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 12, 2015

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 12, 2015, Capricor Therapeutics, Inc., a Delaware corporation (the "Company"), issued a press release announcing its financial results for the fiscal quarter ended September 30, 2015. 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 Third Quarter 2015 Business & Financial Highlights", dated November 12, 2015.

SIGNATURES

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

CAPRICOR THERAPEUTICS, INC.

Date: November 12, 2015

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

Exhibit 99.1

Capricor Therapeutics Reports Third Quarter 2015 Business & Financial Highlights

Positive Six-Month Safety and Efficacy Signals Reported for the DYNAMIC Clinical Trial at American Heart Association Scientific Sessions

Company to Host Conference Call and Webcast at 4:30 p.m. EST, Today, November 12, 2015

LOS ANGELES, November 12, 2015 – Capricor Therapeutics, Inc. (NASDAQ: CAPR), a biotechnology company focused on the discovery, development and commercialization of first-in-class therapeutics, today provided a business and financial update for the third quarter ended September 30, 2015.

Third Quarter and Recent Operational Highlights

- Capricor presented positive six-month DYNAMIC (**D**ilated cardiom**Y**opathy i**N**tervention with **A**llogeneic **M**yocard**I**ally-regenerative **C**ells) clinical trial results of its cardiosphere derived cell (CDC) therapy, CAP-1002, for the treatment of advanced heart failure.
- The Company appointed Deborah Ascheim, M.D., as its Chief Medical Officer. Dr. Ascheim is a heart failure cardiologist with significant experience directing national and international clinical trials.

"We have made significant advances for the CAP-1002 clinical development program this quarter," said Linda Marbán, Ph.D., Chief Executive Officer of Capricor. "Data from the DYNAMIC clinical trial presented at the American Heart Association Scientific Sessions earlier this week confirmed the bioactivity of our CDC therapy as seen in earlier clinical trials. In addition, the multi-vessel intracoronary infusion technique used in the DYNAMIC trial was safe and well tolerated and will be used in our HOPE-Duchenne clinical trial, which is now open for enrollment. We are encouraged by the concordance of the clinical data with the physiologic outcomes in the previous CDC clinical trials, CADUCEUS, ALLSTAR and now DYNAMIC, and are hopeful that the reduction of scarring in damaged hearts will also translate into positive outcomes for DMD-related cardiomyopathy patients in the HOPE-Duchenne clinical trial."

Clinical Development Program Update

CAP-1002 Program

DYNAMIC Clinical Trial Results
The Phase I DYNAMIC trial is evaluating CDCs (CAP-1002) in patients with advanced heart failure. The trial enrolled 14 patients with either ischemic or non-ischemic dilated cardiomyopathy with left ventricular ejection fraction (LVEF) of 35% or below and New York Heart Association (NYHA) Class III or Ambulatory Class IV heart failure. Suitable patients underwent sequential intracoronary infusion of CAP-1002 in up to three coronary territories. The triple vessel infusion was designed to deliver cells to wide areas of myocardium since patients with advanced heart failure have significant fibrosis in all areas of the heart. The Phase I trial is being funded in part through a grant of approximately $3.0 million from the National Institutes of Health (NIH).

Results of the DYNAMIC trial were presented on Monday, November 9, 2015 at the American Heart Association Scientific Sessions. Multi-vessel intracoronary infusion of CAP-1002 in subjects with dilated cardiomyopathy was shown to be safe in this study with no major adverse cardiac events reported at one month or at six months post-infusion. Though this trial was intended as an early safety study, the six-month data demonstrated encouraging and congruent preliminary efficacy signals in multiple parameters, including subjective well-being, exercise capacity, ejection fraction and ventricular volumes.

