

**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)

June 6, 2017

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.

Item 7.01 Regulation FD Disclosure.

On June 6, 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. slide presentation dated June 6, 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: June 6, 2017

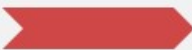


By: /s/ Linda Marbán, Ph.D.
Linda Marbán, Ph.D.
Chief Executive Officer



NASDAQ: CAPR

June 2017

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; 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 prospectus supplements thereto, and in its Quarterly Report on Form 10-Q for the quarter ended March 31, 2017, as filed with the Securities and Exchange Commission on May 15, 2017. All forward-looking statements in this presentation are based on information available to Capricor as of the date hereof, and Capricor assumes no obligation to update these forward-looking statements.

Product Candidate	Indication	Development Phase				Status
		Preclinical	I	II	III	
CAP-1002 (allogeneic CDC)	Duchenne Muscular Dystrophy					<ul style="list-style-type: none"> Positive six-month results from randomized clinical trial of single-dose, intra-coronary CAP-1002 recently reported Plan to initiate clinical trial of repeat-dose, intravenous CAP-1002 in 2H17*
	Inflammatory Disorders					<ul style="list-style-type: none"> Plan to submit IND in 2018
CAP-2003 (CDC exosomes)	Hypoplastic Left Heart Syndrome					<ul style="list-style-type: none"> Awarded NIH grant of up to \$4.2 M

CDC = cardiosphere-derived cells

* Subject to regulatory approval.

- Recent interim analysis of Phase II ALLSTAR trial in people who had suffered a myocardial infarction (“heart attack”) showed low probability of CAP-1002 achieving primary endpoint of scar size reduction, however:
 - ⇒ Scar data in patients with low ejection fraction (<40%) at baseline indicate CAP-1002 effect in this segment
 - ⇒ Ventricular volume data from the entire cohort indicate potential for reverse remodeling with CAP-1002
- Prior clinical data in advanced heart failure (DYNAMIC)* suggest the ability of CDCs to improve muscle function and facilitate reverse remodeling in the setting of more severe pump dysfunction

The cumulative clinical findings support the potential future development of CAP-1002 in the heart failure indication



***Cell Therapy Program for
Duchenne Muscular Dystrophy***

DMD is a rare genetic disorder characterized by progressive muscle wasting, leading to weakness, loss of motor function, and early death



- Orthopedic, respiratory, and cardiac complications
- Results from lack of dystrophin, an essential structural muscle protein
- Variety of mutations are known to occur in the dystrophin gene
- X-linked disorder → nearly all of those affected are male

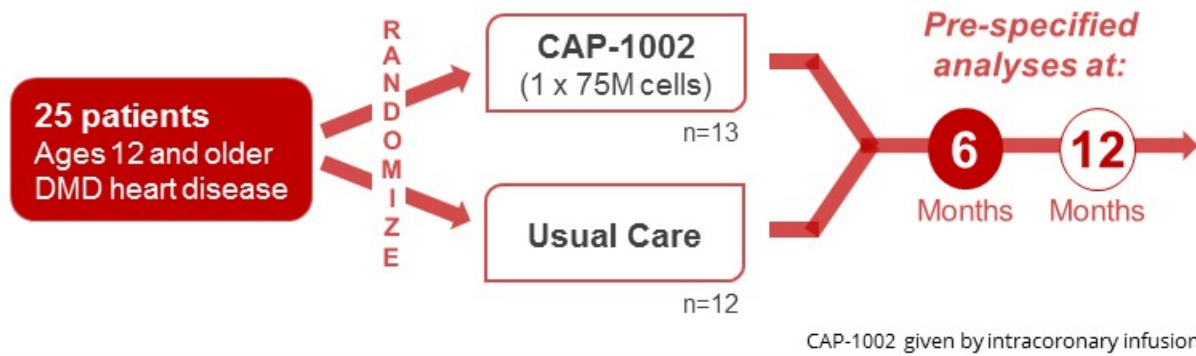
- Annual WW incidence estimated to be one per 3,500 – 5,000 male births
 - Estimated 15,000 – 20,000 cases in U.S.

