

**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 11, 2021**

**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.

Securities registered pursuant to Section 12(b) of the Act:

Title of Each Class	Trading Symbol(s)	Name of Each Exchange on Which Registered
Common Stock, par value \$0.001 per share	CAPR	The Nasdaq Capital Market

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

On March 11, 2021, 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, 2020. A copy of the press release is being furnished herewith as Exhibit 99.1 to this Current Report on Form 8-K.

**Item 7.01 Regulation FD Disclosure.**

Additionally, on March 11, 2020, the Company provided an update on the Company's recently announced preclinical results from its exosomes platform, in the form of a slide presentation during its quarterly earnings call. The slide presentation is located on the "Investors" section of the Company's website at [www.capricor.com](http://www.capricor.com). A copy of the slide presentation is also attached hereto as Exhibit 99.2 and is incorporated by reference into this Item 7.01 of this Current Report on Form 8-K.

The information contained in this Form 8-K (including Exhibits 99.1 and 99.2 attached hereto) is being furnished and shall not be deemed to be "filed" for the 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 and shall not be incorporated by reference in any filing under the Securities Act of 1933, as amended, or the Exchange Act, except as shall be expressly set forth by specific reference in such filing.

**Item 9.01 Financial Statements and Exhibits.**

**(d) Exhibits**

99.1 [Press Release, titled “Capricor Therapeutics Reports Fourth Quarter and Full Year 2020 Financial Results and Provides Corporate Update”, dated March 11, 2021.](#)

99.2 [Capricor Therapeutics, Inc. slide presentation dated March 11, 2021.](#)

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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 11, 2021

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 2020 Financial Results and Provides Corporate Update

### *Exosomes Platform Technology*

- Pre-IND Meeting with FDA this Quarter to Discuss Multivalent Exosome-mRNA Vaccine-
- Pipeline Expansion Underway Using Engineered Exosomes-

### *Cell Therapy Program*

- In Discussions with FDA on Pathway to Approval for Duchenne Muscular Dystrophy-
- Phase II INSPIRE Top-Line Data Expected in Third Quarter-
- To Host Conference Call and Webcast Today at 4:30 p.m. ET-

LOS ANGELES, March 11, 2021 – Capricor Therapeutics (NASDAQ: CAPR), a biotechnology company focused on the development of transformative cell- and exosome-based therapeutics for the treatment and prevention of a broad spectrum of diseases, announced today its financial results for the fourth quarter and full year 2020 and provided a corporate update.

"2020 was a tremendously important and meaningful year for Capricor marked by advances in our engineered exosome platform technology and continued progress in our clinical-stage cell therapy programs for Duchenne muscular dystrophy and COVID-19," said Linda Marbán, Ph.D., Capricor's president and chief executive officer. "Pivotal to the plan to initiate our engineered exosome platform technology was the appointment of Dr. Stephen Gould as executive consultant to guide the development of this platform. In order to validate the technology, we developed a multi-antigen vaccine for SARS-CoV-2 which led to several publications describing that our vaccine candidate can induce long-lasting immune responses to multiple SARS-CoV-2 proteins, and potentially elicit a broad-based, cellular and humoral immunity. We are now planning on moving this vaccine into the clinic in 2021, subject to regulatory approval."

"One of the reasons the exosomes are potentially so useful and transformative is their ability to speak the language of a cell. We believe that exosomes loaded with biologic payloads will be important in the development of new therapeutics and vaccines, added Dr. Marbán. "Capricor, in 2021, is focused on becoming a leading exosome-RNA company and all of our work in the development of a vaccine for SARS-CoV-2 is simply a prelude to the future development of exosome-based vaccines and therapeutics, with the ultimate goal of generating formulations of engineered exosomes and synthetic mRNAs to potentially prevent and treat human diseases. The opportunities for pipeline expansion are very exciting."

Dr. Marbán continued, "we have now conducted two positive clinical trials in Duchenne muscular dystrophy. Our HOPE-2 trial demonstrated statistically significant results in upper limb skeletal muscle and cardiac function. We are currently discussing this program with FDA to determine the appropriate path forward and are actively discussing partnership opportunities for this asset. We believe these initiatives position us well as we look forward to a productive year in our therapeutics development programs."



