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)

November 10, 2016

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))

Item 2.02 Results of Operations and Financial Condition.

On November 10, 2016, Capricor Therapeutics, Inc., a Delaware corporation (the "Company"), issued a press release announcing, among other items, its financial results for the quarter ended September 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 they be incorporated by reference into any of the Company's filings under the Securities Act of 1933, as amended (the "Securities Act"), or the Exchange Act, unless expressly set forth as being incorporated by reference into such filing.

Item 7.01 Regulation FD Disclosure.

On November 10, 2016, the Company issued a press release announcing, among other items, a clinical update for its Duchenne muscular dystrophy program. A copy of the press release is attached hereto as Exhibit 99.2 and is incorporated by reference into this Item 7.01 of this Current Report on Form 8-K.

The information under Item 7.01 of this Current Report on Form 8-K and Exhibit 99.2 attached hereto are being furnished and shall not be deemed to be "filed" for the purposes of Section 18 of the Exchange Act, or otherwise subject to the liabilities of that section, nor shall they be incorporated by reference into any of the Company's filings under the Securities Act 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 Third Quarter 2016 Financial Results and Provides Corporate Update", dated November 10, 2016.
99.2	Press Release, titled "Capricor Therapeutics Announces Plans to Expand Clinical Development Program in Duchenne Muscular Dystrophy to Evaluate Peripheral and Respiratory Muscle Function", dated November 10, 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: November 10, 2016

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

Exhibit 99.1

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

Completed Treatment in Phase I/II HOPE-Duchenne and Phase II ALLSTAR Clinical Trials of CAP-1002

Announced Planned Expansion of Clinical Program in Duchenne Muscular Dystrophy to Evaluate CAP-1002 for Peripheral and Respiratory Muscle Improvement

Strengthened Balance Sheet with Net Proceeds of $9.9 Million from Common Stock Offerings

Company to Host Conference Call and Webcast Today at 5:00 p.m. ET

LOS ANGELES, November 10, 2016 – Capricor Therapeutics, Inc. (NASDAQ: CAPR), a clinical-stage biotechnology company developing first-in-class biological therapies for cardiac and other serious medical conditions, today provided a corporate update and announced financial results for the third quarter ended September 30, 2016.

Linda Marbán, Ph.D., president and chief executive officer, said, "The third quarter was marked by meaningful progress in the development of our lead candidate, CAP-1002 (allogeneic cardiosphere-derived cells), as we completed treatment in both our randomized, controlled Phase I/II HOPE-Duchenne trial in boys and young men with Duchenne muscular dystrophy (DMD)-associated cardiomyopathy as well as in the randomized, double-blind, placebo-controlled Phase II ALLSTAR trial in patients with large myocardial scar following a heart attack. We believe the rapid enrollment in HOPE reflects the need to address what is currently recognized as the number one cause of death in the DMD population—the progressive deterioration of the heart muscle due to the lack of the dystrophin protein. We look forward to reporting top-line six-month data from HOPE early in the second quarter of next year."

Capricor successfully completed two concurrent common stock offerings in September, adding approximately $9.9 million in combined net proceeds to the company's cash resources. Capricor is sufficiently capitalized to advance CAP-1002 through several important clinical milestones and activities, including the report of top-line six-month results from the HOPE trial as well as the initiation of a second clinical trial in DMD to evaluate CAP-1002's potential to improve peripheral and respiratory muscle. The company remains on track to submit an Investigational New Drug application (IND) to develop CAP-2003 (cardiosphere-derived cell exosomes) for the treatment of ocular graft-versus-host disease, a debilitating eye condition, in the first half of 2017. Capricor is also exploring its exosome technology in other therapeutic areas.

"Today we also announced that we have expanded our clinical development program in DMD to evaluate CAP-1002's ability to improve skeletal muscle through systemic intra-vascular delivery. We are committed to developing products that can offer the broadest therapeutic potential to boys and young men with this progressively debilitating genetic disorder," added Dr. Marbán.

