As filed with the Securities and Exchange Commission on May 7, 2020

Registration No. 333-

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

FORM S-3

REGISTRATION STATEMENT
UNDER
THE SECURITIES ACT OF 1933

Capricor Therapeutics, Inc.
(Exact name of Registrant as specified in its charter)

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

Capricor Therapeutics, Inc.
8840 Wilshire Blvd., 2nd Floor
Beverly Hills, CA 90211
(310) 358-3200
(Address, including zip code, and telephone number, including area code, of Registrant's principal executive offices)

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Beverly Hills, CA 90211
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(Name, address, including zip code, and telephone number, including area code, of agent for service)

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

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

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

If any of the securities being registered on this Form are to be offered on a delayed or continuous basis pursuant to Rule 415 under the Securities Act of 1933, other than securities offered only in connection with dividend or interest reinvestment plans, check the following box: ☒

If this Form is filed to register additional securities for an offering pursuant to Rule 462(b) under the Securities Act, please check the following box and list the Securities Act registration statement number of the earlier effective registration statement for the same offering. ☐

If this Form is a post-effective amendment filed pursuant to Rule 462(c) under the Securities Act, check the following box and list the Securities Act registration statement number of the earlier effective registration statement for the same offering. ☐

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

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

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

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

If an emerging growth company, indicate by check mark if the registrant has elected not to use the extended transition period for complying with any new or revised financial accounting standards provided pursuant to Section 7(a)(2)(B) of the Securities Act ☐

CALCULATION OF REGISTRATION FEE

Title of Each Class of Securities to be Registered	**Amount to be Registered[(1)]**	**Proposed Maximum Offering Price Per Share[(3)]**	**Proposed Maximum Aggregate Offering Price**	**Amount of Registration Fee**
Common Stock, par value $0.001 per share, issuable upon exercise of warrants	4,200,000[(2)]	$ 6.65	$ 27,930,000.00	$ 3,625.32

Total:	4,200,000		$ 27,930,000.00	$ 3,625.32

(1) Pursuant to Rule 416(a) under the Securities Act of 1933, as amended, this Registration Statement shall also cover any additional shares of the Registrant's Common Stock that become issuable by reason of any stock dividend, stock split, recapitalization or other similar transaction effected without receipt of consideration.

(2) All 4,200,000 shares of Common Stock issuable upon exercise of warrants are to be offered by the selling stockholders named herein, which such warrants were acquired by the selling stockholders in a private placement completed in March 2020.

(3) Estimated solely for the purpose of calculating the amount of the registration fee pursuant to Rule 457(c) under the Securities Act of 1933, as amended. The offering price per share and aggregate offering price are based upon the average of the high and low prices for the Registrant's Common Stock as reported on the Nasdaq Capital Market on May 5, 2020, a date within five business days prior to the filing of this Registration Statement.

The registrant hereby amends this registration statement on such date or dates as may be necessary to delay its effective date until the registrant shall file a further amendment which specifically states that this registration statement shall thereafter become effective in accordance with Section 8(a) of the Securities Act of 1933, as amended, or until the registration statement shall become effective on such date as the Commission, acting pursuant to said Section 8(a), may determine.

The information in this prospectus is not complete and may be changed. These securities may not be sold until the registration statement filed with the Securities and Exchange Commission is effective. This prospectus is not an offer to sell these securities, nor does it seek an offer to buy these securities in any jurisdiction where the offer or sale is not permitted.

SUBJECT TO COMPLETION, DATED MAY 7, 2020

PROSPECTUS

CAPRICOR THERAPEUTICS, INC.

4,200,000 SHARES OF COMMON STOCK ISSUABLE UPON EXERCISE OF OUTSTANDING WARRANTS

This prospectus (this "Resale Prospectus") relates to the resale by the selling stockholders named herein, including their respective transferees, donees, pledgees or other successors in interest identified in this prospectus, of up to 4,200,000 shares of our common stock, par value $0.001 per share (our "Common Stock"), comprised of (i) warrants to purchase up to 4,000,000 shares of our Common Stock with an exercise price of $1.27 per share (the "New Warrants"), and (ii) placement agent warrants to purchase up to 200,000 shares of our Common Stock with an exercise price of $1.5313 per share (the "Placement Agent Warrants" and together with the New Warrants, the "Warrants"). The New Warrants were issued by us in a private placement completed on March 25, 2020 and the Placement Agent Warrants were issued by us in a private placement completed on March 27, 2020.

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 our Common Stock by the selling stockholders; however, we will receive proceeds upon the exercise of outstanding Warrants for shares of our Common Stock covered by this prospectus if the Warrants are exercised for cash. We will bear all expenses of registration incurred in connection with this offering, but all selling and other expenses incurred by the selling stockholders will be borne by them.

Our Common Stock is currently listed on the Nasdaq Capital Market ("Nasdaq") under the symbol "CAPR". On May 5, 2020, the closing price of our Common Stock as reported on Nasdaq was $6.85**.**

Investing in our Common Stock involves a high degree of risk. See "Risk Factors" on page 9.

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.

_____, 2020

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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 our 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 clinical-stage biotechnology company focused on the discovery, development and commercialization of innovative cell and exosomes-based therapies for the treatment and prevention of diseases.

We are currently conducting HOPE-2, a Phase II clinical trial in the United States with our product candidate, CAP-1002, a cardiac cell derived therapy which is being used to treat patients with late-stage DMD. We plan to report final 12-month data from HOPE-2 by the middle of the second quarter of 2020. Following the receipt of this data, if positive, we plan to continue with the next stages of development towards potential FDA approval, and whether or not that approval is obtained following HOPE-2, pursuing a partnership to conduct a Phase III trial.

Additionally, in March and April 2020, we infused six patients with severe COVID-19 symptoms (five of six whom were on ventilators) under a compassionate use protocol with our product candidate, CAP-1002, all of whom have survived through May 6, 2020, with four of the five ventilated patients off of such therapy. All patients are alive as of May 6, 2020, but two patients remain in critical condition as of May 6 and there is no assurance that those patients will ultimately survive. The efficacy of CAP-1002 in treating COVID-19 was not necessarily demonstrated because the sample size was small, the six patients were contemporaneously on other experimental medications, and no control group was established. This would be a limited observational study with a primary objective of determining whether CAP-1002 can be safely used in subjects who are critically ill from the COVID-19 infection. We are also in the early planning stages to conduct a randomized, placebo-controlled trial to treat patients with moderate and severe COVID-19 disease with CAP-1002, which is currently intended to be funded by non-equity sources such as grants, should they be awarded to the Company.

