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)

August 9, 2018

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 9, 2018 Capricor Therapeutics, Inc., a Delaware corporation (the "Company"), issued a press release announcing its financial results for the fiscal quarter ended June 30, 2018. 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 Therapeutics Reports Second Quarter 2018 Financial Results and Provides Corporate Update", dated August 9, 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: August 9, 2018

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

Exhibit 99.1

Capricor Therapeutics Reports Second Quarter 2018 Financial Results and Provides Corporate Update

To Host Conference Call and Webcast Today at 4:30 p.m. ET

LOS ANGELES, August 9, 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 announced its financial results for the second quarter, which ended June 30, 2018, and provided a corporate update.

"Capricor continues to move forward with 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 are actively enrolling patients in HOPE-2, with multiple sites initiated, and we anticipate having all sites up and running during the third quarter of this year. We are thrilled to begin enrolling participants in HOPE-2 because we have seen the potential for improvements in muscle function in both pre-clinical studies and in our earlier HOPE-Duchenne trial."

Capricor has also been granted RMAT and Orphan Drug Designation by the U.S. Food and Drug Administration (FDA).

"These designations will enable us to work closely with the FDA in finalizing the regulatory approval pathway for CAP-1002 and to receive expedited FDA reviews," Dr. Marbán said. "We are hopeful that HOPE-2 may potentially be a registration trial."

Capricor has also recently announced that the development of CAP-2003, the company's other investigational therapy, is moving forward with a collaboration with the U.S. Army Institute of Surgical Research (USAISR) to explore the potential for the exosome-based candidate to address traumatic injuries and conditions.

"This exciting new collaboration with USAISR has the potential to open up a whole new arena in biotechnology, where the benefits of cells can be distilled down to the active pharmaceutical ingredient (API), which we now know is extracellular vesicles," said Dr. Marbán. "If this collaboration proves to be promising, it will result in us working to develop large-scale manufacturing and clinical development of CAP-2003."

Second Quarter Highlights and Recent Clinical and Operational Developments

- Study sites have opened and enrollment has commenced in the HOPE-2 clinical trial. It is a Phase II, randomized, double-blind, placebo-controlled study in patients in the later stage of Duchenne muscular dystrophy, a fatal genetic disease with few treatment options. Current plans are to open a total of 10 to 15 sites and enroll approximately 84 patients. HOPE-2 will evaluate the safety and efficacy of repeat doses of CAP-1002, which consists of allogeneic cardiosphere-derived cells, or CDCs, and has been shown to exert potent immunomodulatory activity and stimulate cellular regrowth.

- Capricor announced it has entered into an agreement with USAISR to study the potential for the company's next-generation investigational therapeutic platform, CAP-2003. The goal of the collaboration is to address a wide spectrum of trauma-related injuries and conditions, which are now the third leading cause of death in the U.S. Capricor will provide CAP-2003 for the testing of function, potency and safety for eventual use in therapeutic indications. CAP-2003 is comprised of nano-scale extracellular vesicles which have the capacity to reduce inflammation, fibrosis or scarring and cell death, as well as increase blood vessel growth.
- Capricor and Parent Project Muscular Dystrophy (PPMD) hosted a webinar on July 18 to provide information about the HOPE-2 clinical trial to the Duchenne muscular dystrophy community. Capricor also provided a corporate overview and a poster presentation at the PPMD 2018 Annual Conference on June 29 in Scottsdale, AZ. The poster presentation reported on pre-clinical data demonstrating CAP-2003's ability to reduce inflammation and improve exercise capabilities in mdx mice after systemic administration.
- In June, Capricor presented a poster at the Keystone Symposia on Molecular and Cellular Biology. The poster reported that CAP-2003's immunomodulatory capacities increased the survival in a disease model of Graft vs. Host Disease (GVHD), a medical complication following the receipt of transplanted tissue from a genetically different person. The poster reported that CAP-2003 was effective in immune-modulating T lymphocytes and macrophages in vitro and increasing the survival in a disease model of GVHD.