Third Quarter and Recent Operational Highlights

- Completed treatment in the randomized Phase I/II HOPE-Duchenne clinical trial (N=25, of which 13 received CAP-1002). The primary outcome measures of the trial will consist of a broad assessment of safety and tolerability of CAP-1002. Efficacy will be evaluated according to pre-specified secondary outcome measures, including absolute and relative changes in cardiac scar tissue and cardiac function as measured by magnetic resonance imaging (MRI), as well as performance on the Six-Minute Walk Test (6MWT), scoring on the Performance of the Upper Limb (PUL) test, and scoring on the Pediatric Quality of Life Inventory (PedsQL).
- Completed treatment in the randomized, double-blind, placebo-controlled Phase II ALLSTAR clinical trial (N=134). For the pre-specified primary efficacy analysis, ALLSTAR is powered to detect a reduction in scar size in the CAP-1002 group, relative to the placebo group, at 12 months post-infusion. Scar size will be assessed by magnetic resonance imaging (MRI).
- Presented positive 12-month results from the open-label DYNAMIC clinical trial of CAP-1002 in 14 patients with advanced heart failure at the 28th Transcatheter Cardiovascular Therapeutics (TCT), the annual scientific symposium of the Cardiovascular Research Foundation. The treated patients demonstrated concordant and durable trends of improvement in functional status and capacity, cardiac function and dimension, and quality-of-life measures out to one-year post-treatment. As had been shown at six months, left ventricular ejection fraction had significantly improved as compared to baseline (p=0.02).
- Announced ocular graft-versus-host disease (oGVHD) as the first clinical development opportunity for CAP-2003. This selection was supported by pre-clinical data which demonstrate the ability of CAP-2003 to significantly improve clinically-meaningful measures of ocular injury and inflammation in a relevant model.
- Completed an underwritten registered public offering and concurrent registered direct offering of common stock, bringing combined net proceeds of approximately $9.9 million.
- Announced a grant award of approximately $2.4 million from the Department of Defense (DoD) to be used toward establishing a scalable, commercially-ready manufacturing process for CAP-2003.
- Announced a grant award of up to approximately $4.2 million from the National Institutes of Health (NIH) to support the investigation of CAP-2003 in hypoplastic left heart syndrome (HLHS).

Anticipated Events and Milestones

- Report top-line six-month data from the HOPE-Duchenne clinical trial of CAP-1002 early in the second quarter of 2017.
- Plan to evaluate re-dosing of CAP-1002 in patients who complete 12-month follow-up in the HOPE-Duchenne trial.
- Initiate a second clinical trial of CAP-1002 in DMD, administered by systemic intra-vascular delivery, in 2017.
- Janssen decision on its license option for CAP-1002 by mid-2017.
- Submit an IND for CAP-2003 for the treatment of ocular graft-versus-host disease in the first half of 2017.

Third Quarter Results

The Company reported a net loss of approximately $5.3 million, or $0.29 per share, for the third quarter of 2016, compared to a net loss of approximately $2.9 million, or $0.18 per share, for the third quarter of 2015. At September 30, 2016, the Company's cash, cash equivalents and marketable securities totaled approximately $20.5 million compared to approximately $13.6 million at December 31, 2015.

Financial Outlook

During the third quarter, Capricor sold approximately 3.4 million shares of common stock at a price of $3.20 per share in an underwritten registered public offering and concurrent registered direct offering that resulted in combined net proceeds of approximately $9.9 million. 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 5:00 p.m. ET today. The live call may be accessed by dialing (866)-320-0174 for domestic callers and (785) 424-1631 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 serious 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 advancing its proprietary exosome product candidate, CAP-2003, for the treatment of ophthalmic disorders and is 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 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 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 June 30, 2016, as filed with the Securities and Exchange Commission on August 15, 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, including CAP-2003, has not yet been approved for clinical investigation.

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

	Three months ended September 30,		Nine months ended September 30,	
	2016	2015	2016	2015
INCOME				
Collaboration income	$ 683,595	$ 911,458	$ 2,506,511	$ 2,864,583
Grant income	63,186	403,426	585,177	1,529,669
TOTAL INCOME	746,781	1,314,884	3,091,688	4,394,252
OPERATING EXPENSES				
Research and development	4,727,111	3,192,657	13,376,178	10,426,548
General and administrative	1,259,744	972,782	3,778,699	3,294,601
TOTAL OPERATING EXPENSES	5,986,855	4,165,439	17,154,877	13,721,149
LOSS FROM OPERATIONS	(5,240,074)	(2,850,555)	(14,063,189)	(9,326,897)
OTHER INCOME (EXPENSE)				
Investment income	5,410	292	16,347	723
Interest expense	(98,749)	(61,681)	(241,760)	(185,043)
TOTAL OTHER INCOME (EXPENSE)	(93,339)	(61,389)	(225,413)	(184,320)
NET LOSS	(5,333,413)	(2,911,944)	(14,288,602)	(9,511,217)
OTHER COMPREHENSIVE GAIN (LOSS)				
Net unrealized gain (loss) on marketable securities	(3,855)	5,414	(8,462)	11,949
COMPREHENSIVE LOSS	$ (5,337,268)	$ (2,906,530)	$ (14,297,064)	$ (9,499,268)
Net loss per share, basic and diluted	$ (0.29)	$ (0.18)	$ (0.81)	$ (0.60)
Weighted average number of shares, basic and diluted	18,286,816	16,242,090	17,594,749	15,783,224

CAPRICOR THERAPEUTICS, INC.
SUMMARY BALANCE SHEETS

	September 30, 2016 (unaudited)	December 31, 2015
Cash, cash equivalents and marketable securities	$ 20,520,850	$ 13,567,316
Total assets	$ 24,471,820	$ 16,069,572
Total deferred revenue	2,050,781	4,557,292
Total liabilities	$ 24,422,689	$ 17,101,346
Total stockholders' equity (deficit) - 21,399,019 and 16,254,985 common shares issued and outstanding at September 30, 2016 and December 31, 2015, respectively	49,131	(1,031,774)
Total liabilities and stockholders' equity	$ 24,471,820	$ 16,069,572

