

CAPRICOR THERAPEUTICS, INC.
Form 424B5
September 15, 2016

The information in this preliminary prospectus supplement is not complete and may be changed. This preliminary prospectus supplement and the accompanying prospectus are not offers to sell these securities and are not soliciting an offer to buy these securities in any jurisdiction where the offer or sale is not permitted.

Subject to Completion

PRELIMINARY PROSPECTUS SUPPLEMENT dated SEPTEMBER 15, 2016

Filed Pursuant to Rule 424(b)(5)

Registration No. 333-207149

PROSPECTUS SUPPLEMENT

(To Prospectus dated October 26, 2015)

Shares of Common Stock

CAPRICOR THERAPEUTICS, INC.

We are offering _____ shares of our common stock, par value \$0.001 per share. Our common stock is listed on the NASDAQ Capital Market under the symbol "CAPR." On September 14, 2016, the last sale price for our common stock as reported on the NASDAQ Capital Market was \$3.90 per share.

As of September 14, 2016, the aggregate market value of our outstanding common stock held by non-affiliates, or public float, was approximately \$45,062,720, based on 17,954,398 shares of our outstanding common stock on such

date, of which approximately 6,936,618 shares were held by affiliates and 11,017,780 shares were held by non-affiliates, and a price of \$4.09 per share, which was the price at which our common stock was last sold on the NASDAQ Capital Market on September 7, 2016 (a date within 60 days of the anticipated date of sale), calculated in accordance with General Instruction I.B.6 of Form S-3. 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 \$4.1 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-7 of this prospectus supplement and on page 7 of the prospectus accompanying this prospectus supplement.

| | Per Share | Total |
|--|--------------|-------|
| Public offering price | \$ | \$ |
| Underwriting discounts and commissions (1) | \$ | \$ |
| Proceeds, before expenses, to us | \$ | \$ |

(1) See “Underwriting” for additional information regarding underwriting compensation.

Cedars-Sinai Medical Center, one of our stockholders, has agreed to purchase _____ shares of our common stock at the public offering price in a concurrent registered direct offering.

We have granted an over-allotment option to the underwriters. Under this option, the underwriters may elect to purchase a maximum of _____ additional shares from us within 30 days following the date of this prospectus supplement to cover over-allotments.

We anticipate that delivery of the shares will be made on or about _____, 2016.

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.

Joint Book-Running Managers

Roth Capital Partners National Securities Corporation

The date of this prospectus supplement is September _____, 2016

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About This Prospectus Supplement

This prospectus supplement and the accompanying prospectus are part of a registration statement that we filed with the Securities and Exchange Commission, or the SEC, utilizing a “shelf” registration process. This document is in two parts. The first part is the prospectus supplement, including the documents incorporated by reference, which describes the specific terms of this offering. The second part, the accompanying prospectus, including the documents incorporated by reference, provides more general information. Generally, when we refer to this prospectus, we are referring to both parts of this document combined. Before you invest, you should carefully read this prospectus supplement, the accompanying prospectus, all information incorporated by reference herein and therein, as well as the additional information described under the sections of this prospectus supplement entitled “Where You Can Find More Information” and “Information Incorporated by Reference”.

These documents contain information you should consider when making your investment decision. This prospectus supplement may add, update or change information contained in the accompanying prospectus. To the extent that any statement that we make in this prospectus supplement is inconsistent with statements made in the accompanying prospectus or any documents incorporated by reference, the statements made in this prospectus supplement will be deemed to modify or supersede those made in the accompanying prospectus and 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 therein and any free writing prospectus we provide you. We have not, and the underwriters have 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 the underwriters are not, making an offer to sell these securities in any jurisdiction where the offer or sale is not permitted. You should assume that the information appearing in this prospectus supplement, the accompanying prospectus, the documents incorporated by reference in this prospectus supplement and the accompanying prospectus 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 and the accompanying prospectus, including the documents incorporated by reference in this prospectus supplement 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.

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Unless otherwise indicated, information contained in this prospectus supplement, the accompanying prospectus or the documents incorporated by reference, 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 and the accompanying prospectus. These and other important factors could cause our future performance to differ materially from our assumptions and estimates. See the section of this prospectus supplement entitled "Special Note Regarding Forward-Looking Statements."

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.