- FDA-approved drugs limited to corticosteroids and eteplirsen
 - Steroids uniquely shown to have some ability to improve function, but are associated with significant liabilities (chronic exposure required)

 - Exondys 51™ (eteplirsen) is the only disease-modifying therapy
 - Granted FDA Accelerated Approval in September 2016
 - Addresses only ~13% of DMD population (mutations amenable to Exon 51-skipping)

- CAP-1002 is an “off the shelf” cell therapeutic candidate
 - CDCs have been the subject of >100 peer-reviewed scientific reports
 - Exerts potent anti-inflammatory, anti-fibrotic, and anti-apoptotic activities
 - Supports the ability of muscle cells to generate power (mitochondria)
 - Improves cardiac and skeletal muscle performance in DMD models¹
 - FDA orphan drug designation for the treatment of DMD

Clinical proof-of-concept recently demonstrated for CAP-1002 in DMD

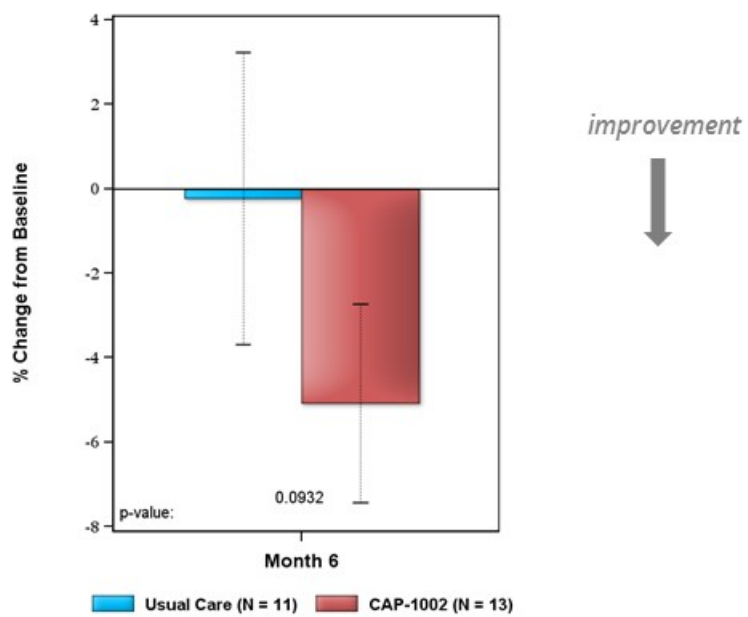


- Trial population characterized by advanced disease:
 - all are receiving steroids
 - majority are non-ambulant
- Most DMD clinical development to date has been conducted in less sick patients

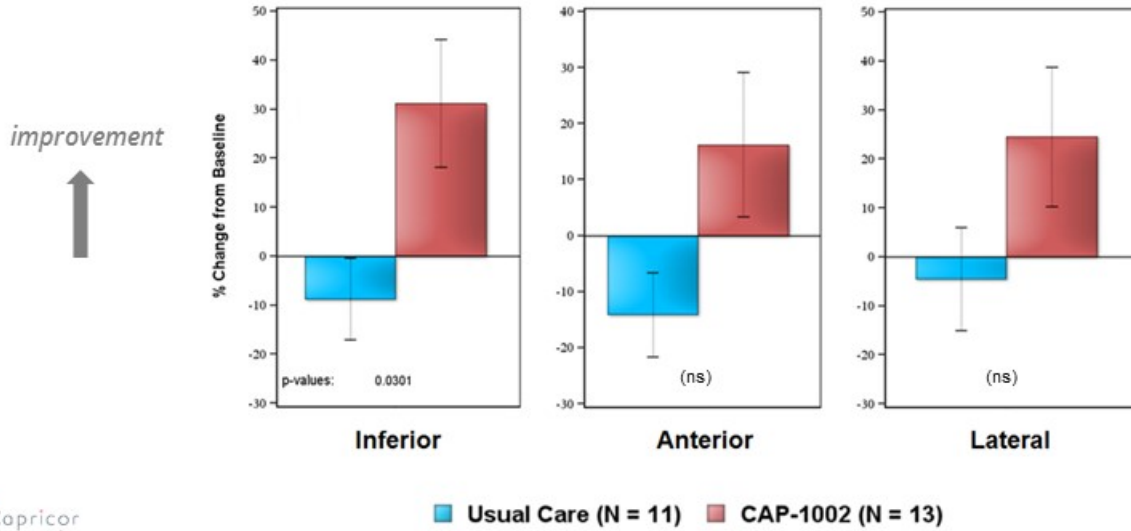
- CAP-1002 was generally safe and well-tolerated
- No early study discontinuations due to adverse events
- Majority of treatment-emergent adverse events rated as mild or moderate
- No clinical events associated with peri-procedural cardiac enzyme elevations