## Fourth Quarter & Full Year 2020 Highlights and Recent Operational Developments

### Pipeline Development

- **Exosomes Platform**
  - o Announced New Advances in Exosome-Mediated mRNA Delivery Platform (*March 2021*)
  - o Announced Positive Preclinical Data for Multivalent Exosome-mRNA Vaccine For COVID-19 (*November 2020*)
  - o Announced strategic plan for exosomes platform technology product expansion (*March 2020*)
  - o Announced appointment of Stephen Gould, Ph.D. as Executive Consultant to oversee our exosomes program (*March 2020*)
- **Cell Therapy (CAP-1002) for Duchenne Muscular Dystrophy**
  - o Announced Manufacturing Collaboration with Lonza for the Development of CAP-1002 for the Treatment of Duchenne Muscular Dystrophy and Other Indications (*January 2021*)
  - o Announced Positive Results from HOPE-2 Study in Patients with DMD Treated with CAP-1002 at World Muscle Society Congress 2020 (*November 2020*)
  - o Announced Positive Top-Line Results from HOPE-2 Study in Patients with DMD Treated with CAP-1002 (*May 2020*)
    - One-Year Results from Randomized, Double-Blind, Placebo-Controlled Study Demonstrated Improved Performance of Upper Limb (PUL) 2.0 ( $p=0.05$ )
    - First Ever Study in DMD that Correlates Stabilization in Cardiac Function with a Reduction in a Biomarker of Cell Damage
- **CAP-1002 for COVID-19**
  - o Announced DSMB Recommendation to Continue Phase II INSPIRE Trial for Severe COVID-19 Patients (*December 2020*)
  - o Initiated Dosing of Patients in Phase II INSPIRE Trial (*November 2020*)
  - o Announced Compassionate Use Data in COVID-19 Patients Treated with CAP-1002 (*April 2020*)
  - o Initiated Compassionate Use Program for Severe COVID-19 Patients using CAP-1002 (*April 2020*)

### Publications & Key Opinion Leader Support

- Announced Publication Demonstrating Advances in our Exosome-Mediated mRNA Delivery Platform (*March 2021*)
- Announced Publication on the Development of Serology Test to Confirm Activity of SARS-CoV-2 Vaccines (*February 2021*)
- Announced Publication Demonstrating Methods for Enhanced Potency of Cardiosphere-Derived Exosomes (*January 2021*)

- Announced Publication Demonstrating Positive Preclinical Data for Multivalent Exosome-mRNA Vaccine For COVID-19 (November 2020)
  - Hosted Key Opinion Leader Call on Cardiac Complications of DMD with a presentation by Michael Taylor, M.D., Ph.D., Director of Advanced Imaging Innovation (Cincinnati Children's Hospital) (April 2020)
  - Hosted Key Opinion Leader Call on Why Exosomes are Uniquely Suited for Vaccine Development with a presentation by Stephen J. Gould, Ph.D., from Johns Hopkins University (March 2020)
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#### **Anticipated Events and Targeted Milestones in 2021**

- Plan for pre-IND meeting with FDA to discuss next steps in exosome-mRNA vaccine clinical strategy
- Plan to file an IND for exosome-mRNA vaccine product candidate for SARS-CoV-2, subject to regulatory approval
- Plan to publish additional preclinical data on exosomes platform
- Plan to announce pipeline expansion with engineered exosomes platform
- Plan to announce further updates on DMD program
- Plan to announce top-line data from INSPIRE study

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

The Company reported a net loss of approximately \$4.2 million, or \$0.21 per share, for the fourth quarter of 2020, compared to a net loss of approximately \$1.5 million, or \$0.34 per share, for the fourth quarter of 2019.

For the year ended December 31, 2020, the Company reported a net loss of approximately \$13.7 million, or \$0.88 per share, compared to a net loss of approximately \$7.6 million, or \$2.06 per share, for the year ended December 31, 2019.

