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)

September 24, 2024

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.)**

10865 Road to the Cure, Suite 150, San Diego, California	**92121**
(Address of principal executive offices)	**(Zip Code)**

(858) 727-1755
(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 7.01. Regulation FD Disclosure.

On September 24, 2024, Capricor Therapeutics, Inc. (the "Company" or "Capricor") announced its intent to file a Biologics License Application ("BLA") supported by existing and natural history cardiac data for deramiocel to treat all patients diagnosed with Duchenne muscular dystrophy ("DMD") cardiomyopathy following its recent meetings with the U.S. Food and Drug Administration ("FDA"). The Company plans to initiate the rolling submission in October 2024. Furthermore, in order to support potential label expansion to treat DMD skeletal muscle myopathy, Capricor plans to combine Cohorts A and B of the Phase 3 HOPE-3 clinical trial to serve as a post-approval study and does not intend to unblind Cohort A at this time, which was expected to occur in the fourth quarter of 2024.

A copy of the press release and slide presentation has been filed as Exhibit 99.1 and Exhibit 99.2 hereto and is incorporated herein by reference.

The information under Item 7.01 of this Current Report on Form 8-K, Exhibit 99.1 and Exhibit it 99.2 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 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 Announces Intent to File Biologics License Application for Full Approval of Deramiocel for the Treatment of Duchenne Muscular Dystrophy Cardiomyopathy", dated September 24, 2024.
99.2	Capricor Therapeutics, Inc. Slide Presentation, dated September 24, 2024.
104	Cover Page Interactive Data File (formatted as inline XBRL).

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: September 24, 2024

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

Exhibit 99.1

Capricor Therapeutics Announces Intent to File Biologics License Application for Full Approval of Deramiocel for the Treatment of Duchenne Muscular Dystrophy Cardiomyopathy

-BLA to be Supported by Existing and Natural History Cardiac Data as Discussed with the FDA-

Initial Label Would Include All Patients with Cardiomyopathy Associated with Duchenne Muscular Dystrophy-

-Rolling Submission Planned to Commence in October 2024-

-Internal GMP Manufacturing Established to Support BLA and Commercialization-

-Investor Webcast Today at 8:30 a.m. ET-

SAN DIEGO, Sept. 24, 2024 (GLOBE NEWSWIRE) --Capricor Therapeutics (NASDAQ: CAPR), a biotechnology company developing transformative cell and exosome-based therapeutics for the treatment of rare diseases, announced today, following recent meetings with the U.S. Food and Drug Administration (FDA), its intent to file a Biologics License Application (BLA) based on existing cardiac and natural history data for deramiocel to treat all patients diagnosed with Duchenne muscular dystrophy (DMD) cardiomyopathy.

Following the FDA meetings:

- Capricor plans to commence the filing of a BLA in October of 2024 seeking full approval of deramiocel for the treatment of DMD-cardiomyopathy with full submission expected by year-end 2024.
- The BLA filing will be based on existing cardiac data from the Phase 2 HOPE-2 and HOPE-2 Open Label Extension (OLE) trials compared to natural history data provided by Vanderbilt University Medical Center and Cincinnati Children's Hospital Medical Center.
- In order to support potential label expansion to treat DMD skeletal muscle myopathy, Capricor plans to combine Cohorts A and B of the Phase 3 HOPE-3 clinical trial to serve as a post-approval study and does not intend to unblind Cohort A at this time, which was expected to occur in the fourth quarter of 2024.

"There are currently no approved therapies for DMD cardiomyopathy, which is the leading cause of death in those with Duchenne. Based on the strength of our cardiac data, combined with the FDA's commitment to advancing therapeutics for the treatment of rare diseases, we are seeking approval for the cardiomyopathy associated with DMD and will look to expand the label for skeletal muscle myopathy post-approval," said Linda Marbán, Ph.D., Capricor's chief executive officer. "This approach is the result of multiple in-depth meetings with FDA where we showed robust and positive cardiac data from our HOPE-2 and HOPE-2 OLE studies compared to natural history data from a large cohort of patients."

