

CAPRICOR THERAPEUTICS, INC.
Form 424B3
June 12, 2015

Filed Pursuant to Rule 424(b)(3)

Registration No. 333-202589

PROSPECTUS

CAPRICOR THERAPEUTICS, INC.

4,095,693 Shares of Common Stock

This prospectus relates to the resale by the selling stockholders, including their respective transferees, donees, pledgees or other successors in interest identified in this prospectus of up to 4,095,693 shares of common stock, \$0.001 par value per share, of Capricor Therapeutics, Inc., a Delaware corporation. All of the shares of common stock held by the selling stockholders were issued by us in private placement transactions. We are not offering any shares of our common stock for sale under this prospectus and we will not receive any part of the proceeds from sales of the shares of common stock by the selling stockholders. The selling stockholders will bear all commissions and discounts, if any, attributable to the sale or other disposition of the shares. We will bear all costs, expenses and fees in connection with the registration of the shares. The selling stockholders may, from time to time, sell, transfer or otherwise dispose of any or all of the shares of common stock offered by this prospectus on terms to be determined at the time of sale through ordinary brokerage transactions or through any other means described in this prospectus under the section entitled "Plan of Distribution" on page 15. The prices at which the selling stockholders may sell the shares will be determined by the prevailing market price for the shares or in negotiated transactions.

Our common stock is currently listed on the NASDAQ Capital Market ("NASDAQ") under the symbol "CAPR". On June 10, 2015, the closing price of our common stock as reported on NASDAQ was \$5.50.

Investing in our common stock involves a high degree of risk. See "Risk Factors" on page 6.

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

June 12, 2015

table of contents

	Page
<u>Prospectus Summary</u>	2
<u>Risk Factors</u>	6
<u>Special Note Regarding Forward-Looking Statements</u>	7
<u>Use of Proceeds</u>	8
<u>Selling Stockholders</u>	9
<u>Plan of Distribution</u>	15
<u>Description of Capital Stock</u>	16
<u>Legal Matters</u>	21
<u>Experts</u>	21
<u>Where You Can Find More Information</u>	21
<u>Information Incorporated by Reference</u>	22

We have not, and the selling stockholders have not, authorized anyone to provide any information or make any representations other than those contained in this prospectus or in any free writing prospectuses prepared by or on behalf of us or to which we have referred you. We do not, and the selling stockholders do not, take responsibility for, and can provide no assurance as to the reliability of, any information that others may give you. This prospectus is an offer to sell only the shares offered hereby, but only under circumstances and in the jurisdictions where it is lawful to do so. The information contained in this prospectus or in any applicable free writing prospectus is current only as of its date, regardless of the time of delivery of this prospectus or of any sale of shares of our common stock. Our business, financial condition and results of operations may have changed since that date.

No action is being taken in any jurisdiction outside the United States to permit a public offering of the common stock or possession or distribution of this prospectus in that jurisdiction. Persons who come into possession of this prospectus in jurisdictions outside the United States are required to inform themselves about and to observe any restrictions as to the offering and the distribution of this prospectus applicable to that jurisdiction.

Prospectus Summary

This summary highlights information contained elsewhere in this prospectus. Because it is a summary, it may not contain all of the information that is important to you. Accordingly, you are urged to carefully review this prospectus in its entirety, including the risks of investing in our securities discussed under the section entitled “Risk Factors” and the other information that is contained in or incorporated by reference into this prospectus or the registration statement of which this prospectus is a part before making an investment decision. 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 develop and commercialize innovative therapies for the treatment of cardiovascular 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 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.

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 a Phase II clinical study for Cenderitide. 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

Our business is subject to numerous risks and uncertainties, including those highlighted in the section of this prospectus entitled “Risk Factors” on page 6, which you should read carefully before making a decision to invest in our common stock. Some of these risks include:

- We need substantial additional funding before we can complete the development of our product candidates;

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;

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;

Our business faces significant government regulation, and there is no certainty that our products will receive regulatory approval;

We have limited manufacturing capability, and may not be able to successfully manufacture our product candidates or maintain our manufacturing licenses;

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

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.