As of December 31, 2020, the Company's cash, cash equivalents and marketable securities totaled approximately \$32.7 million, compared to approximately \$9.9 million on December 31, 2019. Additionally, in 2020, Capricor raised approximately \$22.9 million in net proceeds at an average price of approximately \$6.34 per share under its at-the-market offering program.

#### **Financial Outlook**

Capricor believes that based on the current operating plan and financial resources, the Company expects that the cash, cash equivalents and marketable securities will be sufficient to cover expenses and capital requirements through at least the second quarter of 2023.

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

To participate in the conference call, please dial 877-451-6152 (Domestic/Toll-Free) or 201-389-0879 (International) and reference the conference ID: 13717080  
To participate via a webcast and view the slides, please visit: <http://public.viavid.com/index.php?id=143779>

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 biotechnology company focused on the development of transformative cell- and exosome-based therapeutics and vaccines for the treatment and prevention of a broad spectrum of diseases. Capricor's lead candidate, CAP-1002, is an allogeneic cardiac-derived cell therapy that is currently in clinical development for the treatment of Duchenne muscular dystrophy and the cytokine storm associated with COVID-19. Capricor is also developing our exosomes platform technology as a next-generation therapeutic platform. Our current focus is on the development of exosomes loaded with nucleic acids, including mRNA, to treat or prevent a variety of diseases. For more information, visit [www.capricor.com](http://www.capricor.com) and follow the Company on [Facebook](#), [Instagram](#) and [Twitter](#).



#### **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.

#### **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, revenue projections; 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, 2019 as filed with the Securities and Exchange Commission on March 27, 2020 and in our Quarterly Report on Form 10-Q for the quarter ended September 30, 2020 as filed with the Securities and Exchange Commission on November 13, 2020. 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. None of Capricor's exosome-based candidates have been approved for clinical investigation.*

For more information, please contact:

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

	Three months ended December 31,		Years ended December 31,	
	2020	2019	2020	2019
<b>REVENUE</b>				
Revenue	\$ 57,830	\$ 222,100	\$ 310,250	\$ 1,005,028
<b>TOTAL REVENUE</b>	<u>57,830</u>	<u>222,100</u>	<u>310,250</u>	<u>1,005,028</u>
<b>OPERATING EXPENSES</b>				
Research and development	2,745,104	828,749	8,457,000	5,141,805
General and administrative	1,493,266	876,720	5,543,221	3,597,111
<b>TOTAL OPERATING EXPENSES</b>	<u>4,238,370</u>	<u>1,705,469</u>	<u>14,000,221</u>	<u>8,738,916</u>
<b>LOSS FROM OPERATIONS</b>	<u>(4,180,540)</u>	<u>(1,483,369)</u>	<u>(13,689,971)</u>	<u>(7,733,888)</u>
<b>OTHER INCOME (EXPENSE)</b>				
Investment income	2,608	13,951	32,943	94,791
Loss on disposal of fixed asset	-	-	-	(2,720)
<b>TOTAL OTHER INCOME (EXPENSE)</b>	<u>2,608</u>	<u>13,951</u>	<u>32,943</u>	<u>92,071</u>
<b>NET LOSS</b>	<u>(4,177,932)</u>	<u>(1,469,418)</u>	<u>(13,657,028)</u>	<u>(7,641,817)</u>
<b>OTHER COMPREHENSIVE INCOME (LOSS)</b>				
Net unrealized gain (loss) on marketable securities	-	(757)	757	(13,150)
<b>COMPREHENSIVE LOSS</b>	<u>\$ (4,177,932)</u>	<u>\$ (1,470,175)</u>	<u>\$ (13,656,271)</u>	<u>\$ (7,654,967)</u>
Net loss per share, basic and diluted	<u>\$ (0.21)</u>	<u>\$ (0.34)</u>	<u>\$ (0.88)</u>	<u>\$ (2.06)</u>
Weighted average number of shares, basic and diluted	<u>20,373,647</u>	<u>4,338,434</u>	<u>15,571,056</u>	<u>3,711,333</u>