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Prospectus Supplement Summary

This summary highlights selected information contained elsewhere or incorporated by reference in this prospectus supplement. This summary does not contain all the information that you should consider before investing in our common stock. Before making an investment decision, to fully understand this offering and its consequences to you, you should carefully read this entire prospectus supplement and the accompanying prospectus, including the “Risk Factors” contained in this prospectus supplement and the accompanying prospectus, the financial statements and related notes, and the other information that we incorporate by reference into this prospectus supplement. This prospectus supplement contains forward-looking statements that involve risks and uncertainties. Our actual results could differ materially from the results anticipated in these forward-looking statements as a result of factors described under the “Risk Factors” section and elsewhere in this prospectus supplement, the accompanying prospectus and our Annual Report on Form 10-K for the year ended December 31, 2015. Unless the context otherwise requires, any reference to “Capricor Therapeutics,” “Capricor,” the “Company,” “we,” “our” and “us” in this prospectus supplement refers to Capricor Therapeutics, Inc. and its subsidiaries.

Capricor Therapeutics, Inc.

Company Overview

Capricor Therapeutics, Inc. is a clinical-stage biotechnology company focused on the discovery, development and commercialization of biological therapies for the treatment of cardiac and other serious medical conditions. 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:** Our lead product candidate consists of allogeneic cardiosphere-derived cells, or CDCs. We are currently conducting two clinical trials of CAP-1002: the Phase II portion of the Phase I/II ALLSTAR trial in patients who have had a myocardial infarction (MI, also known as a heart attack), and the Phase I/II HOPE-Duchenne trial in patients with Duchenne muscular dystrophy (DMD)-associated cardiomyopathy. Until 60 days after our delivery of the six-month follow-up results from Phase II of the ALLSTAR trial, Janssen Biotech, Inc., a wholly-owned subsidiary of Johnson & Johnson, or Janssen, has the right to exercise an option to enter into an exclusive license agreement pursuant to which Janssen would receive a worldwide, exclusive license to exploit CAP-1002 as well as certain allogeneic cardiospheres and cardiosphere-derived cells in the field of cardiology, except as may otherwise be

agreed with respect to certain indications as may be determined. We expect to receive Janssen's decision with respect to this option in the first half of 2017 following the delivery of the six-month results from the ALLSTAR trial. We completed enrollment of the HOPE-Duchenne trial in September 2016 and expect to report top-line six-month results from the HOPE-Duchenne trial in the first quarter of 2017. Furthermore, in 2016, we completed a 12-month follow-up in our DYNAMIC clinical trial using CAP-1002 in patients with advanced heart failure and reported positive 12-month clinical data in June 2016.

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Cenderitide (CD-NP): Cenderitide belongs to a class of drugs called natriuretic peptides. Cenderitide is being developed 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. In 2015, we completed a Phase II study in 14 patients with stable, chronic heart failure. This open-label trial assessed the safety, tolerability, pharmacokinetic profiles and pharmacodynamic response to increasing dose levels of Cenderitide administered in a stepwise fashion. Capricor has recently completed an additional study to further assess the safety, tolerability, pharmacokinetic profiles and pharmacodynamic response to increasing dose levels of Cenderitide in patients with stable heart failure with moderate renal impairment. Capricor will determine the future strategy for the development of Cenderitide, which may include exploring potential out-licensing arrangements. Cenderitide has been granted Fast-Track designation by the FDA in the post-acute period.

Exosomes (CAP-2003): Exosomes are nano-sized, membrane-enclosed vesicles, or “bubbles”, that are filled with select molecules, including proteins, RNAs and microRNAs, which, when released, send messages to neighboring cells to regulate cellular functions. Exosomes act as transport vehicles out of cells for microRNA, 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 activity. Their size, ease of crossing cell membranes, and ability to communicate in native cellular language make them a class of exciting and novel therapeutic agents. We are currently conducting pre-clinical studies to explore the possible therapeutic benefits that exosomes may possess, with a focus on ophthalmologic, dermatologic and oncologic disease. We expect to submit an Investigational New Drug application for CAP-2003 in the first half of 2017 and to initiate clinical development in ocular graft-versus-host disease in 2017.

CAP-1001: CAP-1001 consists of autologous CDCs. This product was evaluated in the randomized, double-blind, placebo-controlled Phase I CADUCEUS clinical trial in patients who had recently experienced an MI. The study was sponsored and conducted by Cedars-Sinai Medical Center in collaboration with The Johns Hopkins University. The data from CADUCEUS, using autologous CDCs, suggest that CDCs are effective in reducing scar size 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. 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 asset, at present there is no plan to develop CSps as therapeutic agents.

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.

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 and the accompanying prospectus, including our Annual Report on Form 10-K for the year ended December 31, 2015 and our Quarterly Report on Form 10-Q for the quarter ended June 30, 2016. For instructions on how to find copies of these documents, see “Where You Can Find More Information”.

