# 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)

**August 10, 2017**

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# 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))

Indicate by check mark whether the registrant is an emerging growth company as defined in Rule 405 of the Securities Act of 1933 (17 CFR §230.405) or Rule 12b-2 of the Securities Exchange Act of 1934 (17 CFR §240.12b-2).

Emerging growth company ☐

If an emerging growth company, indicate by check mark if the registrant has elected not to use the extended transition period for complying with any new or revised financial accounting standards provided pursuant to Section 13(a) of the Exchange Act. ☐

**Item 2.02 Results of Operations and Financial Condition.**

On August 10, 2017, Capricor Therapeutics, Inc., a Delaware corporation (the "Company"), issued a press release announcing its financial results for the quarter ended June 30, 2017. 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 August 10, 2017.

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 Second Quarter 2017 Financial Results and Provides Corporate Update", dated August 10, 2017.

99.2 Capricor Therapeutics, Inc. Corporate Update Presentation, dated August 10, 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: August 10, 2017

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

**Exhibit 99.1**

# Capricor Therapeutics Reports Second Quarter 2017 Financial Results and Provides Corporate Update

*Announced Statistically-Significant Improvements in Skeletal and Cardiac Muscle Function in Patients Treated with CAP-1002 in the HOPE-Duchenne Trial*

*Plans to Commence Clinical Trial of I.V. CAP-1002 in Duchenne Muscular Dystrophy in the Fourth Quarter*

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

**LOS ANGELES**, August 10, 2017 – Capricor Therapeutics, Inc. (NASDAQ: CAPR) today announced its financial results for the second quarter ended June 30, 2017 and provided an update on its business.

"In April, we reported positive interim results from our ongoing HOPE-Duchenne clinical trial which have ignited the interest of patients, advocates and thought leaders who constitute the greater Duchenne muscular dystrophy community. These results are particularly notable given the patients' advanced disease as approximately 70% of trial participants were wheelchair-dependent at entry," said Linda Marbán, Ph.D., president and CEO of Capricor. "A key finding in HOPE-Duchenne was that, as compared to usual care controls, patients treated with CAP-1002 demonstrated improvement in skeletal muscle function according to the Performance of the Upper Limb (PUL) test, a validated instrument."

"Having now obtained clarity from the U.S. Food and Drug Administration (FDA) on a development plan that could potentially support a Biologics License Application (BLA) for CAP-1002, we are preparing to conduct our next clinical trial in DMD, which will evaluate the ability of intravenous CAP-1002 to improve skeletal muscle function as measured by the PUL. We expect this to commence in the fourth quarter of this year, subject to regulatory approval."

"We also continue to advance our exosomes technology, with CAP-2003 expected to enter the clinic next year for the treatment of hypoplastic left heart syndrome (HLHS), a life-threatening congenital cardiac malformation," added Dr. Marbán.

**Second Quarter 2017 and Recent Highlights**

*CAP-1002 for Duchenne Muscular Dystrophy*

- Reported positive six-month data from the Phase I/II HOPE-Duchenne clinical trial of intracoronary CAP-1002 in boys and young men with DMD, in which patients treated with CAP-1002 demonstrated statistically-significant ($p<0.05$) improvement compared to usual care controls in certain measures of cardiac and upper limb function.
- Announced the FDA's willingness to accept the Performance of the Upper Limb (PUL) as the basis for the primary efficacy endpoint for clinical studies intended to support a Biologics License Application (BLA) for CAP-1002 in the DMD indication.
- Announced that CAP-1002 had been granted Rare Pediatric Disease Designation by the FDA.
- Formed an Advisory Board of internationally-recognized thought leaders in DMD.

*CAP-1002 for Adult Heart Conditions*

- Announced that a pre-specified administrative interim analysis of the Phase II ALLSTAR clinical trial of intracoronary CAP-1002 in patients who had experienced a large myocardial infarction demonstrated a low probability (futility) of achieving a statistically-significant difference in the 12 month primary efficacy endpoint of percent change from baseline infarct size as a percentage of left ventricular mass, measured by cardiac magnetic resonance imaging (MRI).

*Corporate*

- Announced that Capricor would focus its clinical efforts on the development of CAP-1002 for the treatment of DMD, and completed a workforce restructuring as part of this initiative.

- Announced the retention of full rights to CAP-1002 following the decision by Janssen Biotech, Inc., to not exercise its license option.

- Closed on approximately $3.7 million in gross proceeds from a private placement of common stock, which included participation from certain of the Company's directors.

