CAPRICOR THERAPEUTICS, INC.
Form 424B5
October 19, 2017

PROSPECTUS SUPPLEMENT Filed Pursuant to Rule 424(b)(5)
(To Prospectus dated October 26, 2015) Registration No. 333-207149

$14,000,000

Common Stock

CAPRICOR THERAPEUTICS, INC.

Capricor Therapeutics, Inc. has entered into a Common Stock Sales Agreement, or the Sales Agreement, with H.C. Wainwright & Co. LLC, or Wainwright, relating to the sale of shares of our common stock, par value $0.001 per share, offered by this prospectus supplement. In accordance with the terms of the Sales Agreement, we may offer and sell shares of our common stock having an aggregate offering price of up to $14,000,000 from time to time through Wainwright acting as agent.

Sales of shares of our common stock, if any, under this prospectus supplement will be made in sales deemed to be an "at the market offering" as defined in Rule 415 promulgated under the Securities Act of 1933, as amended, or the Securities Act. Wainwright will act as sales agent on a commercially reasonable efforts basis consistent with its normal trading and sales practices, on mutually agreed terms between Wainwright and us. There is no arrangement for funds to be received in any escrow, trust or similar arrangement.

Wainwright will be entitled to compensation at a fixed commission rate of 3% of the gross proceeds of each sale of shares of our common stock. In connection with the sale of our shares of common stock on our behalf, Wainwright may be deemed to be an "underwriter" within the meaning of the Securities Act and the compensation of Wainwright may be deemed to be underwriting commissions or discounts. We have also agreed to provide indemnification and contribution to Wainwright with respect to certain liabilities, including liabilities under the Securities Act.

Our common stock is listed on The NASDAQ Capital Market under the symbol "CAPR." On October 18, 2017, the last sale price of our shares of common stock as reported on The NASDAQ Capital Market was $2.45 per share. As of October 2, 2017, a date within 60 days of the date of this prospectus supplement, the aggregate market value of our outstanding shares of common stock held by non-affiliates, or public float, was approximately $58.3 million based on 25,184,388 outstanding shares of common stock, of which approximately 16.9 million shares are held by non-affiliates, and a per share price of $3.45, based on the last sale price of our common stock on October 2, 2017.

One-third of our public float, calculated in accordance with Instruction I.B.6 of Form S-3 as of October 19, 2017, is equal to approximately $19.4 million. During the 12 calendar months prior to and including the date of this prospectus supplement, we have sold securities with an aggregate market value of approximately $5.0 million pursuant to General Instruction I.B.6 of Form S-3. In no event will we sell securities registered on this registration statement in a public primary offering with a value exceeding more than one-third of our public float in any 12-month period so long as our public float remains below $75.0 million pursuant to General Instruction I.B.6 of Form S-3.

Investing in our common stock involves risks, including those described in the "Risk Factors" section beginning on page S-4 of this prospectus supplement and on page 4 of the prospectus accompanying this prospectus supplement and in our Annual Report on Form 10-K for the fiscal year ended December 31, 2016 and Quarterly Report on Form 10-Q for the fiscal quarter ended June 30, 2017.

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

H.C. Wainwright & Co.

The date of this prospectus supplement is October 19, 2017

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About This Prospectus Supplement

This prospectus supplement and the accompanying prospectus form a part of a registration statement on Form S-3 that we filed with the SEC utilizing a "shelf" registration process. This document contains two parts. The first part consists of this prospectus supplement, which provides you with specific information about this offering. The second part, the accompanying prospectus, provides more general information, some of which may not apply to this offering. Generally, when we refer only to the "prospectus," we are referring to both parts combined.

Before you invest, you should carefully read this prospectus supplement, the accompanying prospectus, all information incorporated by reference herein and the additional information described under "Where You Can Find More Information" and "Information Incorporated by Reference". These documents contain information you should consider when making your investment decision. To the extent that any statement that we make in this prospectus supplement is inconsistent with statements made in any documents incorporated by reference, the statements made in this prospectus supplement will be deemed to modify or supersede those made in such documents incorporated by reference.

You should rely only on the information contained or incorporated by reference in this prospectus supplement, the accompanying prospectus, the documents incorporated by reference herein and any free writing prospectus we provide you. We have not, and Wainwright has not, authorized anyone to provide you with different information. If anyone provides you with different or inconsistent information, you should not rely on it. We are not, and Wainwright is not, making an offer to sell these securities in any jurisdiction where the offer or sale thereof is not permitted. You should assume that the information appearing in this prospectus supplement, the accompanying prospectus, the documents incorporated by reference herein and any free writing prospectus we provide you is accurate only as of the date on those respective documents. Our business, financial condition, results of operations and prospects may have changed since those dates. You should read this prospectus supplement, including the documents incorporated by reference herein, and the accompanying prospectus when making your investment decision. You should also read and consider the information in the documents we have referred you to in the sections of this prospectus supplement entitled "Where You Can Find More Information" and "Information Incorporated by Reference." The distribution of this prospectus supplement and the offering of the common stock in certain jurisdictions may be restricted by law. Persons outside the United States, or the U.S., who come into possession of this prospectus supplement must inform themselves about, and observe any restrictions relating to, the offering of the common stock and the distribution of this prospectus supplement outside the U.S. This prospectus supplement does not constitute, and may not be used in connection with, an offer to sell, or a solicitation of an offer to buy, any securities offered by this prospectus supplement by any person in any jurisdiction in which it is unlawful for such person to make such an offer or solicitation.

Unless otherwise indicated, information contained in this prospectus supplement or the documents incorporated by reference herein concerning our industry and the markets in which we operate, including our general expectations and market position, market opportunity and market share, is based on information from our own management estimates and research, as well as from industry and general publications and research, surveys and studies conducted by third

parties. Management estimates are derived from publicly available information, our knowledge of our industry and assumptions based on such information and knowledge, which we believe to be reasonable. In addition, assumptions and estimates of our and our industry's future performance are necessarily subject to a high degree of uncertainty and risk due to a variety of factors, including those described in "Risk Factors" in this prospectus supplement, in the accompanying prospectus, in our Annual Report on Form 10-K for the fiscal year ended December 31, 2016, and in our Quarterly Report on Form 10-Q for the fiscal quarter ended June 30, 2017, which are incorporated by reference into this prospectus supplement. These and other important factors could cause our future performance to differ materially from our assumptions and estimates. See "Disclosure Regarding Forward-Looking Statements."

Unless the context requires otherwise or unless otherwise noted, all references to "Capricor" are to Capricor, Inc., a Delaware corporation, and all references to "Capricor Therapeutics," "we," "us" or "our" are to Capricor Therapeutics, Inc. and its subsidiaries, including Capricor.

General information about us can be found on our website at *www.capricor.com*. The information on our website is for informational purposes only and should not be relied on for investment purposes. The information on our website is not incorporated by reference into either this prospectus supplement or the accompanying prospectus and should not be considered part of this or any other report filed with the SEC.

Prospectus Supplement Summary

This summary highlights selected information that is presented in greater detail elsewhere in this prospectus supplement or any documents incorporated by reference in this prospectus supplement. Because it is only a summary, it does not contain all of the information you should consider before investing in our common stock, and it is qualified in its entirety by, and should be read in conjunction with, the more detailed information included elsewhere in this prospectus supplement. Before you decide whether to purchase shares of our common stock, you should read this entire prospectus supplement, the accompanying prospectus and any related free-writing prospectus carefully, including the risks of investing in our securities discussed under the heading "Risk Factors" contained in this prospectus supplement, the accompanying prospectus and any related free writing prospectus, and under similar headings in the other documents that are incorporated by reference into this prospectus supplement. You should also carefully read the information incorporated by reference into this prospectus supplement, including our financial statements, and the exhibits to the registration statement of which this prospectus supplement is a part.

Company Overview

Capricor Therapeutics, Inc. is a clinical-stage biotechnology company focused on the discovery, development and commercialization of first-in-class biological therapies for the treatment of diseases.

We currently have four drug candidates, two of which are in various stages of active development. Our current research and development efforts are focused on CAP-1002 (allogeneic cardiosphere-derived cells, or CDCs) and CAP-2003 (CDC exosomes). CAP-1002 is the subject of two ongoing clinical trials, and we expect to enter CAP-2003 into clinical development in 2018. CAP-1001 (autologous CDCs) was the subject of the Phase I CADUCEUS trial, which was sponsored by Cedars-Sinai Medical Center and Johns Hopkins University, and is not in active development. Both CAP-1002 and CAP-1001 are derived from cardiospheres, or CSps, and we do not plan to develop CSps as a therapeutic.

- **CAP-1002**: Our core therapeutic technology is based on the cardiosphere-derived cell, or CDC, a type of cardiac progenitor cell that composes a minor fraction of the cardiac muscle cell population and was first identified in the academic laboratory of Dr. Eduardo Marbán, the scientific founder of our subsidiary, Capricor Inc. CAP-1002 has been shown to exert potent immunomodulatory activity and alter the immune system's activity to encourage cellular regeneration. Since their initial report in 2007, CDCs have been the subject of over 100 peer-reviewed scientific publications and have been administered to approximately 140 human subjects across several clinical trials. We are currently developing allogeneic CDCs (CAP-1002) as our lead product candidate for the treatment of Duchenne muscular dystrophy. We are currently conducting two clinical trials of CAP-1002, both of which are in various stages of follow-up: the Phase I/II HOPE-Duchenne trial in patients with Duchenne muscular dystrophy-associated cardiomyopathy and the Phase II portion of the Phase I/II ALLSTAR trial in patients who have had a myocardial

infarction. Subject to regulatory approval, we expect to initiate the randomized, double-blind, placebo-controlled HOPE-2 clinical trial of intravenous (IV), repeat-dose CAP-1002 in the first quarter of 2018. We have completed the Phase I portion of the Phase I/II DYNAMIC trial in patients with advanced heart failure.

