

scPharmaceuticals

**8<sup>th</sup> Annual SVB Leerink Global Healthcare Conference**  
February 28, 2019

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# About scPharmaceuticals

## Advancing patient care and reducing healthcare costs through innovative subcutaneous delivery

- Leveraging approved drugs with well-known efficacy and safety profiles through subcutaneous delivery of hospital-based/in-patient IV drugs
- Two late-stage clinical programs in large markets
  - Heart failure (HF)
    - FUROSCIX® NDA expected 2020
  - Gram-positive and gram-negative infections
    - Ceftriaxone NDA expected 2021
- High barriers to competitive entry
  - Patent family covering drug formulation and methods of treatment expires 2034
- Forecast YE18 cash of approximately \$89M; 2019 quarterly burn of \$8-10M

# FUROSCIX®: Path forward for resubmission

## Collaboration with West Pharmaceutical Services to develop the next-generation FUROSCIX®

- West's SmartDose® technology platform offers patients wearable, subcutaneous injector with an integrated drug delivery system that adheres to the body, for outpatient hands-free administration
- Completed preliminary feasibility studies with SmartDose® drug delivery system
  - Drug stability in pre-filled cartridge
  - Drug compatibility
  - Overall performance within FUROSCIX® delivery specifications
- Expected regulatory pathway - 505(b)(2)
  - Meeting request with the U.S. Food and Drug Administration (FDA) to be submitted by end of 1Q19

SmartDose® and the external product configuration of West's SmartDose® drug delivery platform are the intellectual property of West Pharmaceutical Services, Inc. or one of its subsidiaries, in the United States and other countries.

# New FUROSCIX® delivery system incorporates an easy-to-use On-Body Infusor

Incorporates West's SmartDose® platform technology. This platform technology has been previously approved by FDA and EMEA as part of a combination product

- Fully integrated delivery system
  - Container - Elastomer - Device
- Electromechanical drive
  - Delivery volume up to 10mL
- Pre-programmable injection time
- Patient-centric design
- Wireless connectivity
- Pre-filled cartridge



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# Large unmet need in heart failure

## Lead program targets heart failure: a large global market opportunity with a clear value proposition

- Prevalence of HF is 6.5 million adults in the US<sup>1</sup>
  - 10.5 million adults in the G7<sup>2</sup>
- In the US ~4 million HF events occur annually<sup>3</sup>
- \$8B total addressable market opportunity in the US
- HF patients represent 33% (\$123B) of annual Medicare Part A and B spending<sup>4</sup>
- Potential for significant cost reductions for payers and hospitals
  - Potential to reduce patient hospital admission/readmission rates
- Established reimbursement model
  - Medicare Part B/D—will not require hospital formulary inclusion

1. Circulation 2017, Benjamin 2. Decision Resources 2014 Cardium report, note: G7=US, Germany, France, UK, Italy, Spain, Japan 3. 4M is a calculated field adding 3M hospital admissions and 900K clinician interactions with no hospital intervention; 3M source: Decision Resources HF landscape and Forecast Dec 2016 adjusted HCUP all listed 2014 number down based on chart abstraction, KOL interviews, and ARIC study; 900K source: 1.8M clinician events Circulation 2017, Benjamin and based on scPharma Primary Quantitative Research, 50% of 1.8M office visits are sent directly to the hospital, so 1.8M-900K=900K clinician interactions with no hospital intervention; 15M calculated field: 3M from Decision Resources HF landscape and Forecast Dec 2016 report multiplied by 5.2 days avg LOS based on HCUP 2014 CMS pulled by CCS 108 code 4. Cost Burden of Worsening Heart Failure in the Medicare fee for service population, Milliman, 2017