Dr. Marbán continued, "Deramiocel has shown in multiple clinical trials attenuation of the cardiac implications of DMD. Based on the totality of evidence of the safety and efficacy data deramiocel has shown, we believe this is the best path forward to potential approval, allowing us to bring this novel, first-in-class treatment to patients in need in the most expeditious manner. We want to extend our appreciation to the patients, their families and advocates who continue to work with us and to the FDA for their commitment to accelerating treatments for DMD."

Deramiocel for the treatment of DMD, has received FDA Orphan Drug Designation and the regulatory pathway for deramiocel is supported by RMAT (Regenerative Medicine Advanced Therapy Designation). In addition, if Capricor were to receive FDA marketing approval for deramiocel for the treatment of DMD, Capricor would be eligible to receive a Priority Review Voucher (PRV) based on its previous receipt of a rare pediatric disease designation.

Webcast Details

Capricor will host a conference call and webcast at 8:30 a.m. ET today to discuss these updates. To participate in the conference call, please dial 1-800-717-1738 (domestic/toll-free) or 1-646-307-1865 (international) and reference the conference ID: 62574. Participants can use guest dial-in numbers above and be answered by an operator or click here for instant telephone access. To

participate via webcast, please click here to view the slides. A replay of the webcast will be available following the conclusion of the live broadcast and will be accessible on the Company's website.

About Deramiocel (CAP-1002)

Deramiocel consists of allogeneic cardiosphere-derived cells (CDCs), a population of stromal cells that have been shown in preclinical and clinical studies to exert potent immunomodulatory, antifibrotic and regenerative actions in dystrophinopathy and heart failure. CDCs act by secreting extracellular vesicles known as exosomes, which target macrophages and alter their expression profile so that they adopt a healing, rather than a pro-inflammatory, phenotype. CDCs have been the subject of over 100 peer-reviewed scientific publications and have been administered to over 200 human subjects across several clinical trials.

About Duchenne Muscular Dystrophy

Duchenne muscular dystrophy (DMD) is a devastating genetic disorder characterized by progressive weakness and chronic inflammation of the skeletal, heart and respiratory muscles with mortality at a median age of approximately 30 years. It is estimated that DMD occurs in approximately one in every 3,500 male births and that the patient population is estimated to be approximately 15,000-20,000 in the United States. DMD pathophysiology is driven by the impaired production of functional dystrophin, which normally functions as a structural protein in muscle. The reduction of functional dystrophin in muscle cells leads to significant cell damage and ultimately causes muscle cell death and fibrotic replacement. Treatment options are limited and there is no cure.

About Capricor Therapeutics

Capricor Therapeutics, Inc. (NASDAQ: CAPR) is a biotechnology company dedicated to advancing transformative cell and exosome-based therapeutics to redefine the treatment landscape for rare diseases. At the forefront of our innovation is our lead product candidate, deramiocel (CAP-1002), an allogeneic cardiac-derived cell therapy. Extensive preclinical and clinical studies have shown deramiocel to demonstrate immunomodulatory, antifibrotic, and regenerative actions specifically tailored for dystrophinopathies and heart disease. Deramiocel is currently advancing through Phase 3 clinical development for the treatment of Duchenne muscular dystrophy. Capricor is also harnessing the power of its exosome technology, using its proprietary StealthX™ platform in preclinical development focused on the areas of vaccinology, targeted delivery of oligonucleotides, proteins and small molecule therapeutics to potentially treat and prevent a diverse array of diseases. At Capricor, we stand committed to pushing the boundaries of possibility and forging a path toward transformative treatments for those in need. For more information, visit capricor.com, and follow Capricor on Facebook, Instagram and Twitter.

