UNITED STATES
SECURITIES AND EXCHANGE COMMISSION

Washington, D.C. 20549

FORM 8-K

CURRENT REPORT
Pursuant to Section 13 or 15(d) of
The Securities Exchange Act of 1934

Date of Report (Date of earliest event reported)

May 14, 2020

CAPRICOR THERAPEUTICS, INC.

(Exact name of Registrant as Specified in its Charter)

Delaware	**001-34058**	**88-0363465**
(State or other jurisdiction of incorporation)	**(Commission File Number)**	**(I.R.S. Employer Identification No.)**

8840 Wilshire Blvd., 2nd Floor, Beverly Hills, CA	**90211**
(Address of principal executive offices)	**(Zip Code)**

(310) 358-3200
(Registrant's telephone number, including area code)

Not Applicable
(Former name or former address, if changed since last report)

Check the appropriate box below if the Form 8-K filing is intended to simultaneously satisfy the filing obligation of the registrant under any of the following provisions:

☐ Written communications pursuant to Rule 425 under the Securities Act (17 CFR 230.425)

☐ Soliciting material pursuant to Rule 14a-12 under the Exchange Act (17 CFR 240.14a-12)

☐ Pre-commencement communications pursuant to Rule 14d-2(b) under the Exchange Act (17 CFR 240.14d-2(b))

☐ Pre-commencement communications pursuant to Rule 13e-4(c) under the Exchange Act (17 CFR 240.13e-4(c))

Indicate by check mark whether the registrant is an emerging growth company as defined in Rule 405 of the Securities Act of 1933 (17 CFR §230.405) or Rule 12b-2 of the Securities Exchange Act of 1934 (17 CFR §240.12b-2).

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 13(a) of the Exchange Act. ☐

Securities registered pursuant to Section 12(b) of the Act:

Title of Each Class	**Trading Symbol(s)**	**Name of Each Exchange on Which Registered**
Common Stock, par value $0.001 per share	CAPR	The Nasdaq Capital Market

Item 7.01 Regulation FD Disclosure.

On May 14, 2020, Capricor Therapeutics, Inc., a Delaware corporation (the "Company"), provided an update in the form of a slide presentation during its quarterly earnings call. The slide presentation is located on the "Investors" section of the Company's website at www.capricor.com. A copy of the slide presentation is also attached hereto as Exhibit 99.1 and is incorporated by reference into this Item 7.01 of this Current Report on Form 8-K.

The information contained in this Form 8-K (including Exhibit 99.1 attached hereto) is being furnished and shall not be deemed to be "filed" for the purposes of Section 18 of the Securities Exchange Act of 1934, as amended (the "Exchange Act"), or otherwise subject to the liabilities of that section and shall not be incorporated by reference in any filing under the Securities Act of 1933, as amended, or the Exchange Act, except as shall be expressly set forth by specific reference in such filing.

Item 9.01. Financial Statements and Exhibits.

(d) Exhibits

99.1	Capricor Therapeutics, Inc. slide presentation dated May 14, 2020.

SIGNATURES

Pursuant to the requirements of the Securities Exchange Act of 1934, as amended, the registrant has duly caused this report to be signed on its behalf by the undersigned, hereunto duly authorized.

CAPRICOR THERAPEUTICS, INC.

Date: May 14, 2020

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

Exhibit 99.1

Capricor Q1 Earnings Call and Corporate Update

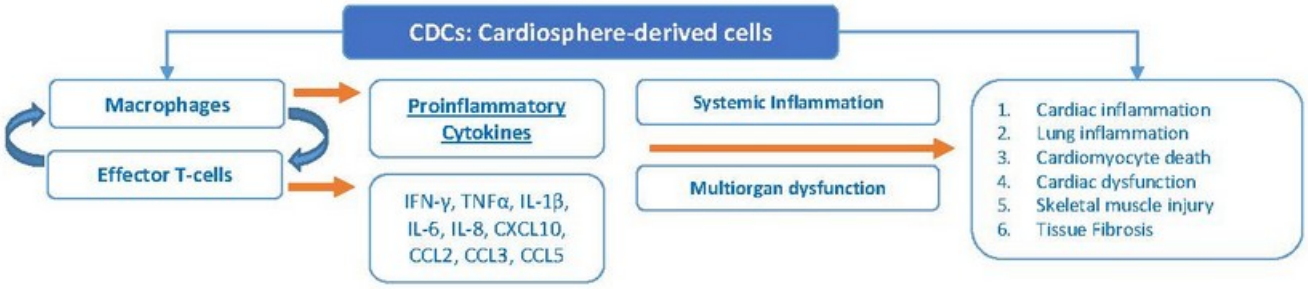
May 14, 2020 Earnings Call
NASDAQ: CAPR

Forward-Looking Statements

Statements in this presentation 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; 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, 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 Capricor's business is set forth in Capricor's Annual Report on Form 10-K for the year ended December 31, 2019 as filed with the Securities and Exchange Commission on March 27, 2020. All forward-looking statements in this press release are based on information available to Capricor as of the date hereof, and Capricor assumes no obligation to update these forward-looking statements.

