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)

December 19, 2017

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 7.01 Regulation FD Disclosure.

On December 19, 2017, Capricor Therapeutics, Inc., a Delaware corporation (the "Company"), posted to the "Investors" section of the Company's website at *www.capricor.com* a corporate presentation providing an update of the Company's current business and products (the "Corporate Presentation"). A copy of the Corporate Presentation is attached hereto as Exhibit 99.1 and is incorporated by reference into this Item 7.01 of this Current Report on Form 8-K.

The information contained in this Current Report on Form 8-K 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 Capricor Therapeutics, Inc. Corporate Presentation, dated December 19, 2017.

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: December 19, 2017

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

NASDAQ: CAPR

December 2017

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, 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.

Investment Highlights

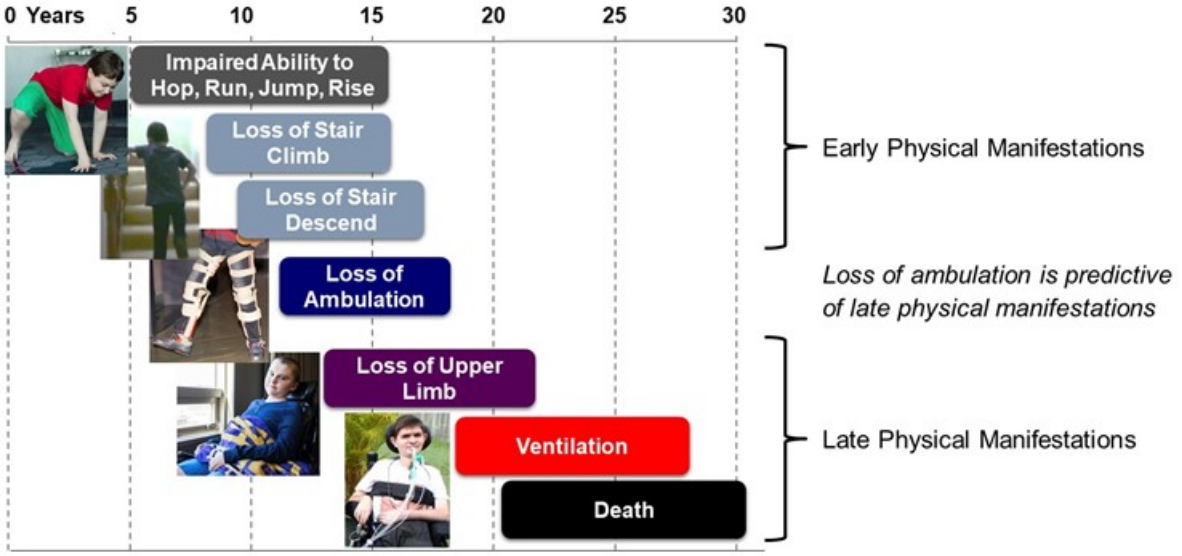
- Pipeline focused on rare pediatric disorders for which current options are inadequate
- Clinical proof-of-concept in lead indication – Duchenne muscular dystrophy
  - To initiate potential registration trial in 1Q18
  - $1B+ U.S. sales opportunity
  - Capricor holds worldwide IP rights
- Novel cell / exosome platform may address several challenging diseases
- Scalable manufacturing process in development
- Significant ownership by insiders

Capricor's Product Pipeline

Candidate	Indication	Development Phase			Status
		Preclinical	Clinical	Market	
CAP-1002 (allogeneic CDCs)	**Duchenne Muscular Dystrophy**				▪ Expect to initiate potential registration trial in 1Q18 ▪ Improvement in skeletal and cardiac muscle function seen in randomized clinical trial in advanced DMD ▪ Orphan Drug and Rare Pediatric Disease Designations; RMAT eligible
CAP-2003 (CDC-exosomes)	**Hypoplastic Left Heart Syndrome**				▪ Plan to submit IND in 2018 ▪ Awarded NIH grant of up to $4.2 M
	Inflammatory Disorders				▪ Exploring potential indications

CAP-1002 is an Investigational New Drug and is not approved for any indications.
Capricor's exosomes technology, including CAP-2003, has not yet been approved for clinical investigation.
CDCs = cardiosphere-derived cells