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; manufacturing capabilities; dates for regulatory meetings; statements about our financial outlook; the ability to achieve product milestones and to receive milestone payments from commercial partners; plans regarding current and future collaborative activities and the ownership of commercial rights; potential future agreements; scope, duration, validity and enforceability of intellectual property rights; future revenue streams and 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, 2023, as filed with the Securities and Exchange Commission on March 11, 2024, and in our Quarterly Report on Form 10-Q for the quarter ended June 30, 2024, as filed with the Securities and Exchange Commission on August 8, 2024. 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.

Capricor has entered into an agreement for the exclusive commercialization and distribution of deramiocel (CAP-1002) for DMD in the United States and Japan with Nippon Shinyaku Co., Ltd. (U.S. subsidiary: NS Pharma, Inc.), subject to regulatory approval. Deramiocel 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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212.896.1204

Capricor Company Contact:
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858.727.1755

Exhibit 99.2


Capricor
Therapeutics™
Linda Marbán, Ph.D.
Chief Executive Officer
Capricor Therapeutics, Inc. NASDAQ: CAPR
September 24, 2024

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; manufacturing capabilities; dates for regulatory meetings; statements about our financial outlook; the ability to achieve product milestones and to receive milestone payments from commercial partners; potential future agreements; plans regarding current and future collaborative activities and the ownership of commercial rights; scope, duration, validity and enforceability of intellectual property rights; future reimbursement prices; future revenue streams and 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, 2023 as filed with the Securities and Exchange Commission on March 11, 2024 and in our Quarterly Report on Form 10-Q for the period ended June 30, 2024 as filed with the Securities and Exchange Commission on August 8, 2024. 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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Capricor
Therapeutics
At Capricor, we stand committed to pushing the boundaries of possibility and forging a path toward transformative treatments for patients in need
Capricor Therapeutics, Inc. | Developing Transformative Therapies from Bench to Bedside
3

Deramiocel for the Treatment of DMD

Pathway to BLA

- Capricor intends to submit a BLA for **full approval**
- BLA filing supported with **Capricor's existing cardiac** and available **natural history data**
- Submission will seek **broad DMD-cardiomyopathy label**
- If approved, this would serve to address an **extensive population of DMD patients** (mutation agnostic)
- This strategy **expedites** our path to market

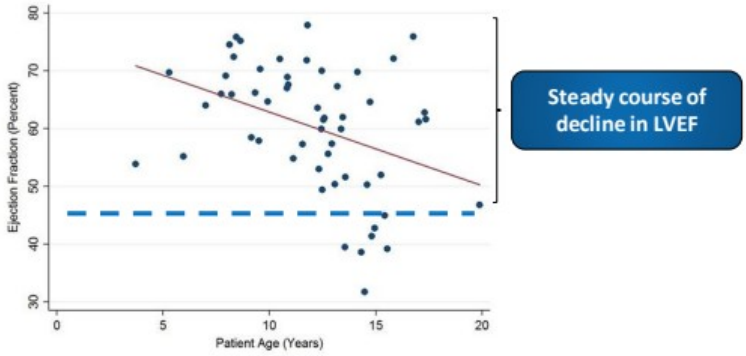
Key Takeaways from Pre-BLA Meeting

- Strength of Capricor's long-term cardiac data
- Emergence of natural history cardiac dataset
- FDA's continued commitment to rare diseases
- **No approved therapies for DMD-cardiomyopathy**

Cardiomyopathy in DMD

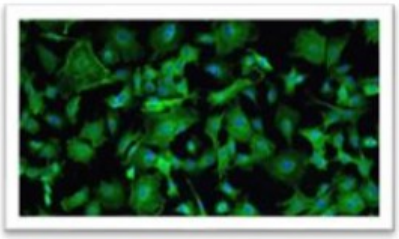
"Cardiopulmonary failure is the leading cause of mortality in DMD in the current era…Unfortunately, standard heart failure therapies are not DMD-specific and have limited efficacy….For maximal efficacy, most therapies should begin early in the disease process…"

Circulation: Heart Failure, (2023) , Soslow J.H., M.D., et al.



