedars-Sinai Medical Center (incorporated by reference to Exhibit 10.36 to the Company's Annual Report on Form 10-K, filed with the Commission on March 31, 2014). +
10.18	10.11	Loan Agreement, dated February 1, 2013, between Capricor, Inc. and the California Institute for Regenerative Medicine (incorporated by reference to Exhibit 10.38 to the Company's Annual Report on Form 10-K, filed with the Commission on March 31, 2014). +
10.19	10.12	Notice of Loan Award, dated February 1, 2013, between Capricor, Inc. and the California Institute for Regenerative Medicine (incorporated by reference to Exhibit 10.39 to the Company's Annual Report on Form 10-K, filed with the Commission on March 31, 2014). +
10.20	10.13	Lease Agreement, dated March 29, 2012, between Capricor, Inc. and The Bubble Real Estate Company, LLC (incorporated by reference to Exhibit 10.2 to the Company's Quarterly Report on Form 10-Q, filed with the Commission on August 14, 2015).
10.21	10.14	First Amendment to the Lease Agreement, dated June 13, 2013, between Capricor, Inc. and The Bubble Real Estate Company, LLC (incorporated by reference to Exhibit 10.3 to the Company's Quarterly Report on Form 10-Q, filed with the Commission on August 14, 2015). +
10.22	10.15	Exclusive License Agreement, dated May 5, 2014 between Capricor, Inc. and Cedars-Sinai Medical Center (incorporated by reference to Exhibit 10.46 to the Company's Amendment No. 1 to Registration Statement on Form S-1, filed with the Commission on May 23, 2014). +
10.23	10.16	Facilities Lease, dated June 1, 2014, between Capricor, Inc. and Cedars-Sinai Medical Center (incorporated by reference to Exhibit 10.1 to the Company's Quarterly Report on Form 10-Q, filed with the Commission on May 15, 2014).

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10.24	10.17	First Amendment to Exclusive License Agreement, dated as of February 27, 2015, by and between Capricor, Inc. and Cedars-Sinai Medical Center (incorporated by reference to Exhibit 10.54 to the Company's Registration Statement on Form S-1, filed with the Commission on March 6, 2015). +
10.25	10.18	Second Amendment to Lease Agreement, dated March 3, 2015, by and between Capricor, Inc. and The Bubble Real Estate Company, LLC (incorporated by reference to Exhibit 10.55 to the Company's Registration Statement on Form S-1, filed with the Commission on March 6, 2015).
10.26	10.19	Second Amendment to Exclusive License Agreement, dated as of June 10, 2015, by and between Capricor, Inc. and Cedars-Sinai Medical Center (incorporated by reference to Exhibit 10.1 to the Company's Quarterly Report on Form 10-Q, filed with the Commission on August 14, 2015). +

10.27 10.20 Joinder Agreement, dated as of September 30, 2015, by and among the Company, Capricor, Inc. and the California Institute For Regenerative Medicine (incorporated by reference to Exhibit 10.1 to the Company's Quarterly Report on Form 10-Q, filed with the Commission on November 13, 2015).

10.28 10.21 Amendment to Notice of Loan Award, dated as of May 12, 2016 by and between Capricor, Inc. and the California Institute for Regenerative Medicine (incorporated by reference to Exhibit 10.1 to the Company's Quarterly Report on Form 10-Q, filed with the Commission on August 15, 2016). +

10.29 10.22 Third Amendment to Lease, dated as of May 25, 2016, by and between Capricor, Inc. and The Bubble Real Estate Company, LLC (incorporated by reference to Exhibit 10.2 to the Company's Quarterly Report on Form 10-Q, filed with the Commission on August 15, 2016).

10.30 10.23 Notice of Award, dated as of June 16, 2016, by and between Capricor, Inc. and the California Institute for Regenerative Medicine (incorporated by reference to Exhibit 10.3 to the Company's Quarterly Report on Form 10-Q, filed with the Commission on August 15, 2016). +

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10.31 10.24 Loan Election Agreement, dated as of June 16, 2016, by and between Capricor, Inc. and the California Institute for Regenerative Medicine (incorporated by reference to Exhibit 10.4 to the Company's Quarterly Report on Form 10-Q, filed with the Commission on August 15, 2016).

10.32 10.25 Second Amendment to Amended and Restated Exclusive License Agreement, dated as of August 5, 2016, by and between Capricor, Inc. and Cedars-Sinai Medical Center (incorporated by reference to Exhibit 10.1 to the Company's Quarterly Report on Form 10-Q, filed with the Commission on November 14, 2016). +

10.33 10.26 Third Amendment to Exclusive License Agreement, dated as of August 5, 2016, by and between Capricor, Inc. and Cedars-Sinai Medical Center (incorporated by reference to Exhibit 10.2 to the Company's Quarterly Report on Form 10-Q, filed with the Commission on November 14, 2016). +

10.34 10.27 Second Amendment to Capricor Therapeutics, Inc. 2012 Restated Equity Plan (incorporated by reference to Exhibit 4.14 to the Company's Registration Statement on Form S-8, filed with the Commission on January 11, 2017). †

10.35 10.28 Third Amendment to Capricor Therapeutics, Inc. 2012 Restated Equity Plan (incorporated by reference to Exhibit 4.15 to the Company's Registration Statement on Form S-8, filed with the Commission on January 11, 2017). †

10.36 10.29 Amendment No. 2 to Notice of Loan Award, dated as of June 7, 2017 (incorporated by reference to Exhibit 10.1 to the Company's Current Report on Form 8-K, filed with the Commission on June 13, 2017).

10.37 10.30 Amendment No. 1 to Notice of Award, dated as of August 8, 2017 (incorporated by reference to Exhibit 10.1 to the Company's Quarterly Report on Form 10-Q, filed with the Commission on November 11, 2017).

10.38 10.31 First Amendment to Facilities Lease, dated as of August 1, 2017, by and between Capricor, Inc. and Cedars-Sinai Medical Center (incorporated by reference to Exhibit 10.2 to the Company's Quarterly Report on Form 10-Q, filed with the Commission on November 11, 2017).

10.39	10.32	Fourth Amendment to Exclusive License Agreement, dated as of December 26, 2017, by and between Capricor, Inc. and Cedars-Sinai Medical Center (incorporated by reference to Exhibit 10.58 to the Company's Annual Report on Form 10-K, filed with the Commission on March 22, 2018). +

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

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10.46	10.39	Common Stock Sales Agreement, dated July 22, 2019, between Capricor Therapeutics, Inc. and H.C. Wainwright & Co., LLC (incorporated by reference to Exhibit 10.1 to the Company's Current Report on Form 8-K, filed with the Commission on July 22, 2019).
10.47	10.40	Capricor Therapeutics, Inc. 2020 Equity Incentive Plan (incorporated by reference to Exhibit 4.9 to the Company's Registration Statement on Form S-8, filed with the Commission on June 17, 2020). †

10.48	10.41	Form of Stock Option Agreement for Capricor Therapeutics, Inc. 2020 Equity Incentive Plan (incorporated by reference to Exhibit 4.10 to the Company's Registration Statement on Form S-8, filed with the Commission on June 17, 2020). †
10.49	10.42	Seventh Amendment to Exclusive License Agreement, dated as of August 20, 2020, by and between Capricor, Inc. and Cedars-Sinai Medical Center (incorporated by reference to Exhibit 10.1 to the Company's Quarterly Report on Form 10-Q, filed with the Commission on November 11, 2020).+
10.50		Exclusive License Agreement, dated as of April 28, 2021, by and between Capricor, Inc. and Johns Hopkins University (incorporated by reference to Exhibit 10.1 to the Company's Quarterly Report on Form 10-Q, filed with the Commission on August 13, 2021).+
10.51	10.43	Capricor Therapeutics, Inc. 2021 Equity Incentive Plan (incorporated by reference to Exhibit 10.2 to the Company's Quarterly Report on Form 10-Q, filed with the Commission on August 13, 2021). †
10.52	10.44	Form of Stock Option Agreement for Capricor Therapeutics, Inc. 2021 Equity Incentive Plan (incorporated by reference to Exhibit 10.3 to the Company's Quarterly Report on Form 10-Q, filed with the Commission on August 13, 2021). †
10.53	10.45	Standard Industrial/Commercial Multi-Tenant Lease, dated as of July 16, 2021, by and between Capricor Therapeutics, Inc. and Altman Investment Company, LLC (incorporated by reference to Exhibit 10.54 to the Company's Annual Report on Form 10-K, filed with the Commission on March 11, 2022). +
10.54	10.46	U.S. Commercialization and Distribution Agreement, dated as of January 25, 2022, by and among Capricor Therapeutics, Inc., Capricor, Inc. and Nippon Shinyaku Co. Ltd. (incorporated by reference to Exhibit 10.55 to the Company's Annual Report on Form 10-K, filed with the Commission on March 11, 2022). +
10.55	10.47	Japan Commercialization and Distribution Agreement, dated as of February 10, 2023, by and among Capricor Therapeutics, Inc., Capricor, Inc. and Nippon Shinyaku Co. Ltd. *+ (incorporated by reference to Exhibit 10.55 to the Company's Annual Report on Form 10-K, filed with the Commission on March 17, 2023). +

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21.1	List of Subsidiaries. *
23.1	Consent of Rose Snyder & Jacobs, LLP. *
24.1	Power of Attorney (included on signature page hereof). *
31.1	Certification of Principal Executive Officer. *
31.2	Certification of Principal Financial Officer. *
32.1	Certification of Principal Executive Officer pursuant to Section 906 of the Sarbanes-Oxley Act of 2002. *
32.2	Certification of Principal Financial Officer pursuant to Section 906 of the Sarbanes-Oxley Act of 2002. *
97	Capricor Therapeutics, Inc. Policy on Recoupment of Incentive Compensation. *

101	The following financial information from Capricor Therapeutics, Inc.'s Annual Report on Form 10-K for the year ended December 31, 2022 December 31, 2023 formatted in Inline eXtensible Business Reporting Language (iXBRL): (i) Consolidated Balance Sheets as of December 31, 2022 December 31, 2023 and 2021, 2022, (ii) Consolidated Statements of Operations and Comprehensive Loss for the years ended December 31, 2022 December 31, 2023 and 2021, 2022, (iii) Consolidated Statement of Stockholders' Equity for the period from December 31, 2020 December 31, 2021 through December 31, 2022 December 31, 2023, (iv) Consolidated Statements of Cash Flows for the years ended December 31, 2022 December 31, 2023 and 2021, 2022, and (v) Notes to Consolidated Financial Statements.
104	Cover Page Interactive Data File (formatted in Inline XBRL and contained in Exhibit 101).

* Filed herewith.

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† Indicates management contract or compensatory plan or arrangement.
+ Portions of the exhibit have been excluded because it is both not material and is the type of information that the registrant treats as private or confidential.

ITEM 16. FORM 10-K SUMMARY

None.

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SIGNATURES

Pursuant to the requirements of Section 13 or 15(d) of the Securities Exchange Act of 1934, the registrant has duly caused this report to be signed on its behalf by the undersigned, thereunto duly authorized, on March 17, 2023 March 8, 2024.

CAPRICOR THERAPEUTICS, INC.

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

KNOW ALL MEN BY THESE PRESENTS, that we, the undersigned officers and directors of Capricor Therapeutics, Inc., hereby severally constitute Linda Marbán, Ph.D. and Anthony J. Bergmann and each of them singly, our true and lawful attorneys with full power to them, and each of them singly, to sign for us and in our names in the capacities indicated below, any and all amendments to said Annual Report on Form 10-K, and generally to do all such things in our names and in our capacities as officers and directors to enable Capricor

Therapeutics, Inc. to comply with the provisions of the Securities Exchange Act of 1934, and all requirements of the U.S. Securities and Exchange Commission, hereby ratifying and confirming our signatures as they may be signed by our said attorneys, or any of them, to any and all amendments hereto.

Pursuant to the requirements of the Securities Exchange Act of 1934, this report has been signed below by the following persons on behalf of the registrant and in the capacities and on the dates indicated.

Signature	Title	Date
/s/ Linda Marbán, Ph.D. Linda Marbán, Ph.D.	Chief Executive Officer and Director *(Principal Executive Officer)*	March 17, 2023 8, 2024
/s/ Anthony J. Bergmann Anthony J. Bergmann	Chief Financial Officer *(Principal Financial and Principal Accounting Officer)*	March 17, 2023 8, 2024
/s/ Frank Litvack, M.D. Frank Litvack, M.D.	Executive Chairman and Director	March 17, 2023 8, 2024
/s/ Earl M. Collier Earl M. Collier	Director	March 17, 2023 8, 2024
/s/ Louis V. Manzo David B. Musket Louis V. Manzo David B. Musket	Director	March 17, 2023 8, 2024
/s/ George W. Dunbar George W. Dunbar	Director	March 17, 2023 8, 2024
/s/ Karimah Es Sabar Karimah Es Sabar	Director	March 17, 2023 8, 2024
/s/ David B. Musket Paul Auwaerter David B. Musket Paul Auwaerter	Director	March 17, 2023 8, 2024
/s/ Michael Kelliher Michael Kelliher	Director	March 8, 2024
/s/ Philip Gotwals Philip Gotwals	Director	March 8, 2024

Exhibit 4.1

DESCRIPTION OF REGISTRANT'S SECURITIES

REGISTERED PURSUANT TO SECTION 12 OF THE

SECURITIES EXCHANGE ACT OF 1934

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

DESCRIPTION OF COMMON STOCK

General

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

Voting Rights

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

Dividend Rights

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

Liquidation Rights

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

No Preemptive or Similar Rights

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

Fully Paid and Nonassessable

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

Preferred Stock

Our board of directors has been authorized to designate and issue up to an aggregate of 5,000,000 shares of preferred stock in one or more series without action by the stockholders. Our board of directors can fix the rights, preferences and privileges of the shares of each series and any of its qualifications, limitations or restrictions. Our board of directors may authorize the issuance of preferred stock with voting or conversion rights that could adversely

affect the voting power or other rights of the holders of common stock. The issuance of preferred stock, while providing flexibility in connection with possible future financings and acquisitions and other corporate purposes could, under certain circumstances, have the effect of delaying or preventing a change in control of our company and might harm the market price of our common stock. As of December 31, 2022December 31, 2023, there were no shares of preferred stock issued and outstanding.

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

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

Section 203 of the DGCL

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

Issuance of Additional Shares

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

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

Special Meetings of Stockholders

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

Advance Notice Provisions for Stockholder Proposals

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

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

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

Filling of Vacancies on the Board of Directors

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

Amendment of Bylaws

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

Transfer Agent and Registrar

The transfer agent and registrar for our common stock is American Stock Transfer & Equiniti Trust Company, LLC. Its address is 6201 15th Avenue, Brooklyn, 48 Wall Street, Floor 23, New York, 11219, New York 10005, and its telephone number is 800-937-5449.

Exhibit 10.55

***Portions of the exhibit have been excluded because it is both not material and is the type of information that the registrant treats as private or confidential.**

COMMERCIALIZATION AND DISTRIBUTION AGREEMENT

This Commercialization and Distribution Agreement ("**Agreement**") is made and entered into as of the 10th day of February, 2023 ("**Effective Date**"), by and between **CAPRICOR THERAPEUTICS, INC**., a corporation organized under the laws of the State of Delaware, with its principal office located at 10865 Road to the Cure, Ste. 150, San Diego, California 92121 USA ("**Capricor**") and **NIPPON SHINYAKU CO., LTD**. a corporation organized under the laws of Japan, with its principal office located at 14, Nishinosho-Monguchi-cho, Kisshoin, Minami-ku, Kyoto 601-8550, Japan ("**Distributor**"). Capricor and Distributor may sometimes individually be referred to herein as a "**Party**" and together as the "**Parties**".

In consideration of the mutual promises contained herein, the Parties agree as follows:

1. **DEFINITIONS**. For purposes of this Agreement, the words, terms and phrases when used in this Section 1 or throughout the Agreement with an initial capital letter, shall have the meanings assigned to them unless the context otherwise requires:

1.1 "**Affiliate**" means any person or entity directly or indirectly controlling or controlled by, or under direct or indirect common control with a Party, during the term of this Agreement and only so long as such control exists. For purposes of this definition, "control" means the power to direct the management and policies of such person or entity directly or indirectly, whether through ownership of voting or other equity securities, by contract or otherwise, and shall include entities which become Affiliates after the Effective Date.

1.2 "**Cell Therapy**" means the administration of living cells to a patient for the treatment of a disease or condition.

1.3 "**Chemistry, Manufacturing and Controls ("CMC")**" means the body of information that defines the manufacturing process and the quality control release testing, specifications and stability of the Product together with the

manufacturing facility and all of its support utilities, including their design, qualification, operation and maintenance for regulatory compliance in the Territory.

1.4 "**Commercially Reasonable Efforts**" means with respect to a Party, those efforts and resources consistent with those typically applied by a biopharmaceutical or biotechnology company of comparable size and resources to such Party and its Affiliates to a product that is at a similar stage of development or commercialization and has similar market potential, taking into account efficacy, safety, patent and regulatory exclusivity, anticipated or approved labelling, present and future market potential, competitive conditions, the profitability of the product in light of pricing and reimbursement issues, and all other relevant factors.

1.5 "**Competing Products**" means any Cell-Therapy product used as a therapeutic for DMD.

1.6 "**Customers**" means hospitals or other healthcare providers equipped with pharmacy services and cold storage capabilities.

1.7 "**DMAH**" has the meaning defined in Section 2.5.

1.8 "**DMD**" means Duchenne muscular dystrophy.

1.9 "**FDA**" means the United States Food and Drug Administration.

1.10 "**First Commercial Sale**" means, with respect to a Product in the Territory, the first bona fide commercial sale to a third party of such Product following Manufacturing and Marketing Approval. Sales or other dispositions by Capricor for clinical trial or other scientific testing purposes, or under early access or compassionate use programs, shall not constitute a First Commercial Sale.

1.11 "**GCTP**" means the Good Gene, Cellular, and Tissue-based Products Manufacturing Practice.

1.12 "**GCP**" means the Good Clinical Practice.

1.13 "**GDP**" means Good Distribution Practices.

1.14 "**GMP**" means Good Manufacturing Practice as set forth in the Quality Agreement.

1.15 "**Governmental Authority**" means any government or any court, administrative agency or commission or other governmental or regulatory authority or agency and shall also include any quasi-governmental authority or agency with jurisdictional or regulatory authority over any activity contemplated by this Agreement.

1.16 "**Manufacturing and Marketing Approval**" means all approvals, licenses, registrations or authorizations of any Governmental Authority necessary for the manufacturing, use, storage, import, transport, marketing and sale of Products in the Territory.