	December 31, 2020	December 31, 2019
Cash, cash equivalents and marketable securities	\$ 32,665,874	\$ 9,885,378
Total assets	<u>\$ 34,618,796</u>	<u>\$ 11,113,637</u>
Total liabilities	\$ 6,419,012	\$ 4,274,251
Total stockholders' equity - 20,577,123 and 5,227,398 common shares issued and outstanding at December 31, 2020 and December 31, 2019, respectively	28,199,784	6,839,386
Total liabilities and stockholders' equity	<u>\$ 34,618,796</u>	<u>\$ 11,113,637</u>

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## Fourth Quarter Earnings Call

## Exosome-mRNA Platform Data Presentation

March 11, 2021 | NASDAQ: CAPR

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### Forward-Looking Statements

Statements in this presentation 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, revenue projections; 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, 2019 as filed with the Securities and Exchange Commission on March 27, 2020 and in our Quarterly Report on Form 10-Q for the quarter ended September 30, 2020 as filed with the Securities and Exchange Commission on November 13, 2020. 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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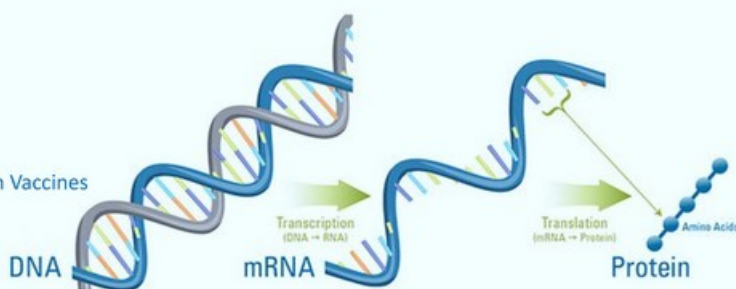
**Stephen J. Gould, Ph.D.** – Professor of Biological Chemistry at Johns Hopkins University and Executive Consultant to Capricor

**Linda Marban, Ph.D.** – Capricor Chief Executive Officer

**AJ Bergmann** – Capricor Chief Financial Officer

## RNA Therapeutics are a New Class of Medicines

- ❖ Broad Market Opportunities
- ✓ Capital Efficiency for Development
  - ❖ Rapid Innovation Possible
  - ✓ Proof of Concept Established in Vaccines

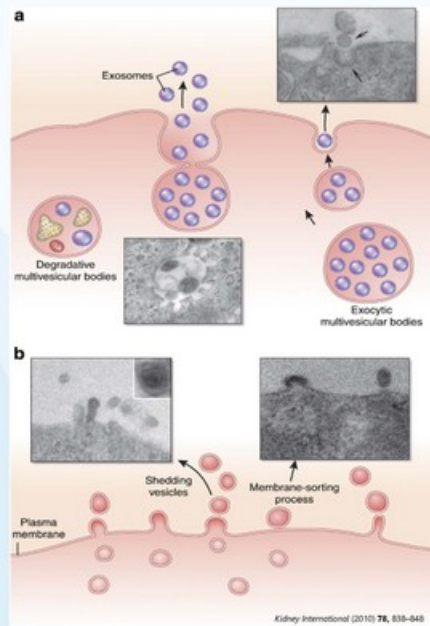


**Barrier to Success: Effective Delivery Systems of Nucleic Acids**



# Exosomes are a Natural Drug Delivery System

- ~100 nanometer vesicles
- Made by nearly all cells
- Abundant in blood and all biofluids
- Transfers signals and molecules to other cells
- Decades of transfusion and transplantation medicine demonstrates safety
- Can be used to deliver RNAs and other drugs