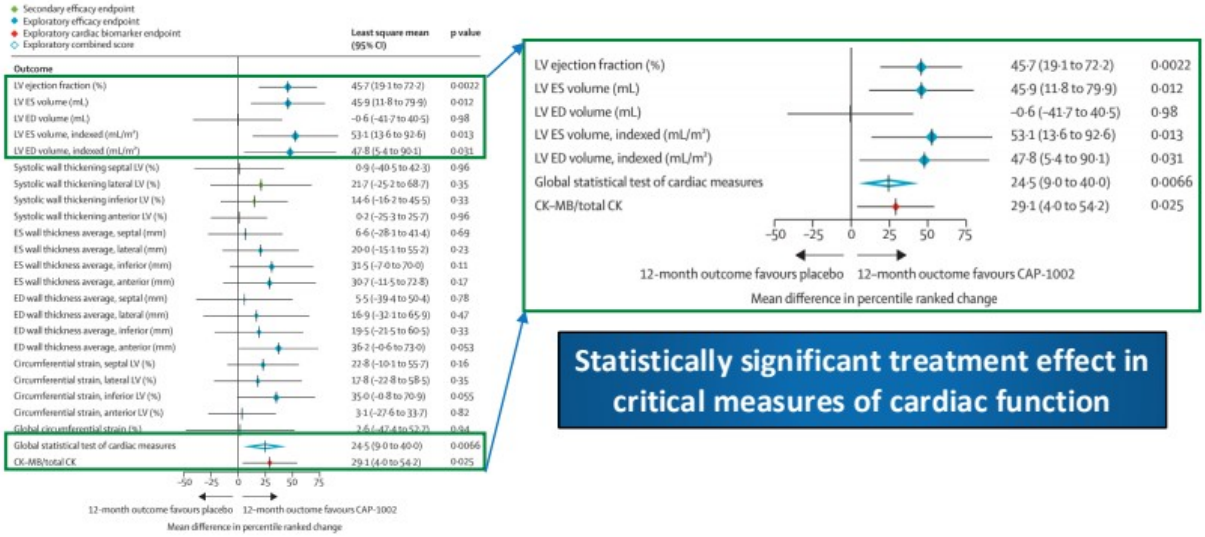
Deramiocel Cell Therapy Overview

- **Deramiocel (CAP-1002):** biologic consisting of allogeneic cardiosphere-derived cells (CDCs)
- **Multiple-modalities**
  - Immunomodulatory
  - Anti-inflammatory
  - Anti-fibrotic
  - Pro-angiogenic
- Investigated in over **200 patients**
- Potency assays accepted by FDA which support MOA
- **FDA designations in DMD**
  - ✓ Orphan Drug Designation
  - ✓ Regenerative Medicine Advanced Therapy (RMAT) designation
  - ✓ **Rare Pediatric Disease Designation**
    - Capricor holds full rights to the PRV, if received



HOPE-2: 21/22 Cardiac Outcomes

Favored Deramiocel Treatment over Placebo



Statistically significant treatment effect in critical measures of cardiac function

