

**UNITED STATES  
SECURITIES AND EXCHANGE COMMISSION**  
Washington, D.C. 20549

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**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 17, 2016**

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**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 17, 2016, Capricor Therapeutics, Inc., a Delaware corporation (the “Company”), issued a press release announcing its financial results for the quarter and fiscal year ended December 31, 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 7.01 Regulation FD Disclosure.**

Attached hereto as Exhibit 99.2 to this Current Report on Form 8-K is an investor presentation that the Company intends to review in conjunction with its earnings release conference call on March 17, 2016.

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 purposes of Section 18 of 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 2015 Financial Results and Business Update”, dated March 17, 2016.
  - 99.2 Capricor Therapeutics, Inc. Exosomes Program Update Presentation, dated March 17, 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: March 17, 2016

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

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## Capricor Therapeutics Reports Fourth Quarter and Full Year 2015 Financial Results and Business Update

*Awarded CIRM Grant of Approximately \$3.4 Million to Support the Phase I/II HOPE-Duchenne Clinical Trial*

*Six-Month Data from Phase II ALLSTAR Clinical Trial Expected to be Available in the First Quarter of 2017 Following Protocol Amendment*

*Company to Host Conference Call and Webcast at 4:30 p.m. EDT, Today,  
March 17, 2016*

LOS ANGELES, March 17, 2015 – [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 fourth quarter and full year ended December 31, 2015 as well as a business update.

“In 2015 and through the early part of 2016, we expanded the scope of our clinical and preclinical programs as well as strengthened our management team with key hires,” said Linda Marbán, Ph.D., president and chief executive officer of Capricor. “We believe these initiatives position us well as we look forward to a productive year in our therapeutics development programs.”

“In addition, we have now completed statistical modelling of the design of ALLSTAR, our ongoing Phase II clinical trial of CAP-1002, Capricor’s cardiosphere-derived cell therapy, in patients who have suffered a heart attack. This modelling incorporated the expanded dataset that has become available from our other clinical trials of CAP-1002. Based on its results, we have elected to decrease the enrollment goal of ALLSTAR to approximately 120 patients, a sample size that is expected to maintain 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, and is a strong positive for Capricor. Under the revised enrollment goal, we expect to have six-month data from ALLSTAR in the first quarter of 2017,” added Dr. Marbán.

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

#### **Fourth Quarter and Recent Operational Highlights**

- Completed \$4.1 million equity offering with new and existing investors.
- Received a grant award of approximately \$3.38 million from CIRM to support the Phase I/II HOPE-Duchenne clinical trial, which is evaluating CAP-1002 in Duchenne muscular dystrophy (DMD)-associated cardiomyopathy.
- Completed enrollment of the pre-specified first patient cohort in the HOPE-Duchenne clinical trial. Topline data from this trial are expected to be reported in the first quarter of 2017.
- Presented positive six-month DYNAMIC clinical trial results of CAP-1002 in advanced heart failure at the American Heart Association (AHA) annual meeting.
- Appointed Leland J. Gershell, M.D., Ph.D., as Chief Financial Officer.

#### **Fourth Quarter and Full Year Financial Results**

The Company reported a net loss of approximately \$3.3 million, or \$0.21 per share, for the fourth quarter of 2015, compared to a net loss of approximately \$1.9 million, or \$0.16 per share, for the fourth quarter of 2014. For the year ended December 31, 2015, the Company reported a net loss of approximately \$12.9 million, or \$0.81 per share, compared to a net loss of approximately \$6.2 million, or \$0.53 per share, for the year ended December 31, 2014. At December 31, 2015, the Company's cash, cash equivalents and marketable securities totaled approximately \$13.6 million compared to \$8.0 million at December 31, 2014.

#### **Conference Call and Slides**

Capricor management will hold a conference call at 4:30 p.m. EDT today. The live call may be accessed by dialing (866) 635-0172 for domestic callers and (785) 424-1629 for international callers, and by using "Capricor" as the conference ID. Access to the live webcast and slides 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 90 days.

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**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's lead programs target post myocardial infarction (heart attack), heart failure and Duchenne muscular dystrophy. Capricor 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, Capricor is conducting research and development on its exosomes platform technology for cardiac diseases and other potential indications. For additional information, visit [www.capricor.com](http://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, 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, 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 September 30, 2015, as filed with the Securities and Exchange Commission on November 13, 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.

