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)

May 3, 2018

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 May 3, 2018, 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 May 3, 2018.

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: May 3, 2018

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

Exhibit 99.1

NASDAQ: CAPR

May 2018

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, 2017 as filed with the Securities and Exchange Commission on March 22, 2018, 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. 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's Mission

Capricor is ***focused*** on the discovery, *development* and commercialization of ***innovative cell*** and ***exosome*** based ***therapies*** for patients with ***immune-inflammatory*** rare diseases with a focus on ***Duchenne muscular dystrophy.***

Corporate Highlights

Innovative, Proprietary Therapeutic Platforms	▪ First-in-class biologics with potential to improve cardiac and skeletal muscle ▪ Product candidates based on cells and extracellular vesicles (exosomes)
Advanced Pipeline	▪ Enrolling HOPE-2, potential registration trial in DMD ▪ Commercial manufacturing process in development ▪ Positive proof-of-concept clinical data in DMD
Strong Scientific Foundation & Leadership Team	▪ Translational approach to product development built upon the research of leading academic scientists ▪ Technology initially developed at Johns Hopkins University ▪ Management has deep domain expertise ▪ Extensive IP portfolio for core technologies
Capital Efficiency	▪ Raised over $50M to date in equity ▪ Successful record of securing non-dilutive funding, over $45M to date
Regulatory Pathway	▪ Granted orphan drug and rare pediatric designations ▪ Granted RMAT designation

Capricor's Product Pipeline

Candidate	Indication	Development Phase			Status
		Preclinical	Clinical	Market	
CAP-1002 (allogeneic CDCs)	**Duchenne Muscular Dystrophy**				▪ HOPE-2 trial enrolling ▪ Improvement in skeletal and cardiac muscle function seen in randomized clinical trial in advanced DMD ▪ Orphan Drug, Rare Pediatric Disease and RMAT Designations
CAP-2003 (CDC-exosomes)	**Hypoplastic Left Heart Syndrome**				▪ Awarded NIH grant of up to $4.2M
	Inflammatory Disorders				▪ Exploring potential indications

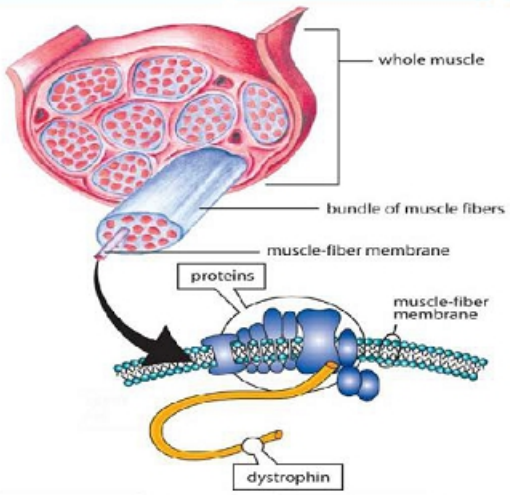
CAP-1002 is an Investigational New Drug and is not approved for any indications.
CAP-2003, Capricor's exosomes technology, has not yet been approved for clinical investigation.

CDCs = cardiosphere-derived cells

CAP-1002: Duchenne Muscular Dystrophy Program

- X-linked genetic disorder
- Incidence: ~1 per 3,600 male births
- Prevalence: US: ~15,000-20,000, WW: ~200,000

Lack of Dystrophin Predisposes Muscle to Damage



- Dystrophin is a structural protein in muscle
- Acts both as a cushion and a kind of glue
- Without dystrophin, muscles are unable to function properly, suffer progressive damage and eventually die
- **Much of the muscle injury that occurs in dystrophin-deficiency is attributable to secondary damage caused by an immune response to the necrotic cells**

Functional decline of ambulation in childhood → Loss of walking ability by early teenage years → Functional decline of arm function in adolescence → Ventilatory support required by late teens → Average life expectancy of less than 30 years

Treatment Options for DMD are Limited

- Exon Skipping
- Gene therapy
- Utrophin
- NF-kB
- Steroids

Challenges

- EXONDYS 51 –13% of DMD population
- Gene therapy not always effective due to antibody response
- Steroids have adverse long term side-effects
- NF-kB inhibition may not be enough to mediate immune response