DMD Progression is Sequential, Non-Linear and Irreversible



Cardiomyopathy is the #1 Cause of Death in DMD

"Cardiomyopathy is an almost universal finding in boys affected with DMD"

Pediatric Cardiol. (2014) 35: 1279-1285

"As a result of respiratory support and glucocorticoid use, patients with DMD are living longer, bringing the associated cardiomyopathy to the forefront of management for Duchenne patients as they age"

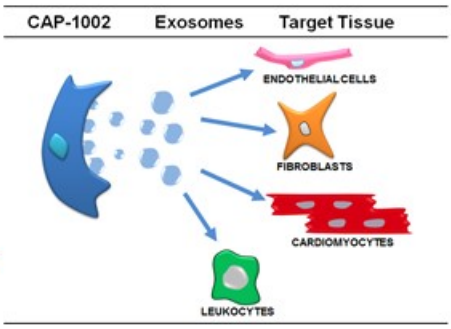
Circulation. 2015;131:1590-1598.

- DMD results from mutation in dystrophin gene, ~1 per 3,600 male births
- Lack of functional dystrophin in heart leads to: inflammation
  cardiomyocyte death
  progressive cardiac fibrosis
- Hearts become dilated and non-compliant, and eventually fail
- No therapies have been shown to address the heart disease associated with DMD

Capricor's Technology

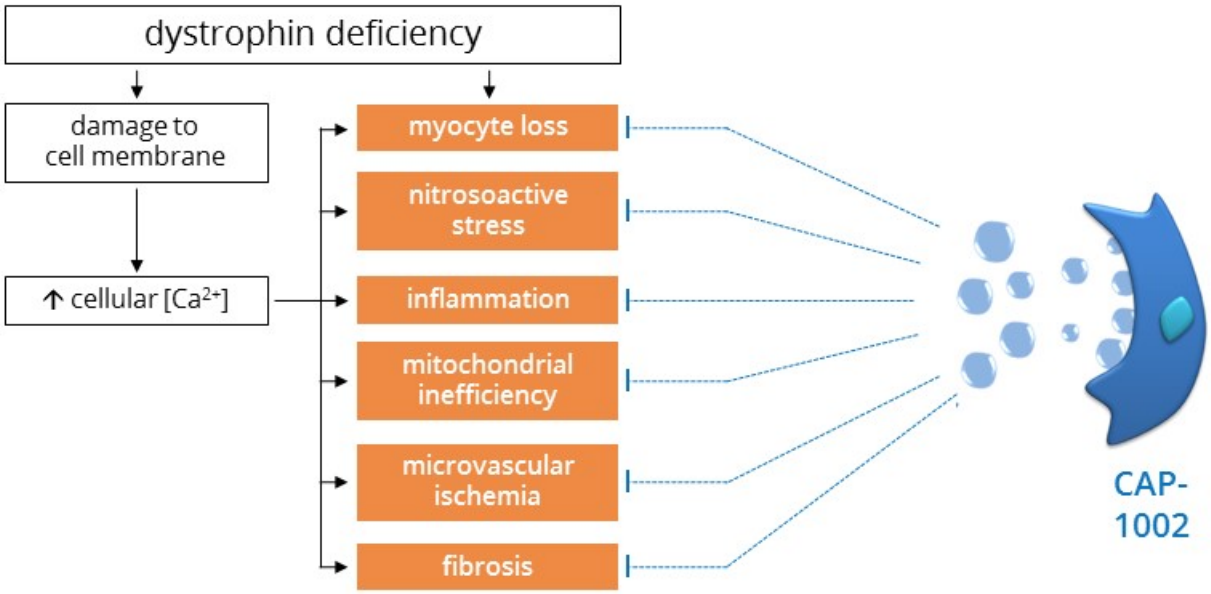
– **CAP-1002 is a biologic product consisting of allogeneic cardiosphere-derived cells (CDCs)**

- Manufactured from donated heart muscle
- Does not act by "stemness" – the cells do not engraft into host tissue
- Acts by releasing extracellular vesicles, or exosomes
  - Contain non-coding RNAs and proteins
  - Internalized by target cells
  - Stimulate diverse and lasting changes in cellular behavior
- CDCs have been the subject of <100 peer-reviewed papers since 2007



- CAP-1002 has been investigated in several clinical trials and more than 130 human subjects

