

# SECURITIES & EXCHANGE COMMISSION EDGAR FILING

## CAPRICOR THERAPEUTICS, INC.

**Form: 8-K**

**Date Filed: 2018-03-14**

Corporate Issuer CIK: 1133869

---

---

**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)

March 14, 2018

---

**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))

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 March 14, 2018 Capricor Therapeutics, Inc., a Delaware corporation (the "Company"), issued a press release announcing its financial results for the quarter and full year ended December 31, 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 is 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 Presents Fourth Quarter and Full Year 2017 Financial Results and Corporate Update", dated March 14, 2018.](#)

---

## 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 14, 2018

By: /s/ Linda Marbán, Ph.D.

Linda Marbán, Ph.D.

Chief Executive Officer

---

**Capricor Presents Fourth Quarter and Full Year 2017 Financial Results and Corporate Update****Planning to Initiate HOPE-2 Clinical Trial****To Host Conference Call and Webcast Today at 4:30 p.m. ET**

LOS ANGELES, March 14, 2018 – Capricor Therapeutics (NASDAQ: CAPR), a clinical-stage biotechnology company focused on the development of first-in-class biological therapeutics for the treatment of Duchenne muscular dystrophy and other rare disorders, today reported its fourth quarter and full year 2017 financial results. It also provided a corporate update.

“This has been an exciting year for Capricor as we have made significant inroads in the clinical development of CAP-1002, our lead cell therapy product, to treat Duchenne muscular dystrophy,” said Linda Marbán, Ph.D., Capricor president and chief executive officer. “We have achieved several important milestones that facilitate our progress in the research, development and potential commercialization of CAP-1002. We will soon be initiating the HOPE-2 clinical trial designed to test CAP-1002 in boys and young men whose ability to walk has been impaired by Duchenne muscular dystrophy. This trial is one of the very few to focus on those patients that are non-ambulant and in the later stages of the disease process.”

**Fourth Quarter Highlights and Recent Clinical and Operational Developments**

- In November, Capricor reported the one-year results of its first clinical trial of CAP-1002, the HOPE-Duchenne trial, at the American Heart Association Scientific Sessions 2017. The study found that a single intracoronary dose of CAP-1002 produced significant and sustained improvement in cardiac and skeletal muscle functions in boys and young men in advanced stages of Duchenne muscular dystrophy, a serious x-linked genetic disorder for which there is no cure and treatment options are limited.
  - The Food and Drug Administration (FDA) cleared Capricor’s Investigational New Drug (IND) application to conduct the HOPE-2 trial which is a randomized, double-blind, placebo-controlled study in later stage Duchenne muscular dystrophy patients.
  - A newly published study in “*Stem Cell Reports*” from the Smidt Heart Institute at Cedars-Sinai Medical Center reported that CAP-1002 improved skeletal, diaphragm and cardiac muscle function in a mouse model of Duchenne muscular dystrophy.
  - Capricor secured two additional FDA designations that may potentially expedite reviews and regulatory approval of CAP-1002 for Duchenne muscular dystrophy: the Regenerative Medicine Advanced Therapy (RMAT) designation, which makes therapies eligible for expedited review, and the Rare Pediatric Disease Designation, which means that if CAP-1002 is approved first for use in Duchenne muscular dystrophy, the company may secure a priority review voucher to fast-track a potential future therapy. These two designations are in addition to the Orphan Drug Designation Capricor secured in February 2017.
-