We have also begun work on developing our exosomes platform technology as a next-generation vaccine and therapeutic platform investigating a variety of disorders. On April 15, 2020, we filed an IND with the FDA to investigate the use of CDC-Exosomes in patients with DMD. We are currently awaiting a response from the FDA on whether the study may proceed.

Our Technologies

Cardiosphere-Derived Cells (CAP-1002)

Our core therapeutic technology is based on cardiosphere-derived cells ("CDCs"), a cardiac-derived cell therapy that was first identified in the academic laboratory of Capricor's scientific founder, Dr. Eduardo Marbán. Since the initial publication in 2007, CDCs have been the subject of over 100 peer-reviewed scientific publications and have been administered to over 150 human subjects across several clinical trials. CDCs have been shown to exert potent immunomodulatory activity and to alter the immune system's activity to encourage cellular regeneration. We have been developing allogeneic CDCs (CAP-1002) as a product candidate for the treatment of Duchenne muscular dystrophy ("DMD") and investigating their effects on skeletal and cardiac function. Preclinical and clinical data support the therapeutic concept of administering CDCs as a means to address conditions in which the heart or skeletal muscle has been damaged.

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

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

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

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

Exosomes

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

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

To build upon the natural ability of exosomes for intercellular communication, we have initiated a program to engineer exosomes and load them with different macromolecules. Our preliminary results demonstrated that it is possible to load exosomes with specific miRNAs which pave the way to use our exosomes to potentially deliver miRNAs to specific target tissue. We are now working on developing exosome-based vaccines for COVID-19, in collaboration with Dr. Stephen J. Gould, Ph.D., from Johns Hopkins University. While these efforts are still in their early stages, our exosome-based vaccine platform technology will aim to combine the improved protection that comes from immunizing individuals with multiple antigens in a manner that mimics the advantages of conventional virus vaccines, with the superior safety profile of virus-free vaccines. We plan to design exosome-based vaccines to elicit strong humoral and cellular immune responses due to the simultaneous expression of antigens.

Our Strategy

Our strategy is to discover, develop and commercialize first-in-class cell-derived therapies for the treatment of diseases. Our drug candidates in active development consist of CAP-1002 (allogeneic CDCs) and our exosome technologies. We believe that CDC-exosomes are primarily responsible for the mechanism of action of our cell therapy product. We are now positioning ourselves to advance our exosome product candidates into a platform technology for clinical development. Additionally, we are also exploring potential strategic alternatives with respect to the Company as well as our product candidates.

Our Product Candidates

Our drug candidates which are in various stages of active development, consist of CAP-1002, our CDC-derived cells, and our exosome technologies. In 2018, we commenced enrollment of patients with DMD in a Phase II clinical trial of CAP-1002 called HOPE-2. CAP-1002 was also the subject of four previous clinical trials conducted by us.

Additionally, we are currently treating patients with COVID-19 with CAP-1002 under a compassionate use protocol. Recently, the FDA approved our expanded access protocol to treat up to 20 additional patients. There is also a randomized, placebo-controlled trial planned to treat patients with moderate and severe disease which is intended to be funded by non-equity capital such as grants.

CAP-1002 is also currently being investigated in two additional trials sponsored by CSMC, which are the REGRESS trial investigating heart failure with preserved ejection fraction and the ALPHA trial investigating pulmonary arterial hypertension. In March 2020, we were informed that the REGRESS study was put on clinical hold by the FDA. The information we received suggested that the issue was related to inadequate patient monitoring at the study site to assess safety for certain patients who were experiencing adverse events after receiving an intracoronary infusion of CAP-1002. Inadequate patient monitoring and reporting was further discussed in additional correspondence from the FDA which we have subsequently received from the study sponsor. It remains uncertain as to when the FDA will release the clinical hold. It is worth noting that Capricor did not use intracoronary infusions in its HOPE-2 trial.

We are also evaluating our exosomes in preclinical studies for the treatment of various indications and have begun work on developing our exosomes platform technology as a next-generation vaccine and therapeutic platform investigating a variety of disorders. We recently filed an IND with the FDA to investigate the use of CDC-Exosomes in patients with DMD.

The following table summarizes our active product development programs:

Product	Indication/Population	Development Stage	Commercial Rights
CAP-1002	Duchenne Muscular Dystrophy*	HOPE-3 Phase III – in planning stages HOPE-2*** Phase II · 6-month interim analysis completed · Final 12-month data expected by mid Q2-2020 HOPE-Duchenne Phase I/II completed**	Capricor
	COVID-19	· Compassionate Use Underway · Expanded Access Protocol approved by FDA · Randomized, placebo-controlled clinical trial in planning stages	Capricor
Exosome Technologies	COVID-19 · Exosome VLP Display Vaccine · Exosome mRNA Vaccine	Preclinical	Capricor
	Duchenne Muscular Dystrophy	IND submitted	Capricor

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

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

***We are planning an OLE for the HOPE-2 trial.

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, including our Annual Report on Form 10-K for the fiscal year ended December 31, 2019. For instructions on how to find copies of these documents, see "Where You Can Find More Information".

Corporate 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 solely as an inactive textual reference. 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.

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 9, 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;
- We have a history of net losses, and we expect losses to continue for the foreseeable future;
- The COVID-19 outbreak could adversely impact our business;
- 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 success depends upon the viability of our product candidates and we cannot be certain any of them will receive regulatory approval to be commercialized;
- Our exosome technologies are based on a novel therapeutic approach which makes it difficult to predict the time and cost of development and of subsequently obtaining regulatory approval, if at all;
- The clinical data we intend to generate for the COVID-19 indication may not be sufficient for regulatory approval, which could adversely affect our stock price;
- 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 maintain our manufacturing licenses;
- We have no prior experience in manufacturing products for large clinical trials or commercial use;
- We may face uncertainty and difficulty in obtaining, retaining and enforcing our patents and other proprietary rights;
- We are largely dependent on our relationships with our licensors, collaborators, and grantors and there is no guarantee that such relationships will be maintained or continued;
- Our products will likely face intense competition;
- 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; and
- We expect that our stock price will continue to fluctuate significantly.