For more information, please contact:

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Exhibit 99.2

Capricor Therapeutics Announces Plans to Expand Clinical Development Program in Duchenne Muscular Dystrophy to Evaluate Peripheral and Respiratory Muscle Function

Planning Submission to Conduct Clinical Trial of Systemically-Delivered CAP-1002

To Explore Repeat Dosing Possibility of CAP-1002 in HOPE Clinical Trial Participants

Company to Host Conference Call and Webcast Today at 5:00 p.m. ET

LOS ANGELES, November 10, 2016 – Capricor Therapeutics, Inc. (NASDAQ: CAPR), a clinical-stage biotechnology company developing first-in-class biological therapies for cardiac and other serious medical conditions, today announced that it intends to expand its CAP-1002 clinical development program in Duchenne muscular dystrophy (DMD) to encompass the skeletal muscle aspects of the disease, in addition to the cardiac complications. Based on preclinical data in DMD models that show significant improvement in skeletal, including diaphragmatic, muscle function with CAP-1002 (allogeneic cardiosphere-derived cells), Capricor is designing a clinical trial to evaluate the potential ability of CAP-1002 to benefit skeletal muscle function in boys and young men with DMD. In the planned study, the medication will be given by systemic intra-vascular administration. This trial is expected to begin in 2017 subject to regulatory approval, and is intended to enroll people with DMD irrespective of their mutation or ambulatory status.

Linda Marbán, Ph.D., president and chief executive officer, said, “In a standard preclinical model of DMD, CAP-1002 is able to positively affect peripheral and respiratory muscles and to partially restore muscle cell energetics and function. These encouraging results indicate that CAP-1002 has the potential to not only address the heart disease in Duchenne, but to also treat the progressive failure that occurs in the peripheral and respiratory musculature. Toward this goal, we have developed a formulation of CAP-1002 that can be infused into the systemic circulation. We are hopeful that the muscle function improvements we have observed in preclinical models can be recapitulated in boys and young men with DMD.”

Capricor is currently conducting the randomized, controlled Phase I/II HOPE clinical trial of CAP-1002 in DMD-associated cardiomyopathy. In HOPE, 13 patients received a single dose of CAP-1002 via intra-coronary triple-vessel infusion and 12 patients are receiving usual care, with those randomized to the control arm to be eligible to receive CAP-1002 following the completion of their 12-month follow-up. Subject to regulatory review, Capricor is exploring the possibility of re-dosing patients in the active arm who complete the 12-month trial period. It is hoped that patients who initially respond to CAP-1002 will become eligible for repeat dosing.

Barry J. Byrne, M.D., Ph.D., Director of the Powell Gene Therapy Center and Professor of Pediatrics and Molecular Genetics & Microbiology at the University of Florida, and Principal Investigator of the HOPE-Duchenne clinical trial, stated, “The prospect of sustainably preserving heart function in DMD via repeated dosing of CAP-1002 is supported by studies in preclinical models. We look forward to learning more about the treatment potential of CAP-1002 through an amendment to the HOPE trial, as well as through the anticipated trial of CAP-1002 to be given by systemic intra-vascular administration.”

About the HOPE Clinical Trial

The Phase I/II HOPE-Duchenne clinical trial is a randomized, open-label, multi-center study in boys with DMD-associated cardiomyopathy, defined as the presence of scar tissue in at least four left ventricular segments as determined by magnetic resonance imaging (MRI). Of the 25 subjects enrolled, 13 subjects were randomized to the active treatment arm and received CAP-1002 via intracoronary infusion into each of the three main coronary arteries during a single procedure. The 12 subjects randomized to the control arm are receiving usual care and did not receive an infusion.

The primary outcome measures of the HOPE trial include a broad assessment of safety and tolerability of CAP-1002. Efficacy will be evaluated according to pre-specified secondary outcome measures, including absolute and relative changes in cardiac scar tissue and cardiac function as measured by MRI, as well as performance on the Six-Minute Walk Test (6MWT), scoring on the Performance of the Upper Limb (PUL) test, and scoring on the Pediatric Quality of Life Inventory (PedsQL). Capricor expects to report top-line six-month results from HOPE early in the second quarter of 2017.

The HOPE-Duchenne trial is being conducted at Cincinnati Children's Hospital Medical Center in Cincinnati, Ohio, Cedars-Sinai Heart Institute in Los Angeles, California, and the University of Florida in Gainesville, Florida. HOPE-Duchenne is being funded in part through the support of the California Institute for Regenerative Medicine.

About Duchenne Muscular Dystrophy (DMD)

DMD is believed to afflict approximately 20,000 boys and young men in the U.S. It is caused by a genetic abnormality in the dystrophin complex, a structural element which plays a critical role in muscle fiber integrity, and leads to chronic skeletal and cardiac muscle damage. Following years of progressive weakness, patients often die in their twenties. Heart disease is currently the most common cause of death among those with DMD.

Conference Call and Webcast

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For more information, please contact:

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