CAP-1002

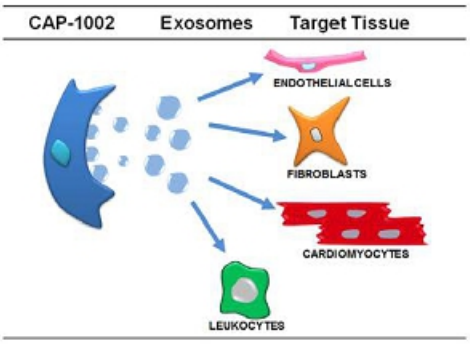
- Immunomodulatory
- Anti-fibrotic
- Pro-angiogenic
- Pro-regenerative
- Cellular Energy

We believe CAP-1002 may be used synergistically with other therapeutics aimed to treat the underlying genetic mutation with DMD

Capricor's CAP-1002 Technology

– CAP-1002 is a biologic 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**
- MOA: cells secrete exosomes
  - Contain non-coding RNAs and proteins
  - Internalized by target cells
  - Stimulate diverse and lasting changes in cellular behavior



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

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"

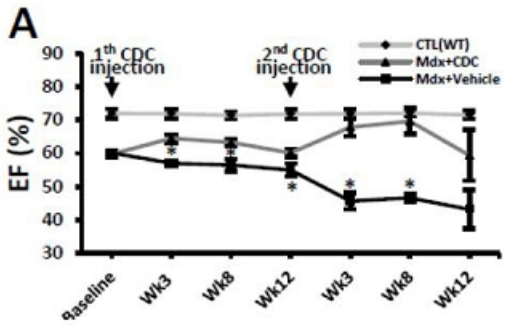
Circulation. 2015;131:1590-1598.

- 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

Effects of CDCs in mdx Mouse Model

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

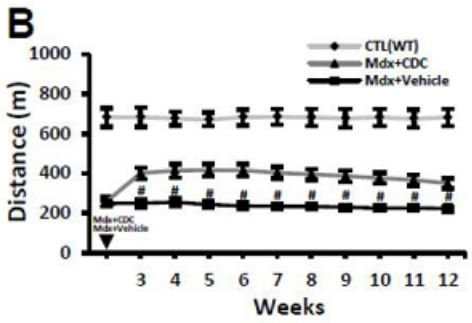
Improved cardiac function



- 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

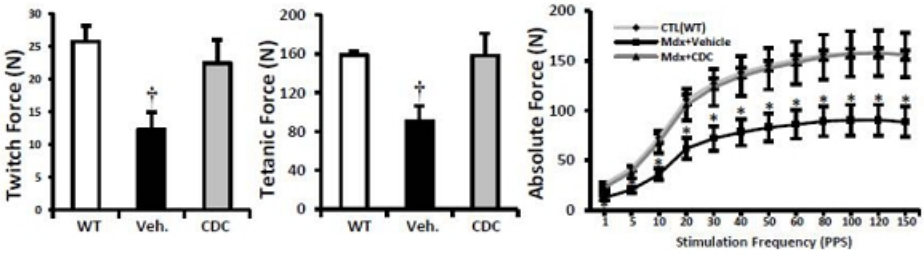
  (p<0.005 at all timepoints through 12 weeks of follow-up)

Aminzadeh et al, Stem Cell Reports 2018 (http://www.cell.com/stem-cell-reports/fulltext/S2213-6711(18)30049-3). 11