Natural History Data Summary

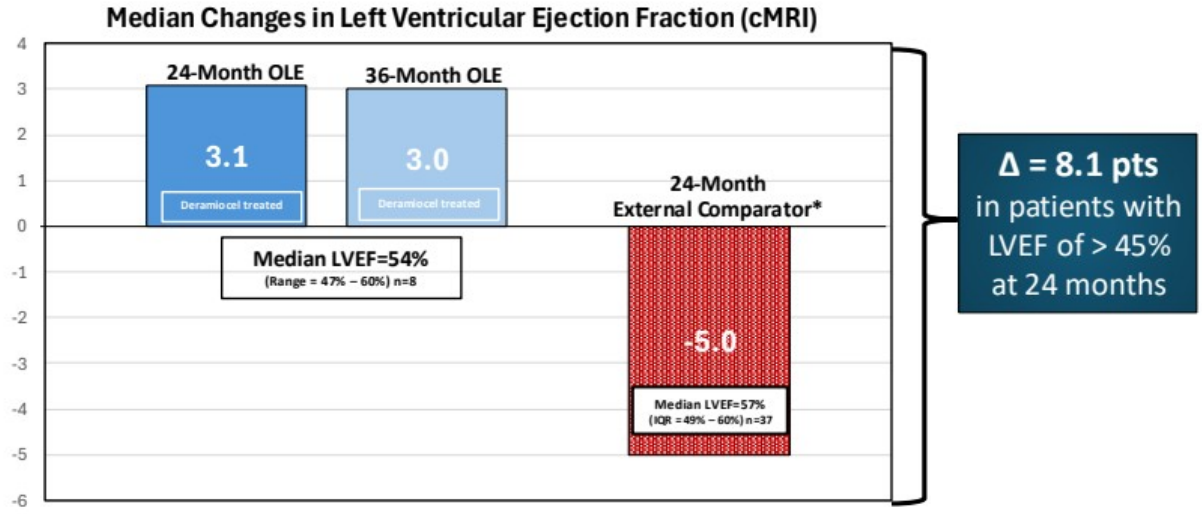
Source	PI	Data	Status	In Process
Vanderbilt University Medical Center /FDA†	Jonathan Soslow	Cardiac MRI	Summary Stats from publication	*Patient-level data*

† "This study aims to focus on cardiomyopathy (heart muscle disease), which is the leading cause of death in Duchenne muscular dystrophy. The study will combine genetic differences with imaging and blood biomarkers to identify surrogate biomarkers that predict the risk of cardiac dysfunction in Duchenne muscular dystrophy and other related diseases. This information has the potential to improve future clinical trial efficiency in these diseases by decreasing their size and cost."

https://www.fda.gov/news-events/press-announcements/fda-awards-two-grants-natural-history-studies-rare-diseases

HOPE-2 OLE: 3-Year Cardiac Results

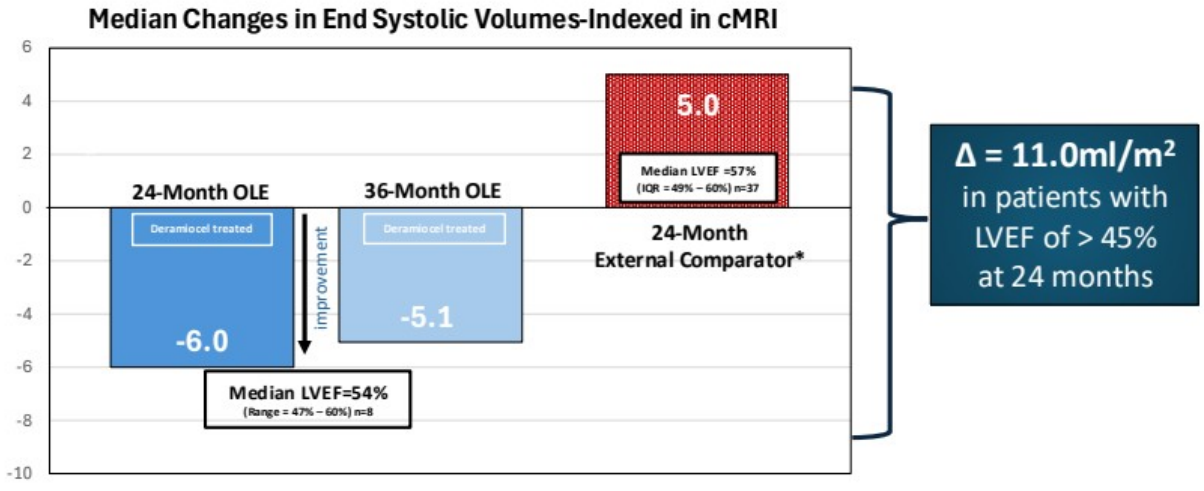
Ejection Fraction Compared to External Comparator



