

**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 12, 2016

CAPRICOR THERAPEUTICS, INC.

(Exact name of Registrant as Specified in its Charter)

Delaware
(State or other jurisdiction
of incorporation)

001-34058
(Commission
File Number)

88-0363465
(I.R.S. Employer
Identification No.)

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

90211
(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))
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Item 2.02 Results of Operations and Financial Condition.

On May 12, 2016, Capricor Therapeutics, Inc., a Delaware corporation (the “Company”), issued a press release announcing its financial results for the quarter ended March 31, 2016. A copy of the press release is being furnished herewith as Exhibit 99.1 to this Current Report on Form 8-K.

The information under Item 2.02 of this Current Report on Form 8-K and Exhibit 99.1 attached hereto are being furnished and shall not be deemed to be filed for 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, nor shall it be incorporated by reference into any of the Company’s filings under the Securities Act of 1933, as amended, or the Exchange Act, unless expressly set forth as being incorporated by reference into such filing.

Item 9.01 Financial Statements and Exhibits.

(d) Exhibits

- 99.1 Press Release, titled “Capricor Therapeutics Provides Corporate Update and Reports First Quarter 2016 Financial Results”, dated May 12, 2016.
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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 12, 2016

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



Capricor Therapeutics Provides Corporate Update and Reports First Quarter 2016 Financial Results

HOPE-Duchenne and ALLSTAR Clinical Trials on Track to Complete Enrollment in the Third Quarter

Company to Host Conference Call and Webcast at 4:30 p.m. EDT, Today, May 12, 2016

LOS ANGELES, May 12, 2016 – Capricor Therapeutics, Inc. (NASDAQ: CAPR), a biotechnology company focused on the discovery, development and commercialization of first-in-class therapeutics, today provided financial results for the first quarter ended March 31, 2016 as well as a business update.

“The first quarter was a productive start to this year on both the clinical and financial fronts for Capricor. We had two positive developments in our lead CAP-1002 development programs—first, reducing the enrollment goal of the Phase II ALLSTAR trial in people who have experienced a large heart attack with persistent cardiac dysfunction and second, successfully completing a pre-specified safety review in our HOPE-Duchenne trial, a randomized Phase I/II trial in boys with Duchenne muscular dystrophy-associated cardiomyopathy,” said Linda Marbán, Ph.D., president and chief executive officer of Capricor. “Later this year, we expect to announce the first clinical indication for our exosomes program. We believe that our activities in 2016 will position Capricor for a transformational 2017, as we look forward to clinical results from both the HOPE-Duchenne and ALLSTAR trials, expected in the first quarter of next year.”

Dr. Marbán continued, “On the financing front, we raised approximately \$4.1 million in a registered direct offering and received approval for an approximate \$3.4 million grant award from the California Institute for Regenerative Medicine (CIRM) in the first quarter. We believe our current balance sheet will fund our clinical programs beyond key data readouts in the first quarter of 2017.”

First Quarter and Recent Operational Highlights

- Modified the enrollment goal of ALLSTAR to approximately 120 patients, based on statistical modeling that incorporated the expanded dataset from other clinical studies of our cardiosphere-derived cells (CDCs) and is expected to provide sufficient statistical power to detect a reduction in infarct, or scar, size as measured by MRI at twelve months; this decision was made with the concurrence of the ALLSTAR Data Safety Monitoring Board (DSMB)
- Resumed enrollment in the HOPE-Duchenne trial following a successful pre-specified DSMB review
- Received approval for a grant award of approximately \$3.4 million from CIRM to support the HOPE-Duchenne trial
- Completed an equity offering of approximately \$4.1 million with new and existing investors
- Appointed Leland J. Gershell, M.D., Ph.D., as chief financial officer

Anticipated Milestones*CAP-1002 (CDCs)*

- Complete enrollment in the HOPE-Duchenne and ALLSTAR trials in the third quarter of 2016
- Report 12-month results from the DYNAMIC trial in advanced heart failure in the third quarter of 2016
- Report six-month top-line data from HOPE-Duchenne in the first quarter of 2017
- Six-month top-line data from ALLSTAR expected in the first quarter of 2017

CAP-2003 (CDC exosomes)

- Announce first indication in mid-2016
- Submit Investigational New Drug application in the first half of 2017

First Quarter Results

The Company reported a net loss of approximately \$4.3 million, or \$0.26 per share, for the first quarter of 2016, compared to a net loss of approximately \$3.5 million, or \$0.23 per share, for the first quarter of 2015. At March 31, 2016, the Company's cash, cash equivalents and marketable securities totaled approximately \$14.3 million compared to \$13.6 million at December 31, 2015.