Effects of CDCs in mdx Mouse Model

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

Enhanced skeletal muscle function

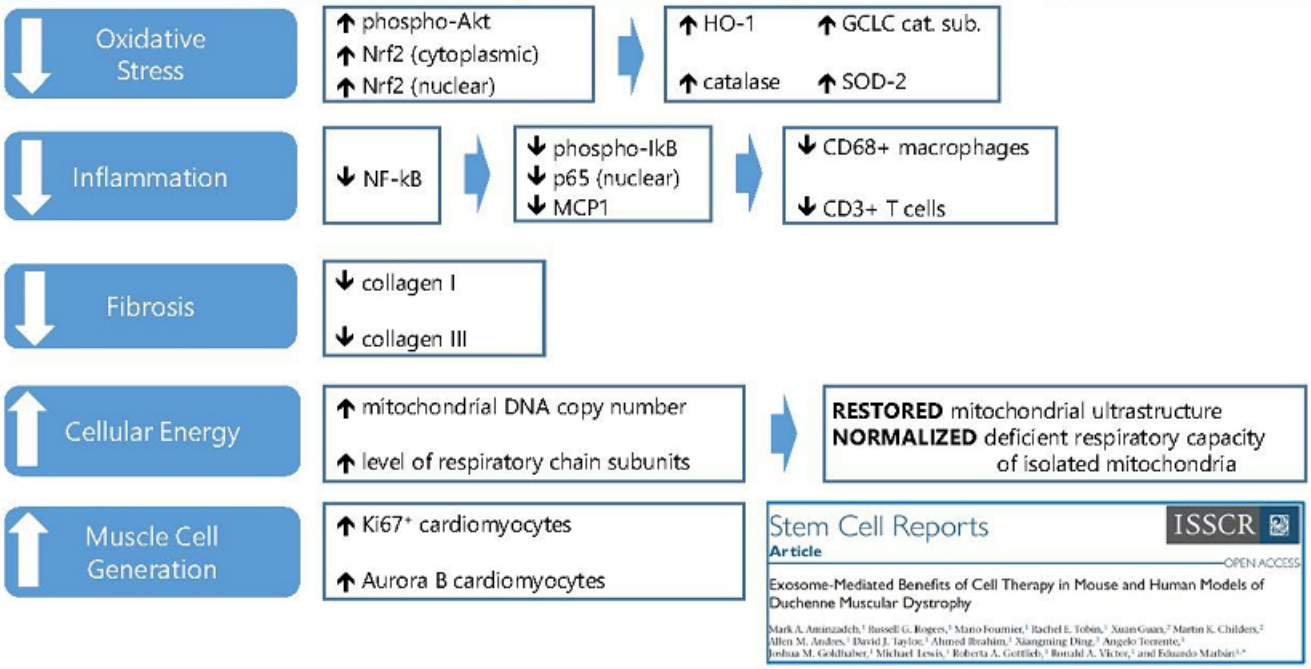


- Twitch force, tetanic force, and fibrosis in soleus (slow-twitch) and extensor digitorum longus (fast-twitch) muscles significantly improved vs. control

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

Aminzadeh et al, Stem Cell Reports 2018 (http://www.cell.com/stem-cell-reports/fulltext/S2213-6711(18)30049-3). 12

Mechanism of Action Defined in *"Stem Cell Reports"*



Stem Cell Reports
ISSCR
Article
OPEN ACCESS
Exosome-Mediated Benefits of Cell Therapy in Mouse and Human Models of Duchenne Muscular Dystrophy
Mark A. Aminzadeh,[1] Russell G. Rogers,[1] Mario Fournier,[1] Rachel E. Tobin,[1] Xuan Guan,[2] Martin K. Childers,[2] Allen M. Andres,[1] David J. Taylor,[1] Ahmed Ibrahim,[1] Xiangming Ding,[3] Angelo Torrente,[3] Joshua M. Goldhaber,[1] Michael Lewis,[1] Roberta A. Gottlieb,[4] Ronald A. Victor,[1] and Eduardo Marbán[1,*]

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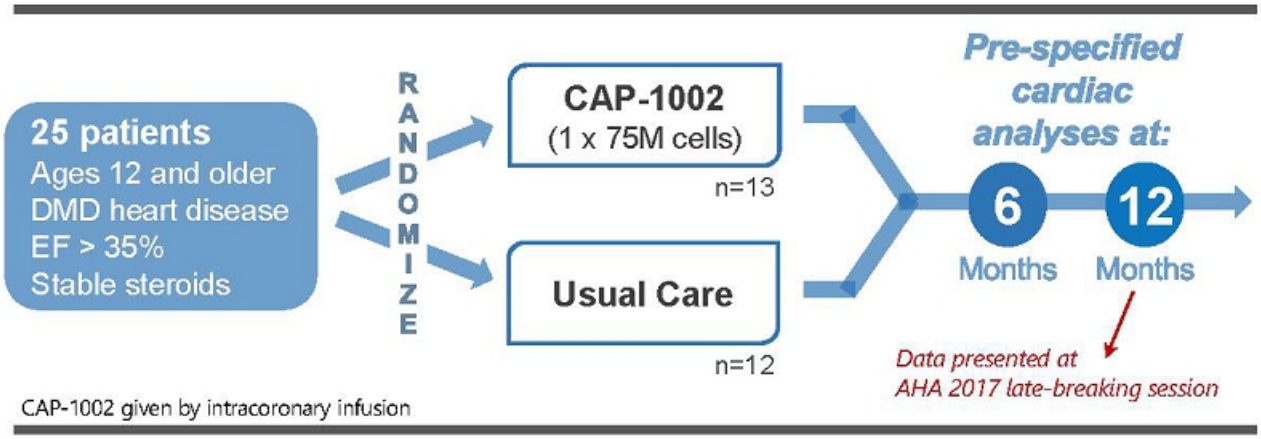
*CDCs have been the subject of > 100 peer-reviewed papers since 2007