The Offering

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

| | |
|---|-----------------------------|
| Issuer | Capricor Therapeutics, Inc. |
| Common stock to be offered | Shares |
| Common stock to be outstanding after the offering | Shares |

Use of proceeds We intend to apply the net proceeds of this offering and the concurrent registered direct 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 and the concurrent registered direct offering in response to developments in our business and other factors.

NASDAQ symbol for common stock Our common stock is listed on the NASDAQ Capital Market under the symbol "CAPR."

Risk factors Investing in our common stock 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 shares of our common stock.

The number of shares of common stock to be outstanding after this offering is based on 17,952,323 shares of common stock outstanding as of June 30, 2016 and does not take into account, as of June 30, 2016:

6,650,729 shares of our common stock issuable upon exercise of outstanding stock options to purchase shares of our common stock at a weighted average exercise price of \$1.65 per share;

1,081,903 shares of our common stock issuable upon the exercise of outstanding warrants with a weighted average exercise price of \$4.01 per share;

497,711 shares of our common stock reserved for issuance 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. On June 2, 2016, the 2012 Restated Equity Incentive Plan was amended to automatically increase the number of shares reserved for issuance on January 1 of each year, commencing with January 1, 2016, by 2% of the outstanding shares of our common stock as of the last day of the immediately preceding fiscal year. Such increase is included in the number of the shares reserved for issuance as shown above; and

shares of our common stock sold in the concurrent registered direct offering to Cedars-Sinai Medical Center.

Except as otherwise indicated, all information in this prospectus supplement assumes no exercise by the underwriters of their option to purchase up to an additional shares of our common stock.

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Risk Factors

Investing in any securities offered pursuant to this prospectus supplement and the accompanying prospectus involves a high degree of risk. Before making an investment decision, you should carefully consider the following risks and uncertainties and the risks described under “Risk Factors” in the accompanying prospectus 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 supplement and the accompanying prospectus, 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. Additional risks not presently known to us or that we currently believe are immaterial may also significantly impair our business operations.

Risks Related to this Offering

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

We currently anticipate that the net proceeds from this offering and the concurrent registered direct offering will be used 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. However, we have not determined the specific allocation of the net proceeds from this offering and the concurrent registered direct offering among these potential uses. Our management will have broad discretion as to the application of the net proceeds from this offering and the concurrent registered direct offering and could use them for purposes other than those contemplated at the time of this 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 the concurrent registered direct offering.

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. See “Dilution” for a more detailed description of the dilution to new investors in this offering.

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 14, 2016, we had 17,954,398 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.

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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 shares of 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.

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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,” “contemplates,” “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 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 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.

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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

The net proceeds from the sale of the shares of common stock in this offering and the concurrent registered direct offering are estimated to be approximately \$ million, or approximately \$ million if the underwriters exercise in full their option to purchase additional shares in this offering, after deducting the underwriting discounts and commissions and estimated offering expenses payable by us.

We currently intend to use the net proceeds from this offering and the concurrent registered direct 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.

The amounts and timing of our use of the net proceeds from this offering and the concurrent registered direct 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 and the concurrent registered direct 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. We reserve the right, at the sole discretion of our Board of Directors, to reallocate the proceeds of this offering and the concurrent registered direct offering in response to developments in our business and any other factors.

Price Range of Common Stock

Our common stock is listed on the NASDAQ Capital Market under the symbol “CAPR.”

The following table shows the high and low closing sale prices for our common stock as reported by the NASDAQ Capital Market during the periods indicated:

| | High | Low |
|--|--------|--------|
| Year Ending December 31, 2016 | | |
| Third Quarter (Through September 14, 2016) | \$4.27 | \$3.37 |
| Second Quarter | \$4.75 | \$2.61 |
| First Quarter | 2.97 | 2.01 |
| Year Ended December 31, 2015 | | |
| Fourth Quarter | \$4.60 | \$2.65 |
| Third Quarter | 5.10 | 3.86 |
| Second Quarter | 8.65 | 4.68 |
| First Quarter | 10.25 | 3.43 |
| Year Ended December 31, 2014 | | |
| Fourth Quarter | \$4.25 | \$3.20 |
| Third Quarter | 4.45 | 3.51 |
| Second Quarter | 8.50 | 4.11 |
| First Quarter | 17.15 | 2.50 |

The last reported sale price of our common stock on the NASDAQ Capital Market on September 14, 2016 was \$3.90 per share. As of September 14, 2016, there were 124 holders of record of our common stock.

