

**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)

August 15, 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 August 15, 2016, Capricor Therapeutics, Inc., a Delaware corporation (the "Company"), issued a press release announcing, among other items, its financial results for the quarter ended June 30, 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 Second Quarter 2016 Financial Results and Provides Clinical Update", dated August 15, 2016.

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: August 15, 2016

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



Capricor Therapeutics Reports Second Quarter 2016 Financial Results and Provides Clinical Update

Duchenne Muscular Dystrophy Trial on Track to Report Top-Line Six-Month Results in the First Quarter of 2017

Six-Month Results of ALLSTAR to be Delivered to Janssen Biotech in the First Half of 2017

Exosome Program Advances with Ocular Graft-Versus-Host Disease as First-in-Man Indication; IND Submission in the First Half of 2017

Company to Host Conference Call and Webcast at 4:30 p.m. EDT, Today, August 15, 2016

LOS ANGELES, August 15, 2016 – [Capricor Therapeutics, Inc.](http://www.capricortherapeutics.com) (NASDAQ: CAPR), a biotechnology company focused on the discovery, development and commercialization of first-in-class therapeutics, today provided an update on its clinical development programs directed toward the treatment of heart disease, including that associated with Duchenne Muscular Dystrophy (DMD), as well as defined the initial development path for its proprietary exosomes technology. Capricor also announced financial results for the quarter ended June 30, 2016.

Linda Marbán, Ph.D., president and chief executive officer of Capricor said, “Later this quarter, we expect to announce the completion of enrollment in our two ongoing clinical trials of CAP-1002 (allogeneic cardiosphere-derived cells, or CDCs): the HOPE trial in boys with Duchenne heart disease and the ALLSTAR trial in adults with cardiac dysfunction following a large heart attack. These are important milestones as we look toward reporting top-line six-month data from HOPE in the first quarter of 2017 as well as delivering six-month ALLSTAR data to Janssen. These readouts follow our recent report of positive 12-month results from our DYNAMIC study of CAP-1002 data, which show persistent improvement in patients with advanced heart failure out to one year post-treatment. We believe the DYNAMIC data support the potential of CAP-1002 to address the heart disease associated with DMD, the number one cause of death in boys afflicted with DMD.”

“As we advance our exosome-based candidate CAP-2003 toward the clinic, we are building on the unique properties of Capricor’s proprietary CDC technology outside of cardiovascular areas. We have identified ocular graft-versus-host disease as the first clinical development opportunity for CAP-2003. This selection is supported by compelling pre-clinical results in relevant models and the need for effective treatment options for this debilitating condition of the eye. We look forward to submitting an IND application for CAP-2003 in the first of 2017,” added Dr. Marbán.

Anticipated Milestones

- Complete enrollment in the randomized Phase I/II HOPE-Duchenne clinical trial of CAP-1002 in the third quarter of 2016.
- Complete enrollment in the Phase II ALLSTAR clinical trial of CAP-1002 in the third quarter of 2016.
- Report top-line six-month data from HOPE-Duchenne in the first quarter of 2017.
- Janssen decision on license option for CAP-1002 in the first half of 2017.
- Submit an Investigational New Drug application for CAP-2003 for the treatment of ocular graft-versus-host disease in the first half of 2017.

Second Quarter and Recent Operational Highlights

- Announced in June that enrollment in the randomized HOPE-Duchenne clinical trial, which had begun in February 2016, had exceeded 50% of its 24-patient goal.
- Reported positive top-line 12-month data from the open-label DYNAMIC clinical trial of CAP-1002 in 14 patients with advanced heart failure. The data demonstrated directional improvements from baseline in key efficacy measures, including assessments of functional status, cardiac function and dimensions, and quality-of-life. As had been shown at six months, left ventricular ejection fraction, a general measure of cardiac function, had significantly improved as compared to baseline ($p=0.02$).
- Reported pre-clinical data demonstrating the ability of CAP-2003 to significantly improve clinically-meaningful measures of ocular injury and inflammation following alkali chemical burns.

Second Quarter Results

The Company reported a net loss of approximately \$4.7 million, or \$0.26 per share, for the second quarter of 2016, compared to a net loss of approximately \$3.1 million, or \$0.19 per share, for the second quarter of 2015. At June 30, 2016, the Company's cash, cash equivalents and marketable securities totaled approximately \$11.4 million compared to \$13.6 million at December 31, 2015.