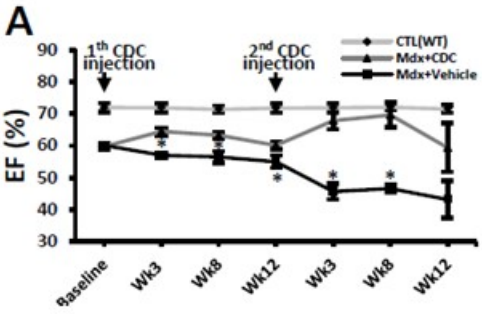
CAP-1002 Targets Multiple Disease Processes in DMD



Effects of CDCs in mdx Mouse Model

- Following a single administration of CDC or vehicle to mdx mice:

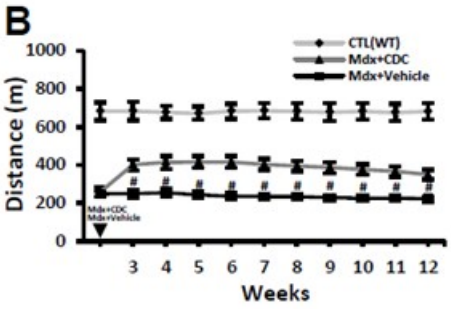
Improved cardiac function



- Left ventricular ejection fraction markedly improved vs. control

  (p<0.05 at all timepoints through 12 weeks of follow-up)

Increased exercise capacity



- Exercise performance approximately doubled vs. control

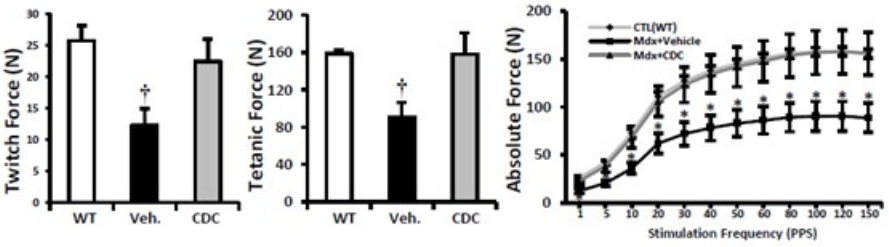
  (p<0.005 at all timepoints through 12 weeks of follow-up)

Aminzadeh et al, **2017** (http://biorxiv.org/content/early/2017/04/20/128900).

Effects of CDCs in mdx Mouse Model

- Following a single administration of CDC or vehicle to mdx mice:

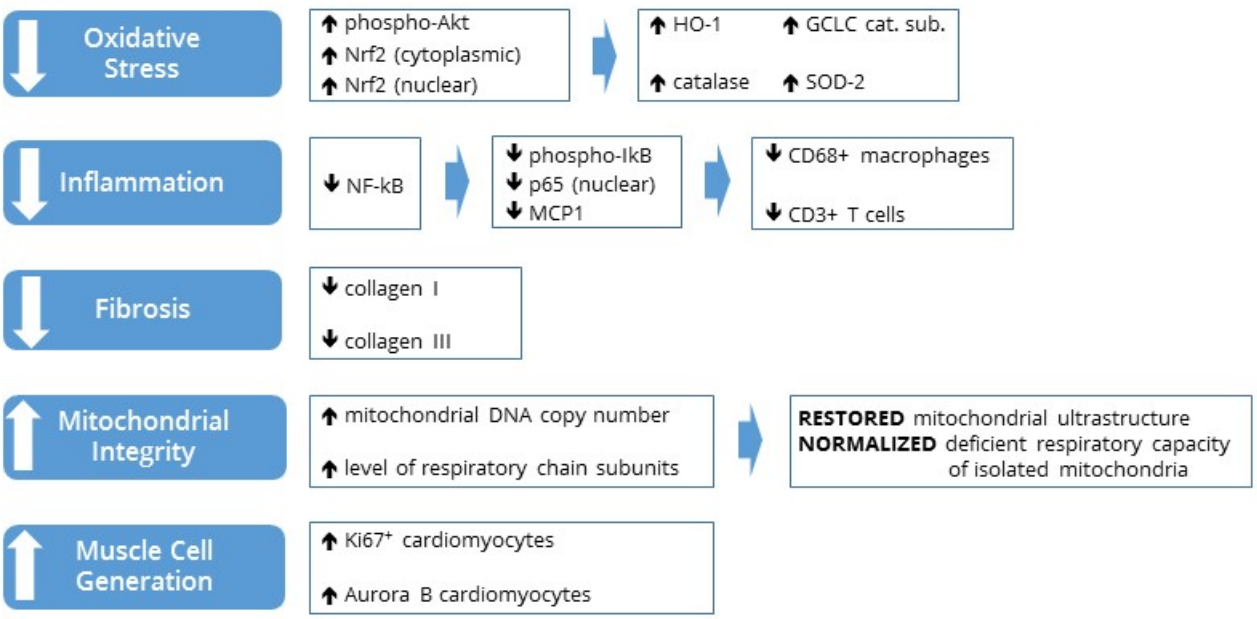
Enhanced skeletal muscle function



- Twitch force, tetanic force, and fibrosis in soleus (slow-twitch) and extensor digitorum longus (fast-twitch) muscles significantly improved vs. control

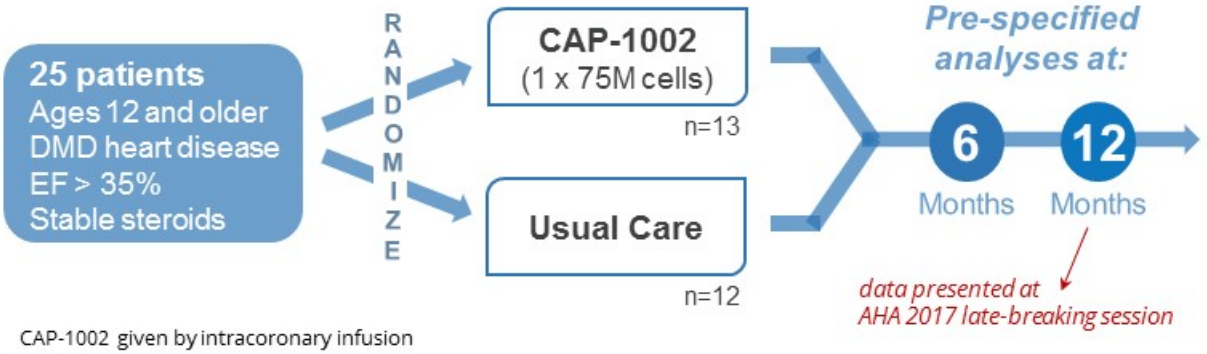
  ($p<0.05$; muscles isolated at three weeks post-treatment)

Physiological Effects of CDC in mdx Model



Adapted from Aminzadeh et al, **2017** (http://biorxiv.org/content/early/2017/04/20/128900).

Phase I / II HOPE-Duchenne Clinical Trial



CAP-1002 given by intracoronary infusion

- One-time, multi-vessel, intracoronary delivery of cells
- Safety trial with multiple exploratory efficacy endpoints
- Three U.S. sites: Cedars-Sinai Medical Center
  Cincinnati Children's
  University of Florida

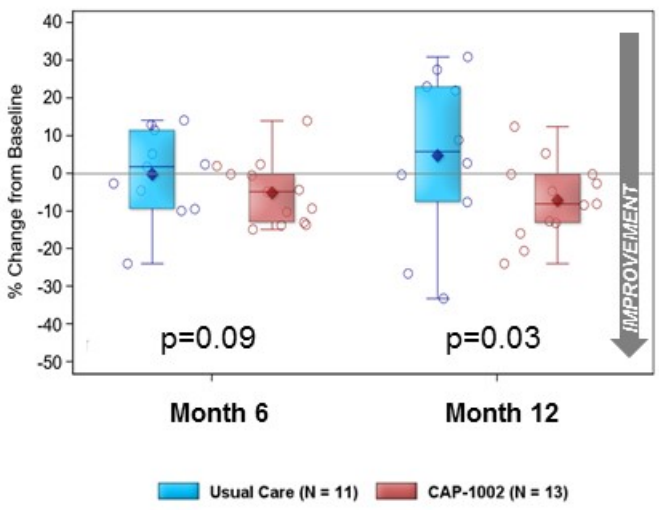
Baseline Characteristics

	Usual Care (n=12)	CAP-1002 (n=13)
Age, median years (range)	17.5 (12–20)	18 (14–25)
Wheelchair Use Always (%)	7 (58)	10 (77)
Cardiac Scar Size, mean % (SD)	21.4 (10.8)	17.6 (6.8)
LV Ejection Fraction, mean % (SD)	48.4 (7.5)	49.6 (6.7)
Intracoronary Dose, M cells (SD)	n/a	73.7 (3.6)

Patients were all male, were all receiving chronic treatment with systemic steroids, and were mostly Caucasian.