1.17 **"Marketing Authorization Holder"**means, with respect to a Product, the Party that holds Manufacturing and Marketing Approval in the Territory.

1.18 **"MHLW"** means the Ministry of Health, Labor and Welfare who has authority to issue final approval of a new drug application and the marketing authorization for the Product.

1.19 **"NDA"** means New Drug Application as defined by the MHLW as a request for permission to introduce, or deliver for introduction, a biologic product into commerce in Japan.

1.20 **"Net Sales"** is defined on Exhibit A hereto.

1.21 **"NHI"** means the Japanese national health insurance system, or its successor system.

1.22 **"NHI Price"** means the reimbursement price of the maximum daily dose of the Product for purposes of the NHI.

1.23 **"NHI Price Listing"** means the listing of the NHI Price by Central Social Insurance Medical Council (Chuikyo) of the MHLW.

1.24 "**Person**" means an individual, corporation, partnership, limited liability company, unincorporated syndicate, association or organization, trust, trustee, executor, administrator or other legal representative, governmental authority or

agency, or any group of Persons acting in concert.

1.25 **"PMDA"** means the Japanese Pharmaceuticals and Medical Devices Agency, and local counterparts thereto, and any successor agency(ies) or authority thereto having substantially the same function.

1.26 **"Product(s)"** means the commercial Cell Therapy product using human allogeneic cardiosphere-derived cells ("CDCs") developed by Capricor and known as "CAP-1002", used for the treatment of diseases and symptoms in humans for DMD.

1.27 **"Product Specifications"** means specifications for the Product set forth in the Quality Agreement (as hereinafter defined).

1.28 "**Purchase Order(s)**" means a formal offer to buy a specified number of units of Product at a specified price within a specified timeframe.

1.29 "**Regulations**" means all laws, statutes, rules, regulations (including, without limitation, all health and safety legislation) of the Territory in which the Products are sold by Distributor.

1.30 **"Quality Agreement"** means the agreement between Capricor and Distributor, which defines the responsibilities of each Party with respect to the practices to be followed to ensure Product quality and compliance with GMP, including, but not limited to, requirements for packaging, labeling and distributing the Products. The terms of the Quality Agreement shall be incorporated by reference into this Agreement.

1.31 "**Supply Price**" means the price at which Capricor shall sell the Products to Distributor determined in accordance with the provisions set forth on **Exhibit A**.

1.32 "**Territory**" means the country of Japan.

1.33 "**Trademarks**" means the Trademarks of Capricor listed on **Exhibit B**, together with any further trademarks and trade names of which Capricor may become the proprietor or which Capricor may have the right to use on or in relation to the Products at any time during the term of this Agreement, and in each case which Capricor adds to **Exhibit B** in its sole discretion.

1.34 "**Transfer Price**" means the price paid by Distributor to Capricor on the Delivery of the Product to the Distribution Warehouse (as hereinafter defined), as set forth on **Exhibit A**.

1.35 **"Wholesaler"** means a company or individual designated by Distributor to purchase or facilitate the distribution of Product to Distributor's Customers.

2. **PRODUCT DEVELOPMENT BY CAPRICOR**

2.1 **Obligations Regarding Preclinical Development.** Capricor shall, at its responsibility and expense, conduct non-clinical studies required to apply for the Manufacturing and Marketing Approval of the Product for DMD in the Territory and shall complete any tests or studies necessary and/or desired to complete the preclinical development of the Product for DMD which Capricor, in its discretion, believes to be necessary to advance the clinical development of the Product and the ability to obtain regulatory approval thereof in the Territory. The costs and expense associated with preclinical tests or studies shall be the sole responsibility of Capricor.

2.2 **Obligations Regarding Clinical Development of CAP-1002.** After the execution of this Agreement, Capricor shall, at its responsibility and expense, have the obligation to engage with the PMDA to determine a clinical program (the **"Clinical Program"**) for CAP-1002 for the treatment of DMD in the Territory and use Commercially Reasonable Efforts to obtain Manufacturing and Marketing Approval for the Product in the Territory at its sole cost and expense. For such purpose Capricor shall (a) conduct clinical studies and (b) manufacture the Product for clinical purposes. The protocol for the Clinical Program will be determined by Capricor pursuant to guidance given by the PMDA. Capricor will keep Distributor advised as to the progress of the Clinical Program and Distributor may offer advice to Capricor in connection therewith.

Notwithstanding the foregoing, all decisions with respect to the conduct of the Clinical Program will be made by Capricor including whether to submit an NDA based on the results of the Clinical Program. The costs and expense of the Clinical Program shall be the sole responsibility of Capricor. Capricor shall also be responsible for manufacturing, packaging, supplying and distributing any CAP-1002 Product required for the Clinical Program at its expense.

2.3**CMC Studies.** Capricor shall conduct those CMC studies and gather applicable data required by the PMDA and MHLW at Capricor's sole cost and expense.

2.4 **NDA Documents and Pre-approval Inspections.** Capricor shall, at its responsibility and expense, prepare the NDA documents (CTD Module 1 to Module 5) required for application and approval review for the Manufacturing and Marketing Approval of the Product in the Territory, and apply for and deal with the GCP compliance inspection, data integrity assessment and GCTP compliance inspection which are to be conducted by the PMDA in the course of approval reviews for the Manufacturing and Marketing Approval of the Product. Capricor will keep Distributor advised as to any significant communications from the PMDA with respect thereto and Distributor may offer advice to Capricor in connection therewith.

2.5**Manufacturing and Marketing Approval.** Capricor shall, at its expense, be responsible for obtaining, maintaining and managing the Manufacturing and Marketing Approval of the Product in the Territory. In addition, Capricor shall, at its expense, be responsible for maintaining and managing the Manufacturing and Marketing Approval of the Product in the Territory including appointing, at its discretion, a designated marketing approval holder (**"DMAH"**) to maintain and manage the Manufacturing and Marketing Approval of the Product in the Territory. Capricor will keep Distributor advised as to any significant communications from Governmental Authorities with respect to the Manufacturing and Marketing Approval of the Product, and Distributor may offer advice to Capricor in connection therewith.

2.6 **Pharmacovigilance and Post-Marketing Surveillance.** Capricor shall be responsible for conducting any safety surveillance related to pharmacovigilance and post-marketing surveillance, and shall maintain a global safety database, required for the Product in the Territory with such assistance from Distributor as may be reasonably requested by Capricor. Distributor will provide Capricor with ready access to all materials, data and other information on clinical use and related matters on a timely basis to enable compliance with all regulatory and quality requirements. Capricor shall be responsible for the out-of-pocket costs incurred by Distributor in connection therewith but shall not be required to reimburse Distributor for Distributor's time or efforts by its employees or other representatives of Distributor in providing such information to Capricor. The details of each Party's role in relation to the above-mentioned safety surveillance shall be separately set forth in a Post Marketing Surveillance Agreement and a Pharmacovigilance Agreement to be negotiated by the Parties.

2.7 **Life Cycle Management.** If Capricor decides to develop the Product for any additional indications and/or any label extensions in the Territory or Distributor considers that such development is desirable, both Parties shall discuss such development. Should Capricor and Distributor agree on developing any such label extension for DMD indications in the Territory and on how to share the costs for such development, unless otherwise agreed by the Parties, Capricor will be responsible for conducting development and regulatory activities required to obtain approval thereof. If Capricor decides to develop the Product for indications outside of DMD or Distributor considers that such development is desirable, both Parties shall discuss such matter and the details thereof.

2.8**Joint Steering Committee.**

2.8.1 **Establishment of Committee.** Within thirty (30) days after the Effective Date, Capricor and Distributor will assemble a Japanese Joint Steering Committee (the **"J-JSC"**). Initially, the J-JSC will be composed of at least two, but no more than four, representatives of each Party, with an equal number appointed by each of Capricor and Distributor. Each Party will provide a list of its representatives to the other Party within thirty (30) days after the Effective Date. Each Party will promptly notify the other Party in writing of any change in its appointed representatives. Each Party may invite its employees and its Affiliates' employees and consultants to attend meetings of the J-JSC who are bound to obligations of confidentiality, non-use, and assignment of inventions similar to those of that Party's members of the J-JSC.

2.8.2 **Meetings.** The J-JSC will hold its first meeting within ninety (90) days of the Effective Date. While in existence, the J-JSC will meet at least on a quarterly basis by audio or video teleconference or in person, to be agreed by the Parties. After Manufacturing and Marketing Approval is obtained for the Product, the J-JSC will meet at least on a quarterly basis by audio or video teleconference or in person, to be agreed by the Parties. Each Party will bear its own costs relating to any J-JSC meeting. The Parties will endeavour to schedule meetings of the J-JSC at least two (2) months in advance or as

necessary to resolve any matters requiring a joint decision. All meetings of the J-JSC shall be conducted in the English language.

2.8.3 **Responsibilities.** The duties of the J-JSC will include, but not be limited to, reviewing the progress of the Clinical Program, discussing the application for the Manufacturing and Marketing Approval and making determinations as to forecasts, a pricing strategy, Minimum Sales Requirements (as hereinafter defined), monetary disputes and such other matters that may require the joint decision of the Parties, in each case, subject to the applicable provisions set forth in this Agreement. Distributor shall have the right to render advice to Capricor with respect to the Clinical Program and Capricor will give good faith consideration to Distributor's suggestions provided on a timely basis, but all final decisions with respect to the conduct and operations of the Clinical Program shall be made by Capricor and all final decisions with respect to the marketing, promotion and pricing of the Product in the Territory shall be made by Distributor, provided such decisions are made in accordance with this Agreement (including Section 5.8), applicable law and Regulations.

3. **PAYMENTS TO CAPRICOR FOR PRODUCT DEVELOPMENT**

3.1 **Upfront Payment.** In consideration of the costs and expenses incurred and to be incurred by Capricor in connection with all pre-clinical, clinical, CMC and commercial development of the Product, Distributor shall pay to Capricor Twelve Million U.S. Dollars (US$12,000,000) upon the execution of this

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Agreement (the **"Upfront Payment"**), provided that such payment shall be made by Distributor [***] from Distributor's receipt of the invoice thereof from Capricor. The payment made to Capricor specified in this Section 3.1 shall be non-refundable and non-creditable.

3.2 **Product Development Milestones**. In addition to the payment set forth in Section 3.1 above, Distributor shall pay to Capricor [***] of the milestone payment and documents evidencing the achievement of the relevant milestone, the following amounts:

3.2.1 [***];

3.2.2 [***]; and

3.2.3 [***].

4. **APPOINTMENT OF DISTRIBUTOR**

4.1**Appointment**.

4.1.1Subject to the terms and conditions set forth herein, Capricor hereby appoints Distributor, and Distributor hereby accepts such appointment, to serve during the term of this Agreement as Capricor's exclusive distributor (even as to Capricor, subject further to Section 4.1.2) of the Product in the Territory (subject to Section 4.4), including, without limitation, having the right to sell, have sold, promote, market, advertise, commercialize, and import the Product in the Territory. Except as may be permitted under Section 4.2 hereof, Distributor shall only distribute the Products directly to Wholesalers located in and for use exclusively in the Territory. Distributor shall be entitled to describe itself as Capricor's "Authorized Distributor" solely for the Products in the Territory. Distributor is not authorized to, and shall not, do business in Capricor's name or hold itself out as Capricor's sales agent (but rather as an authorized distributor) of the Products or as being entitled to bind or obligate Capricor in any way.

4.1.2For so long as this Agreement is in full force and effect and Distributor is not in breach or default hereunder, which breach or default has not been cured pursuant to Section 15.2.1 of this Agreement, Capricor shall not sell nor appoint any other distributors to sell the Product in the Territory, without the written consent of Distributor; provided, that Capricor shall have the right (directly and/or through its distributors) to:

(a) distribute Products to customers within the Territory other than through Distributor if and to the extent Distributor is unable to so distribute the Products due to (a) regulatory requirements; (b) Distributor's failure to meet its Minimum Sales Requirements, subject to Section 5.2; or (c) Distributor being otherwise prohibited or prevented from selling and/or distributing the Products or refusing or being unable to sell and/or distribute the Products to any Customer or class of Customers other than by Customer's decision; and

(b) subject to Section 2.7, sell and distribute CAP-1002 through relationships that do not include Distributor for indications other than for DMD; provided that Capricor shall clearly indicate to any third parties to whom Capricor intends to sell

Products, that Distributor is Capricor's "Authorized Distributor" for the Products in the Territory for the DMD indication and Capricor shall promptly forward all inquiries regarding purchase of the Product in the Territory received by Capricor for use in the DMD indication to Distributor.

4.1.3 If the Parties agree to expand the grant of rights to Distributor to cover indications other than DMD, the terms of such expansion shall be set forth in an addendum to this Agreement which will set forth the responsibilities of the respective Parties, remuneration to Capricor, sales and other milestones, and other matters to be agreed upon by the Parties.

4.1.4 This Agreement shall in no way limit the right of Capricor, its Affiliates, sublicensees, distributors or other appointees to market, sell or otherwise distribute the Product outside the Territory, excluding the U.S. for so long as the US Agreement (as defined below) is in force and effect.

4.1.5 If during the term of this Agreement, both Parties concur that any patent rights held by third parties would be infringed by the sale of Product in the Territory pursuant to this Agreement, Capricor shall use Commercially Reasonable Efforts to acquire such rights at its sole responsibility and expense.

4.2**Subdistributors**. Distributor shall not, without the prior written consent of Capricor, which consent shall not be unreasonably withheld, appoint any subdistributors or agents (including the replacing of any previously approved subdistributors) to promote, market, sell and distribute the Product within the Territory. For the avoidance of doubt, subdistributors shall not include Wholesalers which purchase the Product from Distributor. In addition, notwithstanding Capricor's consent to any subdistributor, Distributor shall at all times remain fully liable for the acts or omissions of its subdistributors and/or agents as if such act or omission was undertaken directly by Distributor, and Distributor hereby agrees to indemnify and hold harmless Capricor from any and all damages, losses, liabilities or expenses (including reasonable attorneys' fees and costs) arising from the promotion and distribution of the Product in any manner from any act or omission on the part of Distributor's subdistributors or agents. In addition, any subdistributors permitted to be appointed pursuant to the terms and conditions of this Agreement shall comply with all applicable obligations under this Agreement to the same extent as Distributor. Without amending or limiting Distributor's obligations in this Section 4.2 or elsewhere in this Agreement, (including in respect of any nonperformance or omissions by any approved subdistributor), with respect to Article 4, 5, 6, 7, 8, 9, 12 and 15 and **Exhibit A** and **Exhibit D**, Distributor may cause any such subdistributor to perform and exercise Distributor's obligations and rights in whole or part. For the avoidance of doubt, subdistributor shall, in addition to Distributor, be responsible for any breach of Distributor's obligations under this Agreement assumed by subdistributor, and any action or claim by Capricor in respect of any breach, act, error or omission hereunder by Distributor or subdistributor may be brought against either Distributor or subdistributor, and each of Distributor and subdistributor shall be jointly and severally liable hereunder.

4.3**Territorial Responsibility**. Distributor shall use its Commercially Reasonable Efforts to establish sales policies and procedures to realize the maximum sales potential for the Products in the Territory, consistent with applicable Regulations. Without the prior written consent of Capricor, Distributor shall not advertise, promote or seek customers for Products or establish any office through which orders for Products are solicited for use or distribution outside the Territory, nor knowingly sell Products for use outside the Territory. Any requests or inquiries received by potential Customers, whether directly or indirectly, for the purchase of Product for use or distribution outside the Territory shall be referred to Capricor. For purposes of clarity, so long as the U.S. Agreement remains in force and effect, the limitations contained in this Section 4.3 shall not apply to sales of Product in the United States by

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Distributor and Distributor's U.S. subsidiary, NS Pharma, Inc. pursuant to that certain Commercialization and Distribution Agreement between the Parties dated January 24, 2022 (the **"U.S. Agreement"**).

4.4**Competing Products**. Distributor agrees that any efforts by Distributor to sell Competing Products in the Territory would constitute a conflict of interest with respect to Distributor's obligations to Capricor to market and sell the Products. During the term of this Agreement, neither Distributor, its Affiliates, nor any of its subdistributors shall, either directly or indirectly, without Capricor's prior written consent:

4.4.1 market or promote any product or accept orders through agents or otherwise, to or from any Customer or any Affiliate of any Customer for any Competing Product in the Territory; or

4.4.2 develop or manufacture any Competing Product in the Territory.

4.5 **Independent Contractors**. The relationship of Distributor to Capricor established by this Agreement is that of an independent contractor, and nothing contained in this Agreement shall be construed so that Distributor will be deemed to be an employee, agent, joint venturer, co-owner or otherwise a participant in a common undertaking. Each Party shall be solely responsible for its own financial obligations associated with its respective business. Neither Party shall have, nor represent itself as having, any right or authority to obligate or bind the other in any manner whatsoever.

4.6 **Reservation of Rights.** Except as expressly provided in this Article 4, no right, title, license or interest is granted, whether express or implied, by Capricor to Distributor, and nothing in this Agreement shall be deemed to grant to Distributor rights in any products or technology other than the Products (and with respect to the Products solely as set forth herein), nor shall any provision of this Agreement be deemed to restrict Capricor's right to exploit the technology or other intellectual property rights relating to the Products in products other than the Products. Notwithstanding the foregoing, the Parties acknowledge that Capricor has agreed to discuss label extensions and additional indications with Distributor in accordance with Section 2.7. Distributor acknowledges and agrees that Capricor has and retains the right to appoint other authorized distributors, licensees or resellers of the Products outside the Territory without restriction and without any obligations to Distributor, except as set forth in the U.S. Agreement.

4.7 **Wholesalers.** The Parties acknowledge that a Wholesaler performs its activity independently from Distributor and Distributor shall not be responsible for Wholesaler's performance. All sales and other agreements between Distributor and a Wholesaler are Distributor's exclusive responsibility, provided, however, that Distributor shall select a Wholesaler with an experience of handling a cell therapy product.