Financial Outlook

Based on current operating plans, the Company expects that its existing cash, cash equivalents and marketable securities will fund its research and development programs and other operations through the first quarter of 2017.

Conference Call and Webcast

Capricor management will hold a conference call at 4:30 p.m. EDT today. The live call may be accessed by dialing (877) 830-2629 for domestic callers and (785) 424-1231 for international callers, and by using "CAPRICOR" as the conference ID. Access to the live webcast as well as the link to the replay of the call can be found at <http://capricor.com/news/events/>. The webcast will be archived for approximately 30 days.

About Capricor Therapeutics

Capricor Therapeutics, Inc. (NASDAQ: CAPR) is a clinical-stage biotechnology company focused on the discovery, development and commercialization of first-in-class therapeutics. Capricor has two product candidates under clinical investigation: CAP-1002, a cardiac cell therapy, and Cenderitide, a dual natriuretic peptide receptor agonist. CAP-1002 is in development for the treatment of post myocardial infarction, advanced heart failure and Duchenne muscular dystrophy-associated cardiomyopathy. Cenderitide is in development for the outpatient treatment of heart failure as well as other potential indications. In addition, Capricor is evaluating its exosomes platform technology for cardiac diseases and other therapeutic areas. For additional information, visit www.capricor.com.

ALLSTAR is being funded in part with the support of the California Institute for Regenerative Medicine.

Cautionary Note Regarding Forward-Looking Statements

Statements in this press release regarding the efficacy, safety, and intended utilization of Capricor's product candidates; the conduct, size, timing and results of discovery efforts and clinical trials; plans regarding regulatory filings, future research and clinical trials; 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, expectations with respect to the expected use of proceeds from the recently completed offering and the anticipated effects of the offering, 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 are set forth in Capricor's Annual Report on Form 10-K for the year ended December 31, 2015, as filed with the Securities and Exchange Commission on March 30, 2016, and in its Registration Statement on Form S-3, as filed with the Securities and Exchange Commission on September 28, 2015. 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 and Cenderitide are Investigational New Drugs and are not approved for any indications.

CAPRICOR THERAPEUTICS, INC.
CONSOLIDATED STATEMENTS OF OPERATIONS AND COMPREHENSIVE LOSS
(unaudited)

| | Three months ended March 31, | |
|---|------------------------------|-----------------------|
| | 2016 | 2015 |
| INCOME | | |
| Collaboration income | \$ 911,458 | \$ 1,041,667 |
| Grant income | 303,631 | 746,235 |
| TOTAL INCOME | 1,215,089 | 1,787,902 |
| OPERATING EXPENSES | | |
| Research and development | 4,341,119 | 3,807,087 |
| General and administrative | 1,084,696 | 1,395,540 |
| TOTAL OPERATING EXPENSES | 5,425,815 | 5,202,627 |
| LOSS FROM OPERATIONS | (4,210,726) | (3,414,725) |
| OTHER INCOME (EXPENSE) | | |
| Investment income | 10,510 | 275 |
| Interest expense | (66,125) | (61,681) |
| TOTAL OTHER INCOME (EXPENSE) | (55,615) | (61,406) |
| NET LOSS | (4,266,341) | (3,476,131) |
| OTHER COMPREHENSIVE GAIN (LOSS) | | |
| Net unrealized loss on marketable securities | (6,157) | (3,940) |
| COMPREHENSIVE LOSS | \$ (4,272,498) | \$ (3,480,071) |
| Net loss per share, basic and diluted | \$ (0.26) | \$ (0.23) |
| Weighted average number of shares, basic and diluted | 16,537,502 | 14,869,746 |

CAPRICOR THERAPEUTICS, INC.
SUMMARY BALANCE SHEETS

| | March 31, 2016 (unaudited) | December 31, 2015 |
|---|-------------------------------|-------------------|
| Cash, cash equivalents and marketable securities | \$ 14,264,879 | \$ 13,567,316 |
| Total assets | \$ 16,984,850 | \$ 16,069,572 |
| Total deferred revenue | 3,645,833 | 4,557,292 |
| Total liabilities | \$ 18,067,755 | \$ 17,101,346 |
| Total stockholders' equity (deficit) - 17,952,323 and 16,254,985 common shares issued and outstanding at March 31, 2016 and December 31, 2015, respectively | (1,082,905) | (1,031,774) |
| Total liabilities and stockholders' equity | \$ 16,984,850 | \$ 16,069,572 |

For more information, please contact:

Corporate Contact:

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