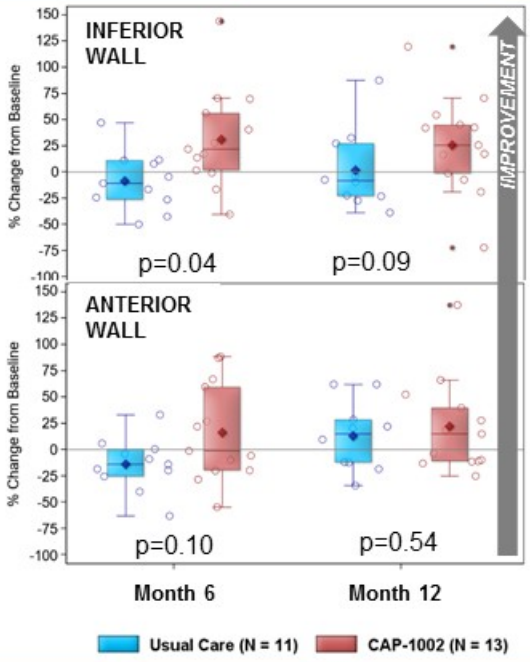
- HOPE population characterized by advanced disease; majority were non-ambulant
- Most DMD clinical development has been conducted in less sick patients

Heart Muscle: Reduced Myocardial Scarring



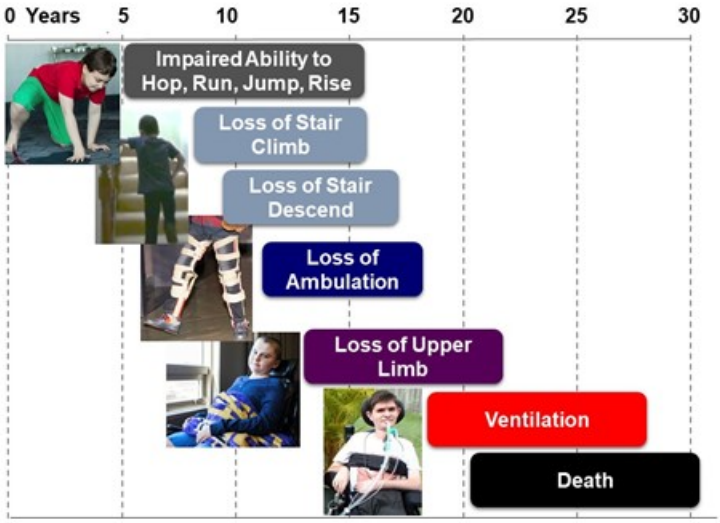
- Assessed by cardiac MRI with blinded analysis by core lab
- Scar increased in the Usual Care group, but decreased in the CAP-1002 group
  - 11.9% group difference in change score at Month 12 (p=0.03)
- Decreased scar is counter to the natural history of DMD

Heart Muscle: Increased Regional Systolic Wall Thickening



- Greatest evidence of improvement seen in inferior wall
- Similar trend in anterior wall
- Lesser trends in lateral and septal walls
- Consistent with natural history of scar progression in DMD
  - Inferior → Anterior → Lateral → Septal
- No effect detected in ejection fraction
  - Baseline EF = low end of normal range

Measuring DMD Progression Requires Use of Multiple Outcome Measures



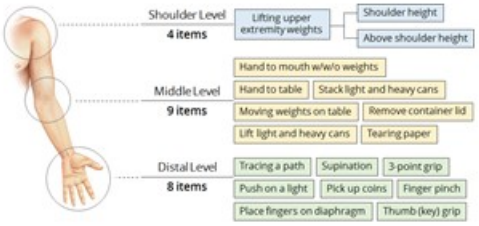
Muscle Function
- 6-minute walk test
- 4-stair climb
- 4-stair descend
- 10m walk / run