		Baseline	Week 6	Month 3	Month 6	Month 12
Imaging	Cardiac magnetic resonance (cMRI)	●			●	○
Functional Tests	Performance of the Upper Limb (PUL)	●	●	●	●	○
	6-Minute Walk Test	●	●	●	●	○
	Spirometry	●	●	●	●	○
Quality of Life	Pediatric QL Inventory	●	●	●	●	○
	PODCI Adolescent Questionnaire	●	●	●	●	○
Biomarkers	Osteopontin, ST2, IL-10, Galectin-3	●	●	●	●	○

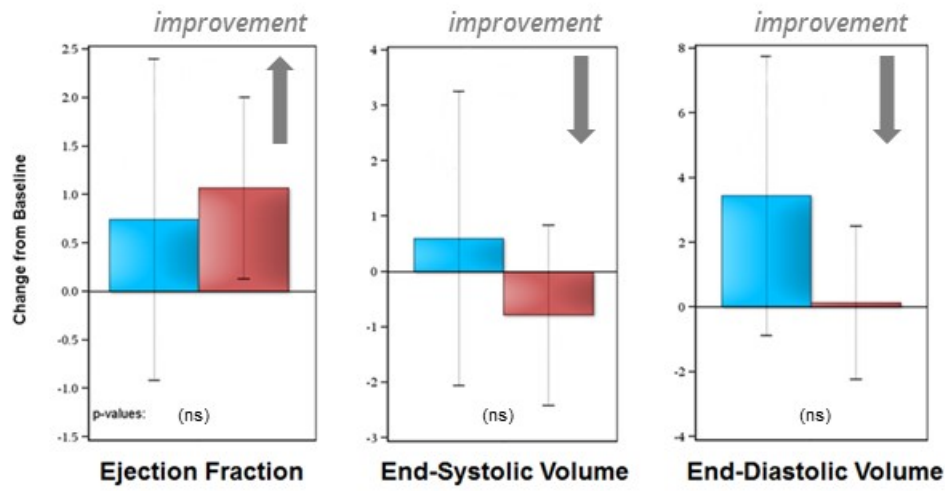
Spontaneous scar reduction is not observed in DMD