5. GENERAL OBLIGATIONS OF DISTRIBUTOR

5.1 **Forecasts.** At least ninety (90) days prior to the anticipated approval of the NDA, the J-JSC shall meet to decide upon a twelve (12) month unit forecast indicating Distributor's intended purchases of Products during each month of such period as well as such other information as Capricor may reasonably request in the format reasonably specified by Capricor from time to time. The intended purchase amounts of the Product will be specified by Distributor on a unit basis (not on a lot basis) in such forecast. Such forecasts shall be updated by Distributor on a rolling quarterly basis for each new twelve (12) month period following the preceding quarter, which updated forecast must be received by Capricor

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no later than the last day of the second month of the applicable quarter during the term of this Agreement. Such rolling forecasts shall be used for the purpose of meeting the lead times required by Capricor. The first three months of this initial forecast and the first three months of each subsequent updated 12-month forecast delivered hereunder shall be binding on the Parties upon the Parties' agreement thereon and shall be covered by a firm Purchase Order for a quantity of Products not less than that forecasted for such quarterly period, provided that any forecast shall be non-binding until the PMDA's approval of a package insert of the Product for DMD and after such approval, the Parties shall discuss a 12-month forecast and agree on the first three months of the forecast. Capricor may, in its discretion, reject Purchase Orders calling for quantities exceeding forecasted quantities in such binding first three months of the forecast but shall be under no obligation to do so. If the Parties are unable to agree on the first three months of the forecast herein, such forecast shall be determined by Expert Determination pursuant to the procedure set forth in Section 17.3.2 below. The cost of such Expert Determination shall be borne equally by the Parties.

5.2 **Sales.** Distributor shall use its Commercially Reasonable Efforts to achieve the First Commercial Sale of the Product as promptly as practicable following the NHI Price Listing of the Product and notification by Capricor that the Products are ready for Delivery, and to make sales of the Products to Wholesalers in the Territory. For clarification, Capricor agrees that (a) Distributor has the right to choose to whom it sells the Products in its sole discretion so long as such sale is to a Wholesaler (as defined in Section 1.35), and (b) Distributor may refuse a Wholesaler's order in its sole discretion. Distributor shall not sell any expired Products, and Capricor shall not have any responsibility under this Agreement with respect to any such expired Products, including, without limitation, any obligation to repurchase or replenish expired Products.

5.2.1**Minimum Sales Requirements.** During the term of this Agreement, Distributor shall be required to sell a certain minimum number of Products in the Territory (**"Minimum Sales Requirements"**) during each calendar year of this Agreement commencing with the year to which the day that is [***] and ending upon termination or expiration of this Agreement. Within [***] thereafter during the term of this Agreement, the J-JSC shall meet and attempt to come to an agreement on the Minimum Sales Requirements for each calendar year following NDA approval. If the Parties are unable to agree on such amounts, the Minimum Sales Requirements shall be determined by Expert Determination pursuant to the procedure set forth in Section 17.3.2 below. The cost of such Expert Determination shall be borne equally by the Parties.

5.2.2 **Shortfall in Minimum Sales**. Distributor shall notify Capricor within thirty (30) days following the end of each calendar year whether it has achieved the Minimum Sales Requirements for that year and shall include a reasonably detailed calculation of any shortfall in sales of Products. [***].

5.2.3 **Failure to Meet Minimum Sales Requirements**.

(a) **Initial 24-Month Period**. [***].

(b) **Subsequent 12-Month Periods**. Following the end of initial 24-month period, the Minimum Sales Requirements shall be determined no later than the last day of September in the preceding year of each calendar year for which such Minimum Sales Requirements shall be applicable. If Distributor fails to meet its Minimum Sales Requirements for any such calendar year, [***].

(c) **Continuous Failure to Meet Minimum Sales Requirements**. If Distributor fails to meet its Minimum Sales Requirements for [***] during the term of this Agreement, [***].

5.2.4 **Payment of Sales Milestones**. Upon reaching the Sales Milestones set forth in **Exhibit C**, Distributor shall pay to Capricor those amounts set forth on said **Exhibit C**, attached hereto. Distributor shall notify Capricor within [***] of achieving each applicable Sales Milestone and Distributor shall pay Capricor the respective accrued and payable Sales Milestones [***] from Capricor with respect thereto. For purposes of calculating the Sales Milestones, the Net Sales shall be calculated based on the quarterly gross sales of the Product by Distributor, subdistributors, Wholsagents or other Persons during the term of this Agreement. If Distributor achieves more than one Sales Milestone in a given calendar year, each Sales Milestone amount [***].

5.3 **Customer Training**. Distributor shall train its Customers with respect to the use, handling, storage and administration of the Products sold in the Territory pursuant to the instructions for use accompanying the Products.

5.4 **Market Access, Pricing, Marketing and Promotion of the Products**. Distributor shall at its own expense, be responsible for market access, patient advocacy, and patient support in the Territory, and shall at its own expense, vigorously promote the sale of the Product in a manner that preserves the existing goodwill and promotes the good image of the Product and of Capricor in the Territory following the Manufacturing and Marketing Approval for the Product. Such promotion shall include, without limitation, distributing promotional and marketing materials in the Territory, detailing the Product on the Product website, and advertising the Product as permitted by the applicable Regulations within the Territory to the extent determined by Distributor. Upon Capricor's request, Distributor shall provide assistance and support to Capricor or the DMAH in its dealings with the MHLW to obtain the NHI Price for the Product in the Territory.

5.4.1 **Promotional Materials.** Distributor shall discuss with Capricor the contents of any promotional or marketing literature or materials to be presented to a third party for promotion or marketing of the Product (**"Promotional Materials"**) created by Distributor for the Products prior to their use or distribution in the Territory. Such Promotional Materials must be consistent with Capricor's approved indications for use and guidelines for the Products and all Regulations and related requirements and must be approved by Capricor. Capricor shall not unreasonably withhold or delay such approval. If Capricor fails to make comments on the Promotional Materials within fourteen (14) days after the submission by Distributor, it shall be deemed that Capricor has approved such Promotional Materials. Capricor shall allocate an adequate sales and marketing staff to discuss with Distributor regarding the contents of such Promotional Materials. Distributor may use any marketing materials which may be provided by Capricor. Capricor will own all right, title, and interest in all Promotional Materials, provided that Capricor shall not own any right, title, and interest related to Distributor's pharmaceutical products other than those related only to the Products. Distributor hereby irrevocably transfers, conveys and assigns to Capricor in perpetuity all right, title, and interest in such Promotional Materials, including all copyrights, the right to make derivative works and collective works with respect thereto. For clarification, Distributor shall have a non-exclusive right to use such

Promotional Materials and with respect thereto solely in the performance of its obligations hereunder during the term of this Agreement.

5.5**Distributor's Obligations**. Distributor shall have the following specific obligations with respect to the handling and distribution of the Products:

5.5.1 to comply with all quality requirements as set forth in a quality agreement to be prepared and executed by the Parties ("**Quality Agreement**");

5.5.2 to respond in a timely fashion, to inquiries from Customers, including complaints and reports of adverse events and other Product incidences necessary for Capricor to perform its obligations of the Marketing Authorization Holder imposed by the PMDA in accordance with the Quality Agreement and Pharmacovigilance Agreement in which the details of handling of pharmacovigilance related information and quality related information will be set forth;

5.5.3 to investigate diligently all leads with respect to potential Customers in the Territory referred to it by any source, including Capricor, and to provide adequate contact with existing and potential Customers within the Territory on a regular basis, consistent with good business practices;

5.5.4 to permit, upon reasonable notice, (a) Capricor personnel and/or (b) individuals designated by Capricor and bound to a duty of confidentiality by written agreement with Capricor, to visit Distributor's place of business and Distribution Warehouse (as hereinafter defined) and inspect its inventories, records, and other relevant documents pertaining to the Products and/or Distributor's performance of its obligations under this Agreement, which inspections shall be limited to records relating to GMP, GDP, inventory management and product traceability for the sole purpose of ensuring compliance by Distributor with the terms and conditions of this Agreement; and

5.5.5to maintain an adequate staff of trained and qualified sales and medical affairs personnel dedicated to the Product and, upon the request of Capricor, to make such personnel available for orientation and training with respect to the selling, use and handling of the Products.

5.5.6 Distributor shall establish a distribution warehouse (the **"Distribution Warehouse"**) whereat it will receive all Products purchased from Capricor. The Distribution Warehouse will have the storage capabilities designed to hold the Products in accordance with the specifications set therefor in accordance with the Quality Agreement. Once Product is delivered to the Distribution Warehouse, Distributor shall bear the risk of loss thereof. Except as otherwise agreed, Distributor will adhere to existing receiving, storage, and shipping practices including such practices applicable to time/temperature-sensitive requirements set forth in the Quality Agreement and Distributor will be responsible for the management of the Distribution Warehouse at its own cost and expense.

5.6 **Shipments to Wholesalers.** Distributor shall, at its discretion, by itself, or shall cause its subdistributor to (a) establish a supply-chain necessary to be able to distribute the Products from the Distribution Warehouse to Wholesaler; and (b) upon receipt of an order from a Wholesaler, deliver the Product to the Wholesaler at appropriate times. The cost of shipping and transportation of the Product from the Distribution Warehouse to each Wholesaler shall be borne solely by Distributor and Distributor shall be responsible for freight claims and resolving any disputes with Wholesalers regarding product deliveries, shortages and overages. Distributor shall also be liable for any accident or unexpected incident occurring within the scope of Distributor's obligations herein (e.g. temperature deviations, damage to containers, accidents etc.). Distributor shall ensure that distribution of the Products in the Territory, including shipment, is performed in accordance with GMP, GDP and the Quality Agreement.

5.7**Post-Sales Service**.

5.7.1 **Credit and Collection**. Distributor shall be responsible for all collection and credit approval processes for all invoices. Distributor shall have the sole authority to issue credits and resolve Wholesaler issues. Distributor shall communicate with Capricor regarding same if there are recurring problems that may affect Capricor's responsibilities.

5.7.2 **Product Complaints**. Customer complaints will be logged by Distributor in accordance with the Quality Agreement and forwarded to Capricor's Vice President of Regulatory Affairs (or such person's designee) at a

frequency to be agreed upon by the Parties or otherwise required by the Regulations. Such complaints may be escalated for resolution per applicable regulatory procedures.

5.8 **Pricing/Billing**. Within [***] after the filing of the NDA, the J-JSC shall meet to discuss (i) a pricing strategy of the Product and (ii) the suggested wholesale price at which Distributor will be selling the Product to its Wholesalers (**"Wholesale Price"**) based on a projected drug price of the Product in the NHI Price list, provided that Distributor is not bound by such discussion at the J-JSC and shall be ultimately free to determine the Wholesale Price so as not to violate Japanese anti-trust laws. Capricor shall be responsible for applying for the NHI pricing of the Product in the Territory through close consultation with Distributor. Capricor shall advise and shall keep Distributor informed on the status of the discussion with the MHLW on application for the NHI Price Listing for the Product in the Territory, including any material discussions with any Governmental Authority with respect thereto and the price proposed by the MHLW. If requested by Distributor, Capricor shall allow Distributor to attend any discussion with the MHLW or any other Governmental Authority to the extent that the MHLW and any other Governmental Authority do not have any objection to Distributor's attendance. Capricor and Distributor shall use Commercially Reasonable Efforts to pursue a drug price of the Product in the NHI Price list that maximizes the revenue for the Product in the Territory. As soon as reasonably practicable but within ten (10) business days after MHLW notifies Capricor of a projected drug price of the Product in the NHI Price list, whether officially or unofficially, the J-JSC shall meet and discuss (i) whether Capricor should accept such projected drug price and (ii) whether to list the Product in the NHI Price List. The Parties shall invite an expert consultant to participate in the J-JSC meeting to assist the Parties in making their determination. Such consultant shall have the qualifications and be subject to the requirements and appointment process of a Presiding Expert described in Section 17.3.2 (b), and shall provide advice to the Parties taking into due consideration the commercial viability of the business on the Product for both Parties. Such advice shall include, if advisable, a proposal for adequate revisions of **Exhibit A** with respect to the Supply Price. If the Parties fail to come to an agreement on either of (i) pricing strategy of the Product, (ii) whether to list the product in the NHI Price List or (iii) whether to accept the notified projected drug price within thirty (30) business days after the holding of the J-JSC meeting mentioned above, then the Parties shall refer the matter for Expert Determination pursuant to Section 17.3.2. Notwithstanding the provisions of Section 17.3.2 (g), the Presiding Expert's decision shall be at first non-binding. Such non-binding decision shall take into due consideration the commercial viability of the business on the Product for both Parties, and shall include, if advisable, a proposal for adequate revisions of **Exhibit A** with respect to the Supply Price. After receipt of the non-binding decision from such Presiding Expert, the Parties will discuss in good faith the implications thereof with respect to subsections (i), (ii) and (iii) above for up to thirty (30) days. Should the Parties not be able to agree on the commercial viability of the decision of the Presiding Expert for both Parties and on the path forward with regards to the NHI Price Listing, then the Parties agree that the non-binding decision of the Presiding Expert will become binding. Neither Party shall implement any of (i), (ii)

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or (iii) above until the Parties agree upon the same or the decision of the Presiding Expert becomes binding.

5.9 **Regulations; Compliance.**

5.9.1 Distributor shall comply fully with all Regulations as they relate to the Products in the Territory, including the storage, promotion and sale of the Products. Distributor shall monitor the appropriate information sources closely for changes in such Regulations and other requirements in the Territory and will notify Capricor promptly in writing of any and all such changes.

5.9.2 Without limiting the foregoing provisions of this Section 5.9, subject to the obligation of the DMAH appointed by Capricor in the Territory to comply with all Regulations which apply to such DMAH, Distributor shall comply with all necessary government and regulatory requirements regarding the marketing, and distribution of Products in the Territory. These include, but are not limited to, specific requirements for traceability, vigilance, complaint reporting and handling. Distributor shall not sell or distribute Products in the Territory until such time as all regulatory/marketing licenses and approvals required by the specific Regulations of the Territory have been obtained. Distributor shall allow Capricor or a Capricor-authorized party to assess, periodically, Distributor's compliance with the aforementioned standards.

5.10 **Representations**. Neither Distributor nor any of its agents, employees, representatives, or subdistributors shall (i) market or promote the Product for uses other than the indications and protocols approved by the MHLW (i.e., no "off-label" promotion), (ii) make any false or misleading representations to Customers or others regarding Distributor, Capricor or the Products, or (iii) make any representations, warranties or guarantees with respect to the specifications,

features or capabilities of the Product that are not consistent with Capricor's documentation accompanying the Product or Capricor's literature describing the Product. Neither Distributor, nor any of its agents, employees, representatives, or subdistributors may change, extend, or alter any representation or obligation which is binding upon Capricor or its Affiliates.

5.11**Governmental Requirements; Regulatory Affairs**. Except as otherwise provided herein, Distributor shall be responsible for compliance with all requirements established by Governmental Authorities within the Territory applicable to its activities under this Agreement. Distributor shall provide Capricor with all reasonably required support to enable it to comply with any local regulatory law and requirements including, but not limited to, assisting and executing all documents necessary to satisfy all regulatory requirements in the Territory where the Products are distributed under this Agreement, whenever it is mandatory or necessary to register the Product.

5.12**Expenses**. Except as otherwise expressly provided herein, Distributor assumes full responsibility for all costs and expenses which it incurs in carrying out its obligations under this Agreement, including but not limited to all rentals, salaries, commissions, advertising, demonstration, travel and accommodation expenses, without the right to reimbursement for any portion thereof from Capricor.

5.13**Insurance**. Distributor shall obtain and keep in full force and effect during the term of this Agreement and for a minimum [***] thereafter, one or more policies of liability insurance which shall cover all liabilities of Distributor, whenever arising, attributable to the activities of Distributor, its agents,

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employees, representatives and subdistributors under this Agreement. [***]. Such policies shall not be cancellable without thirty (30) days prior written notice to Capricor. Capricor shall have the option to be designated as an additional named insured under each such policy and shall be provided with a certificate of insurance within thirty (30) days after the issuance of such policy and each renewal thereof. All policies of insurance maintained by Distributor under this Section 5.13 shall be taken out with insurance companies holding a Financial Strength Rating of at least "A-VII", as set forth in the most current issue of Best's Insurance Reports.

5.14 **Translation.** If requested by Capricor in writing, Distributor shall initiate the translation of all user and technical manuals, advertising and marketing information provided by Capricor into the languages of its Customers in the Territory and provide Capricor with advance copies of all such materials for written approval by Capricor (which approval shall not be unreasonably withheld). Any translations in the possession of Capricor as of the Effective Date shall be offered to Distributor free of charge. Capricor shall own all such translations and all related intellectual property rights in and to such translations, and Distributor hereby assigns to Capricor all right, title and interest it may have therein and thereto; provided, however that Distributor shall have a non-exclusive right to use such translations solely in the performance of its obligations hereunder during the term of this Agreement.

5.15 **Tracking of Products**. Distributor shall keep adequate records to enable the tracking of the Products sold as more particularly set forth in the Quality Agreement (collectively, "**Traceability Information**"). During the term of this Agreement and for a period of at least that time required by applicable Regulations (but in no case for less than ten (10) years following termination or expiration of this Agreement), subject to the compliance of the DMAH with the Regulations applicable to the DMAH, Distributor shall comply with all applicable information security and privacy legal requirements with respect to the collection, storage and processing of Traceability Information, including privacy notice requirements and data subject rights under applicable Regulations, and Distributor shall be solely responsible for the protection and security of Traceability Information while under its or any third party agent's control, including with respect to any data security incidents that may affect such data. Distributor shall keep complete and accurate historical records of the information described in this Section 5.15. Capricor shall have the right, at any time upon no less than seven (7) days' notice, to verify that such records are being properly maintained by Distributor and to receive copies of such records upon Capricor's request. The requirements of this Section 5.15 shall survive the termination or expiration of this Agreement for the duration of Distributor's collection and storage obligations. In the event at the expiration of the tenth year following the termination or expiration of this Agreement (or such longer period if required by applicable Regulation), Distributor does not want to retain such records, Distributor may notify Capricor of its intention to destroy such records, and upon Capricor's election, shall deliver such records to Capricor for its retention thereafter.

5.16 **Sales Reports**. No later than thirty (30) days after the end of each month during the term of this Agreement, Distributor shall provide Capricor with a comprehensive monthly sales report (the "**Monthly Sales Report**") summarizing the sales of the Product during the preceding month. Such Monthly Sales Report shall include, at a minimum, the following: (a)

the total number of units sold to Wholesalers (whether by Distributor, its Affiliates (and its or their subdistributors)); (b) gross revenue in U.S. Dollars, (c) the selling price in U.S. Dollars; (d) any deductions from gross revenue or average selling price taken with respect to such Product to arrive at Net Sales (with reasonable supporting detail provided to enable Capricor to affirm and verify such deductions) of Product during such period; and (e) the approximate

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figure of the aggregate Supply Price that has accrued and is payable with respect to Product sales during such period.