Disease Progression
- North Star Ambulatory Assessment (NSAA)
- Loss of Ambulation

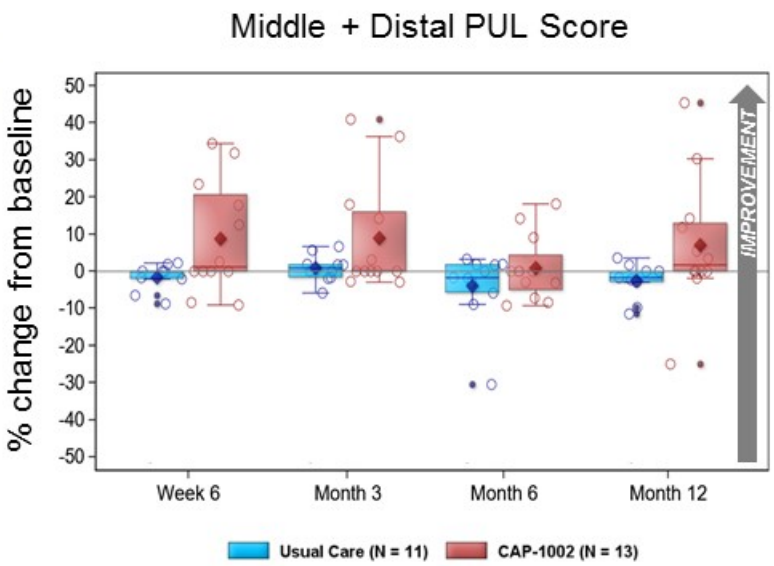
Upper Limb Impairment
- Brooke / EK Scales
- Performance of the Upper Limb (PUL)

Pulmonary Function
- Forced vital capacity

Skeletal Muscle: PUL Results Indicate Functional Benefit

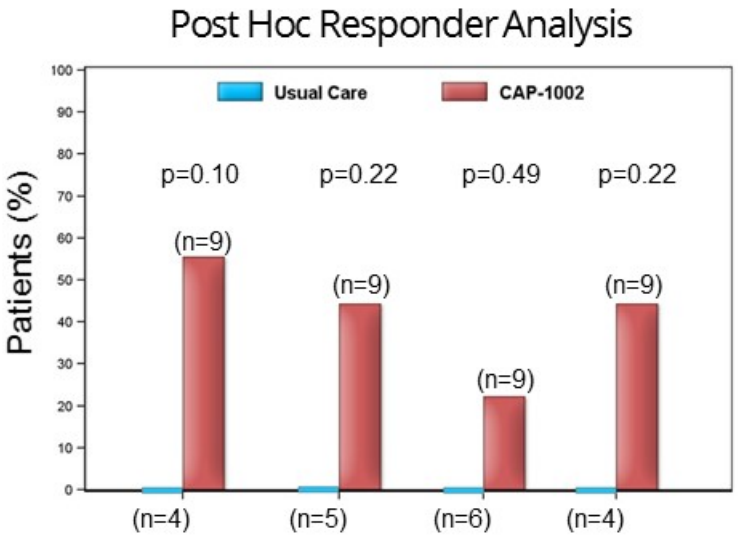


- Performance of the Upper Limb (PUL) test is a validated instrument in DMD
  - Relates to patients' ability to perform common activities of daily living
- Trends towards improvement observed throughout follow-up



Skeletal Muscle: PUL Results Indicate Functional Benefit

- Middle + Distal PUL scores
- Subgroup of patients with more advanced disease (baseline middle + distal PUL score < 55 of 58 max)
- Responder defined as: **≥ 10% improvement from baseline or max possible improvement**



Key Conclusions from HOPE Trial Results

- Early clinical data consistent with preclinical studies showing CAP-1002 benefits both cardiac (scar & thickening) and skeletal (PUL) muscle in DMD
- CAP-1002 (75M cells) generally safe and well-tolerated
  - Adverse events consistent with an intracoronary infusion procedure
- Sustained benefit likely to require repeat doses