Description of Private Placements

On January 9, 2015, we entered into a Share Purchase Agreement, or the PIPE 1 Purchase Agreement, with select investors pursuant to which we agreed to issue and sell to the investors, in a private placement (which we refer to in this prospectus as PIPE 1), an aggregate of 2,839,045 shares of our common stock at a price per share of \$3.523 for an aggregate purchase price of approximately \$10,000,000. The shares of common stock were issued and sold to the PIPE 1 investors in reliance on the exemption from registration afforded by Section 4(2) of the Securities Act of 1933, as amended, or the Securities Act, and Rule 506 of Regulation D promulgated under the Securities Act.

In connection with PIPE 1, we also entered into a Registration Rights Agreement with the PIPE 1 investors on January 9, 2015. Pursuant to the terms of the Registration Rights Agreement, we may be required to effect certain registrations to register for resale the PIPE 1 shares issued to the PIPE 1 investors pursuant to the PIPE 1 Purchase Agreement in connection with certain “piggy-back” registration rights granted to the PIPE 1 investors. We will be required to pay to each PIPE 1 investor liquidated damages equal to 1.0% of the aggregate purchase price paid by such investor pursuant to the PIPE 1 Purchase Agreement for the shares per month (up to a cap of 10.0%) if we do not meet certain obligations with respect to the registration of the shares, subject to certain conditions. In accordance with the terms of the Registration Rights Agreement, we filed a Registration Statement on Form S-1, as may be amended from time to time (SEC File No. 333-202589), or the Form S-1, which was declared effective by the Securities and Exchange Commission on March 30, 2015, to register for resale the shares of common stock issued in PIPE 1. We are filing a Post-Effective Amendment No. 1 to Form S-1 on Form S-3, or the Form S-3, of which this prospectus is a part, in order to update the prospectus that is a part of the Form S-1.

On February 2, 2015, we entered into an amendment to the PIPE 1 Purchase Agreement with certain of the PIPE 1 investors, which amended certain provisions of the PIPE 1 Purchase Agreement limiting our ability to issue additional shares of our common stock until the filing of an effective registration statement for the PIPE 1 shares. As a result of such amendment, the restriction on the issuance of additional shares was eliminated.

On February 3, 2015, we entered into a second Share Purchase Agreement, or the PIPE 2 Purchase Agreement, with certain accredited investors, pursuant to which we agreed to issue and sell to the investors, in a private placement (which we refer to in this prospectus as PIPE 2), an aggregate of 1,658,822 shares of our common stock at a price per share of \$4.25 for an aggregate purchase price of approximately \$7,050,000. The shares of common stock were issued and sold to the PIPE 2 investors in reliance on the exemption from registration afforded by Section 4(2) of the Securities Act and Rule 506 of Regulation D promulgated under the Securities Act.

In connection with PIPE 2, we also entered into a Registration Rights Agreement with the PIPE 2 investors on February 3, 2015. Pursuant to the terms of the Registration Rights Agreement for PIPE 2, we may be required to effect certain registrations to register for resale the PIPE 2 shares in connection with certain “piggy-back” registration rights granted to the PIPE 2 investors. We will be required to pay to each PIPE 2 investor liquidated damages equal to 1.0% of the aggregate purchase price paid by such investor pursuant to the PIPE 2 Purchase Agreement for the shares per month (up to a cap of 10.0%) if we do not meet certain obligations with respect to the registration of the shares, subject to certain conditions. In accordance with the terms of the Registration Rights Agreement, we filed the Form S-1, which was declared effective by the Securities and Exchange Commission on March 30, 2015, to register for resale the shares of common stock issued in PIPE 2. We are filing the Form S-3, of which this prospectus is a part, in order to update the prospectus that is a part of the Form S-1.

The offering

Common stock offered by the selling shareholders 4,095,693 shares

Common stock to be outstanding after the offering 16,223,281 shares

Use of proceeds We will not receive any proceeds from the sale of shares of common stock by the selling stockholders.

Risk Factors You should read the section of this prospectus entitled “Risk Factors” on page 6 for a discussion of factors to consider carefully before deciding to invest in shares of our common stock.

Dividend Policy Currently, we do not anticipate paying cash dividends.

NASDAQ Symbol “CAPR”.