5.17 **Record Retention**. During the term of this Agreement and for a period of at least ten (10) years following the termination or expiration hereof, Distributor shall keep complete and accurate historical records of the sales information described in this Section 5.17. Within thirty (30) days after completion of Distributor's annual audit, Distributor shall have its independent auditors confirm in writing to Capricor that the sales reports delivered to Capricor by Distributor are consistent with the findings of the annual audit. Nothing contained in this Section shall reduce the obligations of Distributor set forth in Section 5.16 above.

5.18**Permits**. Capricor shall be responsible, at its expense, for obtaining the Manufacturing and Marketing Approval for the Product from the MHLW and any other applicable regulatory authority. As the Marketing Authorization Holder, Capricor shall be responsible, at its expense, for obtaining and maintaining all licenses and permits necessary for the distribution and sale of the Products in the Territory, including delivery of the Products from the Distribution Warehouse to Wholesalers in the Territory.

6. **GENERAL OBLIGATIONS OF CAPRICOR**

6.1**Supply of Product.** Capricor shall supply Distributor with finished Product in quantities necessary to fill Distributor's Purchase Orders as set forth in Sections 7.3 and 7.4 for sale in the Territory in accordance with the Supply Price. Capricor shall, at its responsibility and expense, package and label the Products in accordance with the Quality Agreement and applicable Regulations in the Territory for the application for the Manufacturing and Marketing Approval and sale of the Product in the Territory. Subject to the foregoing, Capricor, at its discretion, may use a qualified contractor to perform any or all packaging and labeling of the Products.

6.2 **Information.** Capricor shall provide Distributor with (a) technical information concerning the Products, (b) limited quantities of Capricor's instructional materials, sales literature, if any, and (c) available clinical, preclinical, CMC, data and other Product data that Capricor has or obtains during the term of this Agreement, with all such information, materials and data printed in the English language unless the PMDA requires that any of such materials be provided in the Japanese language. If so required, the cost of the translations shall be borne by Capricor. The costs of any translations not required by the PMDA shall be the responsibility of Distributor.

6.3**Training by Capricor.** Capricor shall provide training to Distributor at Capricor's sole cost and expense (other than the cost and expense of Distributor's trainers' travel costs which shall be borne by Distributor, if any), on the use, storage, handling and shipping requirements for the Products. As part of such training, Capricor shall, at a time that is mutually agreed to by both Parties, conduct an initial Product training session for qualified personnel designated by Distributor. Additionally, Capricor shall conduct a "train the trainer" session with the relevant individuals of Distributor who will be responsible for Customer training. The timing and location of trainings shall be mutually agreed to by the Parties. Capricor shall provide on-going Product training for Distributor personnel as reasonably requested by Distributor.

6.4 **Package Insert, Medication Guide for Patients, Interview Form.** Capricor shall, at its responsibility and expense, prepare and revise a package insert (in electronic form), medication guides

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for patients and interview form for the Products. The package insert (in electronic form), medication guides for patients and interview form for the Products shall be reviewed and approved by Distributor before they are issued or revised, which approval shall not be unreasonably withheld. Capricor and Distributor shall cooperate as needed in the preparation of such package insert (in electronic form), medication guides for patients and interview form for the Products. For clarification, Capricor shall bear the out of pocket costs and expenses incurred by Distributor's cooperation.

6.5 **Product Labelling.** Capricor shall provide labelling for the Products which is compliant with the Regulations. If Distributor requests that Capricor label a serial barcode and/or packaging of the Product in Japanese, Capricor shall cooperate with respect to such requests and discuss in good faith with Distributor how to meet such requests. Any costs for labelling a serial barcode and packaging in Japanese (including but not limited to the procurement of materials) shall be borne by Capricor. Distributor will prepare a serial barcode and information such as a drawing for packaging in Japanese at its expense.

6.6**Regulatory Approval**.

6.6.1 **NDA Approval.** As soon as reasonably practicable, Capricor shall use Commercially Reasonable Efforts to obtain the Manufacturing and Marketing Approval for the Product in the Territory at its own expense including appointing, at its discretion, a DMAH. Capricor shall provide Distributor with notice and a copy of the NDA related to the Product promptly after receipt thereof.

6.6.2**Orphan Drug Designation.** As soon as reasonably practicable, Capricor shall apply for the orphan drug designation in the Territory for the Product for DMD at its own expense.

6.6.3**Other Approvals.** If any additional approvals are necessary to market the Products in the Territory according to the Regulations, Capricor shall use Commercially Reasonable Efforts to obtain those approvals as soon as reasonably practicable at its own expense.

6.6.4**Product Registrations and Certifications.** Capricor shall obtain all necessary registrations and certifications for the Products, and Distributor shall assist Capricor in obtaining such registrations and certifications, provided that Distributor shall not attempt to obtain any such registration or certification in its own name. The Parties understand and agree that Capricor itself, or through the DMAH (but not including Distributor), shall have the sole right to correspond with and submit regulatory applications and other filings to the applicable Governmental Authorities to obtain approvals to import, export, sell or otherwise commercialize the Products. Accordingly, Distributor shall not correspond directly with any Governmental Authority relating to the process of obtaining approvals for Products, without Capricor's prior written consent, unless mandated by applicable Regulations, and in such case, Distributor shall in advance of such communications, provide Capricor in writing notice of any such correspondence and shall provide Capricor with a copy thereof.

6.7**Representations by Capricor**. Neither Capricor nor any of its agents, employees or representatives shall make any false or misleading representations to Customers or others regarding Distributor or the Products.

6.8**Insurance**. Capricor shall obtain and keep in force during the term of this Agreement and for a minimum of [***] thereafter, one or more policies of liability insurance which shall cover all liabilities of Capricor, whenever arising, attributable to the activities of Capricor, its agents, employees and contractors under this Agreement. The limits of the coverage shall be at least [***]. Such policy shall cover

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patient damages for bodily injury that are a direct result of the use of the Products in accordance with the instructions for use. Distributor shall have the option to be designated as an additional named insured under each such policy and shall be provided with a certificate of insurance within thirty (30) days after the issuance of such policy and each renewal thereof. All policies of insurance maintained by Capricor under this Section 6.7 shall be taken out with insurance companies holding a Financial Strength Rating of at least "A-VII", as set forth in the most current issue of Best's Insurance Reports.

6.9 **Customer Leads**. During the term of this Agreement, Capricor shall refer to Distributor any request it receives either directly or via its Affiliates for the purchase of Products in the Territory.

6.10**Marketing Authorization Holder.** Capricor shall be responsible for obtaining and maintaining its status as the Marketing Authorization Holder of the Products for the DMD indication in the Territory including appointing, at its discretion, a DMAH.

6.11 **Decision of Release.** Capricor shall, at its responsibility and expense, (i) release the Product at its manufacturing site and (ii) release the Product for market, and then shall supply the Product to Distributor.

6.12 **Transportation.** Capricor shall transport into the Territory (including through customs clearance) the Product, which have been manufactured and packaged at Capricor's or its contractor's manufacturing facility and of which Capricor has confirmed quality assurance. Following the decision of release as provided in Section 6.11, Capricor shall, at its responsibility and expense, transport the Product to the Distribution Warehouse where Distributor shall transfer it to an ultra-

low-temperature unit (such as a deep freezer etc.). Capricor shall properly handle the Product in accordance with any applicable regulations in the Territory including GDP in transportation to the Distribution Warehouse including, but not limited to, monitoring the temperature etc. Capricor shall bear any costs for transportation from the manufacturing facility to the Distribution Warehouse. Capricor shall be liable for any accident or unexpected incident occurring within the scope of Capricor's obligations herein (temperature deviation, damage to containers, accidents during handling liquid nitrogen etc.) until delivery to the Distribution Warehouse. The title of the Product shall be transferred from Capricor to Distributor at the time when the Product has been delivered from Capricor to Distributor at the Distribution Warehouse. Any costs incurred until the title of the Product is transferred to Distributor, including costs for transportation from the manufacturing facility of Product to the Distribution Warehouse shall be borne by Capricor.

6.13 **Patent Management.** Capricor shall be responsible for maintaining and managing its patents that cover the sale of the Product in the Territory at Capricor's expense and responsibility. For the avoidance of doubt, even if Capricor pays royalties or license fees to any third party in connection with the sale of Products in the Territory, Distributor shall have no responsibility for the payment of any such royalties or license fees. Distributor shall promptly notify Capricor if it learns of any use by any third party of the use of Capricor's patents which may constitute an infringement thereof. Capricor shall have the right in its sole discretion to institute any proceedings against such third party infringers. Distributor agrees to cooperate fully with Capricor in any action taken by Capricor against such third parties, provided that all expenses of such action shall be borne by Capricor and all damages which may be awarded or agreed upon in settlement of such action shall accrue to Capricor.

7. **PURCHASE ORDERS; TITLE and DELIVERY**

7.1**Terms and Conditions**. All purchases of Products by Distributor from Capricor during the term of this Agreement shall be subject to the terms and conditions of this Agreement, and nothing contained in any of Distributor's Purchase Orders shall in any way modify such terms and conditions of purchase or add any additional terms or conditions.

7.2 **Delivery**. All Products delivered pursuant to the terms and conditions of this Agreement shall be suitably packed for shipment in Capricor's designated shipping containers, marked for shipment to the Distribution Warehouse at the address specified by Distributor. All freight, insurance, all applicable taxes, import duties, customs fees, similar charges and other shipping expenses for shipments to the Distribution Warehouse, as well as any special packing expense, shall be paid by Capricor pursuant to the DDP (Delivered Duty Paid) the Distribution Warehouse, INCOTERMS 2020 (Distributor's receipt of the Product at the Distribution Warehouse shall be hereinafter referred to as "Delivery" with a correlative meaning for "Deliver" and "Delivered"). Distributor shall bear all applicable taxes, duties, customs fees and similar charges that may be assessed against the Products following Delivery.

7.3 **Purchase Orders**. Pursuant to this Agreement, Distributor will submit written purchase orders (**"Purchase Orders"**) for the Products consistent with the binding first three months of the forecasts set forth in Article 5. For clarity, the amount of the Product will be specified in Purchase Orders and purchased by Distributor on a unit basis (not on a lot basis). Except with respect to the quantity of Products ordered in accordance with the terms and conditions of this Agreement, no additional terms and conditions contained in a Purchase Order shall be binding on Capricor. Such Purchase Orders shall be subject to Capricor's standard terms and conditions which may be established during the term of this Agreement and shall be agreed by Distributor when such standard terms and conditions are established or revised. If any issue that Capricor or Distributor considers needs to be addressed arises, such issue shall be discussed in good faith between the Parties prior to Distributor's submission of Purchase Orders and the agreement between the Parties on such issue shall be documented and signed in accordance with Section 19.3.

7.4**Acceptance of Purchase Orders**.

7.4.1 No Purchase Order shall be binding upon Capricor until accepted by Capricor in writing, and Capricor shall have no liability to Distributor with respect to Purchase Orders that are not accepted if such Purchase Order is inconsistent with the binding first three months of the forecast set forth in Article 5. Within ten (10) days after receipt of a Purchase Order, Capricor shall notify Distributor of the acceptance or rejection of a Purchase Order and of the assigned date of Delivery (the "**Delivery Date**") for accepted Purchase Orders. Partial acceptances by Capricor shall be permitted. Any portion of a Purchase Order that has not been rejected within such ten (10) day period shall be deemed to have been accepted by Capricor, and Capricor shall notify Distributor of the Delivery Date for the accepted Purchase Order immediately after such ten (10) day period. The Minimum Sales Requirements shall be reduced by an amount equal to any portion of a Purchase

Order that has been rejected by Capricor without Due Cause (as hereinafter defined) for the year in which delivery for the rejected quantities was requested by Distributor. Notwithstanding the foregoing, no such reduction shall occur if the Purchase Order, or portion thereof, was rejected for Due Cause. For purposes hereof, the term "**Due Cause**" shall mean (a) the orders exceed the forecast; (b) the orders were placed during such period of time when Distributor is in arrears with respect to payments to be made pursuant to this Agreement; and (c) Distributor is in material default

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of its obligations under this Agreement, which default has not been cured within the applicable cure periods set forth in Section 15.2.1 hereof.

7.4.2 No partial shipment of a Purchase Order shall constitute the acceptance of the entire Purchase Order. Capricor shall use Commercially Reasonable Efforts to deliver the Products at the times specified in its written acceptance of Distributor's Purchase Orders; provided, however, that the failure to Deliver Products by the agreed upon Delivery Date (or Delivery in advance of such Delivery Date) shall not give Distributor any right of rescission with respect to this Agreement or any right to refuse Delivery. However, Distributor shall have the right to rescind the Purchase Order if Capricor has not completed a Delivery of the Products ordered within thirty (30) days after the accepted Delivery Date. In the event Capricor fails to Deliver the quantities which have been ordered by Distributor and accepted by Capricor within thirty (30) days after the scheduled Delivery Date therefor, the Minimum Sales Requirements for the month in which delivery was scheduled shall be reduced by the quantities accepted but not Delivered by the end of such thirty (30) day period.

8. **PRICING AND TERMS OF PAYMENT**

8.1 **Transfer Prices and Supply Prices**.

8.1.1Capricor shall supply the Products to Distributor at the Supply Price in U.S. Dollars determined in accordance with **Exhibit A**. Upon Delivery of the Products to Distributor, Distributor shall be obligated to pay to Capricor the Transfer Price for such Products as set forth on **Exhibit A**. Shipping charges and insurance associated with the shipment of the Products to the Distribution Warehouse shall be borne by Capricor.

8.1.2**Payment of Transfer Prices**. Payments of Transfer Prices to be made hereunder shall be due and sent to Capricor by wire [***] for all Products Delivered to Distributor in accordance with Section 7.2 during that month. Until payment for the Products is received by Capricor, there shall be no quantities applied to satisfy the Minimum Sales Requirements.

8.1.3 **Payment of Supply Prices**. Distributor shall report to Capricor the approximate figure of the aggregate Supply Price that has accrued and is payable to Capricor during each monthly period (which amount shall correspond to the Monthly Sales Reports for such period) and revise such approximate figure to the definitive figure quarterly. Payments of Supply Prices accruing under this Agreement shall be due and sent to Capricor by wire transfer [***] upon receipt of an invoice from Capricor with respect thereto.

8.1.4 **Revisions of Conditions.** Following NHI Price Listing of the Product, should MHLW subsequently decide to significantly reduce such NHI Price or the cost of the Product increases significantly such that the then current arrangement becomes economically unfeasible for one or both Parties, then both Parties shall discuss in good faith revisions of **Exhibit A** and the other terms and conditions of this Agreement. If the Parties are unable to agree on the revisions of **Exhibit A** and the other terms and conditions of this Agreement [***], then Distributor shall have the right to terminate this Agreement [***] written notice to Capricor.

8.2 **Overdue Payments**. For so long as any payment from Distributor to Capricor shall be overdue, Distributor shall pay (a) interest on the overdue amount at a rate which is [***] of the overdue amount from the date on which such amounts were originally due, or such lower rate as may be the

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maximum legally permissible rate of interest under similar circumstances in the State of California. Such amounts shall automatically become due on all balances outstanding, and any payments received thereon shall be applied first to the payment of accrued interest.

8.3 **Taxes**. Each Party shall be solely responsible for the payment of all taxes imposed on its share of income arising directly or indirectly from the activities of the Parties under this Agreement. Except as otherwise provided in this

Agreement, Distributor agrees to pay, indemnify and hold Capricor harmless from any sales, use, excise, value-added, or similar tax or duty, and any withholding taxes or duties not based on Capricor's net income ("**Transfer Taxes**"), and all government permit fees, license fees or similar fees ("**Fees**") levied upon any deliverables under this Agreement or due to any payment to be made pursuant to this Agreement or the sale of the Products, and any governmental penalties for the non-payment of Transfer Taxes, interest, collection costs and withholding costs associated with any of the foregoing items ("**Additional Costs**"). Transfer Taxes, Fees and Additional Costs required to be paid by Distributor pursuant to this Section 8.3 are in addition to and may not be claimed as a reduction or offset against, any payment due to Capricor hereunder. For clarification, Distributor shall deduct the withholding taxes, if required by applicable laws and Regulations, from the amount paid to Capricor when Distributor pays the amount of the payment provided in this Agreement (including but not limited to the amount specified in Article 3 and Sales Milestones).

8.4**No Acknowledgement**. Neither payments made by Distributor nor the acceptance of payments by Capricor in the amount of or less than the amount shown on any invoice from Capricor shall be construed as an acceptance or agreement with the amount so stated or the amount received. Either Party may recover from the other Party the amount of any overpayment or underpayment. Without limiting the generality of the foregoing, Capricor may supplement any invoice it renders to Distributor hereunder for less than the full amount to which it is entitled; provided that such supplement is made within a reasonable time after the date of the invoice being supplemented.

8.5**Audit**. Capricor shall have the right to audit Distributor's books and records to the extent necessary to determine Distributor's compliance with the terms and conditions of this Agreement. Capricor may use independent auditors who may participate fully in such audit. Such independent auditors shall enter into an agreement with the Parties hereto, on terms that are agreeable to both Parties hereto, under which such independent auditors shall agree to maintain the confidentiality of the information obtained during the course of such audit. Any such audit shall be conducted during regular business hours and in a manner that does not interfere unreasonably with the operations of Distributor. Capricor may perform such an audit one time in each twelve-month period during the term of this Agreement and one time within two (2) years following the expiration of the term; provided that Capricor may perform an additional audit at any time if the preceding audit reveals a failure to conform to the terms and conditions of this Agreement. Each audit shall begin upon the date specified by Capricor in a notice to Distributor a minimum of fifteen (15) days prior to the commencement of the audit and shall be performed diligently and in good faith and shall be completed within a reasonable period of time. If the results of the audit reveal an underpayment to Capricor of more than five percent (5%), then the costs of the audit shall be borne by Distributor.