Dividend Policy

We have never declared or paid any cash dividends on our common stock and we do not anticipate paying any cash dividends on our common stock in the foreseeable future. Dividends on our common stock will be paid only if and when declared by our Board of Directors. The ability of our Board of Directors to declare a dividend is subject to limits imposed by Delaware corporate law. Pursuant to the terms of our Loan Agreement with the California Institute for Regenerative Medicine, or CIRM, as amended, our Board of Directors also may not pay any dividends without the prior consent of CIRM; provided that our Board of Directors may pay dividends solely in shares of our common stock without such consent. In determining whether to declare dividends, our Board of Directors may consider our financial condition, results of operations, working capital requirements, future prospects and other relevant factors.

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Dilution

If you invest in our common stock in this offering, your ownership interest will be immediately 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 this offering and the concurrent registered direct offering.

Our net tangible book value as of June 30, 2016 was approximately \$(6.8) million, or \$(0.38) 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, 2016.

After giving effect to the issuance and sale by us of _____ shares of common stock in this offering and _____ shares of common stock in the concurrent registered direct offering at an offering price of \$ _____ per share, and after deducting underwriting discounts and commissions and estimated offering expense payable by us, our as adjusted net tangible book value as of June 30, 2016 would have been approximately \$ _____ million, or approximately \$ _____ per share. This amount represents an immediate increase in as adjusted net tangible book value of \$ _____ per share to our existing stockholders and an immediate dilution in the as adjusted net tangible book value of approximately \$ _____ per share to new investors purchasing shares of common stock in this offering at the offering price.

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

| | |
|---|----------|
| Public offering price per share | \$ |
| Net tangible book value per share as of June 30, 2016 | \$(0.38) |
| Increase in as adjusted net tangible book value per share attributable to this offering and the concurrent registered direct offering | \$ |
| As adjusted net tangible book value per share after this offering and the concurrent registered direct offering | |
| Dilution per share to new investors participating in this offering | \$ |

The above discussion and table are based on 17,952,323 shares of common stock outstanding as of June 30, 2016, which does not include, as of June 30, 2016:

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6,650,729 shares of our common stock issuable upon exercise of outstanding stock options to purchase shares of our common stock at a weighted average exercise price of \$1.65 per share;

1,081,903 shares of our common stock issuable upon the exercise of outstanding warrants with a weighted average exercise price of \$4.01 per share; and

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497,711 shares of our common stock reserved for issuance 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. On June 2, 2016, the 2012 Restated Equity Incentive Plan was amended to automatically increase the number of shares reserved for issuance on January 1 of each year, commencing with January 1, 2016, by 2% of the outstanding shares of our common stock as of the last day of the immediately preceding fiscal year. Such increase is included in the number of the shares reserved for issuance as shown above.

To the extent any of these outstanding options or warrants set forth above are exercised, there will be further dilution to new investors.

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Underwriting

We have entered into an underwriting agreement with the underwriters named below. Roth Capital Partners, LLC and National Securities Corporation are acting as representatives of the underwriters.

The underwriting agreement provides for the purchase of a specific number of shares of our common stock by each of the underwriters. The underwriters' obligations are several, which means that each underwriter is required to purchase a specific number of shares, but is not responsible for the commitment of any other underwriter to purchase shares. Subject to the terms and conditions of the underwriting agreement, each underwriter has severally agreed to purchase the number of shares of our common stock set forth opposite its name below:

| Underwriter | Number of Shares |
|---------------------------------|------------------|
| Roth Capital Partners, LLC | |
| National Securities Corporation | |
| Total | |

The underwriters have agreed to purchase all of the shares offered by this prospectus supplement (other than those covered by the over-allotment option described below), if any shares of our common stock are purchased. The shares should be ready for delivery on or about September , 2016 against payment in immediately available funds.

The closing of the concurrent registered direct offering to Cedars-Sinai Medical Center is expected to occur on the same day as this offering. This offering is not contingent upon the closing of the concurrent registered direct offering to Cedars-Sinai Medical Center.

The underwriters are offering the shares subject to various conditions and may reject all or part of any order. The underwriters have advised us that they propose to offer the shares directly to the public at the public offering price that appears on the cover page of this prospectus supplement. After the shares are released for sale to the public, the underwriters may change the offering price and other selling terms at various times.

We have granted the underwriters an over-allotment option. This option, which is exercisable for up to 30 days after the date of this prospectus supplement, permits the underwriters to purchase a maximum of additional shares from us to cover over-allotments. If any shares are purchased with this over-allotment option, the underwriters will purchase shares in approximately the same proportion as shown in the table above. If the underwriters exercise all or

part of this option, they will purchase shares covered by the option at the public offering price that appears on the cover page of this prospectus supplement, less the underwriting discount. If this option is exercised in full, the total price to the public will be \$ _____ and the total proceeds to us will be \$ _____ .