HOPE-2 Clinical Trial of CAP-1002 in DMD

— **Potential registration trial to initiate in 1Q 2018**

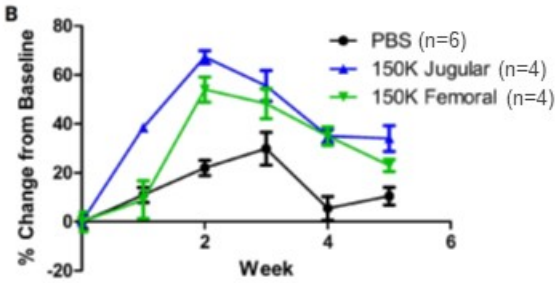
- Randomized, double-blind, placebo-controlled
- Target enrollment of 84 patients with advanced disease
- Peripheral intravenous delivery – supported by preclinical studies
- Repeat-dose design – potential to achieve sustained benefit
- Primary efficacy endpoint – difference in change in mid-PUL scores at Month 12
- Principal Investigator – Craig M. McDonald, M.D.

— **FDA willing to consider PUL as an efficacy endpoint for registration**

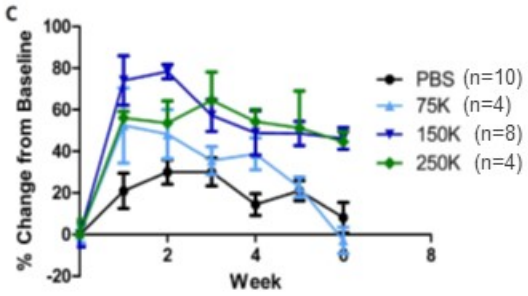
- Type B meeting held in June, following six-month HOPE data

— **IND 30-day review period concluded with no clinical holds**

IV Delivery Studies in mdx Mouse

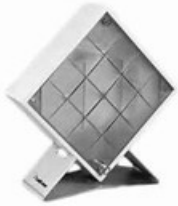


Exercise capacity of mdx mice given CDCs by two IV administration routes.



Exercise capacity of mdx mice given escalating doses of CDCs by IV administration.

Manufacturing

CSps	CDCs	Wash	Formulate	Fill	CAP-1002
					

- CAP-1002 is manufactured from donor hearts via a proprietary process
- Clinical trial material currently produced at Capricor facility
- High-yield process in advanced development

Capricor has Assembled a World-Class DMD Advisory Board

Barry Byrne, M.D., Ph.D.	University of Florida (USA)
Michelle Eagle, Ph.D., M.Sc., MCSP	Atom International Ltd (UK)
Richard Finkel, M.D.	Nemours Children's Hospital (USA)
Pat Furlong	Parent Project Muscular Dystrophy (USA)
Kan Hor, M.D.	Nationwide Children's Hospital (USA)
John Jefferies, M.D.	Cincinnati Children's Hospital Medical Center (USA)
Oscar Henry Mayer, M.D.	Children's Hospital of Philadelphia (USA)
Craig McDonald, M.D.	University of California at Davis (USA)
Eugenio Mercuri, M.D., Ph.D.	Catholic University of the Sacred Heart (Italy)
Francesco Muntoni, M.D.	University College London (UK)
Ron Victor, M.D.	Cedars-Sinai Medical Center (USA)
Thomas Voit, M.D.	University College London (UK)

Relationships with Key DMD Advocacy Organizations

Resources Expected to Fund Operations Through 3Q18

Cash and equivalents	**$13.9 million**	(as of Sept. 30, 2017)
Shares outstanding	**25.7 million**	(as of Nov. 10, 2017)

Capricor reported the above information in its most recent Quarterly Report on Form 10-Q filed with the SEC on November 14, 2017.

Capricor has received over $30 million in competitive grants and a loan award from:

California Institute of Regenerative Medicine
National Institutes of Health
U.S. Department of Defense

Recent and Upcoming Milestones

4Q 2017	☑	Presented six-month HOPE results at World Muscle Society Congress
4Q 2017	☑	Presented 12-month HOPE results at AHA Late-Breaking Session
4Q 2017	☑	Announced IND clearance to conduct HOPE-2 Trial
1Q 2018	☐	Expect to submit request for RMAT designation for CAP-1002
1Q 2018	☐	Expect to initiate HOPE-2 Trial of intravenous, repeat-dose CAP-1002
2018	☐	Expect to submit IND for CAP-2003 in hypoplastic left heart syndrome