Anticipated Events and Milestones in Second Half of 2018

- Meet with the FDA to discuss Capricor's Duchenne program through the RMAT process.
- Continue to add additional sites and enroll patients in the HOPE-2 clinical trial.
- Continue to conduct pre-clinical research for CAP-2003 to treat various diseases of inflammation and fibrosis.
- Continue preparations for manufacturing scale-up and technology transfer of CAP-1002.

Second Quarter Results

The Company reported a net loss of approximately $4.1 million, or $0.14 per share, for the second quarter of 2018, compared to a net loss of approximately $3.5 million, or $0.16 per share, for the second quarter of 2017.

As of June 30, 2018, the Company's cash, cash equivalents and marketable securities totaled approximately $12.3 million, compared to approximately $14.1 million on December 31, 2017. Additionally, in the second quarter of 2018, Capricor raised approximately $2.8 million in net proceeds at an average price of approximately $1.43 per share under its at-the-market offering program. Capricor believes that its current financial resources should be sufficient to fund its operations and meet its financial obligations into the second quarter of 2019 based on the Company's current projections.

Conference Call and Webcast

To participate in the conference call, please dial 866-717-4562 (domestic) or 210-874-7812 (international) and reference the access code 8483546.

To participate via a webcast, please visithttps://edge.media-server.com/m6/p/ch8cwhpt. The webcast will be archived for approximately 30 days and will be available at http://capricor.com/news/events/.

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 the California Institute for Regenerative Medicine. For more information, visit www.capricor.com.

Keep up with Capricor on social media:www.facebook.com/capricortherapeutics, 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 Capricor's stock 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, 2017 as filed with the Securities and Exchange Commission on March 22, 2018, 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 March 31, 2018, as filed with the Securities and Exchange Commission on May 14, 2018. 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 THERAPEUTICS, INC.
CONDENSED CONSOLIDATED STATEMENTS OF OPERATIONS AND COMPREHENSIVE LOSS
(UNAUDITED)

	Three months ended June 30,		Six months ended June 30,	
	2018	2017	2018	2017
INCOME				
Collaboration income	$ -	$ 683,592	$ -	$ 1,367,186
Grant income	287,302	312,870	594,051	510,083
Other income	116,658	-	209,974	-
TOTAL INCOME	403,960	996,462	804,025	1,877,269
OPERATING EXPENSES				
Research and development	3,388,908	3,128,182	6,085,424	6,385,331
General and administrative	1,178,060	1,246,942	2,567,792	2,436,181
TOTAL OPERATING EXPENSES	4,566,968	4,375,124	8,653,216	8,821,512
LOSS FROM OPERATIONS	(4,163,008)	(3,378,662)	(7,849,191)	(6,944,243)
OTHER INCOME (EXPENSE)				
Investment income	39,460	12,052	54,113	16,334
Interest expense	-	(105,527)	-	(210,847)
TOTAL OTHER INCOME (EXPENSE)	39,460	(93,475)	54,113	(194,513)
NET LOSS	(4,123,548)	(3,472,137)	(7,795,078)	(7,138,756)
OTHER COMPREHENSIVE INCOME (LOSS)				
Net unrealized gain (loss) on marketable securities	(2,044)	(2,394)	6,665	3,793
COMPREHENSIVE LOSS	$ (4,125,592)	$ (3,474,531)	$ (7,788,413)	$ (7,134,963)
Net loss per share, basic and diluted	$ (0.14)	$ (0.16)	$ (0.28)	$ (0.33)
Weighted average number of shares, basic and diluted	29,031,888	22,135,198	27,974,484	21,769,142

CAPRICOR THERAPEUTICS, INC.
SUMMARY BALANCE SHEETS

	June 30, 2018 (unaudited)	December 31, 2017
Cash, cash equivalents and marketable securities	$ 12,334,228	$ 14,124,935
Total assets	$ 14,327,071	$ 16,273,789
Total liabilities	$ 4,696,267	$ 5,046,934
Total stockholders' equity - 29,994,316 and 26,270,491 common shares issued and outstanding at June 30, 2018 and December 31, 2017, respectively	9,630,804	11,226,855
Total liabilities and stockholders' equity	$ 14,327,071	$ 16,273,789

For more information, please contact:

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