Description of Warrant Inducement

On March 25, 2020, the Company entered into a letter agreement (the "Exercise Agreement") with a holder (the "Exercising Holder") of certain outstanding warrants to purchase shares of our Common Stock (the "Prior Warrants"). Pursuant to the Exercise Agreement, in connection with exercise by the Exercising Holder of the remaining 4,000,000 Prior Warrants held by the Exercising Holder which had not been previously exercised, the Company agreed to issue 4,000,000 New Warrants. The Prior Warrants had a per share exercise price of $1.10, and pursuant to the Exercise Agreement, the Exercising Holder paid $1.225 per share to cover both the exercise price of the Prior Warrants and a $0.125 per share purchase price for the New Warrants. The New Warrants have an exercise price of $1.27 per share. In addition, certain employees of the placement agent received Placement Agent Warrants equal to 5.0% of the New Warrants issued, or 200,000 shares, with an exercise price of $1.5313 per share for each Placement Agent Warrant.

The Warrants and the shares of our Common Stock issuable upon the exercise of the Warrants were not registered under the Securities Act of 1933, as amended (the "Securities Act"), and were offered pursuant to the exemption provided in Section 4(a)(2) under the Securities Act or Rule 506(b) promulgated thereunder. The New Warrants are exercisable immediately upon issuance, and have a term of exercise of 5 1/2 years. The Placement Agent Warrants are exercisable immediately upon issuance, and have a term of exercise of 5 years. The holders of each of the Warrants has the option to make a cashless exercise of such Warrant if no resale registration statement covering the shares of our Common Stock underlying the Warrant is effective after six months.

THE OFFERING

Common stock offered by the selling shareholders	4,200,000 shares of our Common Stock issuable upon exercise of Warrants
Common stock to be outstanding after the offering	16,664,006 shares
Use of proceeds	We will receive no proceeds from the sale of the shares of our Common Stock issuable upon exercise of the Warrants. We may, however, receive proceeds upon the cash exercise, if any, of the Warrants held by the selling stockholders. If the Warrants as of the date of this prospectus were to be cash exercised in full, we would receive gross cash proceeds of approximately $5.4 million. The Warrants are exercisable at any time. We intend to use any net proceeds received upon exercise of any of the Warrants to further develop our product candidates and for other general working capital purposes. See the section of this prospectus entitled "Use of Proceeds" on page 14 for a more complete description of the intended use of proceeds from the exercise of the Warrants.
Risk Factors	You should read the section of this prospectus entitled "Risk Factors" on page 9 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 our Common Stock that will be outstanding after the offering is based on 12,464,006 shares of our Common Stock outstanding as of April 30, 2020, plus 4,200,000 shares of our Common Stock issuable upon the exercise of Warrants that were issued to the selling shareholders in private placements on March 25, 2020 and March 27, 2020, and excludes:

- 265,088 shares of our Common Stock issuable upon the exercise of warrants, other than the Warrants, outstanding as of April 30, 2020 with a weighted-average exercise price of approximately $1.43 per share;
- 850,719 shares of our Common Stock issuable upon the exercise of options outstanding as of April 30, 2020 with a weighted-average exercise price of approximately $1.58 per share; and
- 74,815 shares of our Common Stock reserved as of April 30, 2020 for future issuance under our (1) 2012 Restated Equity Incentive Plan; and (2) 2012 Non-Employee Director Stock Option Plan.

Except as otherwise indicated, all information in this prospectus assumes the sale of all shares of our 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 ("the SEC") on March 27, 2020, and any updates in our Quarterly Reports on Form 10-Q and in our Current Reports on Form 8-K, before deciding whether to purchase any of the shares of our 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."

Risks Related to Clinical and Commercialization Activities

The clinical data we intend to generate for the COVID-19 indication may not be sufficient for regulatory approval, which could adversely affect our stock price.

While our announcement on April 29, 2020 of our apparently successful treatment of patients with severe COVID-19 symptoms with CAP-1002 has caused significant investor attention resulting in a material increase in the market price of our Common Stock, we will need to successfully conduct at least one randomized, placebo-controlled clinical trial in order to further study and ultimately seek to commercialize CAP-1002 for this indication. We are in the early stages of planning one such trial, which will require significant additional financing, and may not be undertaken, depending upon the results we obtain from the additional 20 compassionate use cases which we have permission to attempt from the FDA. Our stock price may suffer if this use for CAP-1002 is not successful in these additional cases or in future clinical trials.

Risks Related to this Offering

If you purchase shares of our Common Stock in this offering by the selling shareholders, you will incur immediate and substantial dilution in the book value of your shares.

Investors purchasing shares of our 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. 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 by the selling shareholders. 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 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, including delays or difficulties in enrolling patients caused by COVID-19;
- 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 licenses or other strategic alliances or adverse developments with existing licenses or 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;
- disruptions to our workforce and the workforces of companies, research institutions and other organizations with whom we do business;
- 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;
- disruptions to our business or the businesses of third parties with whom we do business or to the stock market or the United States economy generally, caused by sickness, travel restrictions or quarantines; or
- volatility in the stock prices of other companies in our industry.

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

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

We will have broad discretion in the use of the net proceeds from the exercise of warrants by the selling shareholders, if any, and may not use them effectively.

We currently intend to use the net proceeds from the payment of the exercise price for the Warrants held by the selling shareholders for working capital and general corporate purposes, which may include, without limitation, research and development related to our product candidates and manufacturing of our products, as further described in the section of this prospectus 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.

The number of shares being registered for sale is significant in relation to the number of outstanding shares of our Common Stock.

We have filed a registration statement of which this prospectus is a part to register the shares offered hereunder for sale into the public market by the selling stockholders. These shares represent a large number of shares of our Common Stock, and if sold in the market all at once or at about the same time, could depress the market price of our Common Stock during the period the registration statement remains effective and could also affect our ability to raise equity capital.

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, the accompanying prospectus and the documents incorporated by reference in this prospectus include, but are not limited to, statements about:

- how long we expect to maintain liquidity to fund our planned level of operations and our ability to obtain additional funds for our operations;
- the identification and development of our drug candidates, including when we expect to undertake, initiate and complete clinical trials of our product candidates;
- the expectation, plans, projections, initiation, timing, progress and results of our research and development programs, preclinical studies, any clinical trials, Investigational New Drug ("IND") filings, Clinical Trial Application ("CTA") filings, New Drug Application ("NDA") filings, and other regulatory submissions;
- the regulatory approval of any 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 our product candidates and retain commercial rights for our product candidates in the collaborations;
- our ability to manufacture products for clinical and commercial use;
- our reliance on third party suppliers and manufacturers to supply the materials and components for, and manufacture, our research and development, preclinical and clinical trial drug supplies;
- our ability to protect or retain our patents and other intellectual property;
- our ability to commercialize and market any of our products;
- the implementation of our business model and strategic plans for our business, technologies and product candidates;
- our estimates of our expenses, ongoing losses, future revenue and capital requirements;
- our ability to secure and maintain adequate protection for our patents and other intellectual property protection for our technologies and product candidates;
- our ability to operate our business without infringing the intellectual property rights of others;
- our reliance on third parties to conduct our preclinical studies or any clinical trials;
- our ability to compete against other companies and research institutions;
- our ability to expand our operations internationally;
- the effect of potential strategic transactions on our business;
- the rate and degree of acceptance of our product candidates by doctors, patients or payors and the availability of reimbursement for our product candidates;
- our financial performance;
- our ability to attract and retain key personnel; and
- the volatility of our stock price.