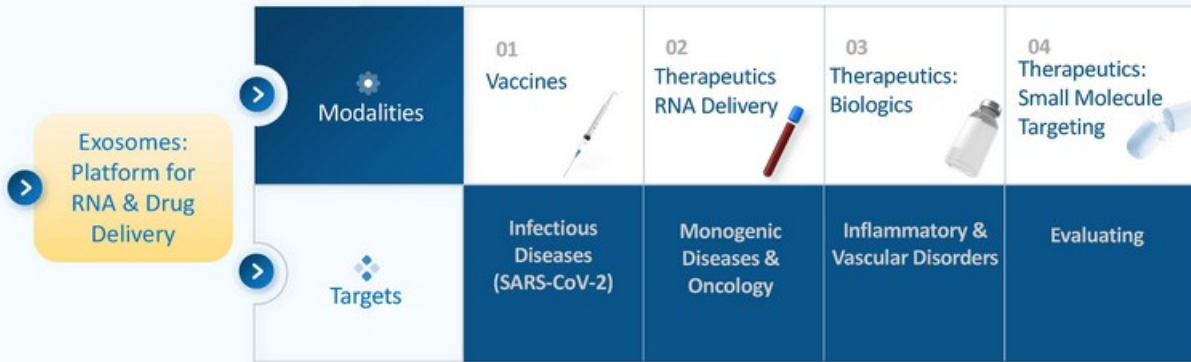
Extracellular vesicles - term for cell-derived vesicles, including exosomes

# Exosomes Platform Goals: Building a New Class of Therapeutics

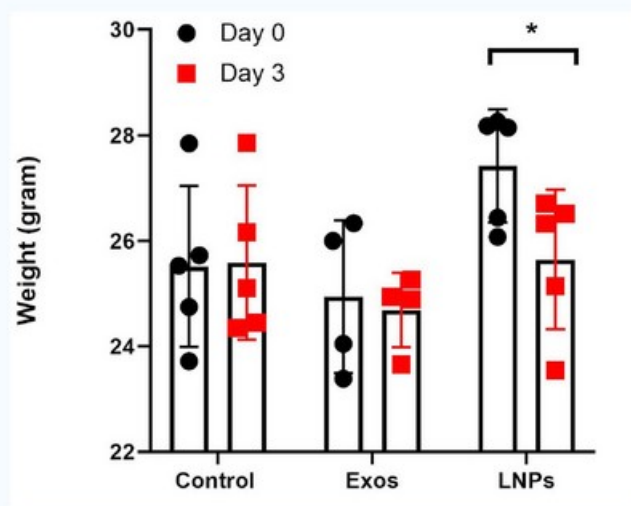


- Monogenic Diseases  
RNA therapeutics
- Oncology  
Vaccines & targeted delivery therapeutics
- Inflammatory & Vascular  
Biologics
- Infectious Diseases  
Vaccines

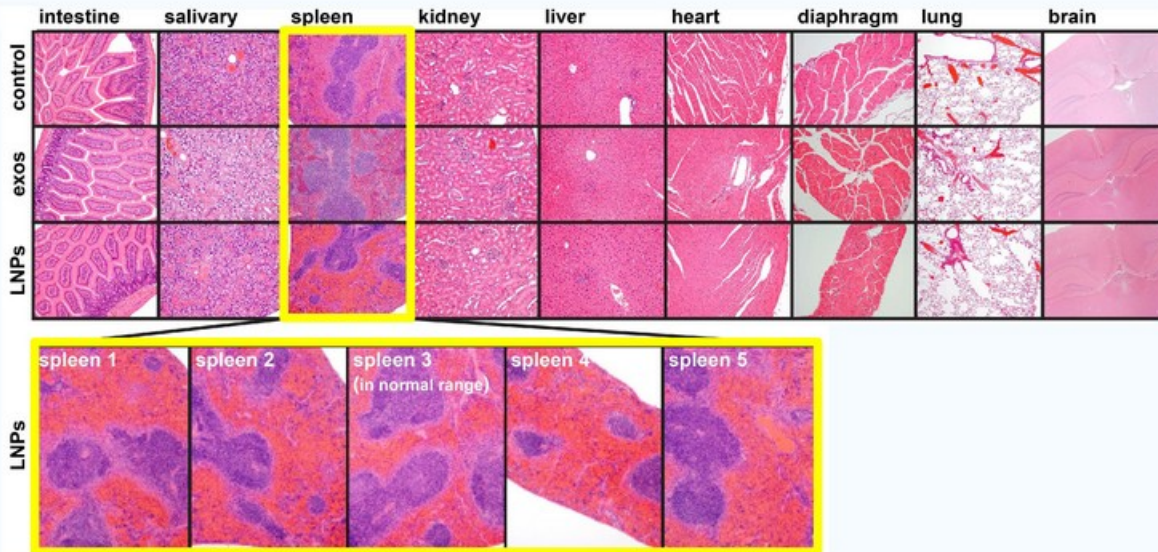
**Goals**
**Scale and partner**
**Drive research through collaborations**
**Expand and exploit platform and IP through partnerships**