Aminzadeh et al, Stem Cell Reports 2018. 13

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

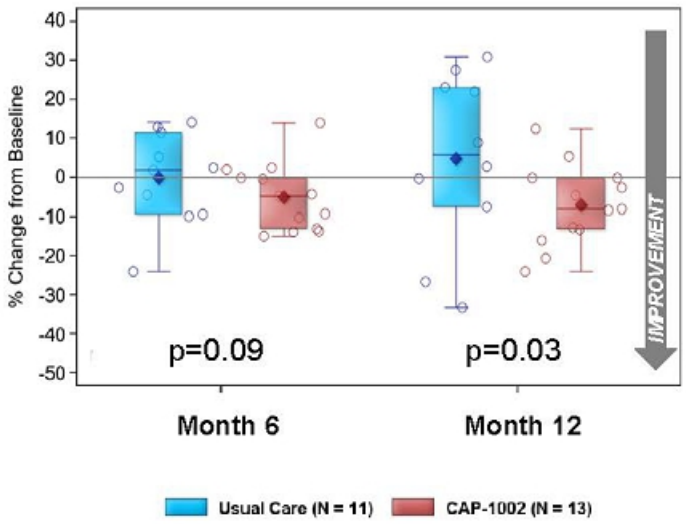
Baseline Characteristics

	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

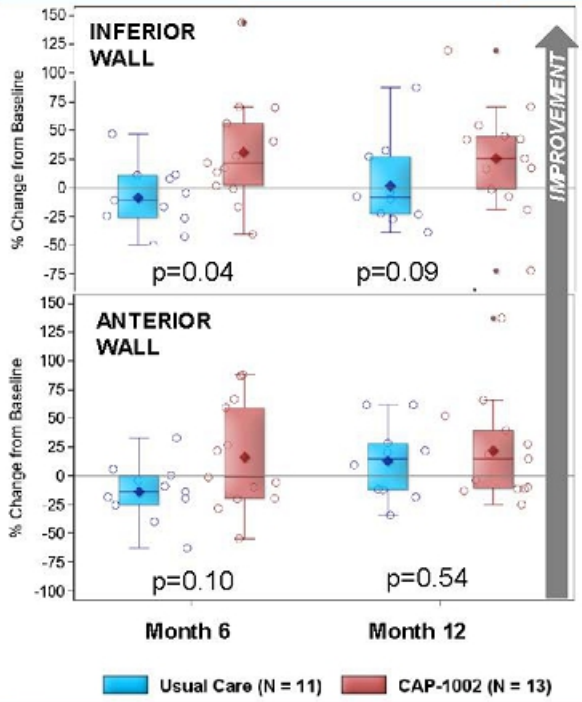
Heart Muscle: Reduced Myocardial Scarring



- 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

*p-values are based on absolute change from baseline

Heart Muscle: Increased Regional Systolic Wall Thickening



- Measurement of cardiac function by MRI allows focus on treated areas
- Magnitude of scar reduction is consistent with natural history of scar progression in DMD
  - Inferior → Anterior → Lateral → Septal
- Measure is important indicator of overall cardiac function in DMD