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The following table provides information regarding the amount of the discount to be paid to the underwriters by us:

| | Without Exercise of | With Full Exercise of |
|-----------|-----------------------------------|-----------------------------------|
| | Over- Allotment Option | Over- Allotment Option |
| Per Share | \$ | \$ |
| Total | \$ | \$ |

We estimate that our total expenses of this offering, excluding the underwriting discount, will be approximately \$, which includes not more than \$100,000 that we have agreed to reimburse the underwriters for the legal fees incurred by them in connection with this offering.

We have agreed to indemnify the underwriters against certain liabilities, including liabilities under the Securities Act of 1933, as amended.

We and our executive officers and directors and certain of our stockholders have agreed to a 90-day “lock up” with respect to shares of our capital stock that they beneficially own, including securities that are convertible into shares of our common stock and securities that are exchangeable or exercisable for shares of our common stock. This means that, subject to certain exceptions, for a period of 90 days following the date of this prospectus supplement, we and such persons may not offer, sell, pledge or otherwise dispose of these securities, except by gift, without the prior written consent of the representatives.

Rules of the SEC may limit the ability of the underwriters to bid for or purchase shares before the distribution of the shares is completed. However, the underwriters may engage in the following activities in accordance with the rules:

Stabilizing transactions – The underwriters may make bids or purchases for the purpose of pegging, fixing or maintaining the price of the shares, so long as stabilizing bids do not exceed a specified maximum.

Over-allotments and syndicate covering transactions – The underwriters may sell more shares of our common stock in connection with this offering than the number of shares that they have committed to purchase. This over-allotment creates a short position for the underwriters. This short sales position may involve either “covered” short sales or “naked” short sales. Covered short sales are short sales made in an amount not greater than the underwriters’ over-allotment option to purchase additional shares in this offering described above. The underwriters may close out any covered short position either by exercising their over-allotment option or by purchasing shares in the open market. To

determine how they will close the covered short position, the underwriters will consider, among other things, the price of shares available for purchase in the open market, as compared to the price at which they may purchase shares through the over-allotment option. Naked short sales are short sales in excess of the over-allotment option. The underwriters must close out any naked short position by purchasing shares in the open market. A naked short position is more likely to be created if the underwriters are concerned that, in the open market after pricing, there may be downward pressure on the price of the shares that could adversely affect investors who purchase shares in this offering.

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Penalty bids – If the underwriters purchase shares in the open market in a stabilizing transaction or syndicate covering transaction, they may reclaim a selling concession from the selling group members who sold those shares as part of this offering.

Similar to other purchase transactions, the underwriters' purchases to cover the syndicate short sales or to stabilize the market price of our common stock may have the effect of raising or maintaining the market price of our common stock or preventing or mitigating a decline in the market price of our common stock. As a result, the price of the shares of our common stock may be higher than the price that might otherwise exist in the open market. The imposition of a penalty bid might also have an effect on the price of the shares if it discourages resales of the shares.

Neither we nor the underwriters make any representation or prediction as to the effect that the transactions described above may have on the price of the shares. These transactions may occur on the NASDAQ Capital Market or otherwise. If such transactions are commenced, they may be discontinued without notice at any time.

The underwriters may in the future provide us and our affiliates with investment banking and financial advisory services for which they may in the future receive customary fees.

The transfer agent and registrar for our common stock is American Stock Transfer and Trust Company. The transfer agent and registrar's address is 10150 Mallard Creek Road, Suite 307, Charlotte, North Carolina 28262.

Electronic Delivery of Prospectus Supplements: A prospectus supplement in electronic format may be delivered to potential investors by the underwriters participating in this offering. The prospectus supplement in electronic format will be identical to the paper version of such prospectus supplement. Other than the prospectus supplement in electronic format, the information on the underwriters' web sites and any information contained in any other web site maintained by the underwriters is not part of the prospectus supplement or the registration statement of which this prospectus supplement forms a part.

Notice to Non-U.S. Investors

Belgium

The offering is exclusively conducted under applicable private placement exemptions and therefore it has not been and will not be notified to, and this document or any other offering material relating to the shares has not been and will not be approved by, the Belgian Banking, Finance and Insurance Commission (“Commission bancaire, financière et des assurances/Commissie voor het Bank, Financie en Assurantiewezen”). Any representation to the contrary is unlawful.