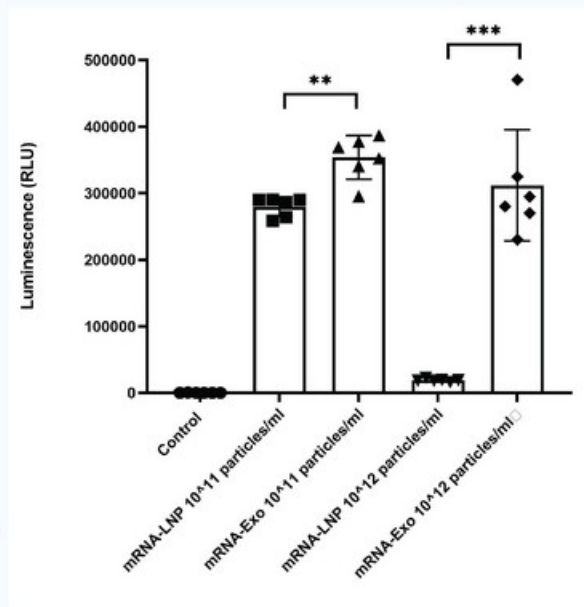
## Exosomes: Less Toxic than Lipid Nanoparticles



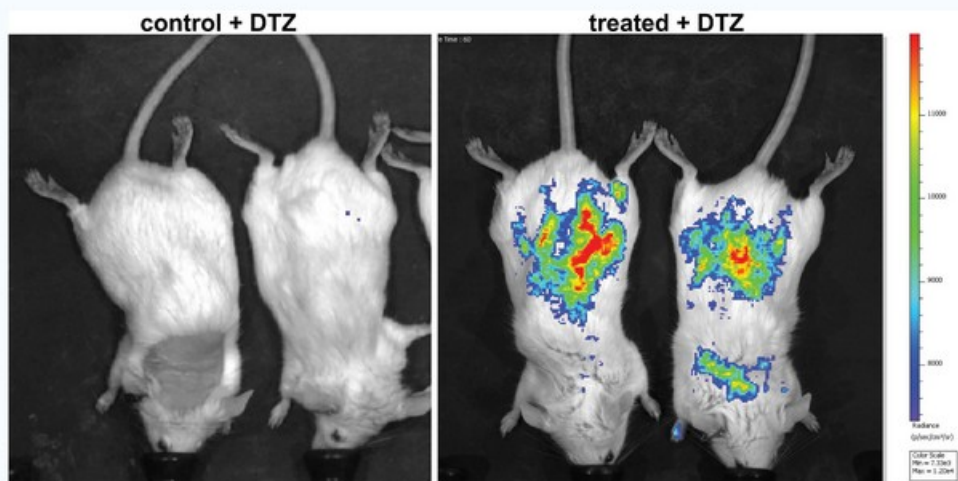
# Exosomes: Less Toxic than Lipid Nanoparticles



