

**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)

March 15, 2017

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 March 15, 2017, Capricor Therapeutics, Inc., a Delaware corporation (the “Company”), issued a press release announcing, among other items, its financial results for the quarter and fiscal year ended December 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 Reports Fourth Quarter and Full Year 2016 Financial Results and Provides Corporate Update”, dated March 15, 2017.

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: March 15, 2017

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



Capricor Therapeutics Reports Fourth Quarter and Full Year 2016 Financial Results and Provides Corporate Update

To Report Top-Line Six-Month Results from the Randomized HOPE-Duchenne Clinical Trial in April 2017

Company to Host Conference Call and Webcast Today at 4:30 p.m. ET

LOS ANGELES, March 15, 2017 – Capricor Therapeutics, Inc. (NASDAQ: CAPR), a clinical-stage biotechnology company developing first-in-class biological therapies for cardiac and other medical conditions, today provided a corporate update and announced financial results for the fourth quarter and full year ended December 31, 2016.

“2016 was an eventful year for Capricor, marked by meaningful advances in our clinical development programs as well as notable corporate achievements,” said Linda Marbán, Ph.D., president and chief executive officer. “Patient follow-up in both the Phase I/II HOPE-Duchenne and Phase II ALLSTAR clinical trials of CAP-1002 continues following the completion of dosing in each of these trials last fall. We look forward to announcing top-line six-month results from HOPE next month. By the third quarter, we anticipate hearing from Janssen on its decision with regard to its license option, following our anticipated delivery of the six-month administrative analysis from ALLSTAR. Our exosomes program continues to generate encouraging preclinical data in models of inflammatory disease, and we look forward to submitting the first Investigational New Drug application for CAP-2003 in the second half of this year.”

“Capricor ended 2016 with approximately \$16.2 million in cash, cash equivalents and marketable securities, which we believe will fund our operations into the fourth quarter of 2017. Importantly, we expect our existing resources to enable us to achieve important near-term milestones for our CAP-1002 program,” added Dr. Marbán.

Fourth Quarter Highlights and Recent Clinical and Operational Developments

- Strengthened team through the appointments of Maritza McIntyre, Ph.D. in Regulatory Affairs and Karen Edward in Manufacturing.
 - Announced plans to expand clinical development program of CAP-1002 (allogeneic cardiosphere-derived cells) in Duchenne muscular dystrophy (DMD) to evaluate peripheral and respiratory muscle function, as supported by preclinical studies.
 - Completed enrollment in the randomized Phase I/II HOPE-Duchenne clinical trial of CAP-1002 in 25 boys and young men with DMD-associated cardiomyopathy.
 - Completed enrollment in the randomized, double-blind, placebo-controlled Phase II ALLSTAR clinical trial of CAP-1002 in adults who experienced a large myocardial infarction (heart attack), in which 134 patients received study medication.
 - Presented positive 12-month results from the DYNAMIC clinical trial of CAP-1002 in patients with advanced heart failure at the Cardiovascular Research Foundation’s 2016 TCT conference.
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- Awarded up to approximately \$4.2 million from the National Institutes of Health to evaluate CAP-2003 (cardiosphere-derived cell exosomes) for hypoplastic left heart syndrome.
- Returned rights to natriuretic peptides licensed from the Mayo Clinic following a portfolio review.

Anticipated Events and Milestones in 2017

- Report top-line six-month data from the HOPE-Duchenne clinical trial in April 2017.
- Expect Janssen decision on its license option for CAP-1002 by the third quarter of 2017.
- Initiate a second clinical trial in DMD in the second half of 2017, subject to regulatory approval, in which CAP-1002 is administered systemically.
- Report top-line 12-month data from the ALLSTAR and HOPE-Duchenne clinical trials in the fourth quarter of 2017.
- Submit IND for CAP-2003 in the second half of 2017.

Fourth Quarter and Full Year Financial Results

The Company reported a net loss of approximately \$4.5 million, or \$0.21 per share, for the fourth quarter of 2016, compared to a net loss of approximately \$3.3 million, or \$0.21 per share, for the fourth quarter of 2015. For the year ended December 31, 2016, the Company reported a net loss of approximately \$18.8 million, or \$1.01 per share, compared to a net loss of approximately \$12.9 million, or \$0.81 per share, for the year ended December 31, 2015. As of December 31, 2016, the Company's cash, cash equivalents and marketable securities totaled approximately \$16.2 million compared to approximately \$13.6 million on December 31, 2015.