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

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. 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 prospectus.

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, if any.

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 the resale by the selling stockholders of the shares of our Common Stock issued upon the exercise of the Warrants. We may, however, receive up to approximately $5.4 million upon the cash exercise of the Warrants. We intend to use the proceeds received from any cash exercise of the Warrants to further develop our product candidates and for other general corporate and working capital purposes.

Our management will have broad discretion regarding the use of proceeds from the cash exercise of any of the Warrants, and investors will be relying on the judgment of our management regarding the application of the proceeds from the cash exercise of the Warrants. We may change the use of these proceeds from those described in this prospectus as a result of various factors such as competitive developments, the results of our early clinical development, manufacturing and commercialization efforts, the timing and progress of any partnering efforts, and other factors.

SELLING STOCKHOLDERS

This prospectus covers the resale by the selling stockholders identified below of a total of up to 4,200,00 shares of our Common Stock issuable upon the exercise of the Warrants. These New Warrants were previously issued on March 25, 2020 and the Placement Agent Warrants were previously issued on March 27, 2020, in each case to the selling stockholders in private placements. A description of the private placements is set forth above under the section entitled "Prospectus Summary – Description of Warrant Inducement" on page 7.

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 5, 2020. 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.

The following table sets forth information with respect to the beneficial ownership of our Common Stock held, as of May 5, 2020, by the selling stockholders and the number of shares of our Common Stock being offered hereby and information with respect to shares to be beneficially owned by the selling stockholders after completion of this offering. The percentages in the following table reflect the shares beneficially owned by the selling stockholders as a percentage of the total number of shares of our Common Stock outstanding as of May 5, 2020. As of such date, 12,464,006 shares of our Common Stock were outstanding.

	Beneficial Ownership Prior to the Offering[1]		Number of shares offered hereby	Beneficial Ownership After the Offering[1]	
	Number of Shares	Percent		Number of Shares	Percent
Selling Stockholders					
Armistice Capital Master Fund Ltd[2]	654,619	4.99	4,000,000	-	-
James Cappuccio[3]	76,744	*	38,000	38,744	*
Noam Rubinstein[3]	50,489	*	25,000	25,489	*
Michael Vasinkevich[3]	259,775	2.0	128,250	131,525	1.0
Craig Schwabe[3]	6,750	*	6,750	-	-
Charles Worthman[3]	4,039	*	2,000	2,039	*
Total:			**4,200,000**		

* Represents less than 1%.

(1)We have based percentage ownership of our Common Stock on 12,464,006 shares of our Common Stock outstanding as of May 5, 2020. Beneficial ownership is determined in accordance with Rule 13d-3 under the Exchange Act, and includes any shares as to which the security or holder has sole or shared voting power or dispositive power, and also any shares which the security holder has the right to acquire within 60 days of May 5, 2020, whether through the exercise or conversion of any stock option, convertible security, warrant or other right. The indication herein that shares are beneficially owned is not an admission on the part of the security holder that he, she or it is a direct or indirect beneficial owner of those shares.

(2) Includes 654,619 shares of our Common Stock issuable upon the exercise of warrants held by Armistice Capital Master Fund, Ltd. Does not include 3,345,381 shares of our Common Stock issuable upon exercise of warrants held by Armistice Capital Master Fund, Ltd. that may not be issued due to a 4.99% Beneficial Ownership Limitation in the Warrants. Armistice Capital, LLC, the investment manager of Armistice Capital Master Fund Ltd. ("Armistice"), and Steven J. Boyd, the managing member of Armistice hold shared voting and dispositive power over the ordinary shares held by Armistice. Armistice and Mr. Boyd disclaim beneficial ownership in the shares, except to the extent of his or its pecuniary interest therein. The address for Armistice Capital Master Fund, Ltd., Armistice and Stephen J. Boyd is c/o Armistice Capital, LLC, 510 Madison Avenue, 7th Floor, New York, NY 10022.

(3)Consists of shares of our Common Stock underlying the Placement Agent Warrants. The address for such person is c/o H.C. Wainwright & Co., LLC, 430 Park Ave., New York, NY 10022. Referenced person is affiliated with H.C. Wainwright, a registered broker dealer. H.C. Wainwright is a registered broker-dealer and acted as our placement agent in our December 2019 financing and in the March 2020 warrant inducement and has acted as a sales agent in our at-the-market equity offering.

PLAN OF DISTRIBUTION

The selling stockholders and any of their assignees and successors-in-interest may, from time to time, sell any or all of their shares of Common Stock on any stock exchange, market or trading facility on which the shares are traded or in private transactions. These sales may be at fixed or negotiated prices. The selling stockholders may use any one or more of the following methods when selling shares:

- ordinary brokerage transactions and transactions in which a broker-dealer solicits purchasers;
- block trades in which a broker-dealer will attempt to sell the shares as agent but may position and resell a portion of the block as principal to facilitate the transaction;
- purchases by a broker-dealer as principal and resale by the broker-dealer for its account;
- an exchange distribution in accordance with the rules of the applicable exchange;
- privately negotiated transactions;
- broker-dealers may agree with the selling stockholders to sell a specified number of such shares at a stipulated price per share;
- a combination of any such methods of sale; and
- any other method permitted pursuant to applicable law.

The selling stockholders may also sell shares under Rule 144 under the Securities Act of 1933, as amended, if available, rather than under this prospectus.

Broker-dealers engaged by the selling stockholders may arrange for other broker-dealers to participate in sales. Broker-dealers may receive commissions or discounts from the selling stockholders (or, if any broker-dealer acts as agent for the purchaser of shares, from the purchaser) in amounts to be negotiated. The selling stockholders do not expect these commissions and discounts to exceed what is customary in the types of transactions involved.

The selling stockholders and any broker-dealers or agents that are involved in selling the shares may be deemed to be "underwriters" within the meaning of the Securities Act in connection with such sales. In such event, any commissions received by such broker-dealers or agents and any profit on the resale of the shares purchased by them may be deemed to be underwriting commissions or discounts under the Securities Act.