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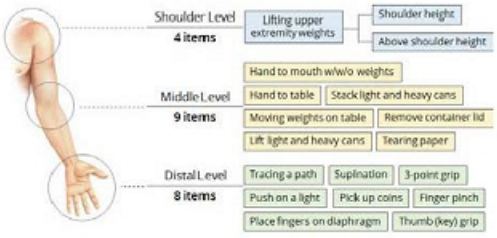
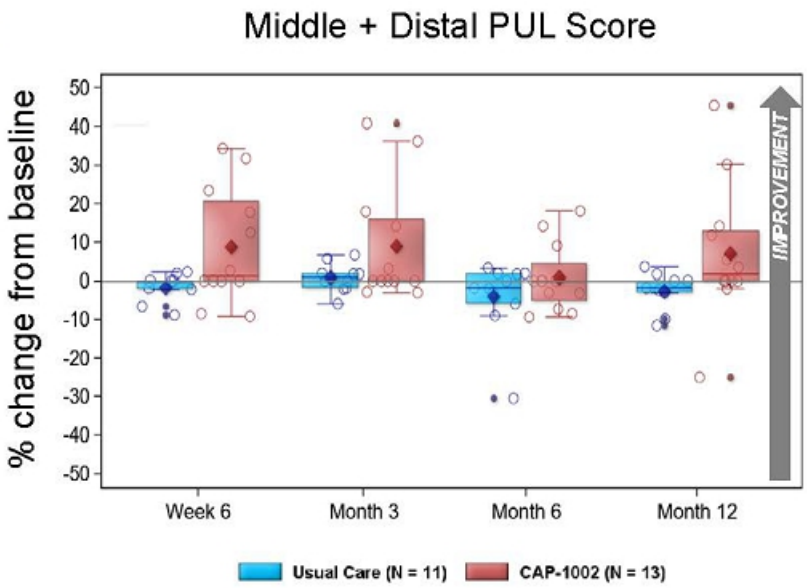
*p-values are based on absolute change from baseline

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



HOPE-2 Clinical Trial of CAP-1002 in DMD

- HOPE-2 – currently enrolling
  - 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-Duchenne Phase I/II data
- Granted RMAT designation

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
- Previous 3-year collaboration with Janssen Biotech focused on chemistry, manufacturing and controls (CMC)

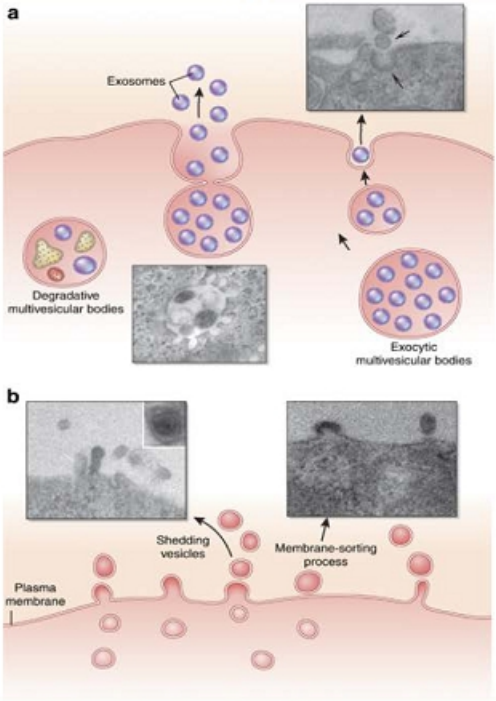
Exosomes (CAP-2003)
A New Regenerative Medicine Platform

Potential Benefits of Exosomes vs. Cells

- Extended shelf life (lyophilize)
- Penetrate cells and tissues not readily accessed by cells
- Reduced manufacturing costs

Extracellular Vesicles (Exosomes): Cell Free Regenerative Medicine

- Extracellular vesicles - term for cell-derived vesicles, includes exosomes
- Nanometer-sized lipid-bilayer vesicles
- Rich in RNAs and proteins
- Secreted by nearly all cell types
- Cell signaling modality
- Potential for broad therapeutic applicability
- **IP**: Exclusive world-wide license agreement with Cedars-Sinai Medical Center for IP rights related to the exosomes technology originating from cardiosphere-derived cells (CDCs)



Capricor Therapeutics

Kidney International (2010) **78**, 838–848

Senior Management

Linda Marbán, PhD
Chief Executive Officer, Co-founder and Director

Under her direction, Capricor has secured over $45 million in non-dilutive funding and over $50 million in equity capital. Earlier in her career, Dr. Marbán was with Exigen, Inc. where she was responsible for business development and operations supervising the development of gene therapy products in a joint development agreement with Genzyme Corp. Dr. Marbán began her career at the Cleveland Clinic Foundation working on the biophysical properties of cardiac muscle. That work continued when she moved to a postdoctoral fellowship at Johns Hopkins University. While at JHU, she advanced to the rank of Research Assistant Professor in the Department of Pediatrics, continuing her work on the mechanism of contractile dysfunction in heart failure. Dr. Marbán earned a Ph.D. from Case Western Reserve University in cardiac physiology.