The number of shares of common stock that will be outstanding after the offering is based on 16,223,281 shares of our common stock outstanding as of May 20, 2015, and excludes:

5,808,554 shares of our common stock issuable upon the exercise of outstanding stock options with a weighted average exercise price of \$1.46 per share as of May 20, 2015;

235,830 shares of our common stock issuable upon the exercise of outstanding warrants with a weighted average exercise price of \$2.27 per share as of May 20, 2015; and

1,051,678 shares of our common stock reserved for issuance as of May 20, 2015 under our: (1) Amended and Restated 2005 Stock Option Plan; (2) 2006 Stock Option Plan; (3) 2012 Restated Equity Incentive Plan; and (4) 2012 Non-Employee Director Stock Option Plan ((1) through (4), collectively, the “Plans”).

Except as otherwise indicated, all information in this prospectus assumes the sale of all shares of common stock covered by this prospectus.

Risk Factors

Investing in our common stock involves a high degree of risk. You should carefully review the risks and uncertainties set forth in the documents that are incorporated by reference into this prospectus, including the risks and uncertainties described under the heading “Risk Factors” in our most recent Annual Report on Form 10-K as filed with the Securities and Exchange Commission on March 16, 2015, before deciding whether to purchase any of the shares of common stock being offered. If any of these risks actually occur, our business, financial condition, results of operations or cash flow could be seriously harmed. This could cause the trading price of our common stock to decline, resulting in a loss of all or part of your investment.

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.”

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,” “believes,” “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, 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 history of operating losses;
 - our ability to secure adequate protection for our intellectual property;
 - our ability to compete against other companies and research institutions;
 - the effect of potential strategic transactions on our business;
- acceptance of our products by doctors, patients or payors and the availability of reimbursement for our product candidates;
 - our ability to attract and retain key personnel; 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 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

We will receive no proceeds from any sale by the selling stockholders of the common shares covered by this prospectus.

SELLING STOCKHOLDERS

This prospectus covers the resale by the selling stockholders identified below of a total of 4,095,693 shares of our common stock. All of these securities were previously issued to the selling stockholders in two private placement transactions, consisting of: (i) 2,839,045 shares of common stock issued pursuant to the Share Purchase Agreement, dated as of January 9, 2015, as amended, and (ii) 1,658,822 shares of common stock issued pursuant to the Share Purchase Agreement, dated as of February 3, 2015, in each case less any shares of common stock previously sold by the selling stockholders under the Registration Statement on Form S-1 (File No. 333-202589), as filed by the Company with the Securities and Exchange Commission on March 6, 2015. A description of these transactions is set forth above under the section entitled “Prospectus Summary – Description of Private Placements” on page 3.

The information presented in the below table has been calculated based on the assumption that all shares offered hereby will be sold and that no other shares of our common stock will be acquired or disposed of by the stockholders named below prior to the termination of this offering. However, we do not know when or in what amounts the selling stockholders may sell or otherwise dispose of the shares covered hereby. The selling stockholders might not sell any or all of the shares covered by this prospectus or may sell or dispose of some or all of the shares other than pursuant to this prospectus. The beneficial ownership set forth below has been determined in accordance with Rule 13d-3 under the Securities Exchange Act of 1934, as amended (the “Exchange Act”). This table has been prepared based on information supplied to us by the selling stockholders, and reflects holdings as of May 20, 2015. Except as provided below, none of the selling stockholders has held any position or office or had any other material relationship with us or any of our predecessors or affiliates within the past three years other than as a result of the ownership of our securities. Additionally, except as indicated by footnote, and subject to applicable community property laws, we believe that (i) the beneficial owners of the common stock listed below have sole voting power and sole investment power with respect to their shares, (ii) none of the selling stockholders are broker-dealers or affiliates of broker-dealers, and (iii) no selling stockholder has any direct or indirect agreement or understanding with any person to distribute his, her or its shares. To the extent any selling stockholder identified below is, or is affiliated with, a broker-dealer, he, she or it could be deemed to be, under SEC Staff interpretations, an “underwriter” within the meaning of the Securities Act.

In computing the number of shares of common stock beneficially owned by a person and the percentage ownership of such person, we deemed to be outstanding all shares of common stock subject to options an