*Soslow, et al. Cardiovascular Measures of All-Cause Mortality in DMD. *Circ Heart Fail.* 2023

HOPE-2 OLE: 3-Year Cardiac Results

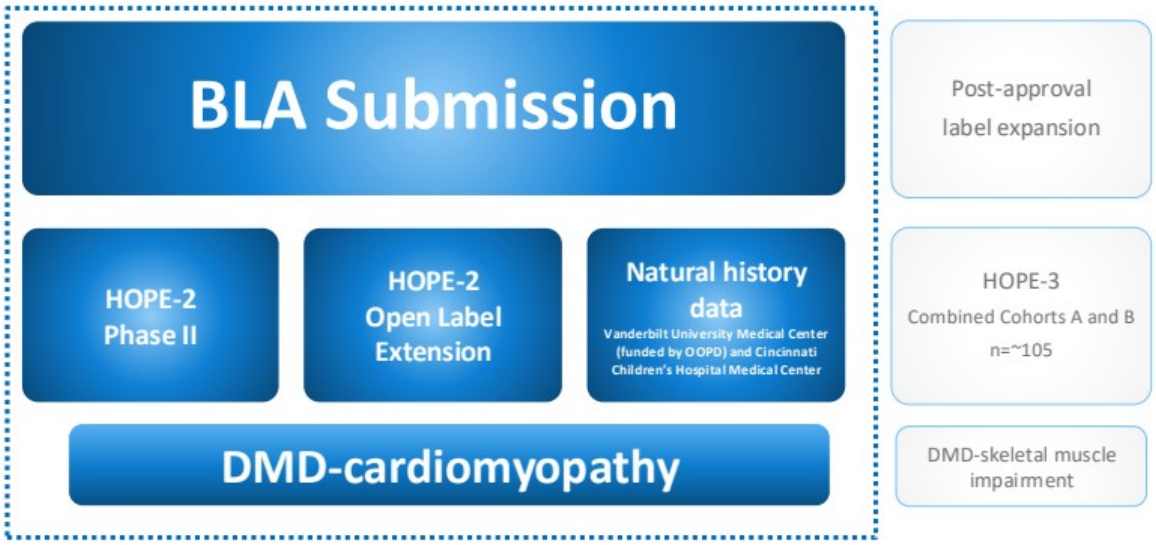
End Systolic Volumes-Indexed Compared to External Comparator



*Soslow, et al. Cardiovascular Measures of All-Cause Mortality in DMD. *Circ Heart Fail.* 2023