- **CAP-2003**: Exosomes are nano-sized, membrane-enclosed extracellular vesicles, or "bubbles" that are secreted by cells and contain bioactive molecules, including proteins, RNAs and microRNAs. They act as messengers to regulate the functions of neighboring cells, and pre-clinical research has shown that exogenously-administered exosomes can direct or, in some cases, re-direct cellular activity, supporting their therapeutic potential. Their size, ease of crossing cell membranes, and ability to communicate in native cellular language makes them an exciting class of potential therapeutic agents. We are currently developing exosomes produced by CDCs (CAP-2003) as a product candidate for the treatment of certain cardiac and other inflammatory conditions. CAP-2003 comprises exosomes secreted by CDCs, and is believed to mediate many of the effects that are observed with these cells, including anti-inflammatory, anti-angiogenic, anti-apoptotic, and anti-fibrotic effects. We are planning to evaluate CAP-2003 in preclinical studies for the treatment of hypoplastic left heart syndrome, or HLHS. We hope to submit an Investigational New Drug application, or IND, for CAP-2003 to enable clinical development in 2018.

For a complete description of our business, financial condition, results of operations and other important information, we refer you to our filings with the SEC that are incorporated by reference in this prospectus supplement, including our Annual Report on Form 10-K for the year ended December 31, 2016. For instructions on how to find copies of these documents, see "Where You Can Find More Information".

Our Contact Information

Our principal executive offices are located at 8840 Wilshire Blvd., 2nd Floor, Beverly Hills, California 90211, and our telephone number is (310) 358-3200. Our website address is *www.capricor.com*. We have included our website address in this prospectus supplement solely as an inactive textual reference. We do not incorporate the information on, or accessible through, our website into this prospectus supplement, and you should not consider any information on, or accessible through, our website as part of this prospectus supplement.

The Offering

The following is a brief summary of the terms of this offering.

Issuer	Capricor Therapeutics, Inc.
Common stock to be offered by us pursuant to this prospectus supplement	Shares having an aggregate offering price of up to $14,000,000.
Common stock to be outstanding after the offering	Up to 28,309,595 shares, assuming a sales price of $2.45 per share, which was the closing price on The NASDAQ Capital Market on October 18, 2017. The actual number of shares issued and outstanding will vary depending on the sales price under this offering.
Manner of offering	“At the market offering” in which sales may be made from time to time at prevailing market prices through our agent, Wainwright. Wainwright will use commercially reasonable efforts consistent with its normal trading and sales practices, on terms mutually agreed upon between Wainwright and us.
Use of proceeds	We intend to apply the net proceeds of this offering for research related to our product candidates, manufacturing of our products, working capital and general corporate purposes, which may include, without limitation, engaging in acquisitions or other business combinations. We reserve the right, at the sole discretion of our Board of Directors, to reallocate the proceeds of this offering in response to developments in our business and other factors. See “Use of Proceeds” on page S-8.
NASDAQ symbol for common stock	Our common stock is listed on The NASDAQ Capital Market under the symbol “CAPR.”
Risk factors	This investment involves a high degree of risk. See “Risk Factors” and other information included in this prospectus supplement, the accompanying prospectus and the documents incorporated by reference in this prospectus supplement and the accompanying prospectus for a discussion of factors you should carefully consider before deciding to invest in our securities.

Except as otherwise indicated, the information contained in this prospectus supplement assumes the sale of all of the shares offered hereby.

The number of shares of common stock to be outstanding after this offering is based on 22,595,310 shares of common stock outstanding as of June 30, 2017, and gives effect to the sale and issuance of up to 5,714,285 shares of common stock, assuming a sales price of $2.45 per share, which was the closing price of our common stock on The NASDAQ Capital Market on October 18, 2017. The actual number of shares issued and outstanding will vary depending on the sales price under this offering and does not take into account, as of June 30, 2017:

- 7,095,579 shares of common stock issuable upon the exercise of options outstanding as of June 30, 2017 with a weighted-average exercise price of $1.66 per share;

- 1,081,716 shares of common stock issuable upon the exercise of outstanding warrants as of June 30, 2017 with a weighted average exercise price of $4.01 per share;

- 401,793 shares of common stock reserved as of June 30, 2017 for future issuance under our (1) 2006 Stock Option Plan; (2) 2012 Restated Equity Incentive Plan; and (3) 2012 Non-Employee Director Stock Option Plan; and

- 2,589,078 shares of common stock issued subsequent to June 30, 2017, pursuant to our prior at the market offering with Wainwright.

Risk Factors

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

Risks Related to this Offering

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

Investors purchasing common stock in this offering may pay a price per share that substantially exceeds the as adjusted book value per share of our tangible assets after subtracting our liabilities. As a result, investors purchasing common stock in this offering will incur immediate dilution of $2.21 per share as of June 30, 2017, based on the assumed sale of 5,714,285 shares of common stock in this offering through Wainwright, at an assumed offering price of $2.45 per share, the last reported sales price for our common stock on October 18, 2017 and after deducting commissions and estimated aggregate offering expenses payable by us. For more information on the dilution you may suffer as a result of investing in this offering, see the section of this prospectus supplement entitled "Dilution". This dilution is due to the substantially lower price paid by our investors who purchased shares prior to this offering as compared to the price offered to the public in this offering. As a result of the dilution to investors purchasing shares in this offering, investors may receive significantly less than the purchase price paid in this offering, if anything, in the event of our liquidation.

The actual number of shares we will issue under the Common Stock Sales Agreement, at any one time or in total, is uncertain.

Subject to certain limitations in the Common Stock Sales Agreement with Wainwright and compliance with applicable law, we have the discretion to deliver placement notices to Wainwright at any time throughout the term of the Common Stock Sales Agreement. The number of shares that are sold by Wainwright after delivering a placement notice will fluctuate based on the market price of the common stock during the sales period and limits we set with Wainwright.

The market price of our common stock may be highly volatile.

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

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

- failure or discontinuation of any of our research or development programs;
- developments in establishing new strategic alliances or adverse developments with existing alliances;
- market conditions in the pharmaceutical, biotechnology and other healthcare related sectors;
- actual or anticipated fluctuations in our quarterly financial and operating results;
- developments or disputes concerning our intellectual property or other proprietary rights;
- introduction of technological innovations or new commercial products by us or our competitors;
- issues in manufacturing our drug candidates or drugs;
- issues with the supply or manufacturing of any devices or materials needed to manufacture or utilize our drug candidates;
- FDA or other United States 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 and if 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; 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. Additionally, the terms of our loan agreement with the California Institute for Regenerative Medicine restrict our ability to declare or pay dividends to our stockholders. 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 will have broad discretion in the use of the net proceeds from this offering and may not use them effectively.

We currently intend to use the net proceeds of this offering for working capital and general corporate purposes, which may include, without limitation, supporting asset growth and engaging in acquisitions or other business combinations, as further described in the section of this prospectus supplement entitled "Use of Proceeds". We will have broad discretion in the application of the net proceeds in the category of other working capital and general corporate purposes and investors will be relying on the judgment of our management regarding the application of the proceeds of this offering.

The amounts and timing of our use of the net proceeds from this offering will depend on a number of factors, such as the timing and progress of our research and development efforts, the timing and progress of any partnering and commercialization efforts, technological advances and the competitive environment for our products. The costs and timing of development activities, particularly conducting clinical trials and preclinical studies, are highly uncertain, subject to substantial risks and can often change. Depending on the outcome of these activities and other unforeseen events, our plans and priorities may change and we may apply the net proceeds of this offering in different manners than we currently anticipate.

The failure by our management to apply these funds effectively could harm our business, financial condition and results of operations. Pending their use, we may invest the net proceeds from this offering in short-term, interest-bearing instruments. These investments may not yield a favorable return to our stockholders.

Special Note Regarding Forward-Looking Statements

This prospectus supplement contains forward-looking statements within the meaning of Section 27A of the Securities Act of 1933, as amended, and Section 21E of the Securities Exchange Act of 1934, as amended, which statements involve substantial risks and uncertainties. Forward-looking statements generally relate to future events or our future financial or operating performance. In some cases, you can identify forward-looking statements because they contain words such as “may,” “will,” “should,” “expects,” “plans,” “anticipates,” “could,” “intends,” “target,” “projects,” “contemplate “estimates,” “predicts,” “potential” or “continue” or the negative of these words or other similar terms or expressions that concern our expectations, strategy, plans or intentions. Forward-looking statements contained in this prospectus supplement, the accompanying prospectus and the documents incorporated by reference in this prospectus supplement include, but are not limited to, statements about:

- the development of our drug candidates, including when we expect to undertake, initiate and complete clinical trials of our product candidates;
- expectation of or dates for commencement of clinical trials, investigational new drug filings and similar plans or projections;
- regulatory developments involving our drug candidates, including the ability to obtain regulatory approvals or otherwise bring products to market;
- the timing of regulatory approvals;
- our use of clinical research centers, third party manufacturers and other contractors;
- our ability to find collaborative partners for research, development and commercialization of potential products;
- our ability to manufacture products for clinical and commercial use;
- our ability to protect our patents and other intellectual property;
- our ability to market any of our products;
- our ability to compete against other companies and research institutions;

- our ability to expand our operations internationally;
- the effect of potential strategic transactions on our business;
- 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; and
- the volatility of our stock price.

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

You should not rely upon forward-looking statements as predictions of future events. We have based the forward-looking statements contained in this prospectus supplement primarily on our current expectations and projections about future events and trends that we believe may affect our business, financial condition, results of operations and prospects. The outcome of the events described in these forward-looking statements is subject to risks, uncertainties and other factors. Moreover, we operate in a very competitive and challenging environment. New risks and uncertainties emerge from time to time, and it is not possible for us to predict all risks and uncertainties that could have an impact on the forward-looking statements contained in this prospectus supplement. We cannot assure you that the results, events and circumstances reflected in the forward-looking statements will be achieved or occur, and actual results, events or circumstances could differ materially from those described in the forward-looking statements. Additionally, final data may differ significantly from preliminary data reported in this prospectus supplement.

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

This prospectus supplement also contains statistical data, estimates and forecasts that are based on independent industry publications or other publicly available information, as well as other information based on our internal sources. Although we believe that the third-party sources referred to in this prospectus supplement are reliable, we have not independently verified the information provided by these third parties. While we are not aware of any misstatements regarding any third-party information presented in this prospectus supplement, their estimates, in particular, as they relate to projections, involve numerous assumptions, are subject to risks and uncertainties, and are subject to change based on various factors.