We will pay all fees and expenses incident to the registration of the shares, but not including fees and disbursements of counsel to the selling stockholders; in addition, a selling stockholder will pay all underwriting discounts and selling commissions, if any.

To the extent required, we will amend or supplement this prospectus to disclose material arrangements regarding the plan of distribution.

We have entered into a letter agreement with Armistice, one of the selling stockholders, pursuant to which Armistice has agreed that following the effectiveness of the registration statement of which this prospectus is a part, Armistice will not sell a number of shares of our Common Stock during any trading day in excess of ten percent of the average reported trading volume of our Common Stock for the five trading days immediately preceding such trading day.

To comply with the securities laws of certain jurisdictions, registered or licensed brokers or dealers may need to offer or sell the shares offered by this prospectus. The applicable rules and regulations under the Securities Exchange Act of 1934, as amended, may limit any person engaged in a distribution of the shares of our Common Stock covered by this prospectus in its ability to engage in market activities with respect to such shares. A selling stockholder, for example, will be subject to applicable provisions of the Exchange Act and the rules and regulations under it, including, without limitation, Regulation M of the Exchange Act, which provisions may limit the timing of purchases and sales of any shares of our Common Stock by that selling stockholder. Regulation M may also restrict the ability of any person engaged in the distribution of the shares of our Common Stock to engage in market-making activities with respect to the shares of our Common Stock. All of the foregoing may affect the marketability of the shares of our Common Stock and the ability of any person or entity to engage in market-making activities with respect to the shares of our Common Stock.

DESCRIPTION OF CAPITAL STOCK

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

General

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

As of April 30, 2020, there were 12,464,006 shares of our Common Stock outstanding, held by 109 stockholders of record not including those held in "street name," and no shares of our preferred stock outstanding. Our Board of Directors is authorized, without stockholder approval, to issue additional shares of our capital stock.

Common Stock

General

The rights, preferences and privileges of the holders of our Common Stock are subject to, and may be adversely affected by, the rights of the holders of any series of preferred stock that we may designate in the future. In addition, our Board of Directors has authority to issue the authorized but unissued shares of our Common Stock without further action by our stockholders.

Voting Rights

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

Dividend Rights

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

Liquidation Rights

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

No Preemptive or Similar Rights

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

Fully Paid and Non-Assessable

All outstanding shares of our Common Stock are fully paid and non-assessable.

Preferred Stock

Our Board of Directors has authority, without further action by the stockholders, to issue up to 5,000,000 shares of preferred stock, in one or more series, and to designate the rights, preferences, powers and restrictions of each such series. The issuance of preferred stock could have the effect of restricting dividends on our Common Stock, diluting the voting power of our Common Stock, impairing the liquidation rights of our Common Stock or delaying or preventing a change in control of the Company without further action by the stockholders.

Options

As of April 30, 2020, there were options outstanding to purchase an aggregate of 850,719 shares of our Common Stock with a weighted-average exercise price of $1.58 per share. The options were issued pursuant to (i) the 2012 Restated Equity Incentive Plan, as amended, and (ii) the 2012 Non-Employee Director Stock Option Plan.

Warrants

As of April 30, 2020, there were warrants outstanding to purchase an aggregate of 4,465,088 shares of our Common Stock with an average weighted exercise price of $1.29 per share. All of our outstanding warrants are currently exercisable, and all outstanding warrants contain provisions for the adjustment of the exercise price in the event of stock dividends, stock splits, reorganizations, reclassifications or mergers. In addition, certain warrants contain a "cashless exercise" feature that allows the holders thereof to exercise the warrants without a cash payment to us under certain circumstances.

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

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

Section 203 of the DGCL

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

Issuance of Additional Shares

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

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

Advance Notice Provisions for Stockholder Proposals

Our Bylaws provide that the nomination of persons to stand for election to the Board of Directors at any annual or special meeting of stockholders may be made by the holders of the Company's Common Stock only if written notice of such stockholder's intent to make such nomination has been given to the Secretary of the Company not later than 30 days prior to the meeting.

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

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

Special Meetings of Stockholders

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

Filling of Vacancies on the Board of Directors

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

Amendment of Our Bylaws

Our Board of Directors is expressly authorized to adopt, amend or repeal our Bylaws.

Listing

Our Common Stock is currently traded on the Nasdaq Capital Market under the symbol "CAPR".

Transfer Agent and Registrar

The transfer agent and registrar for our Common Stock is American Stock Transfer & Trust Company, LLC. Its address is 6201 15th Avenue, Brooklyn, New York 11219, and its telephone number is 800-937-5449.

LEGAL MATTERS

Sidley Austin LLP, Palo Alto, California, which has acted as our counsel in connection with this offering, will pass upon the validity of the shares of our Common Stock being offered by this prospectus.

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, 2019, which is incorporated by reference into this prospectus and elsewhere in the registration statement of which this prospectus 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 have filed with the SEC a Registration Statement on Form S-3 under the Securities Act with respect to the shares of our Common Stock offered by this prospectus. This prospectus, which constitutes a part of the registration statement, does not contain all of the information set forth in the registration statement, some of which is contained in exhibits to the registration statement as permitted by the rules and regulations of the SEC. For further information with respect to us and our Common Stock, we refer you to the registration statement, including the exhibits filed as a part of the registration statement. Statements contained in this prospectus concerning the contents of any contract or any other document are not necessarily complete. If a contract or document has been filed as an exhibit to the registration statement, please see the copy of the contract or document that has been filed. Each statement in this prospectus relating to a contract or document filed as an exhibit is qualified in all respects by the filed exhibit. You may obtain copies of this information by mail from the Public Reference Section of the SEC, 100 F Street, N.E., Washington, D.C. 20549, at prescribed rates. You may obtain information on the operation of the public reference rooms by calling the SEC at 1-800-SEC-0330. The SEC also maintains an Internet website that contains reports, proxy statements and other information about issuers, like us, that file electronically with the SEC. The address of that website is *www.sec.gov*.

We are subject to the informational and reporting requirements of the Securities Exchange Act of 1934, as amended, and have filed and will file annual, quarterly and current reports, proxy statements and other information with the SEC. These periodic reports, proxy statements and other information will be available for inspection and copying at the SEC's public reference facilities and the website of the SEC referred to above. We also maintain a website at *www.capricor.com*. You may access these materials free of charge as soon as reasonably practicable after they are electronically filed with, or furnished to, the SEC. Information contained on our website is not a part of this prospectus and the inclusion of our website address in this prospectus is an inactive textual reference only.