CAP-1002 is an Investigational New Drug and is not approved for any indications. None of Capricor's exosome-based candidates have been approved for clinical investigation.

Immunomodulatory Effects of CAP-1002



CDCs: Mechanism of Action

1. Cardiomyogenesis
2. Cardiomyocyte survival
3. Anti-inflammatory
4. Immunomodulatory
5. Angiogenic
6. Anti-fibrotic

CDCs: Pro-inflammatory cellular targets

1. Enhanced cell debris
2. Decreased TNFα, IL-1β, CCL5 production
3. Increased levels of IL-10 by macrophages

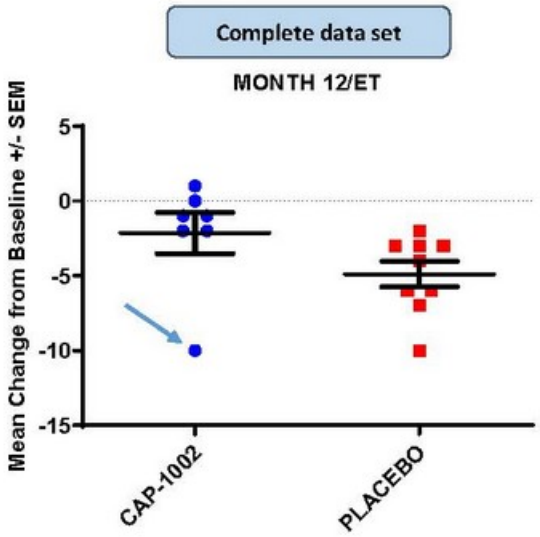
CDCs: Efficacy (Pre-clinical and Clinical)

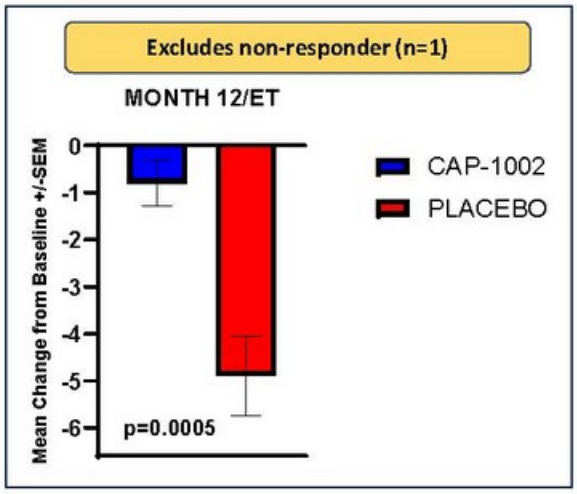
1. **Myocardial ischemia (CADUCEUS, Phase I/II ALLSTAR, DYNAMIC Phase IIa)**
2. Myocarditis
3. **Muscular dystrophy (HOPE-Duchenne, HOPE-2)**
4. **Heart failure with preserved ejection fraction (REGRESS, Phase I)**
5. Senescence
6. Non-ischemic dilated cardiomyopathy
7. **Pulmonary arterial hypertension (ALPHA, Phase I)**

HOPE-2 Top-Line 12-month Data Summary

- **Upper Limb Function:**
  - **Full PUL 2.0 – change observed of 2.4 points (p=0.05)**
  - Mid Level PUL 1.2 – change observed of 2.8 points (p=0.08)
  - Full PUL 1.2 – change observed of 4.1 points (p=0.03)
- **Cardiac Function:**
  - LV Ejection Fraction (%) – change observed of 1.56% (p=0.004)
  - LVESV – improvements observed (p=0.01)
  - LVEDV – improvements observed (p=0.07)
  - CK-MB (% of total CK) – improvements observed (p=0.006)
- **Respiratory Function:**
  - Trends towards improvements in IFR and PEF (% predicted)

Primary Efficacy Endpoint - Performance of the Upper Limb (Mid PUL 1.2)





Performance of the Upper Limb (Full PUL 2.0)