Use of Proceeds

We may issue and sell up to an aggregate amount of $14,000,000 worth of our common stock from time to time through Wainwright, acting as agent. The amount of proceeds we will receive from this offering, if any, will depend upon the actual number of shares of our common stock sold and the market price at which such shares are sold. There can be no assurance that we will be able to sell any shares or fully utilize the Sales Agreement with Wainwright as a source of financing. Because there is no minimum offering amount required as a condition to close this offering, the net proceeds to us, if any, are not determinable at this time.

We currently intend to use the net proceeds from this offering, if any, for research related to our product candidates, manufacturing of our products, working capital and general corporate purposes, which may include, without limitation, engaging in acquisitions or other business combinations. The amounts and timing of our use of the net proceeds from this offering will depend on a number of factors, such as the timing and progress of our research and development efforts, the timing and progress of any partnering and commercialization efforts, technological advances and the competitive environment for our products. As of the date of this prospectus supplement, we cannot specify with certainty all of the particular uses for the net proceeds to us from this offering. Accordingly, our management will have broad discretion in the timing and application of these proceeds. We reserve the right, at the sole discretion of our Board of Directors, to reallocate the proceeds of this offering in response to developments in our business and any other factors.

Dilution

If you invest in this offering, your ownership interest will be diluted to the extent of the difference between the public offering price per share and the as adjusted net tangible book value per share of our common stock after giving effect to this offering.

Our net tangible book value as of June 30, 2017, was approximately $(6.7) million, or $(0.30) per share of common stock. Our net tangible book value per share represents total tangible assets less total liabilities, divided by the number of shares of common stock outstanding at June 30, 2017.

After giving effect to the assumed sale of our common stock in the aggregate of $14,000,000 offered at an assumed offering price of $2.45 per share, the last reported sales price for our common stock on October 18, 2017, and after deduction of commissions and estimated offering expenses payable by us, our as adjusted net tangible book value as of June 30, 2017 would have been approximately $6.8 million, or $0.24 per share of common stock. This amount represents an immediate increase in as adjusted net tangible book value of approximately $0.54 per share to our existing stockholders and an immediate dilution in the as adjusted net tangible book value of approximately $2.21 per share to investors participating in this offering at an assumed offering price of $2.45 per share.

Dilution per share to new investors is determined by subtracting the as adjusted net tangible book value per share after this offering from the public offering price per share paid by purchasers in this offering. The following table illustrates this dilution on a per share basis:

Assumed offering price per share		$2.45
Net tangible book value per share as of June 30, 2017	$(0.30)	
Increase in as adjusted net tangible book value per share attributable to this offering	0.54	
As adjusted net tangible book value per share after this offering		0.24
Dilution per share to new investors participating in this offering		$2.21

The table above assumes for illustrative purposes that an aggregate of 5,714,285 shares of our common stock are sold during the term of the Sales Agreement with Wainwright at a price of $2.45 per share, the last reported sales price for our common stock on The NASDAQ Capital Market on October 18, 2017, for aggregate gross proceeds of $14,000,000. Pursuant to the Sales Agreement with Wainwright, the shares are being sold from time to time at various prices. An increase of $1.00 per share in the price at which the shares are sold from the assumed offering price of $2.45 per share shown in the table above, assuming all of our common stock in the aggregate amount of $14,000,000 are sold at that price during the term of the Sales Agreement with Wainwright, would increase our pro forma net tangible book value per share after the offering to $0.26 per share and would increase the dilution in net tangible book

value per share to new investors in this offering to $3.19 per share, after deducting commissions and estimated aggregate offering expenses payable by us. A decrease of $1.00 per share in the price at which the shares are sold from the assumed offering price of $2.45 per share shown in the table above, assuming all of our common stock in the aggregate amount of $14,000,000 are sold at that price during the term of the Sales Agreement with Wainwright, would decrease our pro forma net tangible book value per share after the offering to $0.21 per share and would decrease the dilution in net tangible book value per share to new investors in this offering to $1.24 per share, after deducting commissions and estimated aggregate offering expenses payable by us. This information is supplied for illustrative purposes only.

The amounts above are based on 22,595,310 shares of common stock outstanding as of June 30, 2017 and do not take into account, as of June 30, 2017:

- 7,095,579 shares of common stock issuable upon the exercise of options outstanding as of June 30, 2017 with a weighted-average exercise price of $1.66 per share;

- 1,081,716 shares of common stock issuable upon the exercise of outstanding warrants as of June 30, 2017 with a weighted average exercise price of $4.01 per share;

- 401,793 shares of common stock reserved as of June 30, 2017 for future issuance under our (1) 2006 Stock Option Plan; (2) 2012 Restated Equity Incentive Plan; and (3) 2012 Non-Employee Director Stock Option Plan; and

- 2,589,078 shares of common stock issued subsequent to June 30, 2017, pursuant to our prior at the market offering with Wainwright.

Plan of Distribution

We have entered into the Sales Agreement with Wainwright, pursuant to which we may issue and sell up to an aggregate of $14,000,000 of our common stock from time to time through Wainwright acting as agent. Wainwright may sell our shares of common stock by any method permitted by law deemed to be an "at the market offering" as defined in Rule 415 promulgated under the Securities Act.

Wainwright will offer our common stock at prevailing market prices subject to the terms and conditions of the Sales Agreement as agreed upon by us and Wainwright. We will designate the number of shares which we desire to sell, the time period during which sales are requested to be made, any limitation on the number of shares that may be sold in one day and any minimum price below which sales may not be made. Either Wainwright or we may suspend the offering of our common stock being made under the Sales Agreement upon proper notice to the other party.

We will pay Wainwright in cash, upon each sale of our shares of common stock pursuant to the Sales Agreement, a commission equal to 3.0% of the gross proceeds from each sale of shares of our common stock. Because there is no minimum offering amount required as a condition to this offering, the actual total public offering amount, commissions and proceeds to us, if any, are not determinable at this time. Pursuant to the terms of the Sales Agreement, we agreed to reimburse Wainwright for the documented fees and costs of its legal counsel up to $20,000. Additionally, pursuant to the terms of the Sales Agreement, at the end of each calendar quarter during the term of the Sales Agreement, we have agreed to reimburse Wainwright for certain documented fees and costs of its legal counsel.

Settlement for sales of shares of our common stock will occur on the third trading day following the date on which any sales are made, or on some other date that is agreed upon by us and Wainwright in connection with a particular transaction, in return for payment of the net proceeds to us. There is no arrangement for funds to be received in an escrow, trust or similar arrangement. Sales of our shares of common stock as contemplated in this prospectus supplement will be settled through the facilities of The Depository Trust Company or by such other means as we and Wainwright may agree upon.

Wainwright will act as sales agent on a commercially reasonable efforts basis consistent with its normal trading and sales practices and applicable state and federal laws, rules and regulations and the rules of The Nasdaq Stock Market LLC. In connection with the sale of the shares of common stock on our behalf, Wainwright will be deemed to be an "underwriter" within the meaning of the Securities Act and the compensation of Wainwright will be deemed to be underwriting commissions or discounts. We have agreed to provide indemnification and contribution to Wainwright against certain civil liabilities, including liabilities under the Securities Act.

The offering of our shares of common stock pursuant to the Sales Agreement will terminate upon the earlier of the (i) sale of all of our shares of common stock provided for in this prospectus supplement, or (ii) termination of the Sales Agreement as permitted therein.

Wainwright and its affiliates may in the future provide various investment banking and other financial services for us and our affiliates, for which services they may in the future receive customary fees. To the extent required by Regulation M, Wainwright will not engage in any market making activities involving our shares of common stock while the offering is ongoing under this prospectus supplement. This summary of the material provisions of the Sales Agreement does not purport to be a complete statement of its terms and conditions. We are filing a copy of the Sales Agreement with the SEC on a Current Report on Form 8-K concurrently with the filing of this prospectus supplement.

Legal Matters

Certain legal matters relating to the issuance of the securities offered by this prospectus supplement will be passed upon for us by Sidley Austin LLP, Palo Alto, California. Wainwright is being represented in connection with this offering by Duane Morris LLP, Newark, New Jersey.

Experts

Rose, Snyder & Jacobs LLP, independent registered public accounting firm, has audited our financial statements included in our annual report on Form 10-K for the year ended December 31, 2016, which is incorporated by reference into this prospectus supplement and elsewhere in the registration statement of which this prospectus supplement is a part. Our financial statements are incorporated by reference in reliance on Rose, Snyder & Jacobs LLP's report, given on their authority as experts in accounting and auditing.

Where You Can Find More Information

We are a reporting company and file annual, quarterly and current reports, proxy statements and other information with the SEC. We have filed with the SEC a registration statement on Form S-3 under the Securities Act with respect to the securities being offered under this prospectus supplement. This prospectus supplement does not contain all of the information set forth in the accompanying prospectus, the registration statement and the exhibits to the registration statement. For further information with respect to us and the securities being offered under this prospectus supplement, we refer you to the accompanying prospectus, the registration statement and the exhibits and schedules filed as a part of the registration statement. You may read and copy the registration statement, as well as our reports, proxy statements and other information, at the SEC's Public Reference Room at 100 F Street, N.E., Washington, D.C. 20549. Please call the SEC at 1-800-SEC-0330 for more information about the operation of the Public Reference Room. The SEC maintains an Internet site that contains reports, proxy and information statements, and other information regarding issuers that file electronically with the SEC, including Capricor Therapeutics, Inc. The SEC's Internet site can be found at *http://www.sec.gov*.

Important Information Incorporated By Reference

The SEC allows us to "incorporate by reference" information into this prospectus supplement, which means that we can disclose important information to you by referring you to another document filed separately with the SEC. The documents incorporated by reference into this prospectus supplement contain important information that you should read about us.

The following documents are incorporated by reference into this prospectus supplement:

(a) The Registrant's Annual Report on Form 10-K for the fiscal year ended December 31, 2016, filed with the SEC on March 16, 2017;

(b) The Registrant's Quarterly Reports on Form 10-Q for the fiscal quarters ended March 31, 2017 and June 30, 2017, filed with the SEC on May 15, 2017 and August 14, 2017, respectively.