- Capricor added seven new patent applications to its existing Exclusive License Agreements with Cedars-Sinai Medical Center, giving Capricor worldwide, exclusive rights to inventions related to cardiosphere-derived cells (CDCs, CAP-1002) and CDC-derived extracellular vesicles, including exosomes.
- Capricor hosted a Key Opinion Leaders Lunch in New York City on March 9 which included four distinguished speakers discussing the emerging paradigms in gene and cellular therapies to treat Duchenne muscular dystrophy. The speakers included Craig McDonald, M.D., professor and chair of the Department of Physical Medicine and Rehabilitation and Director of the Neuromuscular Disease Clinics at the University of California, Davis. He is the national principal investigator of the Capricor HOPE-2 trial. Other speakers were Jeffrey Chamberlain, Ph.D., professor in the departments of Neurology, Medicine and Biochemistry and director of the Seattle Wellstone Muscular Dystrophy Center, and Michelle Eagle, Ph.D., the managing director of ATOM International LTD and one of the creators of, and who has published extensively on, the Performance of the Upper Limb (PUL) test, a validated test for skeletal muscle function in Duchenne muscular dystrophy. PUL is the primary efficacy endpoint for the HOPE-2 trial. The fourth speaker was Pat Furlong, the founding president and CEO of the Parent Project Muscular Dystrophy (PPMD), the largest non-profit organization in the U.S. focused solely on Duchenne.

#### **Anticipated Events and Milestones in 2018**

- Plan to treat the first patients in the HOPE-2 clinical trial.
- Continue to conduct pre-clinical research for Capricor's investigational exosome-based therapy, CAP-2003, to treat various diseases of inflammation and fibrosis, including hypoplastic left heart syndrome.
- Continue preparations for manufacturing scale-up and technology transfer of CAP-1002.

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

For the fourth quarter of 2017, after giving effect to the forgiveness of the California Institute of Regenerative Medicine (CIRM) loan payable, the company reported net income of approximately \$12.3 million, or \$0.42 per diluted share, compared to a net loss of approximately \$(4.5) million, or \$(0.21) per diluted share, for the fourth quarter of 2016.

For the year ended December 31, 2017, after giving effect to the forgiveness of the CIRM loan payable, the company reported net income of approximately \$2.4 million, or \$0.09 per diluted share, compared to a net loss of approximately \$(18.8) million, or \$(1.01) per diluted share for the year ended December 31, 2016. As of December 31, 2017, the company's cash, cash equivalents and marketable securities totaled approximately \$14.1 million compared to approximately \$16.2 million on December 31, 2016.

---

In the fourth quarter of 2017, the company notified CIRM of its election to abandon the ALLSTAR (CIRM-funded) project pursuant to the Loan Agreement and entered into an Amendment whereby the total loan balance was forgiven by CIRM, thereby terminating the company's obligation to repay the loan balance. The company classified the forgiveness of the loan payable, a non-cash income, of approximately \$15.7 million as "other income" in its Consolidated Statement of Operations.

#### **Financial Outlook**

Based on current plans and projections, Capricor expects that its cash, cash equivalents and marketable securities will fund its research and development programs and other operations through the fourth quarter of 2018.

#### **Conference Call and Webcast**

To participate in the conference call, please dial 866-717-4562 (U.S.) or 210-874-7812 (international) and enter the conference ID of 4139889. To join via webcast, please visit: <https://edge.media-server.com/m6/p/gwkzzdrc>. 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 therapeutics for the treatment of rare disorders. Capricor's lead candidate, CAP-1002, is an allogeneic cell therapy that is currently in clinical development for the treatment of Duchenne muscular dystrophy. Capricor has also established itself as one of the leading companies investigating the field of extracellular vesicles and is exploring the potential of CAP-2003, a cell-free, exosome-based candidate, to treat a variety of disorders. The HOPE-Duchenne trial was funded in part by CIRM. For more information, visit [www.capricor.com](http://www.capricor.com).