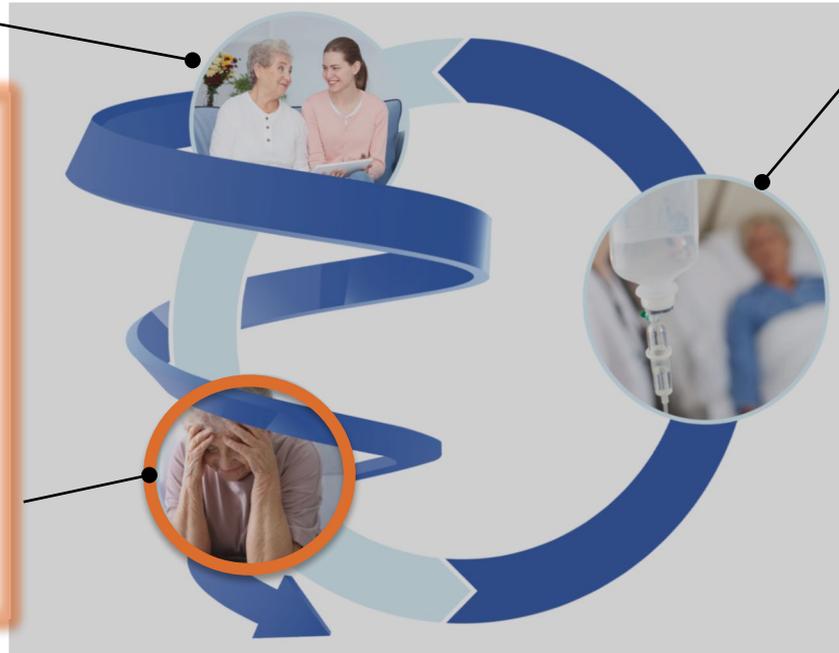
# Cycle of decompensation and hospitalization are the primary burdens for patients suffering from HF

Stable patient treated with oral diuretic

Start of fluid retention - hallmark of HF

Worsening fluid status - oral therapies ↓ efficacy

Decompensation leads to ↓ oral bioavailability



Hospitalized patient treated with IV diuretic

Average length of stay for HF admission is 5.2 days<sup>1</sup>

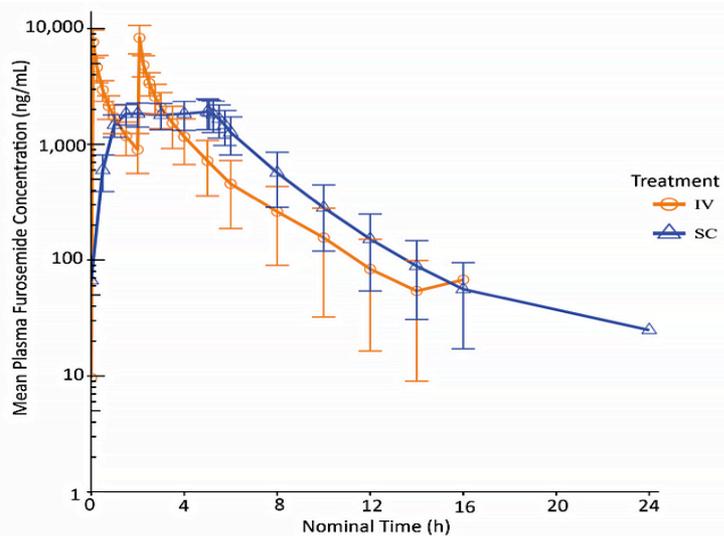
IV furosemide utilized to treat ~90% of HF hospitalizations<sup>2</sup>

High rate of readmissions

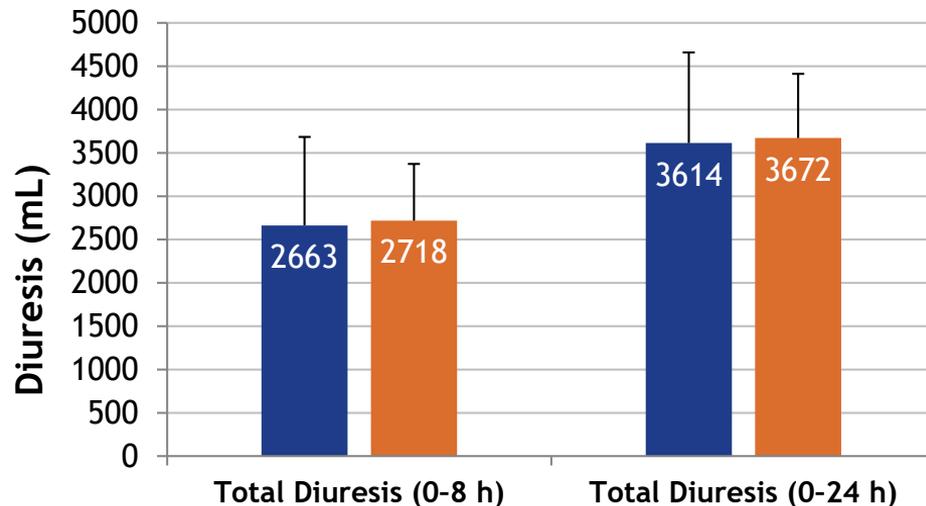
1. HCUP National Inpatient Sample (NIS), 2014, Agency for Healthcare Research and Quality (AHRQ) based on ICD-9 codes  
2. scPharmaceuticals data on file: Decision Resources HF landscape and Forecast December 2016