(c) The Registrant's Definitive Proxy Statement on Schedule 14A filed with the SEC on April 21, 2017;

(d) The Registrant's Current Reports on Form 8-K filed with the SEC on February 16, 2017, March 31, 2017, May 8, 2017 (as amended by the Registrant's Form 8-K/A filed with the SEC on May 9, 2017), May 12, 2017, June 13, 2017, June 20, 2017, July 3, 2017, July 7, 2017, and October 19, 2017; and

(e) The description of the Registrant's common stock contained in the Registrant's Registration Statement on Form 8-A filed on March 5, 2015, including any amendment or report filed for the purpose of updating such description.

Additionally, all reports and other documents subsequently filed by us pursuant to Sections 13(a), 13(c), 14 and 15(d) of the Securities Exchange Act of 1934, as amended, after the date of this prospectus supplement and prior to the termination or completion of this offering, shall be deemed to be incorporated by reference in this prospectus supplement and to be part hereof from the date of filing of such reports and other documents. Any statement contained herein or in a document incorporated or deemed to be incorporated by reference herein shall be deemed to be modified or superseded for purposes hereof to the extent that a statement contained herein or in any other subsequently filed document which is also incorporated or deemed to be incorporated herein modifies or supersedes such statement. Any such statement so modified or superseded shall not be deemed, except as so modified or superseded, to constitute a part of this prospectus supplement.

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

PROSPECTUS

CAPRICOR THERAPEUTICS, INC.

$75,000,000

COMMON STOCK

PREFERRED STOCK

DEBT SECURITIES

warrants

units

We may offer and sell up to $75,000,000 in the aggregate of any combination of the securities identified above from time to time in one or more offerings, either individually or in combination with other securities. We may also offer common stock or preferred stock upon conversion of debt securities, common stock upon conversion of preferred stock, or common stock, preferred stock or debt securities upon the exercise of warrants.

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

We may offer and sell the securities described in this prospectus and any prospectus supplement to or through one or more underwriters, dealers and agents, or directly to purchasers, or through a combination of these methods. If any underwriters, dealers or agents are involved in the sale of any of the securities, their names and any applicable purchase price, fee, commission or discount arrangement between or among them will be set forth, or will be calculable from the information set forth, in the applicable prospectus supplement. See the sections of this prospectus

entitled “About this Prospectus” and “Plan of Distribution” for more information. No securities may be sold without delivery of this prospectus and the applicable prospectus supplement describing the method and terms of the offering of such securities.

Investing in our securities involves a high degree of risk. You should review carefully the risks and uncertainties described under the heading “Risk Factors” beginning on page 4 of this prospectus, any applicable prospectus supplement and in any applicable free writing prospectuses, and under similar headings in the documents that are incorporated by reference into this prospectus.

Our common stock is currently listed on the NASDAQ Capital Market under the symbol “CAPR”. On September 24, 2015, the last reported sales price for our common stock was $4.51 per share. The applicable prospectus supplement will contain information, where applicable, as to any other listing on the NASDAQ Capital Market or any securities market or other exchange of the securities, if any, covered by the applicable prospectus supplement.

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

October 26, 2015

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ABOUT THIS PROSPECTUS

This prospectus is part of a registration statement on Form S-3 that we filed with the Securities and Exchange Commission, or the SEC, utilizing a "shelf" registration process. Under this shelf registration process, we may offer and sell shares of our common stock and preferred stock, various series of debt securities, warrants to purchase any of such securities and/or units consisting of any combination of such securities, either individually or in combination with other securities, in one or more offerings, up to a total dollar amount of $75,000,000. This prospectus provides you with a general description of the securities we may offer.

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

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

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

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

This prospectus contains summaries of certain provisions contained in some of the documents described herein, but reference is made to the actual documents for complete information. All of the summaries are qualified in their entirety by the actual documents. Copies of some of the documents referred to herein have been filed, will be filed or will be incorporated by reference as exhibits to the registration statement of which this prospectus is a part, and you may obtain copies of those documents as described below under the heading “Where You Can Find More Information”.

SUMMARY

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

Company Overview

Capricor Therapeutics, Inc. is a development stage, biopharmaceutical company whose mission is to discover, develop and commercialize innovative therapies for the treatment of diseases. Our initial pipeline products were developed to treat heart disease and its complications. The proprietary methods of Capricor, Inc., or Capricor, our wholly-owned subsidiary, center on producing therapeutic doses of cardiosphere-derived cells to boost the regenerative capacity of the heart and, with that, to perhaps improve cardiac function.

We currently have six drug candidates in various stages of development.

- **CAP-1002**: CAP-1002, Capricor's lead product candidate, consists of allogeneic cardiosphere-derived cells, or CDCs. CAP-1002 is currently being tested in two ongoing clinical trials: the ALLSTAR Phase II clinical trial for patients who have suffered a recent myocardial infarction (heart attack) and the DYNAMIC clinical trial for patients who have advanced heart failure. In each case, CAP-1002 will be evaluated to determine if the cells can lead to a reduction in scar and potentially achieve further clinical benefits for these patients. Additionally, CAP-1002 is being evaluated as a potential treatment for Duchenne muscular dystrophy cardiomyopathy in a planned Phase I/II clinical trial.

- **Cenderitide (CD-NP)**: Cenderitide belongs to a class of drugs called natriuretic peptides. Cenderitide is being designed as an outpatient therapy to be delivered continuously using a validated subcutaneous infusion pump for up to 90 days (the "post-acute" period) following an acute heart failure hospital admission, as well as for other potential indications. We have recently completed enrollment of the first cohort of a Phase II clinical study for Cenderitide and plan to initiate a second cohort of this study to further assess the safety and efficacy of this product. Cenderitide's

treatment goal and target indication is to provide a novel and effective therapeutic option for the outpatient treatment of heart failure, as well as other potential indications.

Exosomes: Exosomes are nano-sized, membrane-enclosed vesicles, or "bubbles," that are filled with select molecules, including proteins and microRNAs, which, when released, send messages to neighboring cells to regulate cellular functions. Exosomes act as a transport vehicle out of the cell for micro RNA, other fragments of genetic material and proteins that act as messengers between cells, ultimately providing regulatory function for many cell processes, including inflammation, angiogenesis, programmed cell death (apoptosis) and scarring. Pre-clinical research has shown that exogenous exosomes can be used as therapeutic agents aimed to direct or, in some cases, re-direct cellular activities. Capricor is currently in pre-clinical testing to explore the possible future therapeutic benefits that exosomes may possess.

CAP-1001: CAP-1001 consists of autologous CDCs. This product was used in the Phase I CADUCEUS clinical trial that was sponsored and conducted by Cedars-Sinai Medical Center in collaboration with The Johns Hopkins University. The data from CADUCEUS, using autologous CDCs, suggests that the cells are effective in reducing scar within several months of a heart attack. At present there is no plan for another clinical trial for CAP-1001.

CU-NP: CU-NP is a pre-clinical rationally-designed natriuretic peptide that consists of amino acid chains identical to those produced by the human body, specifically the ring structure of C-type natriuretic peptide, or CNP, and the N- and C-termini of Urodilatin, or URO. We are currently evaluating whether we will proceed with clinical development of this product.

- **CSps**: CSps are multicellular clusters called cardiospheres, a 3D micro-tissue from which CDCs are derived, and have shown significant healing effects in pre-clinical models of heart failure. While Capricor considers the CSps an important product, at present there is no plan for a clinical trial for CSps.

Corporate Information

Our executive offices are located at 8840 Wilshire Blvd., 2nd Floor, Beverly Hills, California 90211. Our telephone number is (310) 358-3200 and our Internet address is *www.capricor.com.* We do not incorporate the information on, or accessible through, our website into this prospectus, and you should not consider any information on, or accessible through, our website as part of this prospectus. We have included our website address in this prospectus solely as an inactive textual reference.

RISK FACTORS

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

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

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 programs and may not have the capital required to otherwise operate our business.

Developing biopharmaceutical products, including conducting pre-clinical studies and clinical trials and establishing manufacturing capabilities, is expensive. As of June 30, 2015, we had cash and cash resources totaling approximately $20.1 million, plus approximately $0.6 million of restricted cash representing loans for our ALLSTAR clinical trial. We have not generated any product revenues, and will not be able to generate any product revenues until, and only if, we receive approval to sell our drug candidates from the U.S. Food and Drug Administration, or FDA, and other regulatory authorities for our product candidates.

From inception, we have financed our operations through public and private sales of our equity and debt securities, National Institutes of Health, or NIH, grants, and a California Institute for Regenerative Medicine, or CIRM, loan award. In December 2013 we also entered into a collaboration agreement with Janssen Biotech, Inc., or Janssen, which provides for funding for the collaboration of our cell therapy program for cardiovascular applications, including CAP-1002. As we have not generated any revenue from operations 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, thereafter, to fund our research and development, including our long-term plans for clinical trials and new product development.

We expect our research and development expenses to increase in connection with our ongoing activities, particularly if we continue to develop Cenderitide and potentially initiate clinical development of CU-NP. Our research and development expenses will also increase as we further the development of our exosomes program and conduct additional studies with CAP-1002, such as the potential study of DMD. In addition, our expenses could increase beyond expectations if the FDA requires that we perform additional studies beyond those that we currently anticipate, which may also delay the timing of any potential product approval. Other than our cash on hand, we currently have no commitments or arrangements for any additional financing to fund the research and development of Cenderitide, CU-NP, exosomes or CAP-1002 for DMD or any further DYNAMIC studies. We commenced a new clinical trial testing our Cenderitide product candidate in January 2015 and commenced our DYNAMIC Phase I clinical trial in December 2014.

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

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 this estimate 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 Phase II clinical trial of CAP-1002, our DYNAMIC trial, our Cenderitide trial, our planned HOPE trial, our planned exosomes program;
- the continued availability of funding from the NIH and CIRM;
- the costs of developing adequate manufacturing processes and facilities;
- the costs and timing of regulatory approval;
- the costs of filing, prosecuting, defending and enforcing any patent claims and other intellectual property rights;
- the costs and risks involved in conducting clinical trials and manufacturing operations internationally;
- the effect of competing technological and market developments;
- the terms and timing of any collaboration, licensing or other arrangements that we may establish;
- the cost and timing of completion of clinical and commercial-scale outsourced manufacturing activities; and
- the costs of establishing sales, marketing and distribution capabilities for any product candidates for which we may receive regulatory approval.