HOPE-Duchenne Clinical Trial Initiation
The HOPE-Duchenne (**H**alt cardiomy**OP**athy progr**E**ssion in Duchenne) clinical trial is a randomized open-label usual care controlled multi-center study evaluating the safety and preliminary efficacy of CAP-1002 in up to 24 male patients with DMD who have significant cardiac involvement. Patients will receive CAP-1002 in all three coronary arteries using the “non-stop flow technique” safely used in the DYNAMIC trial. The first six subjects randomized will be 18 years or older. Pending a safety review, the trial will then be open to boys 12 years of age or older with cardiomyopathy secondary to DMD, with left ventricular scar involving at least four cardiac segments and ejection fraction equal to 35% or greater. Cardiomyopathy is currently the leading cause of death in patients with DMD, having recently supplanted respiratory causes as a result of treatment improvements for that aspect of the disease.

The HOPE-Duchenne clinical trial is open for enrollment. The Company expects to report topline data from HOPE-Duchenne by the first quarter of 2017.

ALLSTAR Clinical Trial

Capricor is now enrolling ALLSTAR Phase II, a clinical trial evaluating the effectiveness of CAP-1002 in reducing infarct (scar) size in patients who have suffered a myocardial infarction (heart attack) more than 30 days and less than 12 months prior to treatment with CAP-1002. The trial is a randomized, double-blind, placebo-controlled trial powered to detect a reduction in infarct size as measured by MRI. It is Capricor's intent to perform an interim analysis, which, if successful, could result in a reduction in the number of patients necessary for achieving statistical significance for the primary endpoint, a reduction in infarct size at 12 months post infusion. This trial is intended as a proof-of-concept trial to validate the results of CADUCEUS using an allogeneic product while also looking for potential efficacy in patients. Results from the CADUCEUS trial showed that patients treated with autologous CDCs, CAP-1001, had a significant reduction in infarct size and an increase in healthy heart muscle mass.

ALLSTAR is open for enrollment at approximately 24 centers in the United States. If the interim analysis plan is implemented, we expect the trial to be fully enrolled in the third quarter of 2016 and the Company expects to report six-month data in the first quarter of 2017.

Janssen Biotech, Inc., a wholly-owned subsidiary of Johnson & Johnson, has entered into an exclusive option to license CAP-1002, which can be exercised anytime until 60 days after the six-month ALLSTAR Phase II data is available.

Phase II of the ALLSTAR study is being funded in part through the support of the California Institute for Regenerative Medicine.

Cenderitide (CD-NP) Program

Cenderitide belongs to a class of drugs called natriuretic peptides. Preclinical and clinical data have shown that the natriuretic peptide class can act on multiple disease processes that play a role in negative outcomes associated with heart failure. A Phase II clinical study of Cenderitide was initiated in 14 patients with heart failure in January 2015 and completed enrollment in March 2015. The drug was tolerated and there were no significant adverse events. Capricor has decided to conduct an additional small study to further assess the safety and efficacy of higher dose levels of Cenderitide. This study will assess the safety and tolerability, pharmacokinetics profile and pharmacodynamic response to increasing dose levels of Cenderitide. Following these studies, Capricor will determine whether to conduct additional clinical studies to further assess the safety and efficacy of this product candidate.

Exosome Program

Exosomes are nano-sized, membrane-enclosed vesicles or “bubbles” that are filled withRNAs and proteins, which, when released, send messages to neighboring cells to regulate cellular functions. Exosomes act as a transport vehicle out of the cell for microRNA, other fragments of genetic material and proteins that act as messengers between cells, ultimately providing regulatory function for many cell processes, including inflammation, angiogenesis, programmed cell death (apoptosis) and scarring.

Capricor’s preclinical exosome program is progressing and the Company expects to identify the first clinical target and clinical development plan in the first half of 2016 and plans to initiate a Phase I clinical trial before the end of 2016.

Results of Operations for the Quarter Ended September 30, 2015

For the quarter ended September 30, 2015, the Company had cash, cash equivalents and marketable securities of approximately $17.2 million. The increase in cash equivalents and marketable securities from the approximately $8.0 million reported as of December 31, 2014 is a result of approximately $17.0 million raised in two private placements of Capricor common stock, less cash used to fund operations.

