August 6, 2019

# Capricor Therapeutics Reports Second Quarter 2019 Financial Results and Provides Corporate Update

**Positive Results from HOPE-2 Interim Analysis Reported in July**

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

LOS ANGELES, Aug. 06, 2019 (GLOBE NEWSWIRE) -- 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 2019 and provided a corporate update.

“This has been a very exciting quarter as we previously reported the outcome of our pre-specified interim analysis of our HOPE-2 clinical trial which showed meaningful results across several independent measures,” said Linda Marbán, Ph.D., Capricor president and chief executive officer. In the randomized, double-blind placebo controlled study, we observed improvements in assessments of skeletal, pulmonary and cardiac function. For the later stage DMD patients for which the HOPE-2 trial is focused on, we hope that our therapeutic may one day be an important treatment option for these boys and young men. We will continue to discuss the evolution of this program with the U.S. Food and Drug Administration (FDA) and look forward to sharing those updates as they become available.”

Capricor has been granted RMAT and Orphan Drug Designation by the FDA for CAP-1002 for the treatment of Duchenne muscular dystrophy.

“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. “While our major focus this quarter has been on CAP-1002, we continue to be encouraged by exciting developments in our exosome platform technology and we continue to explore their use as a potential therapeutic in a variety of different inflammatory conditions, including DMD,” said Dr. Marbán.

Capricor’s exosome technology, CAP-2003, is comprised of proprietary extracellular vesicles, including exosomes, and are sourced from CDCs and other cell types. Exosomes are nano-sized, membrane-enclosed vesicles, that are secreted by cells and contain bioactive molecules, including proteins, RNAs and microRNAs. Exosomes act as messengers to regulate the functions of neighboring cells. Because of these unique capacities, researchers are increasingly viewing exosomes as both a potential therapeutic and a vehicle to deliver gene and other therapies to targeted tissues in the human body.

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

- In July, Capricor announced positive results from its interim analysis in the HOPE-2 trial. The Company reported that a pre-specified interim analysis performed on 6-month data from the HOPE-2 trial showed meaningful results across several independent clinical measures. In summary, an improvement in outcomes relative to placebo controls was shown in mid-level (elbow) PUL 2.0 at 6 months (p=0.0389). The PUL evaluates manual tasks that relate to activities of daily living that are important for quality of life. The FDA has previously suggested to Capricor the use of the updated PUL 2.0 version as the primary efficacy endpoint in support of a Biologics License Application (BLA). Additionally, Capricor observed positive treatment effects in some independent skeletal and pulmonary assessments. Positive trends were observed in other skeletal, pulmonary and cardiac measures. The HOPE-2 study is a Phase II, randomized, double-blind, placebo-controlled study in patients in the later stages of Duchenne muscular dystrophy, a fatal genetic disease with few treatment options. HOPE-2 is evaluating the safety and efficacy of repeat doses of CAP-1002, which consists of allogeneic cardiosphere-derived cells, or CDCs. CAP-1002 has been shown to exert potent immunomodulatory activity and stimulate cellular regrowth. Following the interim analysis, no further enrollment is planned and, the study is continuing with the 20 previously enrolled subjects.
- Capricor reported that its independent Data and Safety Monitoring Board (DSMB) completed its safety assessment and futility analysis review of the company's ongoing Phase II HOPE-2 study and recommended that the trial continue.
- Capricor and Parent Project Muscular Dystrophy hosted a webinar, to discuss updates on Capricor's HOPE-2 clinical program.

**Anticipated Events and Milestones in 2019**

- Capricor's plans for further clinical development of CAP-1002 in DMD will be based on guidance received from the FDA
- Continue to report updated analyses from the HOPE-2 trial as they become available
- Continue to treat previously enrolled patients in the HOPE-2 study
- Continue to conduct pre-clinical research for CAP-2003 to treat various diseases of inflammation and fibrosis, including DMD

**Second Quarter Financial Results**

The Company reported a net loss of approximately $2.0 million, or $0.59 per share, for the second quarter of 2019, compared to a net loss of approximately $4.1 million, or $1.42 per share, for the second quarter of 2018.