We 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 and increasing net losses for the foreseeable future, and may never achieve or maintain profitability. Our operations to date have been primarily limited to organizing and staffing our company, developing our technology, and undertaking pre-clinical studies and clinical trials of our product candidates. We have not yet obtained regulatory approvals for any of our product candidates. Consequently, any predictions made about our future success or viability may not be as accurate as they could be if we had a longer operating history. 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, as well as other factors described elsewhere in this prospectus:

- our need for substantial additional capital to fund our development programs;
- delays in the commencement, enrollment, and timing of clinical testing;
- the success of our ALLSTAR, DYNAMIC, Cenderitide and planned HOPE clinical trials through all stages of clinical development;
- the success of clinical trials of our CU-NP product candidate, if any, through all stages of clinical development, if commenced;
- the viability of exosomes as a potential product candidate and the success of all stages of its pre-clinical and clinical development;
- the viability of CAP-1002 as a potential product candidate for the treatment of DMD and the success of all stages of its pre-clinical and clinical development, including through the planned HOPE trial;
- any delays in regulatory review and approval of our product candidates in clinical development;
- our ability to receive regulatory approval or commercialize our product candidates, within and outside the United States;
-

potential side effects of our current or future products and product candidates that could delay or prevent commercialization or cause an approved treatment drug to be taken off the market;

- regulatory difficulties relating to products that are in development or which may receive regulatory approval;
- market acceptance of our product candidates;
- our ability to establish an effective sales and marketing infrastructure once our products are commercialized;
- our ability to establish or maintain collaborations, licensing or other arrangements;
- our ability and third parties' abilities to protect intellectual property rights;
- competition from existing products or new products that may emerge;
- guidelines and recommendations of therapies published by various organizations;
- the ability of patients to obtain coverage of, or sufficient reimbursement for, our products;
- our ability to maintain adequate insurance policies;

- our ability to successfully manufacture our product candidates on a timely basis;
- our dependency on third parties to formulate and manufacture our product candidates;
- our ability to maintain our current manufacturing facility and secure other facilities as determined to be necessary;
- costs related to and outcomes of potential intellectual property litigation;
- compliance with obligations under intellectual property licenses with third parties;
- our ability to seek regulatory approvals for our product candidates;
- our ability to implement additional internal systems and infrastructure;
- our ability to adequately support future growth;
- our ability to attract and retain key personnel to manage our business effectively; and
- the ability of our senior management who have limited experience in managing a public company to manage our business and operations.

The Company's technology is not yet proven and each of our product candidates is in an early stage of development.

Each of the Company's six product candidates, CAP-1002, CAP-1001, cardiospheres, exosomes, Cenderitide and CU-NP, is in an early stage of development and requires 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 effectiveness of the Company's technology has not been definitively proven in completed human clinical trials or preclinical studies. The Company's failure to establish the efficacy of its technology 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 ALLSTAR trial, our DYNAMIC trial, our Cenderitide trial, or our planned HOPE trial. Additionally, we cannot predict with any certainty if, or when, we might commence any clinical trials of our product candidates other than the ALLSTAR trial, the DYNAMIC trial, the Cenderitide trial and the HOPE trial, or whether such 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 may not be able to manage our growth.

Should we achieve our near-term milestones, of which no assurance can be given, our long-term viability will depend upon the expansion of our operations and the effective management of our growth, which will place a significant strain on our management and on our administrative, operational and financial resources, especially as 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 product candidates will require substantial time and resources in order to be developed, and there is no guarantee that we will develop them successfully.

We have not completed the development of any products and may not have products to sell commercially for many years, if at all. Our potential products will require substantial additional research and development time and expense, as well as extensive clinical trials and perhaps additional preclinical testing, prior to commercialization, which may never occur. There can be no assurance that products will be developed successfully, perform in the manner anticipated, or be commercially viable.

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

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

The Company has limited experience in conducting clinical trials.

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

To receive regulatory approval for the commercial sale of our product candidates, we must conduct adequate and well-controlled clinical trials to demonstrate efficacy and safety in humans. Clinical failure can occur at any stage of the 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. In addition, negative, delayed or inconclusive results may result in:

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

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

Delays in the commencement, enrollment or completion of clinical testing could significantly affect our product development costs. A clinical trial may be suspended or terminated by the Company, the FDA, or other regulatory authorities due to a number of factors. The commencement and completion of clinical trials requires 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. 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 clinical research organizations, or CROs, and trial sites, the terms of which can be subject to extensive negotiation and may vary significantly among different CROs and trial sites;
- obtaining regulatory approval to commence a clinical trial;
- complying with conditions imposed by a regulatory authority regarding the scope or term of a clinical trial, or being required to conduct additional trials before moving on to the next phase of trials;
- obtaining institutional review board, or IRB, approval to conduct a clinical trial at numerous prospective sites;
- recruiting and enrolling patients to participate in clinical trials for a variety of reasons, including size of 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 availability of approved effective treatments for the relevant disease and competition from other clinical trial programs for similar indications;

- retaining patients who have initiated their participation in a clinical trial but may be prone to withdraw due to the treatment protocol, lack of efficacy, personal issues, or side effects from the therapy, or who are lost to further follow-up;
- manufacturing sufficient quantities of a product candidate for use in clinical trials on a timely basis;
- complying with design protocols of any applicable special protocol assessment we receive from the FDA;
- severe or unexpected drug-related side effects experienced by patients in a clinical trial;
- collecting, analyzing and reporting final data from the clinical trials;
- breaches in quality of manufacturing runs that compromise all or some of the doses made; positive results in FDA-required viral testing; karyotypic abnormalities in our cell product; or contamination in our manufacturing facilities, all of which events would necessitate disposal of all cells made from that source;
- availability of materials provided by third parties necessary to manufacture our product candidates;
- availability of adequate amounts of acceptable tissue for preparation of master cell banks for our products;
- our inability to find a tissue source with an HLA haplotype that is compatible with the recipient, which may lead to limited utility of the product in a broad population; and
- requirements to conduct additional trials and studies, and increased expenses associated with the services of the Company's CROs and other third parties.

In addition, once begun, a clinical trial may be suspended or terminated by us, the FDA, or other regulatory authorities due to a number of factors. If we are required to conduct additional clinical trials or other testing of our product candidates beyond those that we currently contemplate, we or our development partners, if any, may be delayed in obtaining, or may not be able to obtain or maintain, clinical or marketing approval for these product candidates. We may not be able to obtain approval for indications that are as broad as intended, or we may be able to obtain approval only for indications that are entirely different from those indications for which we sought approval.

Delays in our ability to enroll a sufficient number of patients in our ALLSTAR trial could cause CIRM to delay or discontinue the distribution of additional loan proceeds from the CIRM Loan Agreement. The loss of funding under the CIRM Loan Agreement could cause delays under our ALLSTAR trial.

Changes in regulatory requirements and guidance may occur, and we may need to amend clinical trial protocols to reflect these changes with appropriate regulatory authorities. Amendments may require us to resubmit our clinical trial protocols to IRBs for re-examination, which may impact the costs, timing, or successful completion of a clinical trial. If we experience delays in the completion of, or if we terminate, our clinical trials, the commercial prospects for our product candidates will be harmed, and our ability to generate product revenues will be delayed. 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.

As the results of earlier 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 clinical trials are completed as planned, including our ALLSTAR clinical trial of CAP-1002, we cannot be certain that their results will support the claims of our product candidates. Positive results in pre-clinical testing and early clinical trials do not ensure that results from later clinical trials will also be positive, and we cannot be sure that the results of later clinical trials will replicate the results of prior clinical trials and pre-clinical testing. A number of companies in the pharmaceutical industry, including those with greater resources and experience, have suffered significant setbacks in Phase II or Phase III clinical trials, even after seeing promising results in earlier clinical trials.

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

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

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 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.

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, anticipated human clinical trials, and anticipated 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, as outlined in the Code of Federal Regulations. Different regulatory requirements may apply to our products depending on how they are categorized by the FDA under these laws. These regulations can be subject to substantial and significant interpretation, addition, amendment or revision by the FDA and by the legislative process. The FDA may determine that we will need to undertake clinical trials beyond those currently planned. Furthermore, the FDA may determine that results of clinical trials do not support approval for the product. Similar determinations may be encountered in foreign countries. The FDA will continue to monitor products in the market after approval, if any, and may determine to withdraw its approval or otherwise seriously affect the marketing efforts for any such product. The same possibilities exist for trials to be conducted outside of the United States that are subject to regulations established by local authorities and local law. Any such determinations would delay or deny the introduction of our product candidates to the market and have a material adverse effect on our business, financial condition, and results of operations.

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

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

Even if our product candidates receive regulatory approval in the United States, we may never receive approval or commercialize our product candidates outside of the United States. 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. For example, European regulatory authorities generally require a trial comparing the efficacy of the new drug to an existing drug prior or subsequent to granting approval. The time required to obtain approval in other countries might differ from that required to obtain FDA approval. The regulatory approval process in other countries may include all of the risks detailed above regarding FDA approval in the United States as well as other risks. Regulatory approval in one country does not ensure regulatory approval in another, but a failure or delay in obtaining regulatory approval in one country may have a negative effect on the regulatory approval process in others. Failure to obtain regulatory approval in other countries, or any delay or setback in obtaining such approval, could have the same adverse effects detailed above regarding FDA approval in the United States. Such effects include the risks that our product candidates may not be approved for all indications requested, which could limit the uses of our product candidates and have an adverse effect on product sales and potential royalties, and that such approval may be subject to limitations on the indicated uses for which the product may be marketed or require costly, post-marketing follow-up studies.

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

Even if United States 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. 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 has resulted in the proposal of new legislation addressing drug safety issues. If enacted, any new legislation could result in delays or increased costs during the period of product development, clinical trials, and regulatory review and approval, as well as increased costs to assure compliance with any new post-approval regulatory requirements. Any of these restrictions or requirements could force us to conduct costly studies or increase the time for us to become profitable. For example, any labeling approved for any of our product candidates may include a restriction on the term of its use, or it may not include one or more of our intended indications.