Deramiocel BLA Supporting Data

To Support Full Approval



Deramiocel has the Potential to Redefine the Standard of Care for DMD

Capricor Therapeutics

Deramiocel can be used in combination with existing therapeutics

GENE THERAPIES
Elevidys™

EXON SKIPPING THERAPIES
Viltepso® Exondys 51™, Amondys 45™, Vyondys 53™,

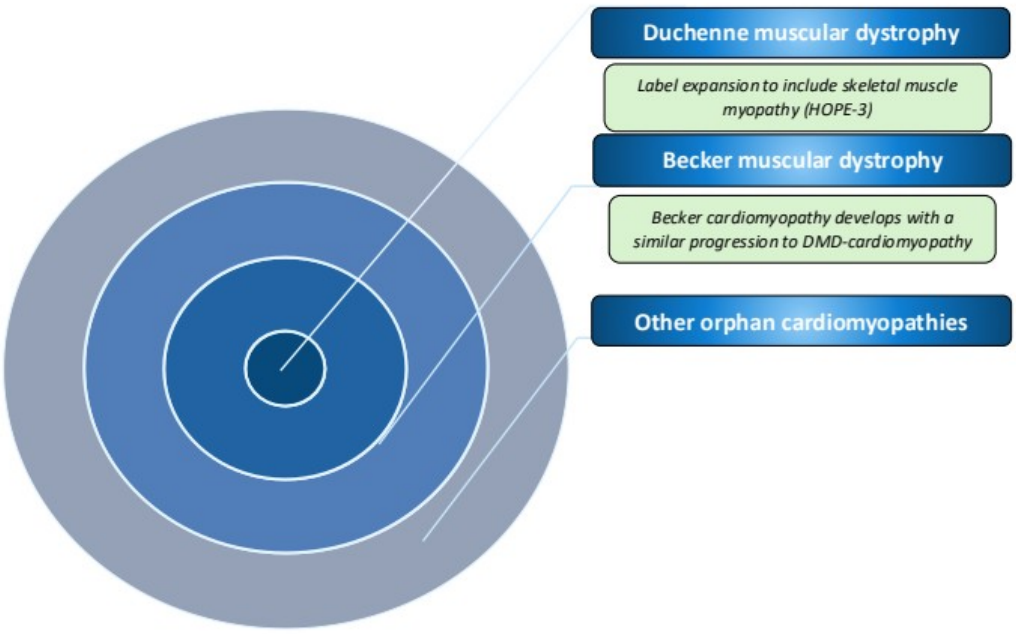
Deramiocel

First-in-class therapy for DMD-cardiomyopathy

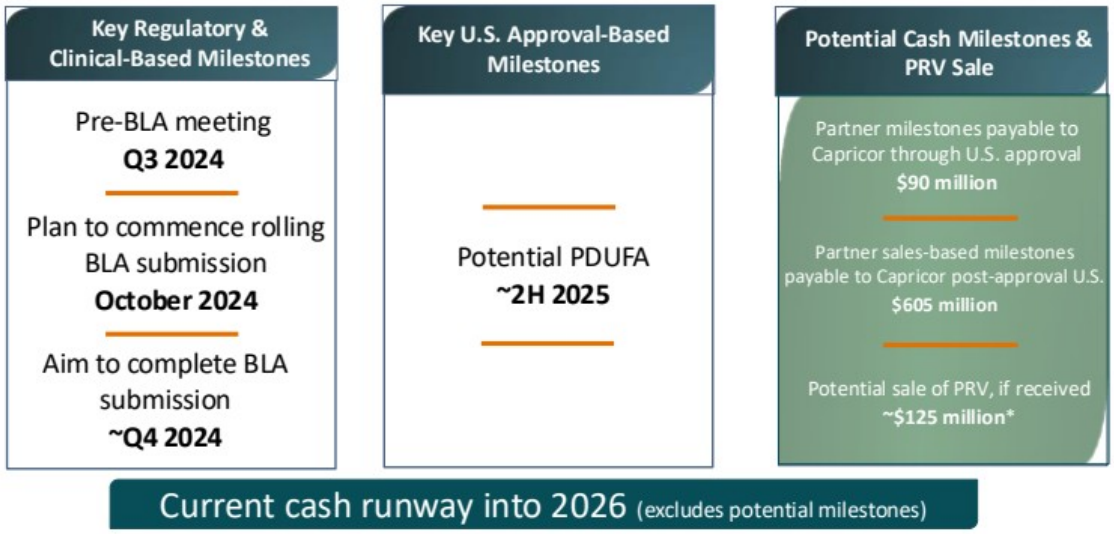
CORTICOSTEROIDS
Emflaza®, Agamree®

OTHER THERAPEUTICS
Duvyzat™

Potential Expansion of Deramiocel



Near-Term Value Driving Catalysts



*Last public sale of PRV = $158M


Capricor
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