

**Capricor Therapeutics, Inc.**

This free writing prospectus relates to the Registration Statement on Form S-3 (File No. 333-254363) (the "Registration Statement") that Capricor Therapeutics, Inc. (the "Company") has filed with the Securities and Exchange Commission (the "SEC") under the Securities Act of 1933, as amended, and was declared effective on June 16, 2021.

**Recent Developments**

On September 29, 2023, the Company announced an update on the Company's positive Type B clinical meeting with the U.S. Food and Drug Administration ("FDA") on the design and execution of HOPE-3, the Company's pivotal Phase 3 trial with lead asset CAP-1002 in treating Duchenne muscular dystrophy ("DMD"). Feedback from the FDA on trial design and timeline confirms CAP-1002's path towards a future Biologics License Application ("BLA") submission.

The FDA has affirmed agreement on the Phase 3 clinical trial's trial design and timeline. Key details for HOPE-3 are as follows:

- Primary endpoints remain unchanged. HOPE-3 (Cohort A) will aim to enroll approximately 58 patients and enrollment is estimated to be completed in the fourth quarter of 2023.
  - As of September 29, 2023, the Company has treated 52 patients in Cohort A.
- The Company plans to submit a BLA for CAP-1002 in 2025, which will be supported by results using product manufactured from by the Los Angeles site (Cohort A).
  - Topline data for HOPE-3 (Cohort A) is expected in the fourth quarter of 2024.
- Following completion of Cohort A enrollment, Cohort B enrollment will commence using product manufactured from by the San Diego site.
  - Cohort B results are intended to support a Prior-Approval Supplement to be filed following registration marketing approval of CAP-1002, if received based on the original BLA submission, to support an expectation of increased commercial demand.
- The Company and the FDA discussed the potential for alternative approval pathways and the Company plans to further discuss these options with the FDA following the completion of enrollment of Cohort A.

Because the Company plans to submit a BLA for CAP-1002 in 2025 supported by results using product manufactured from the Los Angeles site, and not from the Company's San Diego manufacturing site, the Company intends to focus significant time and resources on additional work needed at the Los Angeles site (which is leased under a facilities lease previously disclosed by the Company) to support the BLA submission. The Company will also continue work on its San Diego site with a view toward supporting potential increased commercial demand, subject to the FDA's approval of the CAP-1002 product for treatment of DMD and its approval of the San Diego site.

*The Company has filed a Registration Statement (including a prospectus) with the SEC relating to its securities to which this communication relates. Before you invest, you should read the prospectus in that Registration Statement and other documents the Company has filed with the SEC for more complete information about the Company and this offering. You may get these documents for free by visiting EDGAR on the SEC Website at [www.sec.gov](http://www.sec.gov).*

**Forward Looking Statements**

*Statements in this free writing prospectus regarding the efficacy, safety, and intended utilization of Capricor's product candidates; the initiation, conduct, size, timing and results of discovery efforts and clinical trials; the pace of enrollment of clinical trials; plans regarding regulatory filings, future research and clinical trials; regulatory developments involving products, including the ability to obtain regulatory approvals or otherwise bring products to market; manufacturing capabilities; the ability to achieve product milestones and to receive milestone payments from commercial partners; plans regarding current and future collaborative activities and the ownership of commercial rights; scope, duration, validity and enforceability of intellectual property rights; future royalty streams and revenue projections; expectations with respect to the expected use of proceeds from the recently completed offerings and the anticipated effects of the offerings; and any other statements about Capricor's management team's future expectations, beliefs, goals, plans or prospects constitute forward-looking statements within the meaning of the Private Securities Litigation Reform Act of 1995. Any statements that are not statements of historical fact (including statements containing the words "believes," "plans," "could," "anticipates," "expects," "estimates," "should," "target," "will," "would" and similar expressions) should also be considered to be forward-looking statements. There are a number of important factors that could cause actual results or events to differ materially from those indicated by such forward-looking statements. More information about these and other risks that may impact the Company's business is set forth in the Company's Annual Report on Form 10-K for the year ended December 31, 2022 as filed with the Securities*

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*and Exchange Commission on March 17, 2023 and in the Company's Quarterly Report on Form 10-Q for the period ended June 30, 2023 as filed with the Securities and Exchange Commission on August 8, 2023. All forward-looking statements in this free writing prospectus are based on information available to the Company as of the date hereof, and the Company assumes no obligation to update these forward-looking statements.*

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