Our product candidates will also be subject to ongoing FDA requirements for the labeling, packaging, storage, advertising, promotion, record-keeping, and submission of safety and other post-market information on the drug. In addition, approved products, manufacturers, and manufacturers' facilities are subject to continuous 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 or for use in a clinical study. If our product candidates fail to comply with applicable regulatory requirements, such as GMPs, a regulatory agency may:

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

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

We presently maintain our laboratories and research facilities in leased premises at Cedars-Sinai Medical Center, or CSMC, in Los Angeles, California. We presently manufacture our cells in a facility which is owned by and located within CSMC and in which we follow GMP practices, but which is not a GMP approved facility. Our intention is to manufacture cells at this facility for our ALLSTAR Phase II trial, our DYNAMIC trial, and for any clinical work involving CAP-1002 as a potential treatment for DMD. These plans could change if we decide to expand any of our clinical trials to include international sites, such as in Europe. We also intend to utilize our premises at CSMC to develop and manufacture exosomes. If the lease is terminated or if CSMC revokes its permission to allow us to utilize the manufacturing facility, we would have to secure alternative facilities in which to operate our research and development activities and/or manufacture our products, which would involve a significant monetary investment and would negatively impact the progress of our clinical trials and regulatory approvals. In addition, we may have to build out our own manufacturing facility or establish a collaboration agreement with a third party for any Phase III trial.

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

We obtain the donor hearts from which our CDCs are manufactured from organ procurement organizations, or OPOs. There is no guarantee that the OPOs which currently provide donor hearts to us will be able to continue to supply us with donor hearts in the future or, in that case, that an alternative OPO will be available to us. If those OPOs or an alternative OPO is not able or willing to supply us with donor hearts, we would be unable to produce our CDCs and the development of our lead product candidate 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.

There are additional risks involved in conducting trials internationally.

If we decide to expand one or more of our clinical trials to investigative sites in Europe or other countries outside of the United States, we will have additional regulatory requirements that we will have to meet in connection with our manufacturing, distribution, use of data and other matters. For example, if we decide to conduct our trials in Europe, we will have to either move our manufacturing facility to a facility located in Europe, enter into an agreement with a European manufacturer to manufacture our product candidates for us or enter into an agreement with a domestic manufacturer who maintains an acceptable GMP facility. Any of those options would involve a significant monetary investment, would involve increased risk and may impact the progress of our clinical trials and regulatory approvals. Our current and anticipated future reliance on a limited number of third-party manufacturers exposes us to the following additional risks:

- We may be unable to identify manufacturers needed to manufacture our product candidates or the necessary devices on acceptable terms or at all, because the number of potential manufacturers is limited, and before obtaining 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 intended for use, after receipt of FDA approval, if any.
- Our third-party manufacturers might be unable to manufacture our product candidates in the volume and of the quality required to meet our clinical and commercial needs, if any.
- Our third-party manufacturers might be unable to manufacture or supply us with sufficient quantities of devices or acceptable materials necessary for the development or use of our product candidates.
- Our product candidates may not perform well, or at all, with the devices received from third-party manufacturers.
- 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 or devices needed to manufacture or utilize our product candidates.
- Drug manufacturers are subject to ongoing periodic unannounced inspection by the FDA, the Drug Enforcement Agency, and their foreign counterparts to ensure strict compliance with good manufacturing practice 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

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

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

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

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

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

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

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

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

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

As we continue with the development of Cenderitide or CU-NP, we will rely exclusively on third parties to formulate and manufacture these product candidates and provide us with the devices and other products necessary to administer Cenderitide or CU-NP.

We have no experience in drug formulation or manufacturing and do not intend to establish our own manufacturing facilities for the production of Cenderitide or CU-NP. We lack the resources and expertise to formulate or manufacture these product candidates. As we continue with our clinical trial of Cenderitide or the possible development of CU-NP, we will have to contract with one or more manufacturers to manufacture, supply, store, and distribute drug supplies for our clinical trials. If either of these product candidates receives FDA approval, we will rely on one or more third-party contractors to manufacture supplies of our drug candidates. In addition, these product candidates may require the use of one or more medical devices for infusion into patients. We have contracted with Insulet Corporation to supply us with its OmniPod® pumps to utilize with Cenderitide for our current trial. We will have to enter into additional contracts with one or more device manufacturers to manufacture and supply the devices to be used in the dosing procedures for any future trials of Cenderitide or CU-NP. 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 or the necessary devices 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.
- Some of the raw materials needed to manufacture our product candidates are available from a very limited number of suppliers. Although we believe we have good relationships with these suppliers, we may have difficulty identifying alternative suppliers if our arrangements with our current suppliers are disrupted or terminated.
- Our third-party manufacturers might be unable to formulate and manufacture our drugs in the volume and of the quality required to meet our clinical and commercial needs, if any.
- Our third-party manufacturers might be unable to manufacture or supply us with sufficient quantities of devices or acceptable materials necessary for the development or use of our product candidates.
- Our product candidates may not perform well, or at all, with the devices received from third-party manufacturers.
- 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 or devices needed to manufacture or utilize our product candidates.
- Drug manufacturers are subject to ongoing periodic unannounced inspection by the FDA, the Drug Enforcement Agency, and corresponding state agencies to ensure strict compliance with good manufacturing practice 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.

Business disruptions such as natural disasters could seriously harm our future revenues and financial condition and increase our costs and expenses.

Our corporate headquarters and manufacturing facilities are located in the greater Los Angeles, California area, a region known for seismic activity. A significant natural disaster, such as an earthquake, flood or fire, occurring at our headquarters or facilities could have a material and adverse effect on our business, financial condition and results of operations. In addition, terrorist acts or acts of war targeted at the U.S., and specifically the Los Angeles, California region, could cause damage or disruption to us, our employees, facilities and partners, which could have a material adverse effect on our business, financial condition and results of operations.

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

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

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 products, obtain licenses to use third party technologies, protect our trade secrets and operate without infringing the proprietary rights of others. Legal standards regarding the scope of claims and validity of biotechnology patents are uncertain and evolving. There can be no assurance that our pending, licensed-in or owned patent applications will be approved, or that challenges will not be instituted against the validity or enforceability of any patent licensed-in or owned by us. Additionally, we have entered into various confidentiality agreements with employees and third parties. There is no assurance that such agreements will be honored by such parties or enforced in whole or part by the courts. The cost of litigation to uphold the validity and prevent infringement of a patent is substantial. Furthermore, there can be no assurance that others will not independently develop substantially equivalent technologies not covered by patents to which we own rights or obtain access to our know-how. In addition, the laws of certain countries may not adequately protect our intellectual property. Our competitors may possess or obtain patents on products or processes that are necessary or useful to the development, use, or manufacture of our products. There can also be no assurance that our proposed technology will not infringe patents or proprietary rights owned by others, with the result that others may bring infringement claims against us and require us to license such proprietary rights, which may not be available on commercially reasonable terms, if at all. Any such litigation, if instituted, could have a material adverse effect, potentially including monetary penalties, diversion of management resources, and injunction against continued manufacture, use, or sale of certain products or processes.

Some of our technology has resulted, and will result, from research funded by agencies of the United States government and the State of California. As a result of such funding, the United States government and the State of California have certain rights in the technology developed with the funding. These rights include a non-exclusive, paid-up, worldwide license under such inventions for any governmental purpose. In addition, under certain conditions, the government has the right to require us to grant third parties licenses to such technology. 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. There can be no assurance that we can adequately protect our rights in such non-patented proprietary know-how, or that others will not independently develop substantially equivalent proprietary information or techniques or gain access to our proprietary know-how. 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, the value of our trade secrets, know-how and other proprietary rights would be significantly impaired and our business and competitive position would suffer.

In September 2011, the Leahy-Smith America Invents Act, or the Leahy-Smith Act, was signed into law. The Leahy-Smith Act includes a number of significant changes to U.S. patent law. These include provisions that affect the way patent applications will be prosecuted and may also affect patent litigation. In particular, under the Leahy-Smith Act, the U.S. 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 United States Patent and Trademark Office, or USPTO, and may become involved in opposition, derivation, reexamination, inter-partes review or interference proceedings challenging our patent rights or the patent rights of our licensors. An adverse determination in any such submission, proceeding or litigation could reduce the scope of, or invalidate, our or our licensors’ patent rights, which could adversely affect our competitive position.

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

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

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

We have licensed certain patent and other intellectual property rights that cover our CAP-1002, CAP-1001, and CSps product candidates from University of Rome, The Johns Hopkins University, or JHU, and CSMC. We have also licensed certain patent and other intellectual property rights that cover exosomes from CSMC. Under the license agreements with 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, we have assumed, in coordination with CSMC, responsibility for the prosecution and maintenance of all patents and patent applications. Our enforcement of certain of these licensed patents or defense of any claims asserting the invalidity of these patents would also be subject to the cooperation of the third parties.

We also license certain patent and other intellectual property rights that cover our Cenderitide and CU-NP product candidates from the Mayo Foundation for Medical Education and Research, or Mayo. In the past, we have relied on Mayo to file, prosecute, and maintain patent applications, and otherwise protect the intellectual property to which we have a license, and, prior to our entry into the Amended and Restated License Agreement with Mayo, or the Amended Mayo License Agreement, we did 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 the activities conducted by Mayo 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. With the execution of the Amended Mayo License Agreement, we are responsible for the prosecution and maintenance of the Mayo patents and patent applications covered by our license, and the associated costs and expenses. Our enforcement of certain of these licensed patents or defense of any claims asserting the invalidity of these patents would be subject to the cooperation of third parties.

In October 2014, we entered into a Transfer Agreement with Medtronic, Inc., or Medtronic, pursuant to which we received an assignment of patent rights that were owned or co-owned by Medtronic relating to natriuretic peptides. We have responsibility for the prosecution and maintenance of such patents and patent applications at our expense. We cannot be certain that the activities conducted by Medtronic prior to our acquisition of these patents and patent rights were conducted in compliance with applicable law and regulations, or will result in valid and enforceable patents. Our enforcement of certain of these assigned patents or defense of any claims asserting the invalidity of these patents would be subject to the cooperation of third parties.