For the quarter ended September 30, 2015, the Company reported a net loss of approximately $2.9 million, or $0.18 per basic and diluted share, compared to a net loss of approximately $1.5 million, or $0.13 per basic and diluted share, for the same period in the prior year. Research and development expenses increased to approximately $3.2 million in the quarter ended September 30, 2015, compared to approximately $2.0 million for the same period in the prior year. The increase was primarily due to increased expenses related to ongoing or planned clinical trials. General and administrative expenses increased to approximately $1.0 million in the quarter ended September 30, 2015, compared to approximately $0.8 million for the same period in the prior year. The increase was primarily due to increases in compensation costs and non-cash stock-based compensation.

Conference Call
Capricor management will hold a conference call at 4:30 p.m. EST today. The live call may be accessed by dialing 1-888-632-3382 (Conference ID: Capricor) for domestic callers and 1-785-424-1677 for international callers. Access to the live webcast and link for the replay can be found at http://capricor.com/news/events/. The conference call 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. The Company's lead programs target post myocardial infarction (heart attack), heart failure and Duchenne Muscular Dystrophy. The Company has two lead product candidates under investigation: CAP-1002, a cardiac cell therapy, and Cenderitide, a 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 potential other indications. In addition, the Company is conducting research and development on its exosomes platform technology for cardiac diseases and other potential indications. For additional information, visit www.capricor.com.

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, 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, 2014, as filed with the Securities and Exchange Commission on March 16, 2015, 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, 2015, as filed with the Securities and Exchange Commission on August 14, 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.

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

	Three months ended September 30,		Nine months ended September 30,	
	2015	2014	2015	2014
INCOME				
Collaboration income	$ 911,458	$ 1,041,667	$ 2,864,583	$ 3,125,001
Grant income	403,426	259,800	1,529,669	259,800
TOTAL INCOME	1,314,884	1,301,467	4,394,252	3,384,801
OPERATING EXPENSES				
Research and development	3,192,657	1,966,889	10,426,548	5,203,766
General and administrative	972,782	819,683	3,294,601	2,332,579
TOTAL OPERATING EXPENSES	4,165,439	2,786,572	13,721,149	7,536,345
LOSS FROM OPERATIONS	(2,850,555)	(1,485,105)	(9,326,897)	(4,151,544)
OTHER INCOME (EXPENSE)				
Investment income	292	1,210	723	3,129
Interest expense	(61,681)	(60,091)	(185,043)	(140,122)
TOTAL OTHER INCOME (EXPENSE)	(61,389)	(58,881)	(184,320)	(136,993)
NET LOSS	(2,911,944)	(1,543,986)	(9,511,217)	(4,288,537)
OTHER COMPREHENSIVE GAIN (LOSS)				
Net unrealized gain (loss) on marketable securities	5,414	(733)	11,949	(627)
COMPREHENSIVE LOSS	$ (2,906,530)	$ (1,544,719)	$ (9,499,268)	$ (4,289,164)
Net loss per share, basic and diluted	$ (0.18)	$ (0.13)	$ (0.60)	$ (0.37)
Weighted average number of shares, basic and diluted	16,242,090	11,700,136	15,783,224	11,694,004

CAPRICOR THERAPEUTICS, INC.
SUMMARY BALANCE SHEETS

	September 30, 2015 (unaudited)	December 31, 2014
Cash, cash equivalents and marketable securities	$ 17,217,854	$ 8,034,765
Total Assets	$ 19,882,289	$ 13,632,072
Total deferred revenue	5,468,750	8,333,333
Total liabilities	$ 17,956,623	$ 19,880,795
Total stockholders' equity (deficit) - 16,254,985 and 11,707,051 common shares issued and outstanding at September 30, 2015 and December 31, 2014, respectively	1,925,666	(6,248,723)
Total liabilities and stockholders' equity	$ 19,882,289	$ 13,632,072

For more information, please contact:

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