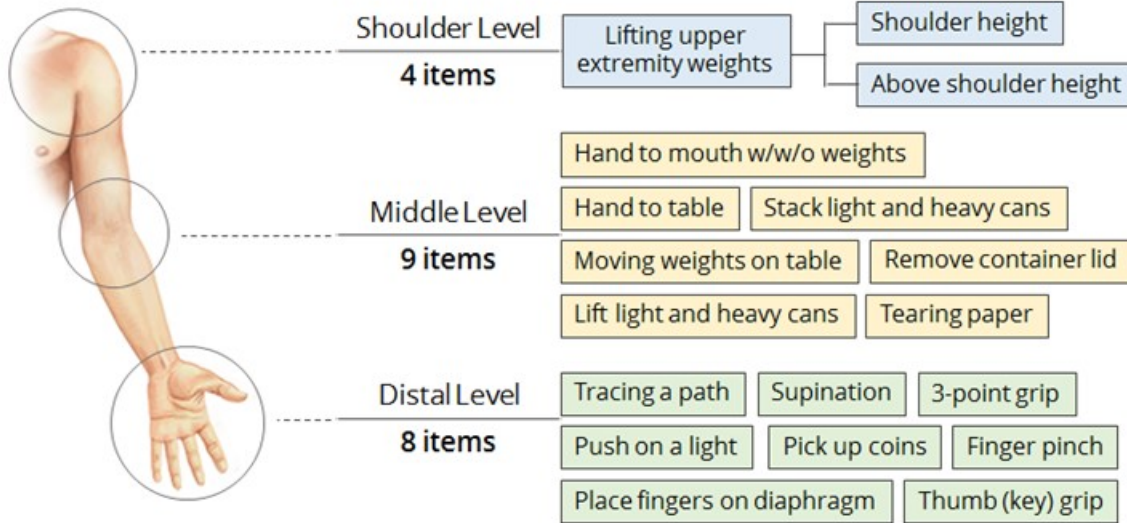
Systolic thickening is believed to be a principal mechanism of cardiac output generation in DMD