Financial Outlook

Capricor currently expects that its cash, cash equivalents and marketable securities will fund its research and development programs and other operations into the fourth quarter of 2017.

Conference Call and Webcast

Capricor management will hold a conference call at 4:30 p.m. ET today. The live call may be accessed by dialing 1-866-682-6100 for domestic callers and 1-862-255-5401 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 biological therapies for the treatment of cardiac and other medical conditions. Capricor's lead candidate, CAP-1002, is a cardiac cell therapy that is currently being evaluated for the treatment of heart disease associated with Duchenne muscular dystrophy and myocardial infarction (heart attack). Capricor is exploring CAP-2003, its exosome product candidate, for use in cardiac and inflammatory conditions. For additional information, visit www.capricor.com.

The ALLSTAR and HOPE-Duchenne clinical trials are funded in part by the California Institute for Regenerative Medicine. The DYNAMIC clinical trial was funded in part by the National Institutes of Health.

Cautionary Note Regarding Forward-Looking Statements

Statements in this press release 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; 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 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 will be set forth in Capricor's Annual Report on Form 10-K for the year ended December 31, 2016, to be filed with the Securities and Exchange Commission, 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 is an Investigational New Drug and is not approved for any indications. Capricor's exosomes technology, including CAP-2003, has not yet been approved for clinical investigation.

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

	Three months ended December 31,		Years ended December 31,	
	2016	2015	2016	2015
INCOME				
Collaboration income	\$ 683,595	\$ 911,458	\$ 3,190,106	\$ 3,776,041
Grant income	223,335	211,938	808,512	1,741,607
TOTAL INCOME	906,930	1,123,396	3,998,618	5,517,648
OPERATING EXPENSES				
Research and development	2,665,904	3,330,731	16,042,082	13,757,279
General and administrative	1,154,355	1,077,594	4,933,054	4,372,195
TOTAL OPERATING EXPENSES	3,820,259	4,408,325	20,975,136	18,129,474
LOSS FROM OPERATIONS	(2,913,329)	(3,284,929)	(16,976,518)	(12,611,826)
OTHER INCOME (EXPENSE)				
Investment income (loss)	(1,940)	2,390	14,407	3,113
Interest expense	(102,905)	(63,583)	(344,665)	(248,626)
Impairment of in-process research and development	(1,500,000)	-	(1,500,000)	-
TOTAL OTHER INCOME (EXPENSE)	(1,604,845)	(61,193)	(1,830,258)	(245,513)
NET LOSS	(4,518,174)	(3,346,122)	(18,806,776)	(12,857,339)
OTHER COMPREHENSIVE GAIN (LOSS)				
Net unrealized gain (loss) on marketable securities	2,601	(2,564)	(5,861)	9,385
COMPREHENSIVE LOSS	\$ (4,515,573)	\$ (3,348,686)	\$ (18,812,637)	\$ (12,847,954)
Net loss per share, basic and diluted	<u>\$ (0.21)</u>	<u>\$ (0.21)</u>	<u>\$ (1.01)</u>	<u>\$ (0.81)</u>
Weighted average number of shares, basic and diluted	<u>21,399,019</u>	<u>16,254,985</u>	<u>18,551,013</u>	<u>15,902,133</u>

CAPRICOR THERAPEUTICS, INC.
SUMMARY BALANCE SHEETS

	December 31, 2016	December 31, 2015
Cash, cash equivalents and marketable securities	\$ 16,194,888	\$ 13,567,316
Total assets	\$ 18,747,355	\$ 16,069,572
Total deferred revenue	1,367,186	4,557,292
Total liabilities	\$ 22,750,509	\$ 17,101,346
Total stockholders' equity (deficit) - 21,399,019 and 16,254,985 common shares issued and outstanding at December 31, 2016 and December 31, 2015, respectively	(4,003,154)	(1,031,774)
Total liabilities and stockholders' equity	\$ 18,747,355	\$ 16,069,572

For more information, please contact:

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