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

	Years ended December 31,	
	2015	2014
<b>INCOME</b>		
Collaboration income	\$ 3,776,041	\$ 4,166,667
Grant income	1,741,607	620,033
<b>TOTAL INCOME</b>	<b>5,517,648</b>	<b>4,786,700</b>
<b>OPERATING EXPENSES</b>		
Research and development	13,757,279	7,787,384
General and administrative	4,372,195	3,017,301
<b>TOTAL OPERATING EXPENSES</b>	<b>18,129,474</b>	<b>10,804,685</b>
<b>LOSS FROM OPERATIONS</b>	<b>(12,611,826)</b>	<b>(6,017,985)</b>
<b>OTHER INCOME (EXPENSE)</b>		
Investment income	3,113	1,898
Interest expense	(248,626)	(200,505)
<b>TOTAL OTHER INCOME (EXPENSE)</b>	<b>(245,513)</b>	<b>(198,607)</b>
<b>NET LOSS</b>	<b>(12,857,339)</b>	<b>(6,216,592)</b>
<b>OTHER COMPREHENSIVE GAIN</b>		
Net unrealized gain on marketable securities	9,385	980
<b>COMPREHENSIVE LOSS</b>	<b>\$ (12,847,954)</b>	<b>\$ (6,215,612)</b>
Net loss per share, basic and diluted	<b>\$ (0.81)</b>	<b>\$ (0.53)</b>
Weighted average number of shares, basic and diluted	<b>15,902,133</b>	<b>11,696,980</b>

CAPRICOR THERAPEUTICS, INC.  
Summary Balance Sheet

	December 31, 2015	December 31, 2014
Cash, cash equivalents and marketable securities	\$ 13,567,316	\$ 8,034,765
Total Assets	\$ 16,069,572	\$ 13,632,072
Total deferred revenue	4,557,292	8,333,333
Total liabilities	\$ 17,101,346	\$ 19,880,795
Total stockholders' equity (deficit) - 16,254,985 and 11,707,051 common shares issued and outstanding at December 31, 2015 and December 31, 2014, respectively	(1,031,774)	(6,248,723)
Total liabilities and stockholders' equity	\$ 16,069,572	\$ 13,632,072

For more information, please contact:

**Corporate Contact:**

**Capricor Therapeutics, Inc.**

AJ Bergmann, Vice President of Finance

+1-310-358-3200

[abergmann@capricor.com](mailto:abergmann@capricor.com)

**Investor Relations:**

**Argot Partners**

Angeli Kolhatkar

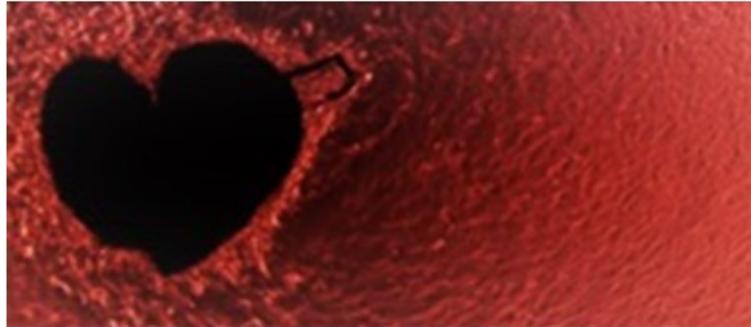
+1-212-600-1902

[angeli@argotpartners.com](mailto:angeli@argotpartners.com)

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*Transformative Therapies from Bench to Bedside*



NASDAQ: CAPR

[www.capricor.com](http://www.capricor.com)

## **Exosomes Program Update**

March 17, 2016

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## Forward-Looking Statements

This presentation contains forward-looking statements and information that are based on the beliefs of the management of Capricor Therapeutics, Inc. (Capricor) as well as assumptions made by and information currently available to Capricor. All statements other than statements of historical fact included in this presentation are forward-looking statements, including but not limited to statements identified by the words “anticipates,” “believes,” “estimates,” and “expects” and similar expressions. Such forward-looking statements also include any expectation of or dates for commencement of clinical trials, IND filings, similar plans or projections and other matters that do not relate strictly to historical facts. These statements reflect Capricor’s current views with respect to future events, based on what we believe are reasonable assumptions; however, the statements are subject to a number of risks, uncertainties and assumptions. 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 September 30, 2015, as filed with the Securities and Exchange Commission on November 13, 2015. Should one or more of these risks or uncertainties materialize, or should underlying assumptions prove incorrect, actual results may vary materially from those in the forward-looking statements. Further, Capricor’s management does not intend to update these forward-looking statements and information after the date of this presentation.



## **CAP-2003 (CDC Exosomes)**

### **Rabbit Keratitis Proof-of-Concept Study**

- 18-animal, six-day study which compared CAP-2003 to placebo for the treatment of ocular surface injury and inflammation as caused by induced keratoconjunctivitis.
- Over three days, ocular wounds were created on one eye, followed by administration of a pro-inflammatory agent.
- After development of severe inflammation, eyes were treated with a single administration of CAP-2003, then followed clinically for 3 days.

## **CAP-2003 (CDC Exosomes)** **Demonstrated Dose-Dependent Improvement**

- Histopathology was performed on eyes after third (final) day.



**Placebo**



**CAP-2003  
(low-dose)**



**CAP-2003  
(high-dose)**

## **CAP-2003 (CDC Exosomes)**

### **Conclusions**

- The totality of the clinical and histological data in this rabbit keratitis proof-of-concept study suggests that CAP-2003 is capable of improving several relevant clinical and histological endpoints, including:
  - 1. corneal wound healing**
  - 2. ocular surface inflammation**
  - 3. conjunctivitis**
  - 4. corneal edema**