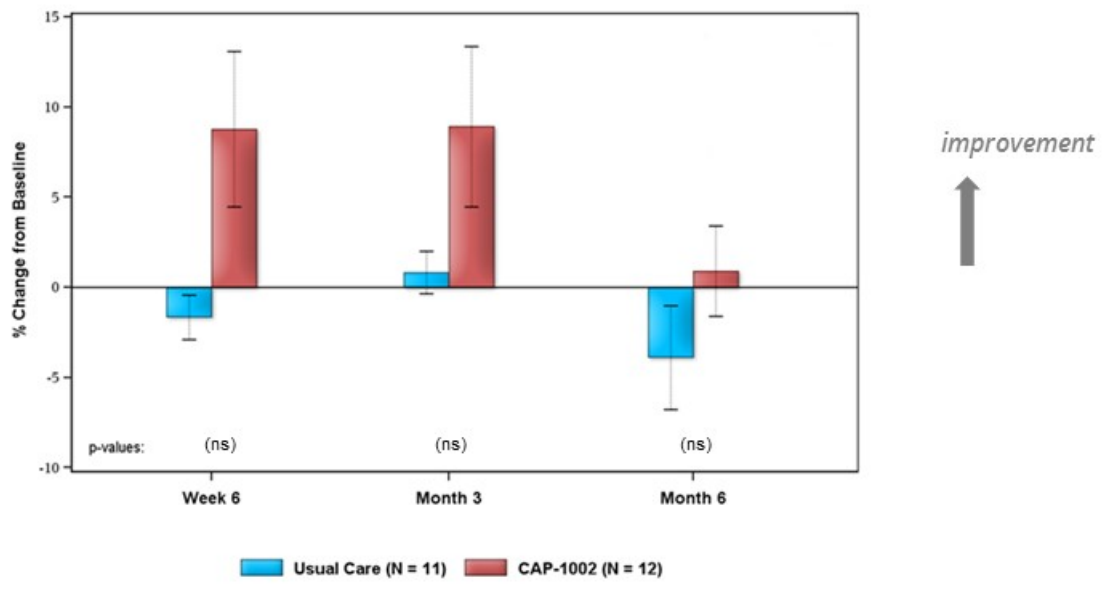


Patients had near-normal ejection fraction and low volumes at baseline

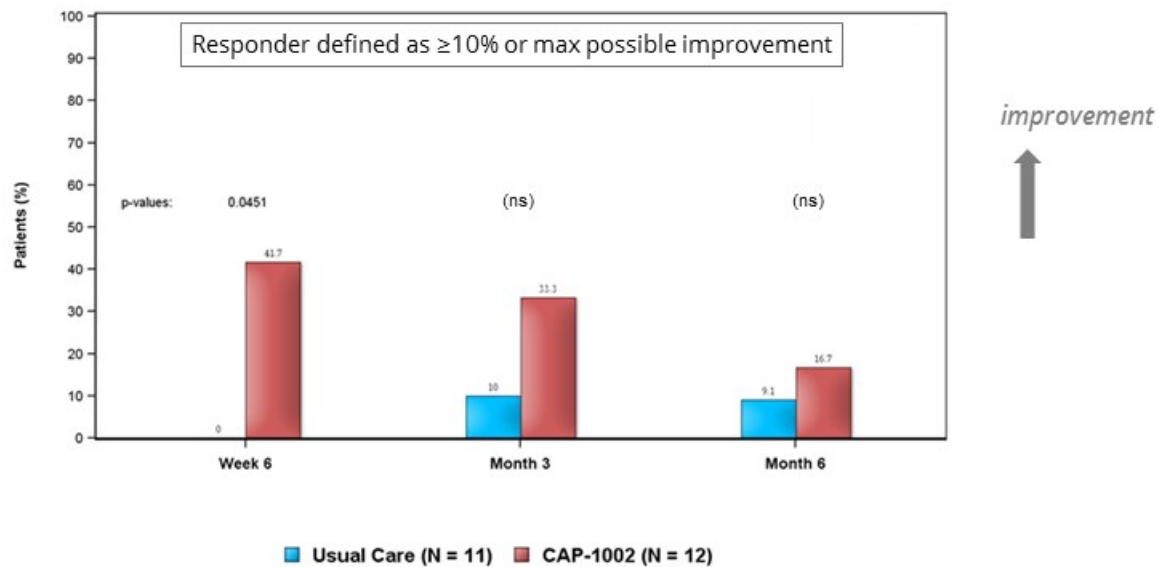


■ Usual Care (N = 11) ■ CAP-1002 (N = 13)

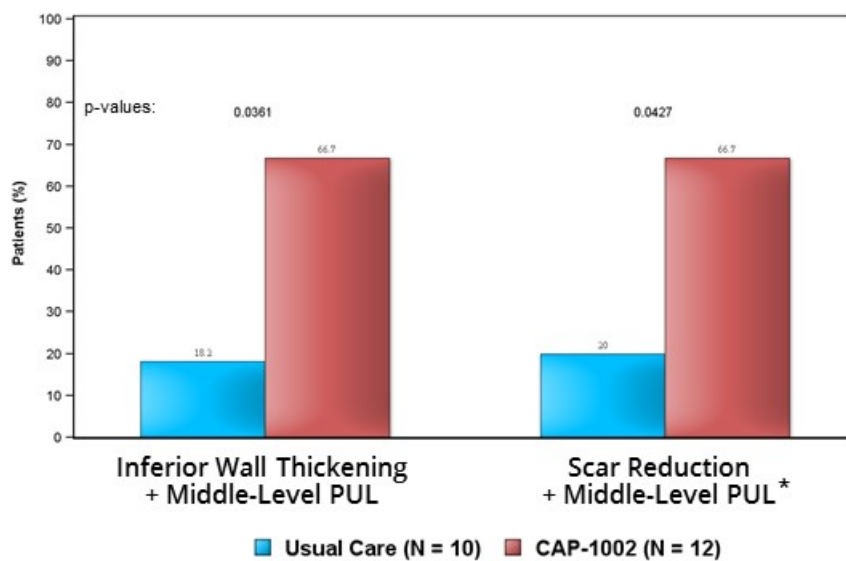




Potential functional improvement in skeletal muscle









Supportive of a treatment effect



- Data support the potential benefit of CAP-1002 to boys and young men with advanced Duchenne muscular dystrophy
- CAP-1002 was generally safe and well-tolerated
- Limited duration of effect following a single dose indicates that sustained benefit will require repeat administration