INFORMATION INCORPORATED BY REFERENCE

The SEC allows us to "incorporate by reference" into this prospectus the information we file with it, which means that we can disclose important information to you by referring you to those documents. The information we incorporate by reference is an important part of this prospectus and information that we subsequently file with the SEC will automatically update and supersede information in this prospectus and in our other filings with the SEC.

We incorporate by reference the documents listed below, which we have already filed with the SEC, and any filings we make with the SEC under Section 13(a), 13(c), 14 or 15(d) of the Exchange Act (1) on or after the date of filing of the registration statement of which this prospectus forms a part and (2) on or after the date of this prospectus until the earlier of the date on which all of the securities registered hereunder have been sold or the registration statement of which this prospectus is a part has been withdrawn (in each case, other than information that is deemed, under SEC rules, not to have been filed):

- our Annual Report on Form 10-K for the fiscal year ended December 31, 2019, filed with the SEC on March 27, 2020;
- our Definitive Proxy Statement on Schedule 14A, filed with the SEC on April 17, 2020;
- our Current Reports on Form 8-K, filed with the SEC on (i) February 18, 2020; (ii) March 18, 2020; (iii) March 26, 2020; and (iv) May 4, 2020; and
- the description of our Common Stock contained in our Registration Statement on Form 8-A filed on March 5, 2015, including any amendment or report filed for the purpose of updating such description.

We also incorporate by reference any future filings (other than current reports furnished under Item 2.02 or Item 7.01 of Form 8-K and exhibits filed on such form that are related to such items unless such Form 8-K expressly provides to the contrary) made with the SEC pursuant to Sections 13(a), 13(c), 14 or 15(d) of the Exchange Act, including those made after the date of the initial filing of the registration statement of which this prospectus is a part and prior to effectiveness of such registration statement, until we file a post-effective amendment that indicates the termination of the offering of our Common Stock made by this prospectus, and such filings will become a part of this prospectus from the respective dates that such documents are filed with the SEC. Any statement contained herein or in a document incorporated or deemed to be incorporated by reference herein shall be deemed to be modified or superseded for purposes hereof or of the related prospectus to the extent that a statement contained herein or in any other subsequently filed document which is also incorporated or deemed to be incorporated herein modifies or supersedes such statement. Any such statement so modified or superseded shall not be deemed, except as so modified or superseded, to constitute a part of this prospectus.

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

4,200,000 Shares

Common Stock

Prospectus

Dated _____, 2020

We 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 take responsibility for, and can provide no assurance as to the reliability of, any information that others may give you. This prospectus relates to the resale by the selling stockholders identified in this prospectus of up to 4,200,000 shares of common stock, $0.001 par value per share, of Capricor Therapeutics. All of the shares of common stock held by the selling stockholders were issued by us in a private placement transaction. 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; however, we will receive proceeds upon the exercise of outstanding Warrants for shares of common stock covered by this prospectus if the Warrants are exercised for cash. 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”. 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. 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.

PART II

INFORMATION NOT REQUIRED IN PROSPECTUS

ITEM 14. OTHER EXPENSES OF ISSUANCE AND DISTRIBUTION.

The following table sets forth all expenses payable by the Registrant in connection with the sale of the shares of our common stock being registered. The security holders will not bear any portion of such expenses. All the amounts shown are estimates except for the registration fee.

SEC registration fee	$	3,625
Legal fees and expenses		30,000
Accounting fees and expenses		2,000
Transfer agent and registrar fees and expenses		500
Miscellaneous fees and expenses		2,000
Total	$	38,125

ITEM 15. INDEMNIFICATION OF DIRECTORS AND OFFICERS.

Section 145 of the General Corporation Law of the State of Delaware (the "DGCL") authorizes a corporation's board of directors to grant, and authorizes a court to award, indemnity to officers, directors and other corporate agents.

The Registrant's Certificate of Incorporation, as amended (the "Certificate"), requires the Registrant to indemnify its directors and officers to the fullest extent permitted by the DGCL as it presently exists or as may hereafter be amended. Therefore, a director of the Registrant will not be liable to the Registrant or the Registrant's stockholders for monetary damages for any breach of fiduciary duty as a director, provided that the individual acted in good faith and in a manner the individual reasonably believed to be in or not opposed to the best interests of the corporation and, with respect to any criminal action or proceeding, had no reasonable cause to believe his or her conduct was unlawful. Any amendment to, or repeal of, these provisions will not eliminate or reduce the effect of these provisions in respect of any act, omission or claim that occurred or arose prior to that amendment or repeal. If the DGCL is amended to provide for further limitations on the personal liability of directors of corporations, then the personal liability of the Registrant's directors will be further limited to the greatest extent permitted by the DGCL.

Additionally, the provisions of the Certificate and of the Registrant's bylaws require the Registrant to indemnify and hold harmless, to the fullest extent permitted by applicable law as it presently exists or as may hereafter be amended, any person who was or is made or is threatened to be made a party or is otherwise involved in any action, suit or proceeding, whether civil, criminal, administrative or investigative, by reason of the fact that he or she, or a person for whom he or she is the legal representative, is or was a director or officer of the Registrant or, while a director or officer of the Registrant, is or was serving at the request of the Registrant as a director, officer, employee or agent of another corporation or of a partnership, joint venture, trust, enterprise or nonprofit entity, including service with respect to employee benefit plans, against all liability and loss suffered and expenses (including attorneys' fees) reasonably incurred by such person. Notwithstanding the preceding sentence, the Registrant shall be required to indemnify such a person in connection with a proceeding (or part thereof) commenced by such person only if the commencement of such proceeding (or part thereof) by the person was authorized in the specific case by the Board of Directors. The Registrant's bylaws also provide that the Registrant shall, to the fullest extent not prohibited by applicable law, promptly pay the expenses, including attorneys' fees, incurred by a director or officer in defending any proceeding in advance of its final disposition, subject to certain limited exceptions.

The Registrant's bylaws permit the Registrant to purchase and maintain insurance on behalf of any person that the Registrant is permitted to indemnify in accordance with the bylaws against any liability asserted again any such person and incurred by such person, whether or not the Registrant would have the power to indemnify such person against such liability under the DGCL. In accordance with the provisions of the bylaws, the Registrant currently maintains directors' and officers' liability insurance, which may insure against director or officer liability arising under the Securities Act. In addition, the Registrant has entered into various agreements whereby it has agreed to indemnify its directors and officers for specific liabilities that they may incur while serving in such capacities. These indemnification agreements provide for the maximum indemnity allowed to directors and officers by applicable law. The Registrant believes that these agreements are necessary to attract and retain qualified individuals to serve as directors and executive officers.