9. **ACCEPTANCE AND REJECTION OF PRODUCTS**

9.1**Acceptance and Rejection**. Distributor shall inspect all shipments of the Products promptly upon Delivery thereof. In the event of any damage, visible defect, shortage or discrepancy in or

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to a shipment of the Products, Distributor shall inspect all incoming shipments as soon as reasonably practicable and, no later than ten (10) days after the Delivery (the "**Rejection Period**"), promptly report the same to Capricor and furnish such written evidence or other documentation as Capricor may reasonably deem appropriate. Capricor shall not be liable for any such damage, visible defect, shortage, or discrepancy unless Capricor has received notice and substantiating evidence thereof from Distributor within the Rejection Period. Any Product not properly rejected within the Rejection Period shall be deemed accepted and any claims thereto, except for claims in relation to Latent Defects as provided in Section 9.4, shall be deemed waived. If any unit of a Product is shipped by Distributor to its Wholesaler/Customer prior to expiration of the Rejection Period, then that unit shall be deemed accepted upon shipment by Distributor. If the substantiating evidence delivered by Distributor reasonably demonstrates that the damage, visible defect, shortage or discrepancy in or to a shipment of the Products meets the criteria for rejection of the Product by Distributor, Capricor shall promptly deliver additional or substitute Products to Distributor in accordance with the delivery procedures set forth herein, but in no event shall Capricor be liable for any additional costs, expenses or damages incurred by Distributor, directly or indirectly, as a result of such damage, visible defect shortage or discrepancy in or to a shipment discovered in Distributor's acceptance inspection provided above in this Section 9.1. Such criteria for rejection of the Product shall be specified in the Quality Agreement. Capricor shall not be liable for any such damage, visible defect, shortage, or discrepancy unless Capricor has received notice and such substantiating evidence thereof from Distributor within the Rejection Period.

9.2**Method of Rejection**. To reject a Product, Distributor shall, within the Rejection Period, notify Capricor in writing of its rejection and request that Capricor provide a Return Goods Authorization number ("**RGA**") to Distributor and Distributor shall

otherwise comply with the procedures set forth on **Exhibit D**, attached hereto. Capricor may elect either to have the rejected Products shipped back or to have them destroyed at Capricor's expense. If Capricor elects to have the Products returned, within ten (10) days after receipt of the RGA number, Distributor shall return to Capricor the rejected Products, freight prepaid, in their original shipping carton (if reasonably practicable) with the RGA number displayed on the outside of the carton. Provided that Capricor has provided a RGA to Distributor, Capricor reserves the right to refuse to accept any rejected Products that do not bear an RGA number on the outside of the carton. As promptly as possible, but no later than thirty (30) days after receipt by Capricor of properly rejected Products, if the Products were properly rejected due to damage, visible defect, shortage or discrepancy, Capricor shall, at Distributor's option, either replace the Products or credit Distributor therefor. Capricor shall pay the shipping charges back to Distributor and shall credit Distributor for any prepaid shipping charges paid by Distributor for properly rejected Products, and Capricor shall be responsible for the shipping charges for any shipment of replacement Products to Distributor.

9.3 **Title and Risk of Loss**. Title and risk of loss of the Product will transfer from Capricor to Distributor upon Delivery of the Product to the Distribution Warehouse.

9.4 **Latent Defects**. If Distributor becomes aware of any damage, defect or non-conformance to Product Specifications in or to the Products which was not discoverable at its visual inspection described in Section 9.1, Distributor shall promptly report such damage, defect or non-conformance to Capricor and furnish Capricor with such written evidence or other documentation. If the written evidence delivered by Distributor shall demonstrate that such damage, defect or non-conformance meet the criteria for the latent defect ("**Latent Defect**"), Capricor shall promptly deliver additional or substitute

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Products to Distributor in accordance with the delivery procedures set forth in Section 9.1. The criteria for the Latent Defect shall be specified in the Quality Agreement.

10. **WARRANTIES; LIMITATION OF LIABILITY**

10.1**Product Warranty**. Capricor warrants to Distributor that, at the time of Delivery to the Distribution Warehouse: (a) the Products have been manufactured, tested, stored and handled in accordance with the Quality Agreement; (b) the Products have been manufactured to the Product Specifications; (c) the Products shall not be adulterated or misbranded within the meaning of the Act on Securing Quality, Efficacy and Safety of Products Including Pharmaceuticals and Medical Devices (as amended) (the "**Act**") or the Regulations issued thereunder; (d) the Products shall not violate any other medical or health law, statute, Regulation or directive applicable to the Products or their distribution in the Territory; (e) the Products shall not violate any applicable customs, trade or environmental law, statute, Regulation or directive; and (f) Capricor shall have good and marketable title to all Products free and clear of all liens or encumbrances (other than any created by Distributor). If the Products fail to satisfy one of the warranty conditions (a), (b), (c), (d), (e), and (f) above, such Products shall be referred to as "**Non-Conforming Products**". The warranties set forth in this Article 10 are intended solely for the benefit of Distributor. All claims hereunder shall be made by Distributor and may not be made by Distributor's Customers. In the event any of the Products shipped to Distributor are Non-Conforming Products, Capricor will replace the Non-Conforming Products at no charge to Distributor, subject to the following:

10.1.1The Product and its package are returned to Capricor (or destroyed at its instruction), at which time they become the sole property of Capricor; and

10.1.2The Product has not been altered, mishandled, improperly stored, reprocessed, misused, or subject to unusual physical stress, nor has it been subject to temperature incursions, and the tamper proof seal has not been removed.

10.2**Disclaimer. THE FOREGOING WARRANTY IS EXCLUSIVE AND IN LIEU OF ALL OTHER WARRANTIES OF ANY KIND, WHETHER STATUTORY, WRITTEN, ORAL, EXPRESS OR IMPLIED, INCLUDING ANY WARRANTIES OF FITNESS FOR A PARTICULAR PURPOSE AND MERCHANTABILITY. IN NO EVENT, WHETHER AS A RESULT OF BREACH OF CONTRACT, TORT LIABILITY (INCLUDING NEGLIGENCE) OR OTHERWISE, SHALL CAPRICOR BE LIABLE TO DISTRIBUTOR FOR ANY SPECIAL, INDIRECT, INCIDENTAL OR CONSEQUENTIAL DAMAGES.**

10.3**Limitation of Liability. [***].**

10.4 Capricor shall not be liable with respect to any Product labeling or package inserts provided or used by Distributor or for any noncompliance with the foregoing due to the handling or packaging of Products by Distributor in a manner inconsistent with Capricor's instructions.

10.5 Capricor's warranty shall not apply to or cover any Product which Capricor can demonstrate has not been stored under the required conditions after Delivery of the Products, or to any Product that has in any way been affected by handling or distribution by anyone other than Capricor after Delivery of the Products, or any adulteration occurring after Delivery of the Products unless this has been directed by Capricor.

11. **INDEMNIFICATION**

11.1**By Distributor**. In addition to any indemnification obligation described elsewhere in this Agreement, Distributor shall indemnify, defend and hold harmless Capricor and the Capricor Indemnified Parties (as hereinafter defined) from and against and in respect of (a) any and all claims by, and liabilities to, third parties ("**Third-Party Claims**") asserted against or incurred by Capricor or any of the Capricor Indemnified Parties, and (b) any and all expenses, interests, fines, penalties, damages or other liabilities payable to third parties (including reasonable fees and expenses of counsel, travel costs and other out of pocket costs) by Capricor or any of the Capricor Indemnified Parties in connection with actual, pending or threatened litigation or other proceedings regarding such Third-Party Claims ("**Expenses**"), in each instance that arise out of or relate to:

11.1.1 any tort claim (including any claim for personal injury, wrongful death or property damage) to the extent such claim arises from any negligent act or omission or willful misconduct by Distributor (or its employees, agents, subdistributors or contractors) in the course of its performance pursuant to this Agreement, including any misrepresentation concerning the characteristics or method of usage of Products or relating to the storage, handling or delivery of Products;

11.1.2 the creation, extension or alteration of any warranty, representation or obligation by Distributor or any of its agents, employees, representatives or subdistributors, which is inconsistent with the provisions of this Agreement;

11.1.3 any action taken or omitted to be taken by Distributor or Distributor's agents, employees, representatives or subdistributors which is inconsistent with the provisions of this Agreement;

11.1.4 claims arising from the use of materials created or prepared by or on behalf of Distributor without obtaining the written approval of Capricor;

11.1.5 any violation by Distributor, its agents, employees, representatives or subdistributors of any law, Regulation or order of any Governmental Authority in the Territory applicable to Distributor including, without limitation, any sale or import of the Products into any countries or regions outside the Territory (other than to the extent that any violation is caused by a breach of this Agreement by Capricor or any of its agents, employees, representatives or Affiliates or any negligence or intentional act or omission of any such persons or entities);

11.1.6any material breach by Distributor of this Agreement or any of the representations, warranties or covenants of Distributor contained in this Agreement; and

11.1.7 any actual or alleged patent, copyright or trademark infringement, or misappropriation or violation of any other proprietary right, arising out of Distributor's performance pursuant to this Agreement (but not arising out of or relating to any of the proprietary rights in the Products as delivered); provided that this Section 11.1 shall not apply to any Third-Party Claim or Expense to the extent that the Parties agree, or it is finally determined pursuant to Article 10 that the Third-Party Claim or Expense is within the scope of Capricor's indemnity obligation set forth in Section 11.2 below. The "Capricor Indemnified Parties" shall mean and include (i) Capricor's Affiliates (ii) the respective directors, officers, agents and employees of and counsel to Capricor and its Affiliates, (iii) each other Person, if any, controlling Capricor or any of its Affiliates, and (iv) the successors, assigns, heirs and personal representatives of any of the foregoing.

11.2**By Capricor**. In addition to any indemnification obligation described elsewhere in this Agreement, Capricor shall indemnify and hold Distributor and Distributor Indemnified Parties (as hereinafter defined) harmless from and against, and in respect of, any and all Third-Party Claims asserted against or incurred by, and any and all Expenses payable by, Distributor or any of Distributor Indemnified Parties that arise out of or relate to:

11.2.1 any actual or alleged breach of any warranty (including written warranties included within the Product packaging) or obligation, if any, accompanying the Products, subject to the limitations provided in Section 10.3;

11.2.2 the creation, extension or alteration of any warranty, representation or obligation by Capricor or any of its agents, employees or representatives which is inconsistent with the provisions of this Agreement;

11.2.3 any action taken or omitted to be taken by Capricor or Capricor's agents, employees or representatives which is inconsistent with the provisions of this Agreement;

11.2.4 claims arising from the use of materials created or prepared by or on behalf of Capricor;

11.2.5 death or bodily injury to patients on whom a Product was properly used in accordance with the instructions for use accompanying the Product; provided, however, that such indemnification shall not apply to the extent that such death or personal injury was caused by (a) any breach of this Agreement by Distributor; (b) any act of negligence, willful misconduct or intentional act or omission to act by Distributor, its agents, employees, representatives, subdistributors, Wholesalers, Customers and/or the hospital at which the Product was used, its employees, medical staff, contractors, agents and the medical personnel administering the Product; or (c) any material violation of any applicable Regulations by Distributor. Capricor will be entitled to offset from its indemnification obligation described herein all collateral sources, including amounts covered by third-party payers or any other source;

11.2.6 any violation by Capricor of any Regulation, law or order of any Governmental Authority in the Territory applicable to Capricor (other than to the extent that any violation is caused by the breach of this Agreement by Distributor or any of its agents, employees, representatives, subdistributors or Affiliates or any negligence or intentional act or omission of any such persons or entities);

11.2.7 any material breach by Capricor of this Agreement or any of the representations, warranties or covenants of Capricor contained in this Agreement; and

11.2.8 actual or alleged infringement or misappropriation alleged by third parties of patents, copyrights, trademarks, or other intellectual property rights by the using or selling of Product(s) (except to the extent arising from Distributor's use or sale of the Product(s) in a manner not approved by Capricor);

provided that this Section 11.2 shall not apply to any Third-Party Claim or Expense to the extent that the Parties agree, or it is finally determined pursuant to Article 10 that the Third-Party Claim or Expense is within the scope of Distributor's indemnity obligation set forth in Section 11.1 above. The "Distributor Indemnified Parties" shall mean and include (i) Distributor's Affiliates, (ii) the respective directors, officers,

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agents and employees of and counsel to Distributor and its Affiliates, (iii) each other Person, if any, controlling Distributor or any of its Affiliates, and (iv) the successors, assigns, heirs and personal representatives of any of the foregoing.

11.3Neither Party shall be liable to the other or to such other Party's Indemnified Persons for any indirect, special, consequential, punitive or incidental damages resulting from any claim arising out of this Agreement, nor shall the foregoing indemnification obligations extend to any such damages.

11.4**Procedure**.

11.4.1If any third party shall make any claim or commence any arbitration proceeding or suit against any one or more of Distributor's Indemnified Parties or Capricor's Indemnified Parties ("**Indemnified Persons**") with respect to which an Indemnified Person intends to make any claim for indemnification against Capricor under Section 11.2 or against Distributor under Section 11.1 (as the case may be, the "**Indemnitor**") such Indemnified Persons, (each an "**Indemnitee**") shall promptly (but in no event more than thirty (30) days after learning of such Third-Party Claim) give written notice to the Indemnitor of such Third Party Claim, arbitration proceeding or suit and the following provisions shall apply. The Indemnitee shall provide the Indemnitor all information and documentation necessary to support and verify the losses so claimed and the Indemnitor and its representatives shall be given access to all books and records in the possession or control of the Indemnitee which the Indemnitor reasonably determines to be related to such Third-Party Claim. Indemnitee shall tender the defense thereof to the Indemnitor. Indemnitor shall have the right, but not the obligation, to assume sole control of the defense, settlement or disposition thereof, including, without limitation, the selection of defense counsel reasonably acceptable to Indemnitee. The Indemnitee will reasonably cooperate with the Indemnitor in the defense and settlement of all such Third-Party Claims at the Indemnitor's request and expense. The Indemnitor will keep the Indemnitee advised concerning the relevant Third-Party Claim(s), and the Indemnitor shall not admit liability with respect thereto without the express prior written consent of the Indemnitee. A failure to promptly notify the Indemnitor of a claim shall serve to reduce

the indemnity rights of the Indemnitee only to the extent that such delay or failure to promptly notify the Indemnitor actually prejudiced or damaged the Indemnitor's defense of the claim. If the Indemnitor elects to assume any such defense, the Indemnitor shall not be liable for any legal or other expenses subsequently incurred directly by the Indemnitee in connection with such defense.

11.4.2 So long as the Indemnitor is conducting the defense of the Third Party Claim in accordance with this Article 11, (a) the Indemnitee will not consent to the entry of any judgment or enter into any settlement with respect to the Third-Party Claim without the prior written consent of the Indemnitor, and (ii) the Indemnitor will not consent to the entry of any judgment or enter into any settlement with respect to the Third-Party Claim without the prior written consent of the Indemnitee, which consent will not be unreasonably withheld or delayed; provided, however, that such consent of the Indemnitee will not be required if the judgment or settlement contains a full release of claims against the Indemnitee with no admission of liability or wrongdoing. Notwithstanding any other provision of this Section 11.4, if an Indemnitee withholds its consent to a bona fide settlement offer, where, but for such action, the Indemnitor could have settled such Third-Party Claim, the Indemnitor will be required to indemnify the Indemnitee only up to a maximum of the bona fide settlement offer for which the Indemnitor could have settled such Third-Party Claim.

11.4.3 If the Indemnitor does not assume and conduct the defense of any such Third Party Claim for which it is obligated to provide indemnification under Section 11.4.1 or Section 11.4.2 (as applicable), notwithstanding anything to the contrary in this Agreement, (a) the Indemnitee may defend against, consent to the entry of any judgment, or enter into any settlement in any manner the Indemnitee may deem reasonably appropriate and the Indemnitee need not consult with, or obtain any consent from, the Indemnitor, and (b) the Indemnitor shall remain liable to indemnify the Indemnitee for any damages, losses and expenses (including without limitation the attorney's fee and arbitration costs) as provided in this Agreement.

11.5**Entire Obligations**. The foregoing provisions of this Article 11 state the entire obligations of the Parties and the exclusive remedy of the Parties and any Indemnified Persons with respect to any alleged infringement of patents, copyrights, trademarks or other intellectual property rights by the Products or the use or sale of the Products.

12. **NOTIFICATIONS**

12.1 **Safety Notifications**. In case a Product is potentially deviating from Capricor's Product Specifications, or under any other circumstance where such Product might cause, or already has caused, harm to a patient, user or other person, each Party shall notify the other Party in writing ("**Safety Notification**"), irrespective of the time or location of detection of the potentially faulty Product, as soon as the respective party gains knowledge of such. It is Capricor's sole right and responsibility to file safety reports or vigilance reports to any legal authority for the Products in order to comply with the applicable Regulations in the Territory. Nothing in this Agreement shall prevent Distributor from complying with any applicable law or Regulation that requires Distributor to report medical incidents, provided that Distributor shall concurrently provide Capricor with a copy of any such reports. Safety Notifications and any other complaints with respect to the Product are to be promptly delivered to the following addresses:

Capricor Therapeutics, Inc.	**NIPPON SHINYAKU, INC.**
10865 Road to the Cure Suite 150 San Diego, CA 92121 USA Attn: Director of Regulatory Affairs With a copy to: General Counsel 8840 Wilshire Blvd., 2nd Floor Beverly Hills, CA 90211 USA	14 Nishinosho-Monguchi-cho Kisshoin, Minami-ku, Kyoto 601-8550, Japan Attn: Head of Regulatory Affairs Supervision and Assurance Div.

12.2**Statements**. In the event of an actual or alleged defect of a Product, Distributor or its representatives or agents shall not make any statement as to the cause, before having informed Capricor and having received Capricor's written report on the initial analysis of the defect, which shall be provided by Capricor within thirty (30) days after its receipt of notification from Distributor, and shall then not render statements different from or in addition to the results of such analysis. Notwithstanding the foregoing, Distributor shall be free to make such reports as are required by applicable law. Unless

otherwise proscribed by law, Distributor shall concurrently provide Capricor with a copy of any report filed pursuant to this Section.

12.3**Product Recalls**. If either Party believes that a recall of any Product in the Territory is desirable or required by Regulations in the Territory or elsewhere, it shall immediately notify the other Party. The Parties shall then discuss reasonably and in good faith whether such recall is appropriate or required and the manner in which any recall should be handled. Notwithstanding Section 10.3, if the reason for such recall is finally determined to have been caused due to Capricor's gross negligence, willful misconduct or breach of this Agreement, Capricor shall reimburse Distributor for all of the costs and expenses actually incurred by Distributor in connection with such recall. If the reason for such recall is finally determined to have been caused due to Distributor's gross negligence, willful misconduct or breach of this Agreement, Distributor shall reimburse Capricor for all of the costs and expenses actually incurred by Capricor in connection with such recall. Any Product Recall shall be conducted in accordance with the relevant provisions set forth in the Quality Agreement.

12.4**Remedial Actions**. It is Capricor's exclusive right and obligation to issue recalls, safety alerts, advisory notices or similar remedial actions with respect to the Product. In such case, Capricor and Distributor shall each support and fully cooperate with each other to comply with all applicable laws and Regulations. Furthermore, in such case, Distributor shall notify its Wholesalers/Customers and, upon Capricor's request, retrieve identified Products. Notwithstanding the foregoing, Distributor shall be free to take any actions required by applicable Regulations. Unless otherwise proscribed by law, Distributor shall concurrently inform Capricor about all actions taken by Distributor in connection with any remedial actions.