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 policy regarding the breadth of claims allowed in biopharmaceutical patents has emerged to date in the United States. The biopharmaceutical patent situation outside the United States is even more uncertain. Changes in either the patent laws or in interpretations of patent laws in the United States and other countries may diminish the value of our intellectual property. Accordingly, we cannot predict the breadth of claims that may be allowed or enforced in the patents we own or to which we have a license or third-party patents. Further, if any of our patents are deemed invalid and unenforceable, it could impact our ability to commercialize or license our technology.

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

- others may be able to make compounds that are similar to our product candidates but that are not covered by the claims of any of our patents;
- we might not have been the first to make the inventions covered by any issued patents or patent applications we may have (or third parties from whom we license intellectual property may have);
- we might not have been the first to file patent applications for these inventions;
- it is possible that any pending patent applications we may have will not result in issued patents;

- any issued patents may not provide us with any competitive advantages, or may be held invalid or unenforceable as a result of legal challenges by third parties;
- we may not develop additional proprietary technologies that are patentable; or
- 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 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 the disclosure 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 may not provide adequate protection for our trade secrets, know-how or other proprietary information in the event of any unauthorized use or disclosure or the lawful development by others of such information. In addition, enforcing a claim that a third party illegally obtained and is using any of our trade secrets is expensive and time consuming, and the outcome is unpredictable. If any of our trade secrets, know-how or other proprietary information is 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 proceedings relating to patent and other intellectual property rights and we may be unable to protect our rights to, or use of, our technology.

If we choose to go to court to stop a third party from using the inventions claimed in our patents, that individual or company has the right to ask the court to rule that such patents are invalid and/or should not be enforced against that third party. These lawsuits are expensive and would consume time and other resources, even if we were successful in discontinuing the infringement of our patents. In addition, there is a risk that the court will decide 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 United States Supreme Court has in the past invalidated tests used by the USPTO in granting patents over the past 20 years. As a consequence, issued patents may be found to contain invalid claims according to the newly revised standards. Some of our own or in-licensed patents may be subject to challenge and subsequent invalidation in a re-examination proceeding before the USPTO or during litigation under the revised criteria, which make it more difficult to obtain patents.

Furthermore, a third party may claim that we or our manufacturing or commercialization partners are using inventions covered by the third party's patent rights and may go to court to stop us from engaging in our normal operations and activities, including making or selling our product candidates. These lawsuits are costly and could affect our results of operations and divert the attention of managerial and technical personnel. There is a risk that a court could decide that we or our commercialization partners are infringing the third party's patents and order us or our partners to stop the activities covered by the patents. In addition, there is a risk that a court could order us or our partners to pay the other party damages for having violated the other party's patents. We have agreed to indemnify certain of our commercial

partners against certain patent infringement claims brought by third parties. The biotechnology industry has produced a proliferation of patents, and it is not always clear to industry participants, including us, which patents cover various types of products or methods of use. The coverage of patents is subject to interpretation by the courts, and the interpretation is not always uniform. If we are sued for patent infringement, we would need to demonstrate that our products 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 showing of 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 application may have priority over our patent applications or patents, which could further require us to obtain rights to issued patents covering such technologies. 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 United States 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 could have a material adverse effect on our ability to raise the funds necessary to continue our operations.

Risks Related to Our Relationships with Third Parties

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

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

Our rights to our Cenderitide and CU-NP drug candidates were both derived from separate license agreements between us and Mayo. On November 14, 2013, we entered into the Amended Mayo Agreement, pursuant to which the rights to both Cenderitide and CU-NP were included in the Amended Mayo Agreement and many of the terms of the former agreements were revised on terms more favorable to us. We are substantially dependent on our relationship with Mayo with respect to the rights to these two drug candidates. If requirements under our license agreement are not met, we could suffer significant harm. In order to develop these products, we will need to maintain the intellectual property rights to these product candidates. The Amended Mayo Agreement requires us to perform certain obligations that affect our rights under the Amended Mayo Agreement, including making cash payments if we were to enter into certain types of business transactions. If we fail to comply with our obligations under the Amended Mayo Agreement, we could lose important patent and other intellectual property rights which may be critical to our business.

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

Finally, we may be required to obtain licenses to patents or other proprietary rights of third parties 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 to fund various projects, including Phase I of the ALLSTAR trial. In 2014, we received a grant from the NIH to fund the planned DYNAMIC trial. These awards are subject to annual and quarterly reporting requirements. If we fail to meet these requirements, the NIH could cease further funding.

On February 5, 2013, we entered into the CIRM Loan Agreement, pursuant to which CIRM has agreed to disburse $19.8 million to us over a period of approximately three and one-half years to support Phase II of our ALLSTAR clinical trial. Under the CIRM Loan Agreement, we are required to repay the CIRM loan with interest at maturity. The loan also provides for the payment of a risk premium whereby we are required to pay CIRM a premium of up to 500% of the loan amount upon the achievement of certain revenue thresholds. The loan has a term of five years and is extendable annually up to ten years from the original issuance at our option if certain conditions are met. CIRM has the right to cease disbursements if a no-go milestone occurs or certain other conditions are not satisfied. The timing of the distribution of funds pursuant to the CIRM Loan Agreement is contingent upon the availability of funds in the California Stem Cell Research and Cures Fund in the State Treasury, as determined by CIRM in its sole discretion. So long as we are not in default, the loan may be forgiven during the term of the project period if we abandon the trial due to the occurrence of a no-go milestone. After the end of the project period, the loan may be forgiven if we elect to abandon the project under certain circumstances. Under the CIRM Loan Agreement, we are also required to meet certain financial milestones by demonstrating to CIRM prior to each disbursement of loan proceeds that we have funds available sufficient to fund all costs and expenses anticipated to be required to continue Phase II of the ALLSTAR trial for at least the following 12-month period, less the costs budgeted to be covered by planned loan disbursements. We are also required to meet certain progress milestones specified in the CIRM Notice of Loan Award. Capricor and CIRM have agreed to adjust future disbursements of loan proceeds to align with actual patient enrollment. There is no assurance that we will meet our milestones under the CIRM Loan Agreement, that CIRM will not delay or discontinue the disbursement of funds or that CIRM will not terminate the Loan Agreement for failure to meet certain loan conditions. If that were to happen, we may not have the funds necessary to complete the ALLSTAR Trial.

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.

If we do not establish strategic partnerships, we will have to undertake development and commercialization efforts on our own, which would be costly and adversely impact our ability to commercialize any future products or product candidates. If we enter into any strategic partnerships with pharmaceutical, biotechnology or other life science companies, we will be subject to a number of risks, including:

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

There is a risk that Janssen may not exercise its option for an exclusive license.

The Company has entered into a Collaboration Agreement and Exclusive License Option with Janssen Biotech, Inc., or Janssen. There is no guarantee that Janssen will exercise its option for an exclusive license and enter into an agreement with the Company. If Janssen declines to exercise the option it could have a material adverse effect on the business, financial condition, or results of operations of the Company.

Risks Related to Competitive Factors

Our products will likely face intense competition.

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

Our future success will depend in part on our ability to maintain a competitive position with respect to evolving therapies as well as other novel technologies. There can be no assurance that existing or future therapies developed by others will not 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 employees and consultants render services on a part-time basis to us or to other companies.

All former employees of Nile Therapeutics, Inc., or Nile (our former corporate name), were terminated upon consummation of the merger between Nile and Capricor, Inc. We do not currently have any employees who have experience in the development of natriuretic peptides.

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

Because of the specialized nature of our technology, we are dependent upon existing key personnel and on our ability to attract and retain qualified executive officers and scientific personnel for research, clinical studies, and development activities conducted or sponsored by us. There is intense competition for qualified personnel in our fields of research and development, and there can be no assurance that we will be able to continue to attract additional qualified personnel necessary for the development and commercialization of our product candidates or retain our current personnel. Dr. Linda Marbán, our Chief Executive Officer and employee, also provides services on a limited part-time basis to CSMC as do several other of our employees. Dr. Frank Litvack is only a part-time consultant to the Company and provides services to other non-competing enterprises. These individuals' multiple responsibilities on behalf of the Company and other entities could cause the Company harm in that such employees are unable to devote their full time and attention to the Company.

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

An element of our business strategy includes potentially partnering with pharmaceutical, biotechnology and other companies to obtain assistance for the development and potential commercialization of our product candidates, including the cash and other resources we need for such development and potential commercialization. We may not be able to negotiate strategic partnerships on acceptable terms, or at all. If we are unable to negotiate strategic partnerships for our product candidates we may be forced to curtail the development of a particular candidate, reduce or delay 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 have sufficient funds, we will not be able to bring our product candidates to market and generate product revenue.

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

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

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

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

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

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

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

Our ability to generate significant sales of our products 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.

In addition, the market for our future products will depend significantly on access to third-party payors' drug formularies, or lists of medications for which third-party payors provide coverage and reimbursement. Industry competition to be included in such formularies results in downward pricing pressures on pharmaceutical companies. Third-party payors may refuse to include a particular branded drug in their formularies when a generic equivalent is available.

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

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

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

Risks Related to Product and Environmental Liability

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

The testing, marketing, and sale of human cell therapeutics, pharmaceuticals, and services entail an inherent risk of adverse effects or medical complications to patients and, as a result, product liability claims may be asserted against us. A future product liability claim or product recall could have a material adverse effect on the Company. There can be no assurance that product liability insurance will be available to us in the future on acceptable terms, if at all, or that coverage will be adequate to protect us against product liability claims. In the event of a successful claim against the Company, insufficient or lack of insurance or indemnification rights could result in liability to us, which could

have a material adverse effect on the Company and its future viability. The use of our product candidates in clinical trials and the sale of any products for which we obtain marketing approval, if at all, expose the Company to the risk of product liability claims. Product liability claims might be brought against the Company by consumers, health care providers or others using, administering or selling our products. If we cannot successfully defend ourselves against these claims, we will incur substantial liabilities. Regardless of merit or eventual outcome, liability claims may result in:

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

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

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

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

Our business depends on compliance with ever-changing environmental 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. 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 laws and regulations. However, both federal and state environmental laws have changed in recent years and the Company may become subject to stricter environmental standards in the future and may face large capital expenditures to comply with environmental laws. We have limited capital and we are uncertain whether we will be able to pay for significantly large capital expenditures that may be required to comply with new laws. Also, future developments, administrative actions or liabilities relating to environmental matters may have a material adverse effect on our financial condition or results of operations.