The limitation of liability and indemnification provisions that are included in the Certificate, the Registrant's bylaws and in indemnification agreements that the Registrant enters into with its directors and officers may discourage stockholders from bringing a lawsuit against the Registrant's directors and officers for breach of their fiduciary duties. They may also reduce the likelihood of derivative litigation against the Registrant's directors and officers, even though an action, if successful, might benefit the Registrant and other stockholders. Further, a stockholder's investment may be adversely affected to the extent that the Registrant pays the costs of settlement and damage awards against directors and executive officers as required by the applicable indemnification provisions. At present, the Registrant is not aware of any pending litigation or proceeding involving any person who is or was one of its directors, officers, employees or other agents or is or was serving at its request as a director, officer, employee or agent of another corporation, partnership, joint venture, trust or other enterprise, for which indemnification is sought, and the Registrant is not aware of any threatened litigation that may result in claims for indemnification.

The foregoing statements are subject to the detailed provisions of the DGCL and the full text of the corporate documents and agreements referenced above.

Reference is made to Item 17 for the Registrant's undertakings with respect to indemnification for liabilities arising under the Securities Act of 1933, as amended.

ITEM 16. EXHIBITS AND FINANCIAL STATEMENT SCHEDULES.

(a) Exhibits.

2.1	Agreement and Plan of Merger, dated as of August 15, 2007, by and among SMI Products, Inc., Nile Merger Sub, Inc. and Nile Therapeutics, Inc. (incorporated by reference to Exhibit 2.1 to the Company's Current Report on Form 8-K, filed with the SEC on August 17, 2007).
2.2	Agreement and Plan of Merger and Reorganization, dated as of July 7, 2013, by and among Nile Therapeutics, Inc., Bovet Merger Corp. and Capricor, Inc. (incorporated by reference to Exhibit 2.1 to the Company's Current Report on Form 8-K, filed with the SEC on July 9, 2013).
2.3	First Amendment to Agreement and Plan of Merger and Reorganization, dated as of September 27, 2013, by and between Nile Therapeutics, Inc., Bovet Merger Corp. and Capricor, Inc. (incorporated by reference to Exhibit 2.1 to the Company's Current Report on Form 8-K, filed with the SEC on October 3, 2013).
3.1	Certificate of Incorporation of the Company (incorporated by reference to Exhibit 3.1 to the Company's Current Report on Form 8-K, filed with the SEC on February 9, 2007).
3.2	Certificate of Amendment of Certificate of Incorporation of the Company (incorporated by reference to Exhibit 3.1 to the Company's Current Report on Form 8-K, filed with the SEC on November 26, 2013).
3.3	Certificate of Amendment of Certificate of Incorporation of the Company (incorporated by reference to Exhibit 3.1 to the Company's Current Report on Form 8-K, filed with the SEC on June 4, 2019).
3.4	Bylaws of the Company (incorporated by reference to Exhibit 3.2 to the Company's Current Report on Form 8-K, filed with the SEC on February 9, 2007).
5.1	Opinion of Sidley Austin LLP. *
23.1	Consent of Rose Snyder & Jacobs, LLP. *
23.2	Consent of Sidley Austin LLP. (included in Exhibit 5.1). *
24.1	Power of Attorney (included on signature page hereof). *

* Filed herewith.

ITEM 17. UNDERTAKINGS.

The undersigned registrant hereby undertakes:

(1) To file, during any period in which offers or sales are being made, a post-effective amendment to this registration statement:

(i) To include any prospectus required by Section 10(a)(3) of the Securities Act of 1933;

(ii) To reflect in the prospectus any facts or events arising after the effective date of the registration statement (or the most recent post-effective amendment thereof) which, individually or in the aggregate, represent a fundamental change in the information set forth in the registration statement. Notwithstanding the foregoing, any increase or decrease in volume of securities offered (if the total dollar value of securities offered would not exceed that which was registered) and any deviation from the low or high end of the estimated maximum offering range may be reflected in the form of prospectus filed with the Commission pursuant to Rule 424(b) if, in the aggregate, the changes in volume and price represent no more than a 20% change in the maximum aggregate offering price set forth in the "Calculation of Registration Fee" table in the effective registration statement; and

(iii) To include any material information with respect to the plan of distribution not previously disclosed in the registration statement or any material change to such information in the registration statement;

Provided, however, that:

Paragraphs (1)(i), (1)(ii) and (1)(iii) of this section do not apply if the information required to be included in a post-effective amendment by those paragraphs is contained in reports filed with or furnished to the Commission by the registrant pursuant to section 13 or section 15(d) of the Securities Exchange Act of 1934 that are incorporated by reference in the registration statement, or is contained in a form of prospectus filed pursuant to Rule 424(b) that is part of the registration statement.

(2) That, for the purpose of determining any liability under the Securities Act of 1933, each such post-effective amendment shall be deemed to be a new registration statement relating to the securities offered therein, and the offering of such securities at that time shall be deemed to be the initial bona fide offering thereof.

(3) To remove from registration by means of a post-effective amendment any of the securities being registered which remain unsold at the termination of the offering.

(4) That, for the purpose of determining liability under the Securities Act of 1933 to any purchaser:

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

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

(5) That, for purposes of determining any liability under the Securities Act of 1933, each filing of the registrant's annual report pursuant to Section 13(a) or 15(d) of the Securities Exchange Act of 1934 (and, where applicable, each filing of an employee benefit plan's annual report pursuant to Section 15(d) of the Securities Exchange Act of 1934) that is incorporated by reference in the registration statement shall be deemed to be a new registration statement relating to the securities offered therein, and the offering of such securities at that time shall be deemed to be the initial bona fide offering thereof.

(6) Insofar as indemnification for liabilities arising under the Securities Act of 1933 may be permitted to directors, officers and controlling persons of the registrant pursuant to the foregoing provisions, or otherwise, the registrant has been advised that in the opinion of the Securities and Exchange Commission such indemnification is against public policy as expressed in the Act and is, therefore, unenforceable. In the event that a claim for indemnification against such liabilities (other than the payment by the registrant of expenses incurred or paid by a director, officer or controlling person of the registrant in the successful defense of any action, suit or proceeding) is asserted by such director, officer or controlling person in connection with the securities being registered, the registrant will, unless in the opinion of its counsel the matter has been settled by controlling precedent, submit to a court of appropriate jurisdiction the question whether such indemnification by it is against public policy as expressed in the Act and will be governed by the final adjudication of such issue.