Deborah Ascheim, MD
Chief Medical Officer

Previously, she was Professor of Health Policy and Medicine and was the director of the International Center for Health Outcomes and Innovation Research's Clinical Trial Unit at the Icahn School of Medicine at Mount Sinai in New York. Prior to her tenure at Mount Sinai, Dr. Ascheim was on faculty in the Department of Medicine and division of Cardiology at the College of Physicians & Surgeons at Columbia University. Dr. Ascheim received her M.D. from New York University School of medicine and a B.A. from Wellesley College.

Karen Krasney, JD
EVP & General Counsel

Ms. Krasney's career spans over 35 years and has been focused on domestic and international corporate and business law, as well as litigation. Ms. Krasney served as legal counsel of Biosensors International Group Ltd., a multinational medical device company that develops, manufactures and sells medical devices for cardiology applications. Ms. Krasney received her Bachelor of Arts degree from the University of California, Los Angeles and her Juris Doctorate from the University of Southern California.

AJ Bergmann, MBA
Chief Financial Officer

Mr. Bergmann joined Capricor in 2011 and coordinated the Company's reverse merger and financings yielding over $35 million to date. Prior to joining Capricor, Mr. Bergmann had experience in accounting, finance and operations management of various companies. Mr. Bergmann graduated from Providence College and has a M.B.A. from the University of Southern California's Marshall School of Business.

Rachel Smith, PhD
VP of Research & Development

Dr. Smith is a co-inventor of the Cardiosphere technology that forms the core of Capricor's product portfolio. Her research expertise encompasses the areas of stem cell biology, cardiac physiology, electrophysiology, as well as cell and tissue engineering. Dr. Smith obtained her Ph.D. in Biomedical Engineering from Johns Hopkins University She received her undergraduate degree in Biomedical Engineering from Tulane University.

Luis Rodriguez-Borlado, PhD
VP of Regenerative Therapies

Prior to joining Capricor, Dr. Borlado developed a scientific career in academic laboratories in Spain and in The Netherlands studying signal transduction pathways involved in cell transformation and DNA replication. Dr. R-Borlado has a Ph.D in Biochemistry and Molecular Biology from the University Autónoma of Madrid with the study of molecular bases of immune system development.

Jeffrey Rudy
VP of Clinical Operations

He has over 25 years of clinical research and development experience across multiple companies and therapeutic areas. Previously, he was Vice President, Clinical Operations for Celladon, a company investigating SERCA2a enzyme replacement via gene therapy in advanced heart failure Mr. Rudy also held positions at Gilead Science and Amgen. He received his B.S. in Microbiology from The Ohio State University.

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)
Michael Taylor, M.D., Ph.D.	Cincinnati Children's Hospital Medical Center (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)

Current Resources Expected to Fund Operations into 1Q19

Cash and equivalents	**$14.1 million**	(as of Dec. 31, 2017)
Shares outstanding	**27.7 million**	(as of Mar. 20, 2018)

Capricor reported the above information in its most recent Annual Report on Form 10-K filed with the SEC on March 22, 2018.

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

Anticipated Milestones

Recent Accomplishments

Clinical Development
- Announced positive 6 and 12 month data from HOPE-Duchenne
- HOPE-2 IND cleared

Regulatory
- Granted orphan drug designation for DMD
- Granted rare pediatric designation for DMD
- Granted RMAT designation for CAP-1002

Corporate
- Completed ~$9M equity offerings (PIPE and ATM)
- Initiated $14M ATM program in October 2017
- CIRM loan ~$15.7M forgiven

IP
- Key patent awarded for exosomes
- Expanded Cedars-Sinai license for additional IP rights for cells and exosomes

Potential Near Term Catalysts

Pipeline Updates
- Currently enrolling HOPE-2 trial
- Planning to publish HOPE-Duchenne study
- Planning to file IND for exosomes

Manufacturing
- Initiating process scale-up and tech transfer to CMO

Corporate
- Planning key hires in manufacturing and medical teams
- Continue to pursue non-dilutive funding opportunities
- Pursue collaborations with DMD partners