As of June 30, 2019, the Company's cash, cash equivalents and marketable securities totaled approximately $5.9 million compared to approximately $7.3 million on December 31, 2018. Additionally, so far in the third quarter of 2019, Capricor has raised approximately $1.3 million in net proceeds at an average price of approximately $5.06 per share under its July 2019 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 first quarter of 2020 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: 5837419.

To participate via a webcast, please visit: https://edge.media-server.com/mmc/p/6qw63bhf. The webcast will be archived for approximately 30 days and will be available at http://capricor.com/news/events/.

**About Duchenne Muscular Dystrophy**

Duchenne muscular dystrophy is a devastating genetic disorder that causes muscle degeneration and leads to death, generally before the age of 30, most commonly from heart failure. It occurs in one in every 3,600 live male births across all races, cultures and countries. Duchenne muscular dystrophy afflicts approximately 200,000 boys and young men around the world. Treatment options are limited, and there is no cure.

**About CAP-1002**

CAP-1002 consists of allogeneic cardiosphere-derived cells, or CDCs, a type of progenitor cell that has been shown in pre-clinical and clinical studies to exert potent immuno-modulatory activity, and is being investigated for its potential to modify the immune system's activity to encourage cellular regeneration. CDCs have been the subject of over 100 peer-reviewed scientific publications and have been administered to over 150 human subjects across several clinical trials.

**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 DMD. 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.

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 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, 2018 as filed with the Securities and Exchange Commission on March 29, 2019, and as amended by its Amendment No. 1 to Annual Report on Form 10-K/A filed with the Securities and Exchange Commission on April 1, 2019 and in its Quarterly Report on Form 10-Q as filed with the Securities and Exchange Commission on May 14, 2019. 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.*

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**CAPRICOR THERAPEUTICS, INC.**
**CONSOLIDATED STATEMENTS OF OPERATIONS AND COMPREHENSIVE LOSS**
**(UNAUDITED)**

| | Three months ended June 30, | | Six months ended June 30, | |
|---|---|---|---|---|
| | 2019 | 2018 | 2019 | 2018 |
| REVENUE | | | | |
| Revenue | $ 410,353 | $ 403,960 | $ 640,857 | $ 804,025 |
| OPERATING EXPENSES | | | | |
| Research and development | 1,644,110 | 3,388,908 | 3,455,292 | 6,085,424 |
| General and administrative | 831,933 | 1,178,060 | 1,808,423 | 2,567,792 |
| TOTAL OPERATING EXPENSES | 2,476,043 | 4,566,968 | 5,263,715 | 8,653,216 |
| LOSS FROM OPERATIONS | (2,065,690) | (4,163,008) | (4,622,858) | (7,849,191) |
| OTHER INCOME (EXPENSE) | | | | |
| Investment income | 21,956 | 39,460 | 59,779 | 54,113 |
| Loss on disposal of fixed asset | (2,720) | - | (2,720) | - |
| NET LOSS | (2,046,454) | (4,123,548) | (4,565,799) | (7,795,078) |

| | | | | |
|---|---|---|---|---|
| OTHER COMPREHENSIVE INCOME (LOSS) | | | | |
| Net unrealized gain (loss) on marketable securities | - | (2,044) | (12,393) | 6,665 |
| COMPREHENSIVE LOSS | $(2,046,454) | $(4,125,592) | $(4,578,192) | $(7,788,413) |
| Net loss per share, basic and diluted | $ (0.59) | $ (1.42) | $ (1.35) | $ (2.79) |
| Weighted average number of shares, basic and diluted | 3,457,833 | 2,903,177 | 3,374,557 | 2,797,441 |

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

| | June 30, 2019 (unaudited) | December 31, 2018 |
|---|---|---|
| Cash, cash equivalents and marketable securities | $ 5,890,963 | $ 7,256,416 |
| Total assets | $ 7,306,844 | $ 9,247,065 |
| Total liabilities | $ 4,943,061 | $ 4,631,478 |
| Total stockholders' equity - 3,467,459 and 3,138,748 common shares issued and outstanding at June 30, 2019 and December 31, 2018, respectively | 2,363,783 | 4,615,587 |
| Total liabilities and stockholders' equity | $ 7,306,844 | $ 9,247,065 |

Source: Capricor Therapeutics, Inc.