12.5**Material Safety Risk**. In the event that Capricor determines in good faith that the continued manufacture and sale of the Product poses a material safety risk to patients, Capricor shall immediately give notice of such a material safety risk to Distributor and discuss suspension of the continued sale of the Product. If Distributor disputes suspension of the continued sale of the Product, such matter shall be submitted to the J-JSC and the J-JSC shall attempt to resolve the dispute; provided that if the J-JSC is unable to resolve such dispute thereunder within thirty (30) days of referral to the J-JSC, then such dispute shall be submitted to Expert Determination pursuant to Section 17.3.2. Capricor will consider in good faith the determination of the expert, but, if after applying sound scientific judgment and acting only in the interest of patient safety without consideration for any other business reasons Capricor is unable to accept such determination, Capricor shall have the final decision-making authority regarding whether a material safety risk exists and suspension of the continued sale of the Product, and its decision with respect thereto shall not be subject to appeal. For clarification, this Agreement shall continue in effect during such suspension of the continued sale unless terminated in accordance with any provisions of this Agreement. During such suspension of the continued sale of the Product, the performance of Distributor's obligations hereunder shall be suspended except as required to be performed by applicable laws, Regulations or Governmental Authority. When the suspension of the continued sale of the Product is lifted and the sales of the Product resumes, the suspension of the performance of these obligations shall be lifted, provided that the Parties shall agree on when the sales of the Product will resume and discuss the amendment of this Agreement.

13. **PROPERTY RIGHTS AND CONFIDENTIALITY**

13.1**Property Rights**. Distributor agrees that Capricor and/or its Affiliates own all right, title, and interest in the Product and in all of Capricor's patents, trademarks, trade names, inventions, copyrights, know-how, and trade secrets relating to the design, manufacture, operation and/or use of the

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Products. The use by Distributor of any of these property rights is authorized only for the purposes set forth in this Agreement, and upon termination of this Agreement for any reason, such authorization shall cease.

13.2 **Transfer Conveys No Right to Manufacture or Copy**. The Products are being transferred hereunder by Capricor subject in every case to the condition that such transfer does not convey any license, expressly or by implication, to manufacture, duplicate, modify or otherwise copy or reproduce the Product. Distributor shall take appropriate steps with its subdistributors, Wholesalers and Customers, as Capricor may request, to inform them of and assure compliance with the restrictions contained in this Section 13.2.

13.3**Confidentiality**.

13.3.1 **Confidential Information.** This Section 13.3 applies to all Confidential Information disclosed by a Party (the **"Disclosing Party"**) and/or its Affiliates to a receiving Party (the **"Receiving Party"**). **"Confidential Information"** means confidential and/or proprietary information of the Disclosing Party and its licensors and Affiliates, whether in written, printed, verbal or electronic form, including, without limitation: (a) research and development activities, preclinical study information, clinical trial information and data, results, product design details and specifications, manufacturing processes, CMC development, protocols, technology and know-how, regulatory processes and information, sales and marketing plans, finances and business forecasts, procurement requirements, vendor information, customer lists, personnel information, and strategic plans; (b) other information that the Disclosing Party identifies in writing as confidential to the Receiving Party; (c) information that the Receiving Party knows or has reason to know is confidential or proprietary information of the Disclosing Party; (d) information which is of such a nature or the manner or circumstance in which such information is disclosed is such that it may be reasonably inferred to be confidential and/or proprietary to the Disclosing Party; and (e) all notes, analyses, compilations, studies, interpretations or other documents prepared by the Receiving Party or its representatives to the extent they contain, reflect or are based upon, in whole or in part, Confidential Information of a Disclosing Party furnished to the Receiving Party or its representatives in connection with this Agreement by or on behalf of the Disclosing Party and (f) information obtained during an audit or tour of the Disclosing Party's (or its Affiliates' facility).

13.3.2 **Exclusions.**Confidential Information will not include information that: (a) is now, or hereafter becomes generally known or available to the public through no act or failure to act on the part of the Receiving Party; (b) was acquired by the Receiving Party before receiving such information from the Disclosing Party through no breach of any duty of confidentiality owed to the Disclosing Party and without restriction as to its use or disclosure; (c) is hereafter rightfully furnished to the Receiving Party by a third party without any breach of any duty of confidentiality owed to the Disclosing Party and without restriction as to its use or disclosure; or (d) is information that the Receiving Party can document was independently developed by the Receiving Party without any use of the Confidential Information of the Disclosing Party or its Affiliates.

13.3.3 **Restriction on Use and Disclosure.** Distributor and Capricor each agree that during the term of this Agreement and for a period of seven (7) years after the termination hereof, to hold the Disclosing Party's Confidential Information in confidence and not to use it in any way for their own

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account or for the account of any third party, nor disclose to any third party, any Confidential Information of the Disclosing Party, except as specifically permitted or required for their respective performances hereunder. Distributor and Capricor each agree to take all necessary measures to prevent any disclosure of the other Party's Confidential Information and to ensure compliance with the above obligations by its employees, agents, contractors, subdistributors, or consultants. Distributor shall not publish any technical description of the Products beyond the description published by Capricor. Distributor shall not manufacture or have manufactured any pharmaceutical or biologic product utilizing any of Capricor's Confidential Information and shall not alter, amend or modify all or any part of the Product. The Receiving Party shall be responsible for any unauthorized use or disclosure of the Confidential Information by the Receiving Party's employees, agents, contractors, representatives, subdistributors, directors, or consultants.

13.3.4 **Securities Matters.** The Parties acknowledge that each of them is a publicly traded corporation and each agrees that it shall observe the restrictions imposed by applicable United States securities laws and the laws of Japan on the purchase or sale of securities by any person who has received material, non-public information from the issuer of such securities and on the communication of such information to any other person when it is reasonably foreseeable that such other person is likely to purchase or sell such securities in reliance upon such information. Nothing in this Agreement shall be deemed to prohibit a Party from disclosing the existence of this Agreement, the terms and conditions hereof, or any information related hereto where such disclosure is required under the rules of any securities exchange on which such Party is listed, or any other applicable law or regulation.

13.3.5 **Ownership of Confidential Information.** The Receiving Party acknowledges and agrees that all of the Disclosing Party's Confidential Information is owned solely by the Disclosing Party (or its Affiliates or licensors) and that nothing contained in this Agreement will be construed as granting any rights to the Receiving Party, by license or otherwise, to any of the Disclosing Party's Confidential Information or other proprietary rights, all of which rights are specifically reserved by the Disclosing Party. The Receiving Party further agrees not to copy all or any part of the Confidential Information or any documentation related thereto except as may be required to perform its obligations hereunder and further, not to modify,

adapt, translate, reverse engineer, decompile, disassemble, or otherwise attempt to discover any additional information with respect to the Confidential Information of the Disclosing Party.

13.3.6 **Equitable Relief.** The Receiving Party agrees that its obligations hereunder are necessary and reasonable to protect the business interests of the Disclosing Party and its Affiliates and that the unauthorized disclosure or use of the Disclosing Party's Confidential Information may cause irreparable harm and significant injury, the degree of which may be difficult to ascertain. The Receiving Party further acknowledges and agrees that in the event of any actual or threatened breach of this Agreement, the Disclosing Party and its Affiliates may have no adequate remedy at law and accordingly, that the Disclosing Party and its Affiliates will have the right to seek specific performance or an immediate injunction enjoining any breach or threatened breach of this Agreement, without the necessity of proving actual damages, as well as the right to pursue any and all other rights and remedies available at law or in equity for such breach or threatened breach.

13.3.7 **Applicability of Obligations.** The terms contained in Section 13.3 shall apply to any Confidential Information disclosed to the Receiving Party during the Term of this Agreement and shall

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apply to any Confidential Information disclosed earlier to the Receiving Party to the extent the Parties began discussions concerning this Agreement prior to the Effective Date. The obligations of the Receiving Party and any of its representatives as to the Confidential Information it has received hereunder shall continue in full force and effect for the periods set forth in Section 13.3.3 of this Agreement regardless of any attempted or actual termination or expiration hereof.

13.3.8 **Return of Confidential Information**. All documents and other materials, in whatever medium, in the possession of the Receiving Party or its representatives to the extent they embody any of the written Confidential Information of the other Party, regardless of whether such documents or materials were prepared by the Receiving Party or its representatives, will be returned to the Disclosing Party immediately upon its request or destroyed, at the Disclosing Party's option, and the destruction promptly confirmed to the Disclosing Party in writing. Except as required in connection with its obligations under this Agreement, by law or judicial or investigative process, no copies, extracts or other reproductions shall be retained by the Receiving Party or its representatives. If any notes, analyses, compilations, studies, interpretations or other documents prepared by the Receiving Party or its representatives contain, reflect or are based upon, in whole or in part, Confidential Information furnished to the Receiving Party or its representatives along with other information which is not Confidential Information received from the Disclosing Party, the Receiving Party may redact or remove such non-confidential information from the materials to be returned to the Disclosing Party. Notwithstanding the foregoing, the Receiving Party's legal counsel may retain one (1) copy of the Disclosing Party's Confidential Information in its files for archival purposes. Notwithstanding the return or destruction of the documents and materials, the Receiving Party will continue to be bound by its obligations under this Agreement.

13.3.9 **Legal Process.** In the event the Receiving Party or any of its representatives is required to disclose Confidential Information of the Disclosing Party by any applicable law, regulation, legal process, judicial order or by any applicable order or requirement of any Governmental Authority, it may do so only to the extent required; provided, however, the Receiving Party shall (a) first give prompt notice to the Disclosing Party of the required disclosure sufficiently in advance (to the extent reasonably possible) of making the required disclosure to allow the Disclosing Party a reasonable opportunity to take steps to object to, prevent, and/or limit its disclosure or obtain a protective or other similar order with respect to the required disclosure (collectively **"Protective Measures"**); (b) if requested by the Disclosing Party, cooperate with the Disclosing Party in seeking such Protective Measures; and (c) restrict disclosure to only that portion of the Confidential Information which is required to be disclosed. Notwithstanding anything in the foregoing to the contrary, the disclosure by the Receiving Party or its representatives of Confidential Information to the Person compelling disclosure does not mean that any such information is no longer Confidential Information and the Receiving Party and its representatives must continue to treat such information as Confidential Information pursuant to the terms hereof with respect to all other Persons.

13.3.10 **Compliance with Export Laws and Regulations.** The Receiving Party shall comply with all applicable laws and regulations with respect to its receipt, possession and use of Confidential Information, including without limitation the export laws and regulations of the United States, including but not limited to, applicable requirements of the Federal Food, Drug, and Cosmetic Act (as amended) and the FDA, and other applicable jurisdictions. Without limiting the foregoing, the Receiving Party shall not (a) export, directly or indirectly, any technical data acquired pursuant to this

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Agreement or any product utilizing any such technical data to any proscribed country in violation of applicable export laws and regulations; and (b) permit any Person or entity to access or use the Confidential Information in violation of any applicable export embargoes, prohibitions or restrictions.

14. **TRADEMARKS**

14.1**License**.

14.1.1 During the term of this Agreement, Distributor shall have:

(a)the exclusive, non-transferable right to indicate to the public that it is the exclusive distributor of the Product in the Territory; and

(b)the right to advertise, sell, distribute, promote, and market such Product in the Territory under the Trademarks listed on **Exhibit B**, provided such Trademarks are used by Distributor in accordance with Capricor's standards, specifications and instructions, but in no event beyond the term of this Agreement.

(c) Notwithstanding the foregoing, Distributor may sublicense such rights to the approved subdistributors, subject to the provisions set forth in Section 4.2.

14.1.2 Except as set forth in this Section 14.1, nothing contained in this Agreement shall grant to Distributor any right, title, or interest in the Trademarks, and all goodwill accruing from the use of the Trademarks shall inure solely to the benefit of Capricor. At no time during or after the term shall Distributor, directly or indirectly, challenge or assist others to challenge the Trademarks or the registration thereof. Distributor shall afford Capricor reasonable opportunities during the term hereof to inspect and monitor the activities of Distributor in order to ensure Distributor's use of the Trademarks in accordance with Capricor's standards and instructions. Distributor shall acquire no right, title or interest in such Trademarks other than the foregoing limited license and all rights in the Trademarks shall be in the name of Capricor and/or its Affiliates, and Distributor shall not use any Trademarks as part of Distributor's corporate or trade name or permit any third party to do so without the prior written consent of Capricor. In the event Capricor determines in its sole discretion that it is necessary or advisable to enter into a Registered User Agreement or a similar document in connection with protection of such Trademarks, Distributor shall enter into such an agreement.

14.2**Registration**. Capricor shall register the Trademarks in the Territory. In addition, in the event Capricor believes that it is advisable to effect any filing or obtain any governmental approval or sanction for the use by Distributor of any of the Trademarks pursuant to this Agreement, the Parties shall fully cooperate in order to do so. All expenses relating to the registration of the Trademarks in the Territory, as well as the making of any filings or obtaining any governmental approvals for the use by Distributor of the Trademarks shall be borne by Capricor.

14.3**Markings**. Distributor shall not, without the prior written consent of Capricor, remove or alter any patent numbers, trade names, trademarks, notices, serial numbers, labels, tags or other identifying marks, symbols or legends affixed to any Product or containers or packages.

14.4**Infringements**. Distributor shall promptly notify Capricor of any use by any third party of the Trademarks or any similar marks which may constitute an infringement or passing off of the Trademarks. Capricor reserves the right in its sole discretion to institute any proceedings against such

third party infringers and Distributor shall refrain from doing so without Capricor's prior written consent. Distributor agrees to cooperate fully with Capricor in any action taken by Capricor against such third parties, provided that all expenses of such action shall be borne by Capricor and all damages which may be awarded or agreed upon in settlement of such action shall accrue to Capricor. If Capricor elects not to pursue any such action against a third party infringer, Distributor shall have the right, but not the obligation, to pursue such action at its own cost and expense and shall be subject to Capricor's consent, not to be unreasonably withheld. In such case, the costs to be borne and allocation of any recovery Distributor is awarded for any action against the third party infringer shall first be allocated to reimburse Distributor for costs and expenses incurred under such action, and any remaining amounts shall be allocated between the Parties as agreed between the Parties prior to Distributor's initiation of such action.

14.5**Termination of Use**. Distributor acknowledges the proprietary rights of Capricor and/or its Affiliates in and to the Trademarks and any trade names regularly applied by Capricor to the Product, and Distributor hereby waives in favor of Capricor all rights to any trademarks, trade names, trade dress, and logotypes now or hereafter originated by Capricor, and all goodwill accruing from the use of any of the foregoing shall inure solely to the benefit of Capricor. Distributor shall not adopt, use or register any words, phrases or symbols which are identical to any of such trademarks, trade names, trade dress or logotypes. Upon termination of this Agreement, Distributor shall cease and desist from use of the Trademarks in any manner. In addition, Distributor hereby empowers Capricor and agrees to assist Capricor, if requested, to cancel, revoke or withdraw any governmental registration or authorization permitting Distributor to use the Trademarks in the Territory.

14.6**Approval of Representations**. All representations of Capricor's Trademarks that Distributor intends to use shall first be submitted to Capricor for written approval of design, color, and other details or shall be exact copies of those used by Capricor.

15. **TERM AND TERMINATION**

15.1**Term**. Unless sooner terminated under the provisions of this Article 15 or any other termination provision contained elsewhere in this Agreement, the term of this Agreement shall commence on the date of mutual execution hereof and shall continue in full force and effect until [***]. Thereafter, the term of this Agreement will automatically be extended for successive periods of [***] unless either Party gives written notice of its election to terminate at least [***] days prior to the termination of the initial term or any renewal term hereof. If the Agreement is extended, [***].

15.2**Termination**

15.2.1 **Termination By Capricor**. In addition to any termination provisions contained elsewhere in this Agreement, Capricor shall have the right to terminate this Agreement by written notice to Distributor in the following circumstances:

(a)Distributor shall have failed to pay all undisputed amounts for its purchases of Products in accordance with Article 8 or breached any other monetary obligation hereunder, which failure is not cured within sixty (60) days after receiving notification thereof from Capricor; provided, however, that all amounts that are subject to a bona fide dispute ("**Disputed Amounts**") raised by a Party in writing within such sixty (60) day period may be withheld from the specific invoice to which it relates and submitted first to the J-JSC for resolution, and if not resolved, then to General Arbitration

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pursuant to Section 17.3.1 hereof. All Disputed Amounts that Distributor subsequently agrees in writing to pay or that are required to be paid pursuant to a proper arbitration determination shall be paid within thirty (30) days from the date of such agreement or determination.

(b)Distributor shall have breached a material obligation (other than under Section 15.2.1) under this Agreement and failed to cure such breach within ninety (90) days after receiving notice thereof from Capricor; provided, however, that if there is a bona fide dispute as to any non-monetary obligation raised by a Party in writing within such ninety (90) day period, such dispute shall first be submitted to the J-JSC for resolution, and if not resolved, then to General Arbitration pursuant to Section 17.3.1 hereof.

(c)In the event Distributor shall have failed to pay any monetary amounts or failed to cure any non-monetary obligation after determination by the arbitrator that it is obligated to do so, Capricor shall have the right to terminate this Agreement upon thirty (30) days' written notice thereof by Capricor to Distributor.

(d) Upon ten (10) days' written notice, in that event that any Regulation or Governmental Authority enactment or decree suspends or prohibits the performance by Capricor of its obligations hereunder, and, after using Commercially Reasonable Efforts to do so, Capricor is unable to resume its responsibilities hereunder.

15.2.2 **Termination By Distributor**. In addition to any termination provisions contained elsewhere in this Agreement, Distributor shall have the right to terminate this Agreement by written notice to Capricor in the following circumstances:

(a) Capricor shall have breached a material obligation under this Agreement and failed to cure such breach within [***] after receiving written notice thereof from Distributor; provided, however, that if there is a bona fide dispute as to any obligation raised by a Party in writing within such [***] period, such dispute shall first be submitted to the J-JSC for resolution, and if not resolved, then to General Arbitration pursuant to Section 17.3.1 hereof.

(b) Upon ten (10) days' written notice, in that event that any Regulation or Governmental Authority enactment or decree suspends or prohibits the performance by Distributor of its obligations hereunder, and, after using Commercially Reasonable Efforts to do so, Distributor is unable to resume its responsibilities hereunder.