**Anticipated Events and Milestones**

- To commence a randomized, double-blind, placebo-controlled, clinical trial of intravenous, repeat-dose CAP-1002 in the fourth quarter of 2017, subject to regulatory approval.

- To present six-month results from the Phase I/II HOPE-Duchenne clinical trial of intracoronary CAP-1002 at a medical conference in the fourth quarter of 2017.

- To report top-line 12-month results from the HOPE-Duchenne Trial in the fourth quarter of 2017.

- To present six-month results from the ALLSTAR Trial of intracoronary CAP-1002 at a medical conference in the fourth quarter of 2017.

- To submit an Investigational New Drug application (IND) for CAP-2003 (cardiosphere-derived cell exosomes) in 2018.

**Second Quarter Financial Results**

The Company reported a net loss of approximately $3.5 million, or $0.16 per share, for the second quarter of 2017, compared to a net loss of approximately $4.7 million, or $0.26 per share, for the second quarter of 2016.

As of June 30, 2017, the Company's cash, cash equivalents and marketable securities totaled approximately $12.3 million compared to approximately $16.2 million on December 31, 2016. Capricor believes that its current financial resources should be sufficient to fund its operations and meet its financial obligations through the second quarter of 2018 based on the Company's current projections.

**Conference Call and Webcast**

The Company will host a conference call at 4:30 p.m. ET today. To participate, please dial (866) 868-1282 (domestic) or (847) 413-2405 (international) and reference the access code 7522998. Slides to accompany the call may be viewed via the webcast link at http://wsw.com/webcast/cc/capr3.

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 developing first-in-class biological therapies. Capricor's lead candidate, CAP-1002, is a cell-based candidate currently in clinical development for the treatment of Duchenne muscular dystrophy. Capricor is also exploring the potential of CAP-2003, a cell-free, exosome-based candidate, to treat a variety of disorders. For more information, visit www.capricor.com.

The ALLSTAR and HOPE-Duchenne clinical trials are funded in part by the California Institute for Regenerative Medicine.

**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 is set forth in Capricor's Annual Report on Form 10-K for the year ended December 31, 2016, as filed with the Securities and Exchange Commission on March 16, 2017, and in its Registration Statement on Form S-3, as filed with the Securities and Exchange Commission on September 28, 2015, together with prospectus supplements thereto, and in its Quarterly Report on Form 10-Q for the quarter ended March 31, 2017, as filed with the Securities and Exchange Commission on May 15, 2017. 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.
CONDENSED CONSOLIDATED STATEMENTS OF OPERATIONS
AND COMPREHENSIVE LOSS (unaudited)

| | Three months ended June 30, | | Six months ended June 30, | |
|---|---|---|---|---|
| | 2017 | 2016 | 2017 | 2016 |
| INCOME | | | | |
| Collaboration income | $ 683,592 | $ 911,458 | $ 1,367,186 | $ 1,822,916 |
| Grant income | 312,870 | 218,361 | 510,083 | 521,992 |
| TOTAL INCOME | 996,462 | 1,129,819 | 1,877,269 | 2,344,908 |
| OPERATING EXPENSES | | | | |
| Research and development | 3,128,182 | 4,307,948 | 6,385,331 | 8,649,067 |
| General and administrative | 1,246,942 | 1,434,259 | 2,436,181 | 2,518,955 |
| TOTAL OPERATING EXPENSES | 4,375,124 | 5,742,207 | 8,821,512 | 11,168,022 |
| LOSS FROM OPERATIONS | (3,378,662) | (4,612,388) | (6,944,243) | (8,823,114) |
| OTHER INCOME (EXPENSE) | | | | |
| Investment income | 12,052 | 427 | 16,334 | 10,937 |
| Interest expense | (105,527) | (76,887) | (210,847) | (143,011) |
| TOTAL OTHER INCOME (EXPENSE) | (93,475) | (76,460) | (194,513) | (132,074) |
| NET LOSS | (3,472,137) | (4,688,848) | (7,138,756) | (8,955,188) |
| OTHER COMPREHENSIVE GAIN (LOSS) | | | | |
| Net unrealized gain (loss) on marketable securities | (2,394) | 1,551 | 3,793 | (4,607) |
| COMPREHENSIVE LOSS | $ (3,474,531) | $ (4,687,297) | $ (7,134,963) | $ (8,959,795) |
| Net loss per share, basic and diluted | $ (0.16) | $ (0.26) | $ (0.33) | $ (0.52) |
| Weighted average number of shares, basic and diluted | 22,135,198 | 17,952,323 | 21,769,142 | 17,244,912 |