Keep up with Capricor on social media: [www.facebook.com/capricortherapeutics](http://www.facebook.com/capricortherapeutics), [www.instagram.com/capricortherapeutics/](http://www.instagram.com/capricortherapeutics/) and <https://twitter.com/capricor>

---

## 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; regulatory developments involving products, including the ability to obtain regulatory approvals or otherwise bring products to market; 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, in its Registration Statement on Form S-3, as filed with the Securities and Exchange Commission on September 28, 2015, together with the prospectus included therein and prospectus supplements thereto, and in its Quarterly Report on Form 10-Q for the quarter ended September 30, 2017, as filed with the Securities and Exchange Commission on November 14, 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. CAP-2003 has not yet been approved for clinical investigation.*

---



**CAPRICOR THEAPEUTICS, INC.**  
**CONSOLIDATED STATEMENTS OF OPERATIONS AND COMPREHENSIVE INCOME (LOSS)**  
(unaudited)

	Three months ended December 31		Years ended December 31	
	2017	2016	2017	2016
<b>INCOME</b>				
Collaboration income	\$ -	\$ 683,595	\$ 1,367,186	\$ 3,190,106
Grant income	344,575	223,335	1,115,430	808,512
Other income	131,224	-	183,724	-
<b>TOTAL INCOME</b>	<b>475,799</b>	<b>906,930</b>	<b>2,666,340</b>	<b>3,998,618</b>
<b>OPERATING EXPENSES</b>				
Research and development	2,518,395	2,665,904	10,766,095	16,042,082
General and administrative	1,237,827	1,154,355	4,762,642	4,933,054
<b>TOTAL OPERATING EXPENSES</b>	<b>3,756,222</b>	<b>3,820,259</b>	<b>15,528,737</b>	<b>20,975,136</b>
<b>LOSS FROM OPERATIONS</b>	<b>(3,280,423)</b>	<b>(2,913,329)</b>	<b>(12,862,397)</b>	<b>(16,976,518)</b>
<b>OTHER INCOME (EXPENSE)</b>				
Investment income	11,768	(1,940)	38,494	14,407
Interest expense	(80,307)	(102,905)	(398,807)	(344,665)
Forgiveness of loan payable	15,654,133	-	15,654,133	-
Impairment of in-process research and development	-	(1,500,000)	-	(1,500,000)
<b>TOTAL OTHER INCOME (EXPENSE)</b>	<b>15,585,594</b>	<b>(1,604,845)</b>	<b>15,293,820</b>	<b>(1,830,258)</b>
<b>NET INCOME (LOSS)</b>	<b>12,305,171</b>	<b>(4,518,174)</b>	<b>2,431,423</b>	<b>(18,806,776)</b>
<b>OTHER COMPREHENSIVE INCOME (LOSS)</b>				
Net unrealized gain (loss) on marketable securities	3,027	2,601	8,096	(5,861)
<b>COMPREHENSIVE INCOME (LOSS)</b>	<b>\$ 12,308,198</b>	<b>\$ (4,515,573)</b>	<b>\$ 2,439,519</b>	<b>\$ (18,812,637)</b>
Net income (loss) per share - basic	\$ 0.48	\$ (0.21)	\$ 0.10	\$ (1.01)
Weighted average number of shares - basic	25,810,249	21,399,019	23,193,278	18,551,013
Net income (loss) per share - diluted	\$ 0.42	\$ (0.21)	\$ 0.09	\$ (1.01)
Weighted average number of shares - diluted	29,471,009	21,399,019	26,788,076	18,551,013

**CAPRICOR THEAPEUTICS, INC.**  
**SUMMARY BALANCE SHEETS**

	December 31, 2017	December 31, 2016
Cash, cash equivalents and marketable securities	\$ 14,124,935	\$ 16,194,888
Total assets	\$ 16,273,789	\$ 18,747,355
Total deferred revenue	-	1,367,186
Total liabilities	\$ 5,046,934	\$ 22,750,509
Total stockholders' equity (deficit) - 26,270,491 and 21,399,019 common shares issued and outstanding at December 31, 2017 and December 31, 2016, respectively	11,226,855	(4,003,154)
Total liabilities and stockholders' equity	\$ 16,273,789	\$ 18,747,355

For more information, please contact:

AJ Bergmann, Chief Financial Officer  
+1-310-358-3200  
abergmann@capricor.com

---