15.2.3 Either Party may terminate this Agreement immediately upon written notice to the other Party if:

(a)The other Party shall be or become bankrupt or insolvent or if there are instituted by or against it proceedings in bankruptcy or under insolvency laws or for its reorganization, receivership, liquidation or dissolution;

(b)The Product is adjudicated to infringe the intellectual property of a third party and it is not commercially or technically feasible for Capricor or Distributor to obtain a license from the third party or to replace or modify the Product so that it is no longer infringing any third party's intellectual property rights or such replacement or modification of the Product is not acceptable for Distributor.

(c)A failure to meet the primary endpoint in either the HOPE-3 Phase 3 trial in the U.S. or any clinical trial conducted in the Territory.

15.2.4 **Termination for Change of Control**. [***].

15.3**Rights and Obligations on Termination**. In addition to any provision contained elsewhere in this Agreement, in the event of termination of this Agreement for any reason, the Parties shall have the following rights and obligations:

15.3.1 Termination of this Agreement shall not release the Parties from the obligation to make payments of all amounts then due and payable, including, without limitation, any Supply Price payments, Transfer Price payments and Milestone payments accruing through the date of such termination or expiration.

15.3.2 Subject to any provision contained elsewhere in this Agreement, Capricor shall have the right at its option to either (i) cancel any or all accepted Purchase Orders which provide for delivery after the effective date of termination; or (ii) continue to fulfill, subject to the terms of Section 7.4 above, all orders accepted by Capricor prior to the effective date of termination which specify a Delivery Date no later than ninety (90) days after the acceptance of such order, provided that Capricor shall continue to fulfill orders accepted by Capricor prior to the effective date of termination to enable Distributor to fulfill its remaining obligations under any orders which have been given to Distributor prior to the applicable notice of termination, and provided further, that (i) Distributor is in material compliance with Distributor's obligations under this Agreement; and (ii) Capricor is otherwise not restricted in its ability to sell additional Products to Distributor

15.3.3 In case of termination by Capricor pursuant to Section 15.2.1 (a), (b) or (c) or Section 15.2.3(a), Capricor shall have the right, but not the obligation, to repurchase all or any part of the inventories of Products in Distributor's possession as of the termination date at Capricor's invoiced Transfer Price to Distributor for such Products, less freight to Capricor's place of business. Capricor shall exercise its option under this subsection by notifying Distributor in writing no later than fifteen (15) days after the effective termination date. In case of any termination other than a termination by Capricor specified above in this Section 15.3.3, Capricor shall (i) repurchase all or any part of the inventories of Products in Distributor's possession as of the termination date which are unsold, not expired and which have been properly stored and maintained at Capricor's invoiced Transfer Price to Distributor for such Products, and (ii) bear the cost of the freight of the Products to be repurchased by Capricor to Capricor's designated place of business.

15.3.4 In the event Capricor exercises its right to terminate this Agreement pursuant to the foregoing termination provisions, Capricor shall continue to sell Products to Distributor to enable Distributor to fulfill its remaining obligations under any orders which have been given to Distributor prior to the applicable notice, provided that (i) Distributor is in material compliance with the terms and conditions of this Agreement; and (ii) Capricor is otherwise not restricted in its ability to sell additional Products to Distributor.

15.4**Remedies Cumulative**. Any rights or remedies provided by this Agreement to either Party shall be cumulative and in addition to any rights or remedies such Party may have at law, or in equity, or under any other agreements between the Parties.

15.5**Return of Materials**. All of the trademarks, trade names, packaging, photographs, samples, literature and sales aids of every kind of Capricor and/or its Affiliates shall remain the property of Capricor and/or its Affiliates, as applicable. Within thirty (30) days after the termination of this Agreement, Distributor shall prepare all such items in its possession for shipment, as Capricor may direct, at Capricor' expense. Distributor shall not make, use, dispose of, or retain any copies of any Confidential Information or items which may have been entrusted to it except for those materials necessary to satisfy its regulatory obligations. Effective upon the termination of this Agreement, Distributor shall cease to use all of Capricor's trademarks, marks, trade names, data, and literature of every kind.

16. **FORCE MAJEURE**. The obligations of either Party to perform under this Agreement shall be excused during each period of delay caused by matters (not including lack of funds or other financial causes) such as fires, floods, explosions, accidents, acts of God, war, riots, strikes, lockout or other concerted acts of workers, pandemic, epidemic, communicable diseases, acts of Governmental Authorities, supplier delays, shortages of raw materials, actions or failures to act by Governmental Authorities, and Government orders, in each case that are reasonably beyond the control of the Party obligated to perform; provided that nothing contained in this Agreement shall affect either Party's ability or discretion with respect to any strike or other employee dispute or disturbance and all such strikes, disputes or disturbances shall be deemed to be beyond the control of such Party. A condition of force majeure shall be deemed to continue only so long as the affected Party shall be taking all reasonable actions necessary to overcome such condition. If either Party shall be affected by a condition of force majeure, such Party shall give the other Party prompt notice thereof, which notice shall contain the affected Party's estimate of the duration of such condition and a description of the steps being taken or proposed to be taken to overcome such condition of force majeure. Any delay occasioned by any such cause shall not constitute a default under this Agreement, and the obligations of the Parties shall be suspended during the period of delay so occasioned. During any period of force majeure, the Party that is not directly affected by such condition of force majeure shall be entitled to take any reasonable action necessary to mitigate the effects of such condition of force majeure.

17. **DISPUTE RESOLUTION**

17.1 **General**. Any dispute arising out of or relating to this Agreement shall be resolved in accordance with the procedures specified in this Article 17, which shall be the sole and exclusive procedures for the resolution of any such disputes.

17.2 **Escalation**. The Parties will attempt in good faith to resolve any claim or controversy arising out of or relating to the execution, interpretation and performance of this Agreement (including the validity, scope and enforceability of this mediation and arbitration provision) promptly by negotiations between executives of each Party who have authority to settle the controversy and who are at a higher level of management than the persons with direct responsibility for the administration of this Agreement. Any Party may give the other Party written notice of any dispute not resolved in the normal course of business. Within fifteen (15) days after delivery of the notice, the receiving Party shall submit to the other a written response. The notice and the response shall include (a) a statement of each Party's position and a summary of arguments supporting that position, and (b) the name and title of the executive who will represent that Party and of any other person who will accompany the executive. Within thirty (30) days after delivery of the notifying Party's notice, the executives of both Parties shall meet at a mutually acceptable time and place, and thereafter as often as they reasonably deem necessary, to attempt to

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resolve the dispute. All reasonable requests for information made by one Party to the other will be honored. All negotiations pursuant to this clause are confidential and shall be treated as compromise and settlement negotiations for purposes of applicable rules of evidence. All applicable limitation periods and defenses based upon the passage of time shall be automatically tolled while the negotiations pursuant to this section are pending.

17.3 **Arbitration**.

17.3.1 **General Arbitration**.

(a) Except as controlled by Section 17.3.2, any matter submitted to arbitration pursuant to any provision contained in this Agreement or any dispute arising out of or relating to this Agreement or its breach, termination or validity, including whether the claims asserted are arbitrable, which has not been resolved by the specified binding procedure pursuant to Section 17.2 within sixty (60) days of the initiation of the date of delivery of notice shall be settled by binding arbitration under the Rules of Arbitration of the International Chamber of Commerce ("**ICC Rules**"), except as modified in

this Agreement, in effect on the date of this Agreement, by three independent and impartial arbitrators, one of whom shall be appointed by each Party and the third by the two appointees. The arbitration and this arbitration clause shall be governed by United States Arbitration Act, 9 U.S.C. §§ 1-16, and judgment upon the award rendered by the arbitrators may be entered by any court having jurisdiction thereof. The place of the arbitration shall be New York, New York or Los Angeles, California and shall be determined by the Party that initiated the arbitration. The arbitrators may award attorneys' fees in their discretion. Otherwise, the arbitrators are not empowered to award damages in excess of compensatory damages, and each Party hereby irrevocably waives any right to recover such damages. The arbitration shall be conducted in the English language and all writings, documents and other communications shall be in the English language.

(b) The Parties may request limited discovery in accordance with the IBA Rules on the Taking of Evidence in International Arbitration. In addition, the Parties hereby confirm that (i) the arbitrators shall have the power to compel the production of documents at their discretion, (ii) in principle, discovery shall be limited to the minimum necessary scope to allow the Parties a reasonable opportunity to present their cases and fairly establish the facts of the dispute, and (iii) any request for production of documents made by a Party shall be sufficiently detailed in its description of the requested document and accompanied by a statement explaining how such document is relevant to the dispute and why the requesting party believes the requested document is in the possession of the other Party. The statute of limitations under the law of the State of New York shall apply with respect to any notification of a dispute under this Agreement and shall be extended until commencement of arbitration if all interim deadlines have been complied with by the notifying Party.

17.3.2 **Expert Determination**. If the Parties, through the J-JSC or otherwise, are unable to agree on Minimum Sales Requirements, forecasts, issues regarding the NHI Price Listing as provided in Section 5.8 and a material safety risk, either Party may submit such dispute to binding Expert Determination for resolution in accordance with the following provisions:

(a) The submitting Party shall notify the other Party of its decision to initiate the Expert Determination proceeding pursuant to this Section 17.3.2 through written notice;

(b) Within ten (10) days following receipt of such notice, the Parties shall use Commercially Reasonable Efforts to agree on an independent third party expert with at least ten (10) years of experience in a managerial position regarding the marketing, sales and distribution of pharmaceutical compounds or products, or if such dispute is with respect to the NHI Price Listing, an independent third party expert with at least ten (10) years of experience in regulatory matters and direct experience negotiating or advising as an expert on matters related to the NHI Price determination. If the Parties cannot agree on such expert within such time period, each Party shall nominate one independent expert within such ten (10)-day period, and the two experts so selected shall nominate one independent expert within ten (10) calendar days of their nomination. Such independent expert agreed by the Parties or nominated by the two experts nominated by the Parties shall be referred to as the **"Presiding Expert"**. No person nominated by a Party or appointed by the experts shall be entitled to act as the Presiding Expert unless such person satisfies the qualications set out above. Any person appointed or selected as the Presiding Expert in accordance with the above provisions shall be entitled to act as such expert provided that before accepting such appointment, the proposed Presiding Expert shall have fully disclosed in writing any interest or duty which conflicts or may conflict with the function under the appointment and/or may prejudice an opinion. No person shall, without the prior written agreement of both Parties, be appointed as expert who is, or has been, an employee of either Party or either Party's Affiliate or who is, or has been, a consultant to or contractor of either Party or either Party's Affiliate or who holds any financial interest in either Party or either Party's Affiliate. No person shall be appointed as a Presiding Expert who has not agreed to hold in confidence any and all information furnished by the Parties in connection with the dispute and the existence of the dispute and the outcome thereof;

(c) Within ten (10) days of its appointment, the Presiding Expert shall set a date for the hearing, which date shall be no more than thirty (30) days after the date the Presiding Expert has accepted the appointment;

(d) The Expert Determination shall be in an accelerated form; accordingly, at least fourteen (14) calendar days prior to the hearing, each Party shall provide the Presiding Expert with a proposed resolution, along with supporting documentation (each, a **"Proposed Resolution"**) to the issue in question. Such Proposed Resolution may be no more than thirty (30) pages, single spaced, single-sided (inclusive of any graphs or exhibits, and secondary materials), and must clearly provide and identify the Party's position with respect to the disputed matter(s) (**"Position"**) and shall be written in the English language;

(e)After receiving both Parties' Proposed Resolutions, the Presiding Expert will distribute each Party's Proposed Resolution to the other Party. Seven (7) calendar days in advance of the hearing (described in clause (f) below), the Parties shall submit to the Presiding Expert and exchange response briefs of no more than ten (10) pages, with the same rules applied as to the Proposed Resolution. The Parties' Proposed Resolution and responsive briefs may also include or attach demonstratives and/or expert opinion based on the permitted documentary evidence, subject to the page limits. Neither Party may have any other communications (either written or oral) with the Presiding Expert other than for the sole purpose of engaging the Presiding Expert or as expressly permitted in this Section 17.3.2;

(f) The hearing shall consist of a one (1) day hearing of no longer than eight (8) hours, such time to be split equally between the Parties, in the form of presentations by counsel and/or employees and officers of the Parties. No live witnesses shall be permitted except expert witnesses whose

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opinions were provided with the Parties' briefs. The Presiding Expert shall determine whether to hold the meeting in person, in which case it will be held in Tokyo, Japan or by video or teleconference and all hearings and meetings shall be conducted in the English language;

(g) No later than ten (10) calendar days following the hearing, the Presiding Expert shall issue his or her written decision. The Presiding Expert shall take into due consideration each Party's Position and changes in the market environment of the Product but shall be under no obligation to select one Party's Proposed Resolution as his or her decision. The Presiding Expert's decision shall be final and binding on the Parties and the written decision by the Presiding Expert shall constitute a binding agreement between the Parties that may be enforced in accordance with its terms. Each Party shall bear its own costs and expenses in connection with such Expert Determination, and shall share equally the experts' fees and expenses;

(h) The violation of one of the time limits prescribed in this Section 17.3.2 by the expert shall not affect the expert's competence to decide on the subject matter, and shall not affect the final and binding decision rendered by the expert, unless otherwise agreed by the Parties; and

(i) The above Expert Determination shall be the exclusive and binding remedy of either Party if the Parties cannot agree on those matters designated in this Agreement as being subject to Expert Determination, with the exception of Section 12.5 regarding material safety risk.

17.3.3 **Injunctive Relief.** Nothing contained in this Article 17 shall prevent either Party from resorting to judicial process if injunctive or other equitable relief from a court is necessary to prevent serious and irreparable injury to one Party or to others. The use of arbitration procedures will not be construed under the doctrine of laches, waiver or estoppel to affect adversely either Party's right to assert any claim or defense.

18. PUBLICITY AND DISCLOSURES

18.1 On or after the Effective Date of this Agreement, the Parties shall issue a press release substantially in a form to be agreed upon by the Parties. Thereafter, Distributor and Capricor may each disclose to third parties the information contained in such press release without the need for further approval by the other Party, provided that such information is still accurate. Any subsequent press release will contain the same accuracy and truthfulness as the original press release. No other press releases or public disclosures of the transaction contemplated by this Agreement may be made that discloses additional information about such transactions without the mutual consent of the other Party or to the extent required by applicable law, rule or regulation (including stock exchange requirements). To the extent that a release of information is required by applicable law, rule or regulation (including stock exchange requirements), the disclosing Party will use Commercially Reasonable Efforts to ensure that the content is accurate and in accordance with reasonable business standards and will, to the extent practicable, provide the other Party with advance notice of the proposed disclosure and an opportunity to review and comment upon such disclosure. A copy of this Agreement may be filed with the Securities and Exchange Commission, The New York Stock Exchange, the NASDAQ Market and/or the Tokyo Stock Exchange as required by applicable Regulations. In connection with such filing, the Parties will endeavor to obtain confidential treatment of economic and trade secret information.

18.2The restrictions contained in Section 18.1 will not apply to any disclosures to any prospective investor, acquirer, financing source, analyst, consultant, agent, representative, successor or finder, or any licensee of Capricor, or any other third party with whom Capricor is considering entering into a commercial relationship including but not limited to business alliance or M&A provided that Capricor takes reasonable precautions to maintain confidentiality prior to disclosure. Capricor will have taken reasonable precautions for purpose of this Agreement if it obtains a written confidentiality agreement with the intended recipient containing confidentiality provisions substantially similar to those contained in Article 13 of this Agreement. Capricor shall indemnify and hold harmless Distributor for any subsequent breach of such confidentiality agreement by such recipient. Any information that is now, or hereafter becomes generally known or available to the public will be excluded from the prohibitions of this Article 18. In addition to the foregoing, Capricor shall have the right to use without further consent, the names or marks of Distributor on Capricor's website, corporate presentations, and in media segments, provided that Capricor shall not change or modify such names, marks, or logos of Distributor.

19. **GENERAL PROVISIONS**

19.1**Governing Law and Jurisdiction**. This Agreement shall be governed by and construed under the laws of the State of New York, USA. The UN Convention on Contracts for the International Sale of Goods shall not apply.

19.2**Entire Agreement**. This Agreement, including all exhibits attached hereto which are incorporated herein, constitute the entire agreement and understanding of the Parties with respect to the subject matter hereof, and supersedes all previous agreements by and between the Parties as well as all proposals, term sheets, oral or written, and all negotiations, conversations or discussions heretofore had between the Parties related hereto. Distributor acknowledges that it has not been induced to enter into this Agreement by any representations or statements, oral or written, not expressly contained herein.

19.3 **Amendment; Modification**. No modification or amendment to any provision of, nor any consent required by, this Agreement, nor any consent to any departure by either Party there from, shall in any event be effective unless the same shall be in writing and signed by the other Party and then such modification, amendment, or consent shall be effective only in the specific instance and for the purpose for which it is given. No notice to or demand on either Party in any case shall entitle such Party to any other or further notice or demand in the same, similar or other circumstances.

19.4**No Waiver**. To the fullest extent permitted by law, no failure or delay by a Party to insist upon the strict performance of any term, condition, covenant or agreement of this Agreement or any other agreement referred to herein, or to exercise any right, power or remedy hereunder or thereunder or consequent upon a breach hereof or thereof, shall constitute a waiver of any such term, condition, covenant, agreement, right, power or remedy or of any such breach, or preclude such Party from exercising any such right, power, or remedy at any later time or times.

19.5**Notices**. Any notice required or permitted to be given by either Party to the other under this Agreement shall be in writing addressed to the other Party at its registered office or principal place of business or such other address as may at the relevant time have been notified pursuant to this provision to the Party giving the notice. At the time of execution of this Agreement, notices shall be given as follows:

If to Distributor:

NIPPON SHINYAKU CO., LTD.
14, Nishinosho-Monguchicho,
Kisshoin, Minami-ku, Kyoto 601-8550, Japan
[***]

If to Capricor:With a copy to:

Capricor Therapeutics, Inc. General Counsel
10865 Road to the Cure8840 Wilshire Blvd., 2nd Floor
Suite 150Beverly Hills, CA 90211
San Diego, CA 92121
[***][***]

19.6**Assignment**. Distributor agrees that its rights and obligations under this Agreement may not be transferred or assigned, directly or indirectly, without the prior written consent of Capricor. Capricor shall be entitled to assign any or all of its rights and obligations hereunder to any other person or entity excluding any company that had or has been in litigation with Distributor in the period three (3) years prior to the Effective Date of this Agreement to the time of the intended assignment by Capricor, provided that such assignee shall assume all of Capricor's obligations hereunder. Any prohibited assignment shall be null and void. For purposes of clarity, nothing contained herein shall restrict or be construed to limit Capricor's right or the rights of a third party to enter into an acquisition agreement or other form of corporate transaction with Capricor, including, without limitation, a sale, merger, sale of substantially all assets, or change of control of Capricor.