CAPRICOR THERAPEUTICS, INC.
SUMMARY BALANCE SHEETS

| | June 30, 2017 (unaudited) | December 31, 2016 |
|---|---|---|
| Cash, cash equivalents and marketable securities | $ 12,259,417 | $ 16,194,888 |
| Total assets | $ 14,218,267 | $ 18,747,355 |
| | | |
| Total deferred revenue | - | 1,367,186 |
| Total liabilities | $ 20,804,643 | $ 22,750,509 |
| | | |
| Total stockholders' equity (deficit) - 22,595,310 and 21,399,019 common shares issued and outstanding at June 30, 2017 and December 31, 2016, respectively | (6,586,376) | (4,003,154) |
| Total liabilities and stockholders' equity | $ 14,218,267 | $ 18,747,355 |

For more information, please contact:

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

Exhibit 99.2

# Capricor Therapeutics

## Second Quarter 2017
## Corporate Update

## August 10, 2017

# Forward-Looking Statements

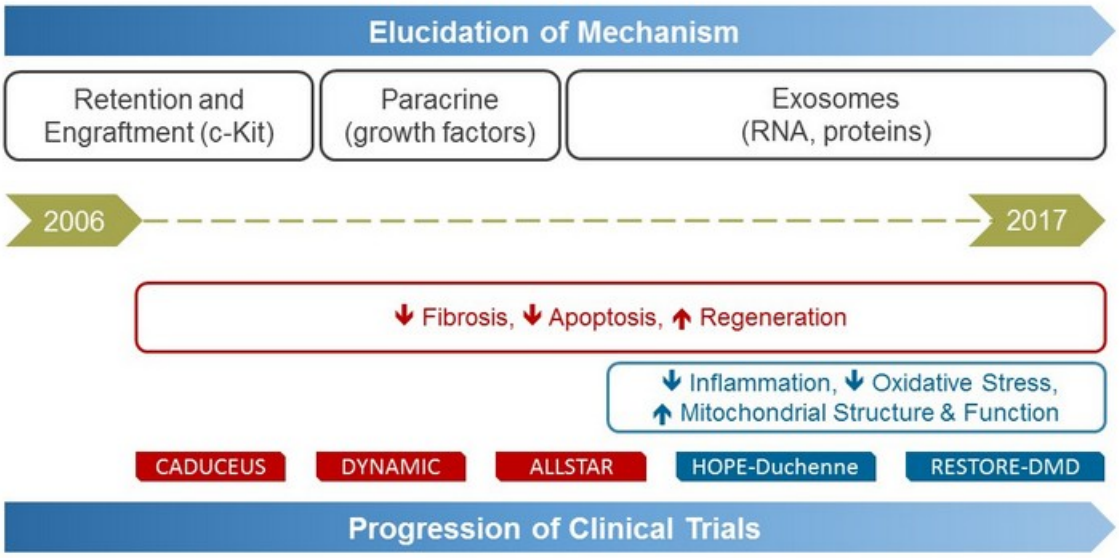
Statements in this press release regarding the efficacy, safety, and intended utilization of Capricor's product candidates; the initiation, conduct, size, timing and results of discovery efforts and clinical trials; the pace of enrollment of clinical trials; plans regarding regulatory filings, future 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 is set forth in Capricor's Annual Report on Form 10-K for the year ended December 31, 2016, as filed with the Securities and Exchange Commission on March 16, 2017, and in its Registration Statement on Form S-3, as filed with the Securities and Exchange Commission on September 28, 2015, together with prospectus supplements thereto, and in its Quarterly Report on Form 10-Q for the quarter ended March 31, 2017, as filed with the Securities and Exchange Commission on May 15, 2017. 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.