The undersigned registrant hereby undertakes that:

(1) For purposes of determining any liability under the Securities Act of 1933, the information omitted from the form of prospectus filed as part of this registration statement in reliance upon Rule 430A and contained in a form of prospectus filed by the registrant pursuant to Rule 424(b) (1) or (4), or 497(h) under the Securities Act shall be deemed to be part of this registration statement as of the time it was declared effective.

(2) For the purpose of determining any liability under the Securities Act of 1933, each post-effective amendment that contains a form of prospectus shall be deemed to be a new registration statement relating to the securities offered therein, and the offering of such securities at that time shall be deemed to be the initial bona fide offering thereof.

SIGNATURES

Pursuant to the requirements of the Securities Act of 1933, the registrant certifies that it has reasonable grounds to believe that it meets all of the requirements for filing on Form S-3 and has duly caused this Registration Statement to be signed on its behalf by the undersigned, thereunto duly authorized, in the City of Beverly Hills, State of California, on May 7, 2020.

CAPRICOR THERAPEUTICS, INC.

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

KNOW ALL MEN BY THESE PRESENTS, that each person whose signature appears below hereby constitutes and appoints each of Linda Marbán, Ph.D. and Anthony J. Bergmann and each of them singly, our true and lawful attorneys-in-fact and agents, with full power of substitution and resubstitution, for him or her in his or her name, place and stead, in any and all capacities, to sign any or all amendments to this registration statement and additional registration statements relating to the same offering, and to file the same, with all exhibits thereto, and all other documents in connection therewith, with the Securities and Exchange Commission, granting unto said attorneys-in-fact and agents, and each of them, full power and authority to do and perform each and every act and thing requisite and necessary to be done in and about the premises, as fully to all intents and purposes as he might or could do in person, hereby ratifying and confirming all that said attorneys-in-fact and agents, or any of them, or their substitutes, may lawfully do or cause to be done by virtue thereof.

Pursuant to the requirements of the Securities Act of 1933, this Registration Statement has been signed by the following persons in the capacities and on the dates indicated.

Signature	Title	Date
/s/ Linda Marbán, Ph.D. Linda Marbán, Ph.D.	Chief Executive Officer and Director *(Principal Executive Officer)*	May 7, 2020
/s/ Anthony J. Bergmann Anthony J. Bergmann	Chief Financial Officer *(Principal Financial Officer)*	May 7, 2020
/s/ Frank Litvack, M.D. Frank Litvack, M.D.	Executive Chairman and Director	May 7, 2020
/s/ Earl M. Collier Earl M. Collier	Director	May 7, 2020
/s/ Louis V. Manzo Louis V. Manzo	Director	May 7, 2020
/s/ George W. Dunbar George W. Dunbar	Director	May 7, 2020
/s/ David B. Musket David B. Musket	Director	May 7, 2020

SIDLEY AUSTIN LLP
1001 PAGE MILL ROAD
BUILDING 1
PALO ALTO, CA 94304
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Exhibit 5.1

SIDLEY

AMERICA · ASIA PACIFIC · EUROPE

May 7, 2020

Capricor Therapeutics, Inc.
8840 Wilshire Blvd., 2nd Floor
Beverly Hills, California 90211

Re: Registration Statement on Form S-3

Ladies and Gentlemen:

We refer to the Registration Statement on Form S-3 (the "Registration Statement") being filed by Capricor Therapeutics, Inc., a Delaware corporation (the "Company"), with the Securities and Exchange Commission on the date hereof, under the Securities Act of 1933, as amended (the "Securities Act"). The Registration Statement relates to the registration under the Securities Act of 4,200,000 shares (the "Shares") of the Company's common stock, par value $0.001 per share (the "Common Stock"), that may be issued upon the exercise of issued and outstanding warrants (the "Warrants"). The Shares may be offered and sold by the selling stockholders named in the Registration Statement.

This opinion letter is being delivered in accordance with the requirements of Item 601(b)(5) of Regulation S-K under the Securities Act.

We have examined the Registration Statement, the Certificate of Incorporation, as amended, of the Company filed with the Secretary of State of the State of Delaware, the bylaws, as amended, of the Company, the Warrants and the resolutions adopted by the board of directors of the Company and the finance committee thereof established by such board relating to the Registration Statement and the issuance of the Warrants and the Shares by the Company. We have also examined originals, or copies of originals certified to our satisfaction, of such agreements, documents, certificates and statements of the Company and other corporate documents and instruments, and have examined such questions of law, as we have considered relevant and necessary as a basis for this opinion letter. We have assumed the authenticity of all documents submitted to us as originals, the genuineness of all signatures, the legal capacity of all persons and the conformity with the original documents of any copies thereof submitted to us for examination. As to facts relevant to the opinions expressed herein, we have relied without independent investigation or verification upon, and assumed the accuracy and completeness of, certificates, letters and oral and written statements and representations of public officials and officers and other representatives of the Company.

Based on the foregoing, and subject to the other qualifications and limitations set forth herein, we are of the opinion that the Shares, when duly issued and delivered in accordance with the terms of the Warrants (including the payment of the applicable exercise price), will be validly issued, fully paid and non-assessable.

In rendering the opinion set forth above, we have assumed that at the time of the issuance of any Shares upon exercise of any Warrant there will be a sufficient number of shares of Common Stock authorized and then available for issuance under the Company's certificate of incorporation as in effect at such time.

This opinion letter is limited to the General Corporation Law of the State of Delaware. We express no opinion as to the laws, rules or regulations of any other jurisdiction, including, without limitation, the federal laws of the United States of America or any state securities or blue sky laws.

We hereby consent to the filing of this opinion letter as an exhibit to the Registration Statement and to all references to our Firm included in or made a part of the Registration Statement. In giving such consent, we do not thereby admit that we are in the category of persons whose consent is required under Section 7 of the Securities Act.

Very truly yours,

/s/ Sidley Austin LLP

Exhibit 23.1

CONSENT OF INDEPENDENT REGISTERED PUBLIC ACCOUNTING FIRM

We hereby consent to the incorporation by reference, in this Registration Statement on Form S-3 of our report dated March 26, 2020, with respect to the consolidated financial statements of Capricor Therapeutics, Inc. and Subsidiary appearing in the Company's Annual Report on Form 10-K for the year ended December 31, 2019.

We also consent to the reference to our Firm under the caption "Experts" in such Registration Statement.

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

Encino, California
May 7, 2020