19.7**Counterparts**. This Agreement shall be executed in two or more counterparts in the English language, and each such counterpart shall be deemed an original hereof. In case of any conflict between the English version and any translated version of this Agreement, the English version shall govern. All correspondence, documents and communications of any kind made under this Agreement shall be made in the English language.

19.8**Severability**. If any provision of this Agreement is held to be invalid, illegal, void or otherwise unenforceable in any jurisdiction by reason of any rule of law, administrative decision, judicial decision, public policy or otherwise, such provision shall be ineffective in such jurisdiction to the extent of such invalidity, illegality, voidness or unenforceability without affecting, impairing or invalidating any remaining provisions of this Agreement. Any such invalid, illegal, void or otherwise unenforceable provisions shall be replaced by valid enforceable substitute provisions that are as similar as possible to such invalid, illegal, void or otherwise unenforceable provisions with respect to the economic and other commercial effects upon the Parties, which substitute provisions shall be established pursuant to the dispute resolution procedure set forth in Article 17.

19.9**Headings; Captions**. The headings and captions of this Agreement are for convenience and reference only and are not to be used to explain, modify, amplify or interpret this Agreement.

19.10**Binding Effect**. Subject to the limitations on assignment contained in Section 19.6 above, this Agreement shall be binding on and inure to the benefit of the parties to this Agreement and their respective heirs, personal representatives, successors, and assigns.

19.11**Authorization**. If any signatory hereto is executing this Agreement on behalf of an entity, such individual represents and warrants that he or she is duly authorized to execute and deliver this Agreement on behalf of said entity and that this Agreement is binding upon said entity in accordance with its terms.

19.12 **Construction; Rules of Construction.** Interpretation of this Agreement will be governed by the following rules of construction: (a) words in the singular will be held to include the plural and vice versa, and words of one gender will be held to include any other gender as the context requires; (b) references to the terms "Section", "Exhibit", or "Schedule" are to a Section, Exhibit, or Schedule of this Agreement unless othenvise specified; (c) the terms "hereof', "hereby", "hereto", and derivative or similar words refer to this entire Agreement; (d) the word "including" and "includes" and words of similar import when used in this Agreement will mean "including without limitation," unless othenvise specified; (e) the word "or" will not be exclusive; (f) references to "written" or "in writing" include in electronic form; (g) each of the Parties has participated in the negotiation and drafting of this Agreement and if an ambiguity or question of interpretation should arise, this Agreement will be construed as if drafted jointly by the Parties and no presumption or burden of proof will arise favoring or burdening either Party by virtue of the authorship of any of the provisions in this Agreement or any interim drafts of this Agreement; (h) the word "shall" will be construed to have the same meaning and effect as the word "will"; (i) references to "days" will mean calendar days, unless otherwise specified; and (j) a reference to any Person includes such Person's successors and permitted assigns.

19.13 **Survival.** Notwithstanding any other provision of this Agreement to the contrary, the provisions of Articles 1, 3, 11, 17 and 19 and Sections 2.6, 4.2, 5.2.4, 5.5.2, 5.5.4, 5.7.1, 5.7.2, 5.9.2, 5.11, 5.13, 5.15, 5.16, 5.17, 6.8, 8.1.3, 8.2, 8.3, 8.5, 10.2, 10.3, 10.4, 10.5, 12.1, 12.2, 12.3, 12.4, 13.3, 14.1.2, 14.5, 15.3, 15.4, 15.5 and 18.1 shall survive the expiration or termination of this Agreement as necessary to give full effect to all of the provisions contained therein, provided that (i) the provisions of Sections 2.6, 5.5.2 and 5.7.2 shall survive the expiration or termination of this Agreement for three (3) months, (ii) the provisions of Sections 5.5.4 and 5.9.2 shall survive the expiration or termination of this Agreement for twelve (12) months and (iii) the provisions of Article 3, Sections 5.2.4, 5.7.1, 5.16, 8.1.3, 8.2 and 8.3 shall apply only to the payment obligations accruing through the date of the expiration or termination of this Agreement.

IN WITNESS WHEREOF, the Parties have executed this Agreement as of the Effective Date.

CAPRICOR THERAPEUTICS, INC.NIPPON SHINYAKU CO., LTD.

By: /s/ Linda Marban By: /s/ Toru Nakai
Name: Linda MarbánName: Toru Nakai
Its: Chief Executive OfficerIts: President
Date: February 10, 2023 Date: February 13, 2023

LIST OF EXHIBITS

EXHIBIT A

PRODUCT PRICING

Transfer Price

[***]

Supply Price

During the term of the Agreement, Distributor shall pay to Capricor in US Dollars the amount calculated by the following formula on an annual basis

Formula,

[***]

Net Sales

"**Net Sales**" means the gross amounts billed or invoiced with respect to sales of the Product by Distributor, Distributor's Affiliates, agents, representatives or subdistributors to any Wholesaler within the Territory during the term of this Agreement, calculated in the same manner as reported in such entity's audited financial statements, less the following to the extent actually incurred:

(a) Credits, refunds or allowances granted upon returns, rejections or recalls and for retroactive price reductions or billing errors;

(b) Rebates, chargeback payments or credits or other equivalents thereof to formularies, government or government agency programs, trade customers, managed health care organizations and pharmacy benefit managers (or equivalents thereof) to obtain listing or purchase of the applicable Products; and

(c) Bad debts, uncollectible amounts, and collection costs relating to the sale of Products that are actually written off.

Currency Exchange Rate

The rate of exchange to be used in computing any conversion of the Net Sales from Japanese Yen to US Dollars (which will be used to calculate the definitive figure of the Supply Price quarterly) shall be the arithmetic average of Monthly-Average TTS rate (published by Mitsubishi UFJ Research and Consulting Co., Ltd.) during an applicable quarter.

EXHIBIT B

TRADEMARKS

To be determined

EXHIBIT C

SALES MILESTONES

[***]

EXHIBIT D

PROCEDURES FOR PRODUCT RETURNS

1. **General Principles**

All returned goods must include a Return Goods Authorization number ("**RGA**") issued by Capricor. Any goods returned to Capricor without an RGA will not be eligible for credit and/or replacement, and will not be returned to Distributor. This policy applies to all returns for any reason, including but not limited to transportation errors, damaged products, defective products, product complaints and/or warranty claims.

2. **Return Authorization Process**

Prior to returning any Capricor product for credit consideration or product replacement, Distributor must request pre-approval for the return by contacting Capricor's Customer Service and completing the RGA Form.

To receive an RGA, Distributor must provide all of the following information on the RGA form: (a) Distributor name; (b) lot number; (c) quantity of each item to be returned; (d) invoice number and (if available) purchase order number; and (e) reason for return.

Upon receipt of a complete RGA form, Customer Service will issue an RGA, which Distributor can use to return the goods, following the procedure in Section 3 (Return Location) below.

3. **Return Location**

After receiving a completed RGA from Distributor, Capricor will validate that all required information has been provided and that all conditions for return of goods have been met. Upon validation, Customer Service will confirm to Distributor that the RGA has been authorized. Within ten (10) business days of receiving RGA authorization, Distributor should return the approved units (and only the approved units) to Capricor via prepaid freight to the following address:

All returned products must be accompanied with the RGA Form in its proper protective packaging and the RGA Number must be written on outside of the box used to return the shipment.

EXHIBIT E

PATENTS COVERING THE PRODUCT OR USE OF THE PRODUCT IN THE TERRITORY

[***]800-468-9716.

Exhibit 21.1

SUBSIDIARIES OF THE REGISTRANT

LEGAL NAME	JURISDICTION OF ORGANIZATION
Capricor, Inc.	Delaware

Exhibit 23.1

CONSENT OF INDEPENDENT REGISTERED PUBLIC ACCOUNTING FIRM

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

We consent to the incorporation by reference in the Registration Statements of Capricor Therapeutics, Inc. on Form S-8 (File Nos. 333-152283, 333-175727, 333-194317, 333-215510, 333-239241, 333-253083, 333-262826, 333-269468 and 333-269468) 333-277154), Form S-3 (File Nos. 333-161339, 333-165167, 333-207149, 333- 207149, 333-212017, 333-219188, 333-227955, 333-238088, and 333-254363), and Form S-1 (File No. 333-235358) of our report dated March 17, 2023 March 8, 2024, relating to the consolidated financial statements, appearing in this Annual Report on Form 10-K.

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

March 17, 2023 8, 2024

Exhibit 31.1

CERTIFICATION OF PRINCIPAL EXECUTIVE OFFICER

I, Linda Marbán, Ph.D., certify that:

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

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

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

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

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

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

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

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

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

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

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

Date: March 17, 2023 March 8, 2024

/s/ Linda Marbán, Ph.D.

Name: Linda Marbán, Ph.D.

Title: Chief Executive Officer and Principal Executive Officer

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Exhibit 31.2

CERTIFICATION OF PRINCIPAL FINANCIAL OFFICER

I, Anthony J. Bergmann, certify that:

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

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

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

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

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

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

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

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

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

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

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

Date: March 17, 2023 March 8, 2024

/s/ Anthony J. Bergmann

Name: Anthony J. Bergmann
Title: Chief Financial Officer, Principal Financial and Principal Financial Accounting Officer

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Exhibit 32.1

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

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

(1) the Annual Report on Form 10-K of the Company for the period ended December 31, 2022 December 31, 2023 (the "**Report**") fully complies with the requirements of Section 13(a) or Section 15(d), as applicable, of the Securities Exchange Act of 1934, as amended; and

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

Date: March 17, 2023 March 8, 2024

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

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Exhibit 32.2

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

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

(1) the Annual Report on Form 10-K of the Company for the period ended December 31, 2022 December 31, 2023 (the "**Report**") fully complies with the requirements of Section 13(a) or Section 15(d), as applicable, of the Securities Exchange Act of 1934, as amended; and

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

Date: March 17, 2023 March 8, 2024

/s/ Anthony J. Bergmann
Name: Anthony J. Bergmann

Title: Chief Financial Officer, Principal Financial and Principal Financial Accounting Officer

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Exhibit 97

CAPRICOR THERAPEUTICS, INC.

POLICY ON RECOUPMENT OF INCENTIVE COMPENSATION

Introduction

The Board of Directors (the "**Board**") of **Capricor Therapeutics, Inc.** (the "**Company**") has adopted this Policy on Recoupment of Incentive Compensation (this "**Policy**"), which provides for the recoupment of compensation in certain circumstances in the event of a restatement of financial results by the Company. This Policy shall be interpreted to comply with the requirements of U.S. Securities and Exchange Commission ("**SEC**") rules and Nasdaq Stock Market ("**Nasdaq**") listing standards implementing Section 954 of the Dodd-Frank Wall Street Reform and Consumer Protection Act of 2010 (the "**Dodd-Frank Act**") and, to the extent this Policy is in any manner deemed inconsistent with such rules, this Policy shall be treated as retroactively amended to be compliant with such rules.

Administration

This Policy shall be administered by the Company's Compensation Committee. Any determinations made by the Compensation Committee shall be final and binding on all affected individuals. The Compensation Committee is authorized to interpret and construe this Policy and to make all determinations necessary, appropriate or advisable for the administration of this Policy, in all cases consistent with the Dodd-Frank Act. The Board or Compensation Committee may amend this Policy from time to time in its discretion.

Covered Executives

This Policy applies to any current or former "executive officer," within the meaning of Rule 10D-1 under the Securities Exchange Act of 1934, as amended, of the Company or a subsidiary of the Company (each such individual, an "**Executive**"). This Policy shall be binding and enforceable against all Executives and their beneficiaries, executors, administrators, and other legal representatives.

Recoupment Upon Financial Restatement

If the Company is required to prepare an accounting restatement due to the material noncompliance of the Company with any financial reporting requirement under the securities laws, including any required accounting restatement to correct an error in previously issued financial statements that is material to the previously issued financial statements, or that would result in a material misstatement if the error were corrected in the current period or left uncorrected in the current period (a "**Financial Restatement**"), the Compensation Committee shall cause the Company to recoup from each Executive, as promptly as reasonably possible, any erroneously awarded Incentive-Based Compensation, as defined below.

No-Fault Recovery

Recoupment under this Policy shall be required regardless of whether the Executive or any other person was at fault or responsible for accounting errors that contributed to the need for the Financial Restatement or engaged in any misconduct.

Compensation Subject to Recovery; Enforcement

This Policy applies to all compensation granted, earned or vested based wholly or in part upon the attainment of any financial reporting measure determined and presented in accordance with the accounting principles used in preparing the Company's financial statements, and any measure that is derived wholly or in part from such measures, whether or not presented within the Company's financial statements or included in a filing with the SEC, including stock price and total shareholder return ("**TSR**"), including but not limited to performance-based cash, stock, options or other equity-based awards paid or granted to the Executive ("**Incentive-Based Compensation**"). Compensation that is granted, vests or is earned based solely upon the occurrence of non-financial events,

such as base salary, restricted stock or options with time-based vesting, or a bonus awarded solely at the discretion of the Board or Compensation Committee and not based on the attainment of any financial measure, is not subject to this Policy.

In the event of a Financial Restatement, the amount to be recovered will be the excess of (i) the Incentive-Based Compensation received by the Executive during the Recovery Period (as defined below) based on the erroneous data and calculated without regard to any taxes paid or withheld, over (ii) the Incentive-Based Compensation that would have been received by the Executive had it been calculated based on the restated financial information, as determined by the Compensation Committee. For purposes of this Policy, "**Recovery Period**" means the three completed fiscal years immediately preceding the date on which the Company is required to prepare the Financial Restatement, as determined in accordance with the last sentence of this paragraph, or any transition period that results from a change in the Company's fiscal year (as set forth in Section 5608(b)(i)(D) of the Nasdaq Listing Rules). The date on which the Company is required to prepare a Financial Restatement is the earlier to occur of (A) the date the Board or a Board committee (or authorized

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officers of the Company if Board action is not required) concludes, or reasonably should have concluded, that the Company is required to prepare a Financial Restatement or (B) the date a court, regulator, or other legally authorized body directs the Company to prepare a Financial Restatement.

For Incentive-Based Compensation based on stock price or TSR, where the amount of erroneously awarded compensation is not subject to mathematical recalculation directly from the information in the Financial Restatement, then the Compensation Committee shall determine the amount to be recovered based on a reasonable estimate of the effect of the Financial Restatement on the stock price or TSR upon which the Incentive-Based Compensation was received and the Company shall document the determination of that estimate and provide it to Nasdaq.

Incentive-Based Compensation is considered to have been received by an Executive in the fiscal year during which the applicable financial reporting measure was attained or purportedly attained, even if the payment or grant of such Incentive-Based Compensation occurs after the end of that period.

The Company may use any legal or equitable remedies that are available to the Company to recoup any erroneously awarded Incentive-Based Compensation, including but not limited to by collecting from the Executive cash payments or shares of Company common stock from or by forfeiting any amounts that the Company owes to the Executive. Executives shall be solely responsible for any tax consequences to them that result from the recoupment or recovery of any amount pursuant to this Policy, and the Company shall have no obligation to administer the Policy in a manner that avoids or minimizes any such tax consequences.

No Indemnification

The Company shall not indemnify any Executive or pay or reimburse the premium for any insurance policy to cover any losses incurred by such Executive under this Policy or any claims relating to the Company's enforcement of rights under this Policy.

Exceptions

The compensation recouped under this Policy shall not include Incentive-Based Compensation received by an Executive (i) prior to beginning service as an Executive or (ii) if he or she did not serve as an Executive at any time during the performance period applicable to the Incentive-Based Compensation in question. The Compensation Committee (or a majority of independent directors serving on the Board) may determine not to seek recovery from an Executive in whole or part to the extent it determines in its sole discretion that such recovery would be impracticable because (A) the direct expense paid to a third party to assist in enforcing recovery would exceed the recoverable amount (after having made a reasonable attempt to recover the erroneously awarded Incentive-Based Compensation and providing corresponding documentation of such attempt to Nasdaq), (B) recovery would violate the home country law that was adopted prior to November 28, 2022, as determined by an opinion of counsel licensed in the applicable jurisdiction that is acceptable to and provided to Nasdaq, or (C) recovery would likely cause the Company's 401(k) plan or any other tax-qualified retirement plan to fail to meet the requirements of Section 401(a)(13) or Section 411(a) of the Internal Revenue Code of 1986, as amended, and the regulations thereunder.

Other Remedies Not Precluded

The exercise by the Compensation Committee of any rights pursuant to this Policy shall be without prejudice to any other rights or remedies that the Company, the Board or the Compensation Committee may have with respect to any Executive subject to this Policy, whether arising under applicable law (including pursuant to Section 304 of the Sarbanes-Oxley Act of 2002), regulation or pursuant to the terms of any other policy of the Company, employment agreement, equity award, cash incentive award or other agreement applicable to an Executive. Notwithstanding the foregoing, there shall be no duplication of recovery of the same Incentive-Based Compensation under this Policy and any other such rights or remedies.

Acknowledgment

To the extent required by the Compensation Committee, each Executive shall be required to sign and return to the Company the Acknowledgement Form attached hereto as **Exhibit A** pursuant to which such Executive will agree to be bound by the terms of, and comply with, this Policy. For the avoidance of doubt, each Executive shall be fully bound by, and must comply with, the Policy, whether or not such Executive has executed and returned such Acknowledgment Form to the Company.

Effective Date and Applicability

This Policy has been adopted by the Board on November 27, 2023, and shall apply to any Incentive-Based Compensation that is received by an Executive on or after October 2, 2023.

EXHIBIT A

DODD-FRANK COMPENSATION CLAWBACK POLICY

ACKNOWLEDGEMENT FORM

Capitalized terms used but not otherwise defined in this Acknowledgement Form (this "***Acknowledgement Form***") shall have the meanings ascribed to such terms in the Policy. By signing this Acknowledgement Form, the undersigned acknowledges, confirms and agrees that the undersigned: (i) has received and reviewed a copy of the Policy; (ii) is and will continue to be subject to the Policy and that the Policy will apply both during and after the undersigned's employment with the Company; and (iii) will abide by the terms of the Policy, including, without limitation, by reasonably promptly returning any recoverable compensation to the Company as required by the Policy, as determined by the Compensation Committee in its sole discretion.

Signature: _____

Print Name: _____

Date: _____

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