# CDCs Possess Broad Bioactivity

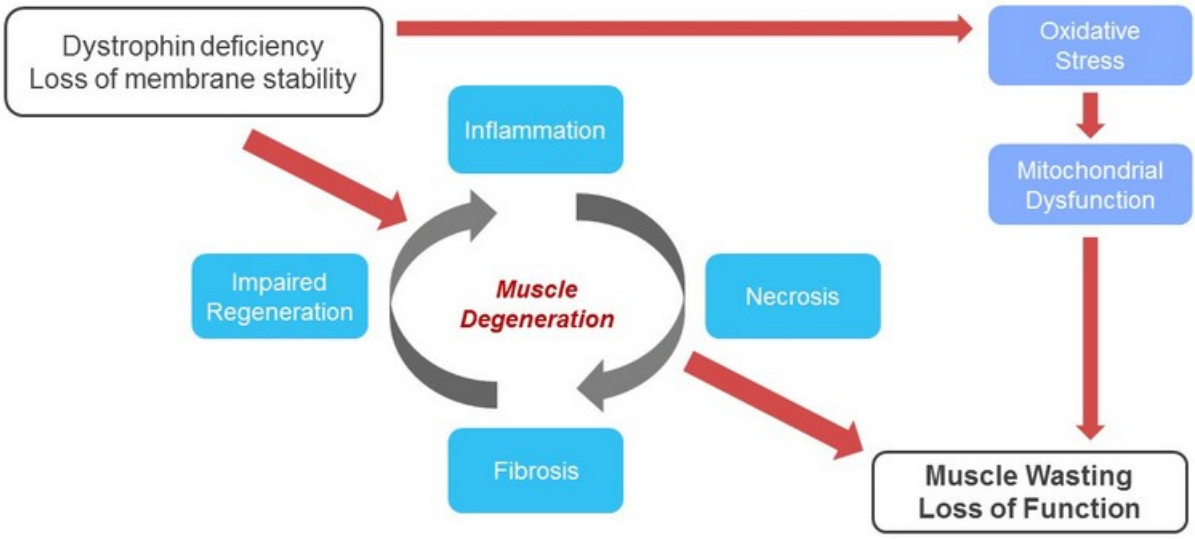
| | Property | References |
|---|---|---|
| ✓ | Regenerative | 1,2 |
| ✓ | Anti-fibrotic | 1-4 |
| ✓ | Anti-apoptotic | 3-5 |
| ✓ | Angiogenic | 1,6 |
| ✓ | Anti-inflammatory | 9 |
| ✓ | Immunomodulatory | 9,10 |


1. Smith et al. Circulation **2007**;*115*:896-908.
2. Makkar et al. Lancet **2012**;*379*:895-904.
3. Tseliou et al. PLoS One **2014**;*9*:e88590.
4. Tseliou et al. Basic Res Cardiol **2014**;*109*:443.
5. Li et al. J Am Coll Cardiol **2012**;*59*:942-53.
6. Chimenti et al. Circ Res **2010**;*106*:971-80.
7. Malliaras et al. Circulation **2012**;*125*:100-12.
8. Malliaras et al. EMBO Mol Med **2013**;*5*:191-209.
9. Aminzadeh et al. Eur Heart J **2015**;*36*:751-62.
10. Lauden et al. Circ Res **2013**;*112*:451-64.

# Evolution of Capricor's Science and Clinical Development

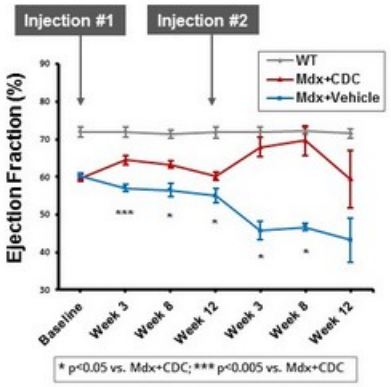


# DMD Pathophysiology

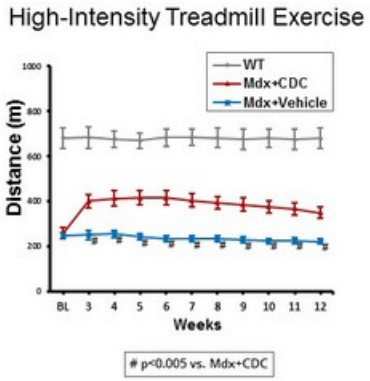



Adapted from Guiraud et al. Curr Opin Pharmacol **2017**;*34*:36-48.

# Cardiac and Ambulatory Effects of CDCs in mdx Model




LV ejection fraction markedly improved after treatment either with CDC or CDC-exosomes compared to vehicle-treated mice (p<0.005)




Ambulatory capacity doubled; the substantial increase in exercise capacity was disproportionate to the improvement in cardiac function (EF increased by <10%)

Adapted from pre-publication manuscript (Aminzadeh et al, http://biorxiv.org/content/early/2017/04/20/128900).

# CAP-1002's Activities in DMD… and Potentially Beyond