Risks Related to Our Common Stock

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

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

- our financial condition, including our need for additional capital;

- 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;
- failure or delays in entering drug candidates into clinical trials;
- failure or discontinuation of any of our research or development programs;
- developments in establishing new strategic alliances or with existing alliances;
- market conditions in the pharmaceutical, biotechnology and other healthcare related sectors;
- actual or anticipated fluctuations in our quarterly financial and operating results;
- developments or disputes concerning our intellectual property or other proprietary rights;
- introduction of technological innovations or new commercial products by us or our competitors;
- issues in manufacturing our drug candidates or drugs;
- issues with the supply or manufacturing of any devices or materials needed to manufacture or utilize our drug candidates;
- FDA or other United States 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; or
- volatility in the stock prices of other companies in our industry.

These and other external factors may cause the market price and demand for our common stock to fluctuate substantially, which may limit or prevent investors from readily selling their shares of common stock and may otherwise negatively affect the liquidity of our common stock. In addition, when the market price of a stock has been volatile, holders of that stock have instituted securities class action litigation against the company that issued the stock. If any of our stockholders brought a lawsuit against us, we could incur substantial costs defending the lawsuit. Such a lawsuit could also divert our management's time and attention.

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. Additionally, the terms of our CIRM Loan Agreement restrict our ability to declare or pay dividends to our stockholders. 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.

There may be issuances of shares of blank check preferred stock 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, the right to the redemption of such shares, together with other rights, none of which will be afforded holders of our common stock.

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

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

We may not be able to attract the attention of securities analysts.

Security analysts of major brokerage firms may not provide coverage of us since there is no incentive to brokerage firms to recommend the purchase of our common stock. No assurance can be given that brokerage firms will want to conduct any secondary offerings on behalf of our Company in the future. The lack of such analyst coverage may decrease the public demand for our common stock, making it more difficult for you to resell your shares when you deem appropriate.

The operational and other projections and forecasts that we may make from time to time are subject to inherent risks.

The projections and forecasts that our management may provide from time to time (including, but not limited to, those relating to timing, progress and anticipated results of clinical development, regulatory processes, clinical trial timelines and any anticipated benefits of our product candidates) reflect numerous assumptions made by management, including assumptions with respect to our specific as well as general business, economic, market and financial conditions and other matters, all of which are difficult to predict and many of which are beyond our control. Accordingly, there is a risk that the assumptions made in preparing the projections, or the projections themselves, will prove inaccurate. There will be differences between actual and projected results, and actual results may be materially different from those contained in the projections. The inclusion of the projections in (or incorporated by reference in) this prospectus should not be regarded as an indication that we or our management or representatives considered or consider the projections to be a reliable prediction of future events, and the projections should not be relied upon as such. Additionally, final data may differ significantly from preliminary reported data. It is Capricor's intent to perform an interim analysis which, if successful, could result in a reduction in the number of patients necessary for achieving statistical significance and meeting the primary endpoint. Whether Capricor performs the interim analysis is subject to the concurrence of interested parties, including the FDA.

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

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

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

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

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

The former stockholders of Capricor, Inc., now a wholly-owned subsidiary of the Company, many of whom are executive officers and directors of the Company, together with their respective affiliates, beneficially own or control a substantial majority of the outstanding shares of the Company. Accordingly, the stockholders, acting individually or as a group, will have substantial influence over the outcome of a corporate action of the Company requiring stockholder approval, including the election of directors, any merger, consolidation or sale of all or substantially all of the Company's assets or any other significant corporate transaction. These stockholders may also exert influence in delaying or preventing a change in control of the Company, even if such change in control would benefit the other stockholders of the Company. In addition, the significant concentration of stock ownership may adversely affect the market value of the Company's common stock due to investors' perception that conflicts of interest may exist or arise.

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 be further limited as a result of the merger with Capricor.

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

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

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

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

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

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

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

Risks Related to this Offering

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

We currently anticipate that any net proceeds from this offering will be used for research related to our product candidates, working capital and general corporate purposes, which may include, without limitation, engaging in acquisitions or other business combinations. However, we have not determined the specific allocation of the net proceeds from this offering, if any, among these potential uses. Our management will have broad discretion as to the application of the net proceeds from this offering, if any, and could use them for purposes other than those contemplated at the time of the offering. Our management may use the net proceeds for corporate purposes that may not improve our financial condition or market value.

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

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

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

Sales of a substantial number of shares of our common stock in the public market, or the perception that these sales might occur, could depress the market price of our common stock and could impair our ability to raise capital through the sale of additional equity securities. As of September 24, 2015, we had 16,254,985 shares of common stock outstanding, all of which shares, other than shares held by our directors and certain officers, were eligible for sale in the public market, subject in some cases to compliance with the requirements of Rule 144, including the volume limitations and manner of sale requirements. In addition, shares of common stock issuable upon exercise of outstanding options and shares reserved for future issuance under our stock incentive plans will become eligible for sale in the public market to the extent permitted by applicable vesting requirements and subject in some cases to compliance with the requirements of Rule 144.

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

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

Special Note Regarding Forward-Looking Statements

This prospectus contains forward-looking statements within the meaning of Section 27A of the Securities Act of 1933, as amended, and Section 21E of the Securities Exchange Act of 1934, as amended, which statements involve substantial risks and uncertainties. Forward-looking statements generally relate to future events or our future financial or operating performance. In some cases, you can identify forward-looking statements because they contain words such as “may,” “will,” “should,” “expects,” “plans,” “anticipates,” “could,” “intends,” “target,” “projects,” “contemplates,” “be “estimates,” “predicts,” “potential” or “continue” or the negative of these words or other similar terms or expressions that concern our expectations, strategy, plans or intentions. Forward-looking statements contained in this prospectus include, but are not limited to, statements about:

- the development of our drug candidates, including when we expect to undertake, initiate and complete clinical trials of our product candidates;
- expectation of or dates for commencement of clinical trials, investigational new drug filings and similar plans or projections;
- the regulatory approval of our drug candidates;
- our use of clinical research centers, third party manufacturers and other contractors;
- our ability to find collaborative partners for research, development and commercialization of potential products;
- our ability to manufacture products for clinical and commercial use;
- our ability to protect our patents and other intellectual property;
- our ability to market any of our products;
- our ability to secure adequate protection for our patents and other intellectual property;
- our ability to compete against other companies and research institutions;
- our ability to expand our operations internationally;
- the effect of potential strategic transactions on our business;
- 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; and
- the volatility of our stock price.

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

You should not rely upon forward-looking statements as predictions of future events. We have based the forward-looking statements contained in this prospectus primarily on our current expectations and projections about future events and trends that we believe may affect our business, financial condition, results of operations and prospects. The outcome of the events described in these forward-looking statements is subject to risks, uncertainties and other factors described in the section of this prospectus entitled “Risk Factors” and elsewhere in this prospectus. Moreover, we operate in a very competitive and challenging environment. New risks and uncertainties emerge from time to time, and it is not possible for us to predict all risks and uncertainties that could have an impact on the

forward-looking statements contained in this prospectus. We cannot assure you that the results, events and circumstances reflected in the forward-looking statements will be achieved or occur, and actual results, events or circumstances could differ materially from those described in the forward-looking statements. Additionally, final data may differ significantly from preliminary data reported in this document.

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

This prospectus also contains statistical data, estimates, and forecasts that are based on independent industry publications or other publicly available information, as well as other information based on our internal sources. Although we believe that the third-party sources referred to in this prospectus are reliable, we have not independently verified the information provided by these third parties. While we are not aware of any misstatements regarding any third-party information presented in this prospectus, their estimates, in particular, as they relate to projections, involve numerous assumptions, are subject to risks and uncertainties, and are subject to change based on various factors, including those discussed under the section of this prospectus entitled “Risk Factors” and elsewhere in this prospectus.

USE OF PROCEEDS

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

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

RATIO OF EARNINGS TO FIXED CHARGES

We present below the ratio of our earnings to fixed charges. Earnings consist of net loss plus fixed charges. Fixed charges consist of interest expense, amortization of debt issuance costs, and that portion of rental expense we believe to be representative of interest. The information presented below from January 1, 2010 through November 20, 2013 is based solely on Capricor, Inc.'s financials and, subsequent to November 20, 2013, the date of the consummation of the merger between Capricor, Inc. and Nile Therapeutics, Inc., (Capricor Therapeutics, Inc.'s former name), includes consolidated financials of Capricor, Inc. and Capricor Therapeutics, Inc.

	Year Ended December 31,					**Six Months Ended June 30,**
	2010	2011	2012	2013	2014	2015
Ratio of earnings (loss) to fixed charges (1)	-	-	-	-	-	-
Deficiency in earnings (loss) to cover fixed charges (2)	$(865)	$(1,149)	$(2,071)	$(8,892)	$(6,217)	$ (6,599)

(1) We did not record earnings for any of the years ended December 31, 2010, 2011, 2012, 2013 or 2014 or the six months ended June 30, 2015. Accordingly, our earnings were insufficient to cover fixed charges

for such periods and we are unable to disclose a ratio of earnings to fixed charges for such periods. The dollar amount of the deficiency in earnings available for fixed charges for the years ended December 31, 2010, 2011, 2012, 2013 and 2014 and the six months ended June 30, 2015 was approximately $0.865 million, $1.149 million, $2.071 million, $8.892 million, $6.217 million and $6.599 million, respectively.

(2) We did not record earnings for any of the years ended December 31, 2010, 2011, 2012, 2013 or 2014 or the six months ended June 30, 2015. To achieve an earnings to fixed charges ratio of 1:1, we would need to generate additional income of approximately $0.865 million, $1.149 million, $2.071 million, $8.892 million, $6.217 million and $6.599 million, respectively.

Description of CAPITAL STOCK

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

General

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