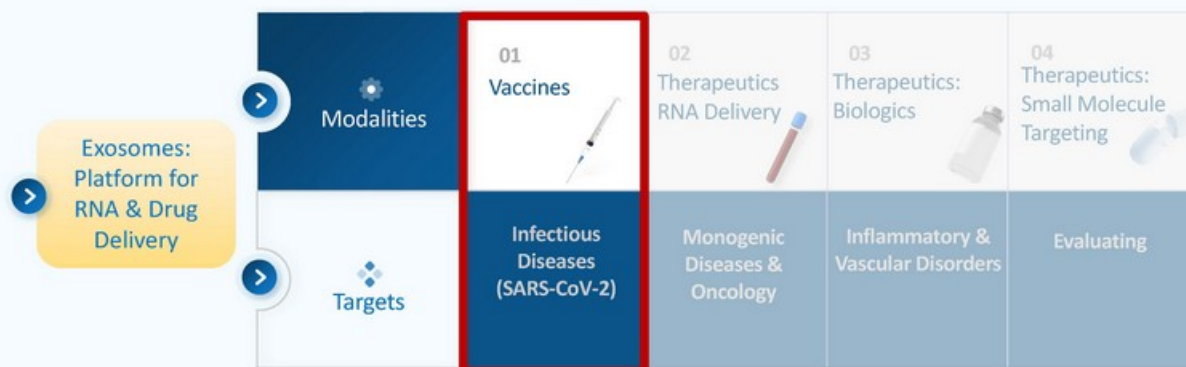
# Exosomes: More Efficient mRNA Delivery



# Capricor's Exosome-mRNA Delivery Platform: A real-time view of mRNA delivery, protein expression and enzymatic activity



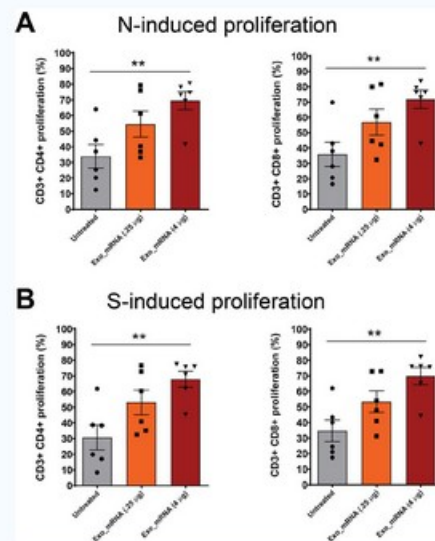
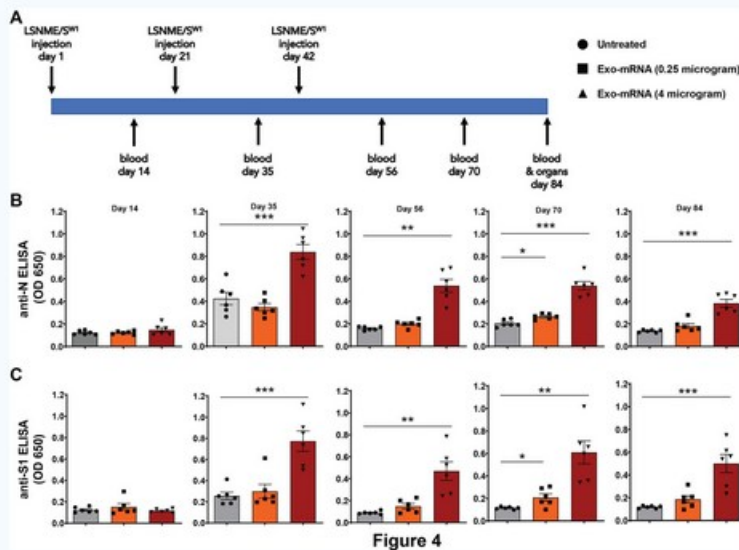
## Exosome Platform: Potential Vaccines and Therapeutics