Financial Outlook

Based on its current operating plans, Capricor 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 and slide presentation at 4:30 p.m. EDT today. The live call may be accessed by dialing (800) 862-7924 for domestic callers and (785) 424-1047 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 CAP-2003 (CDC Exosomes)

Exosomes are nano-sized, membrane-enclosed vesicles, or "bubbles" that are secreted by cells and contain bioactive molecules, including proteins, RNAs and microRNAs. They act as messengers to regulate the functions of neighboring cells, and pre-clinical research has shown that exogenously-administered exosomes can direct or, in some cases, re-direct cellular activity, supporting their therapeutic potential. Their size, ease of crossing cell membranes, and ability to communicate in native cellular language makes them an exciting class of potential therapeutic agents. CAP-2003 consists of exosomes secreted by CDCs, and is believed to mediate many of the effects that are observed with these cells, including anti-inflammatory, anti-angiogenic, anti-apoptotic, and anti-fibrotic effects. Capricor is currently conducting pre-clinical studies to explore the possible therapeutic benefits that exosomes may possess, with a focus on ophthalmologic, dermatologic and oncologic disease. Capricor expects to submit an Investigational New Drug application for CAP-2003 in the first half of 2017 and to initiate clinical development in ocular graft-versus-host disease in 2017.

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 therapeutic products. 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 advancing its proprietary exosome product candidate, CAP-2003, for the treatment of ophthalmic disorders and exploring other therapeutic areas. Capricor's portfolio also features Cenderitide, a dual natriuretic peptide receptor agonist, which may have application for the outpatient treatment of advanced heart failure and other potential indications. For additional information, visit www.capricor.com.

ALLSTAR and HOPE-Duchenne are funded in part by the California Institute for Regenerative Medicine. DYNAMIC 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 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, in its Registration Statement on Form S-3, as filed with the Securities and Exchange Commission on September 28, 2015, and in its Quarterly Report on Form 10-Q for the quarter ended March 31, 2016, as filed with the Securities and Exchange Commission on May 13, 2016. 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's exosomes technology has not yet been investigated in any clinical trial.

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

	Three months ended June 30,		Six months ended June 30,	
	2016	2015	2016	2015
INCOME				
Collaboration income	\$ 911,458	\$ 911,458	\$ 1,822,916	\$ 1,953,125
Grant income	218,361	380,008	521,992	1,126,243
TOTAL INCOME	1,129,819	1,291,466	2,344,908	3,079,368
OPERATING EXPENSES				
Research and development	4,307,948	3,426,803	8,649,067	7,233,891
General and administrative	1,434,259	926,279	2,518,955	2,321,819
TOTAL OPERATING EXPENSES	5,742,207	4,353,082	11,168,022	9,555,710
LOSS FROM OPERATIONS	(4,612,388)	(3,061,616)	(8,823,114)	(6,476,342)
OTHER INCOME (EXPENSE)				
Investment income	427	156	10,937	431
Interest expense	(76,887)	(61,681)	(143,011)	(123,362)
TOTAL OTHER INCOME (EXPENSE)	(76,460)	(61,525)	(132,074)	(122,931)
NET LOSS	(4,688,848)	(3,123,141)	(8,955,188)	(6,599,273)
OTHER COMPREHENSIVE GAIN (LOSS)				
Net unrealized gain (loss) on marketable securities	1,551	10,475	(4,607)	6,535
COMPREHENSIVE LOSS	\$ (4,687,297)	\$ (3,112,666)	\$ (8,959,795)	\$ (6,592,738)
Net loss per share, basic and diluted	<u>(0.26)</u>	<u>(0.19)</u>	<u>(0.52)</u>	<u>(0.42)</u>
Weighted average number of shares, basic and diluted	<u>17,952,323</u>	<u>16,222,754</u>	<u>17,244,912</u>	<u>15,549,988</u>

CAPRICOR THERAPEUTICS, INC.
SUMMARY BALANCE SHEETS

	June 30, 2016 (unaudited)	December 31, 2015
Cash, cash equivalents and marketable securities	\$ 11,351,104	\$ 13,567,316
Total assets	\$ 13,892,196	\$ 16,069,572
Total deferred revenue	2,734,376	4,557,292
Total liabilities	\$ 19,008,373	\$ 17,101,346
Total stockholders' equity (deficit) - 17,952,323 and 16,254,985 common shares issued and outstanding at June 30, 2016 and December 31, 2015, respectively	(5,116,177)	(1,031,774)
Total liabilities and stockholders' equity	\$ 13,892,196	\$ 16,069,572

For more information, please contact:

Corporate

Capricor Therapeutics, Inc.
AJ Bergmann, Vice President of Finance
+1-310-358-3200
abergmann@capricor.com

Investor Relations

Argot Partners
Kimberly Minarovich
+1-212-600-1902
kimberly@argotpartners.com