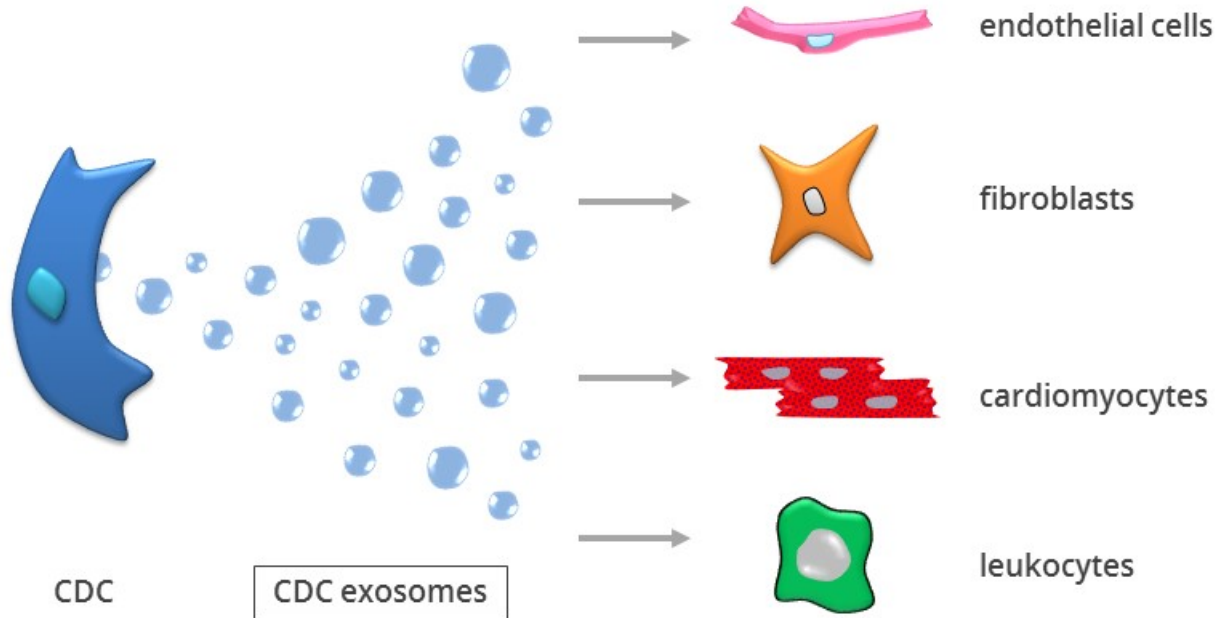
- FDA meeting set for late June to review HOPE data and discuss development toward potential registration
- Plan to apply for Regenerative Medicine Advanced Therapy (RMAT) designation
- **Repeat dosing via intravenous delivery anticipated for next trial**
 - Chronic administration to potentially achieve long-term benefit
 - Systemic delivery supported by studies in several models
 - Plan to initiate in the second half of 2017, subject to regulatory approval

C Sps	CDCs	Wash	Formulate	Fill	CAP-1002
					

- “Off-the-shelf” product
- Expect to be able to generate thousands of doses per donor heart via commercial process in development with Janssen Biotech
- 3-year storage life

Exosome Program

“Next-Gen” Class of Biological Therapies



Cash and cash equivalents*	\$11.7 million	(as of 3/31/17)
Shares outstanding	22.6 million	(as of May 12, 2017)

*\$3.7 million raised in May 2017 PIPE offering.

Capricor has received over \$30 million in competitive grant and loan awards from:

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

Clinical Programs

CAP-1002 in Duchenne Muscular Dystrophy

- ✓ **April 2017:** Reported top-line six-month results of HOPE trial
- Late June 2017:** Type B meeting with FDA scheduled
- 2H 2017:** Plan to initiate clinical trial of repeat-dose, intravenous CAP-1002*

CAP-1002 in Adult Heart Disease

- ✓ **May 2017:** Announced interim analysis of ALLSTAR six-month data
- ✓ **May 2017:** Delivered ALLSTAR data dossier to Janssen
- ✓ **June 2017:** Began transition of all patients in ALLSTAR to long-term follow-up

Preclinical

CAP-2003

- 2018:** Expect to submit IND for inflammatory disorder