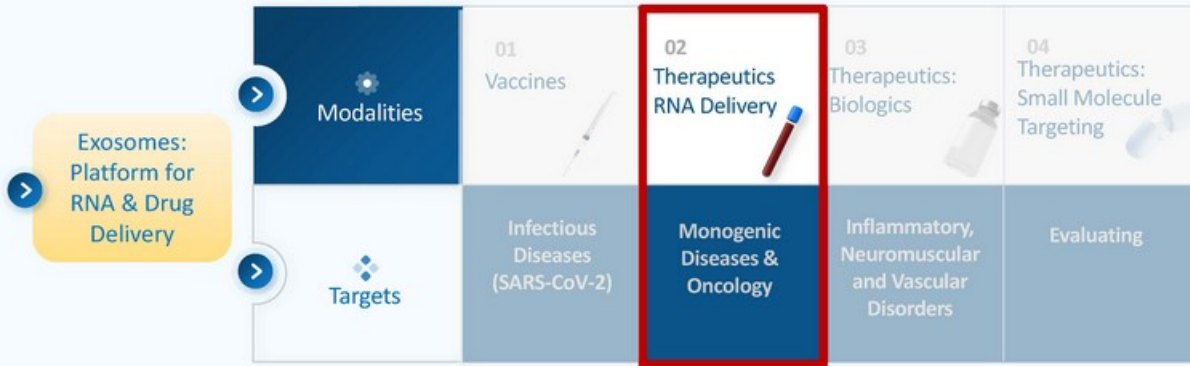
# Exosome-mRNA Preclinical Vaccine Data

- Safe, non-toxic exosome-mRNA formulation
- Drives cell and antibody immunity to nucleocapsid protein (SARS-CoV-2)
- Drives cell and antibody immunity to spike protein (SARS-CoV-2)
- Confirms multiplexed mRNA approach
- Unique antigen design

# Exosome-mRNA Preclinical Vaccine Data

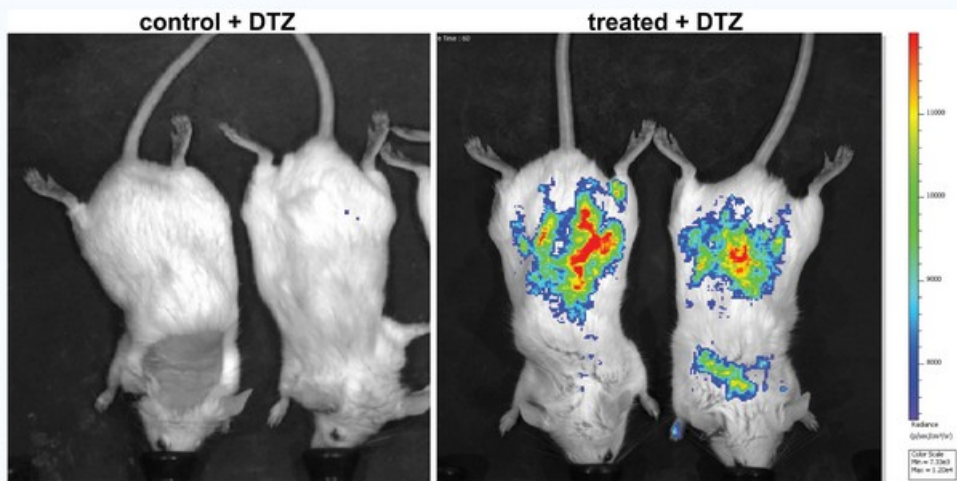


# Exosome Platform: Potential Vaccines and Therapeutics



## Capricor's Exosome-mRNA Delivery Platform:

A real-time view of mRNA delivery, protein expression and enzymatic activity



# Capricor Corporate Summary



- Cell and exosome-based platform therapeutics company
- Products with novel approaches to neuromuscular, infectious, inflammatory and cardiovascular diseases
- Expanding engineered exosome platform delivering RNA
- Late-stage clinical development in DMD and rapidly progressing program in COVID-19 with CAP-1002
- Over 100 publications from multiple institutions worldwide on both platforms with extensive in-vivo and clinical data
- Efficient use of capital including non-dilutive sources
- Experienced management team

NASDAQ  
CAPR

Cash (12/31/20)<sup>1</sup>  
**\$32.7 million**

Non-Dilutive Capital  
**\$45 million**

External Collaborators  
**Stephen Gould, Ph.D.**  
**US Army**  
**US Department of Defense**  
**Cedars-Sinai Medical Center**



## Thank you

## Questions and Answers