# scFurosemide—drug exposures and diuresis comparable to IV furosemide

- Administered via B-Braun pump
- Subcutaneous: 80 mg over 5 hours
- Intravenous: 40 mg x 2 doses over 2 hours



Sica, D. A., de Boer, R. A., & Pitt, B. (2018). Subcutaneous Furosemide in Heart Failure: Pharmacokinetic Characteristics of a Newly Buffered Solution. *JACC Basic Transl Sci.* doi:10.1016/j.jacbst.2017.10.001



■ Subcutaneous scFurosemide (n=15)  
■ Intravenous Furosemide (n=15)

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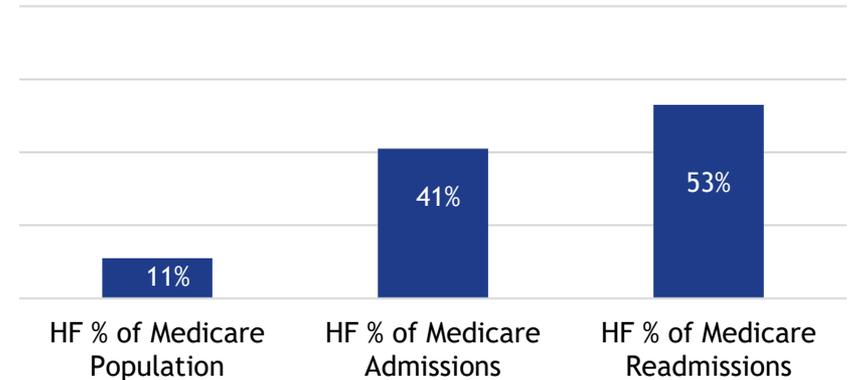
**A New Model of Treating Heart Failure - FUROSCIX®**

# Heart Failure is a large market opportunity with clearly recognized unmet needs

## Heart Failure

- Prevalence of HF in 6.5M adults under care<sup>1</sup>
  - Projected to grow to >8M by 2030<sup>1</sup>
- 33% (\$123B) of total Medicare medical costs<sup>2</sup>
  - \$21B directly attributed to HF treatment<sup>2</sup>
- 52% of costs attributed to in-patient care<sup>2</sup>
- 59% of admissions directly attributed to volume overload<sup>3</sup>

## HF Prevalence and In-Patient Admission



1. Benjamin E, et al. Circulation. 2017;135:e146-e603

2. Fitch K, et al (2017) The cost burden of worsening heart failure in the Medicare fee for service population: an actuarial analysis [white paper]

3. Bennett S, et al. American Journal of Crit Care. 1998;7(3):168-174

# Stakeholders are aligned on the need to reduce the number of HF hospitalizations and treatment costs



## Payer

- Average cost of hospitalization (HF DRG) is \$11,840<sup>1</sup>
- HF is top condition targeted by CMS readmission reduction initiative<sup>2</sup>
- HF will be moving to Medicare Quality Payment Program in 2019<sup>3</sup>



## Hospital and HCP

- Average length of stay is 5.2<sup>4</sup> days with DRG only reimbursing 3.9 days<sup>5</sup>
- Increased financial exposure for providers based on readmission penalty risk
- HF in-patient care represents multi-million dollar loss for targeted hospitals

1. Fitch K, et al (2017) The cost burden of worsening heart failure in the Medicare fee for service population: an actuarial analysis [white paper]

2. Readmission Reduction Program (HRRP) (updated 2018, April 27) Retrieved from <https://www.cms.gov/medicare/medicare-fee-for-service-payment/acuteinpatientpps/readmissions-reduction-program.html>

3. Quality Payment Program from CMS <https://qpp.cms.gov/>

4. Agency for Healthcare Research and Quality (AHRQ). HCUP National Inpatient Sample (NIS), 2014

5. scPharmaceuticals. Data on File. CMS. 2014 data based on DRGs, Table 5: List of MS-DRGs, relative weighting factors and geometric and arithmetic mean length of stay

# Target patient is well identified and represents a large outpatient opportunity

## 1. Hospital-based Events—3M<sup>1</sup>

Hospitalization

IV furosemide

 **FUROSCIX**<sup>®</sup>  
(furosemide injection)



**Go Home**  
Avoid readmission

## 2. Clinic-based Events—1.8M<sup>2</sup>

Clinician Intervention

Increase or Change Diuretic

 **FUROSCIX**<sup>®</sup>  
(furosemide injection)

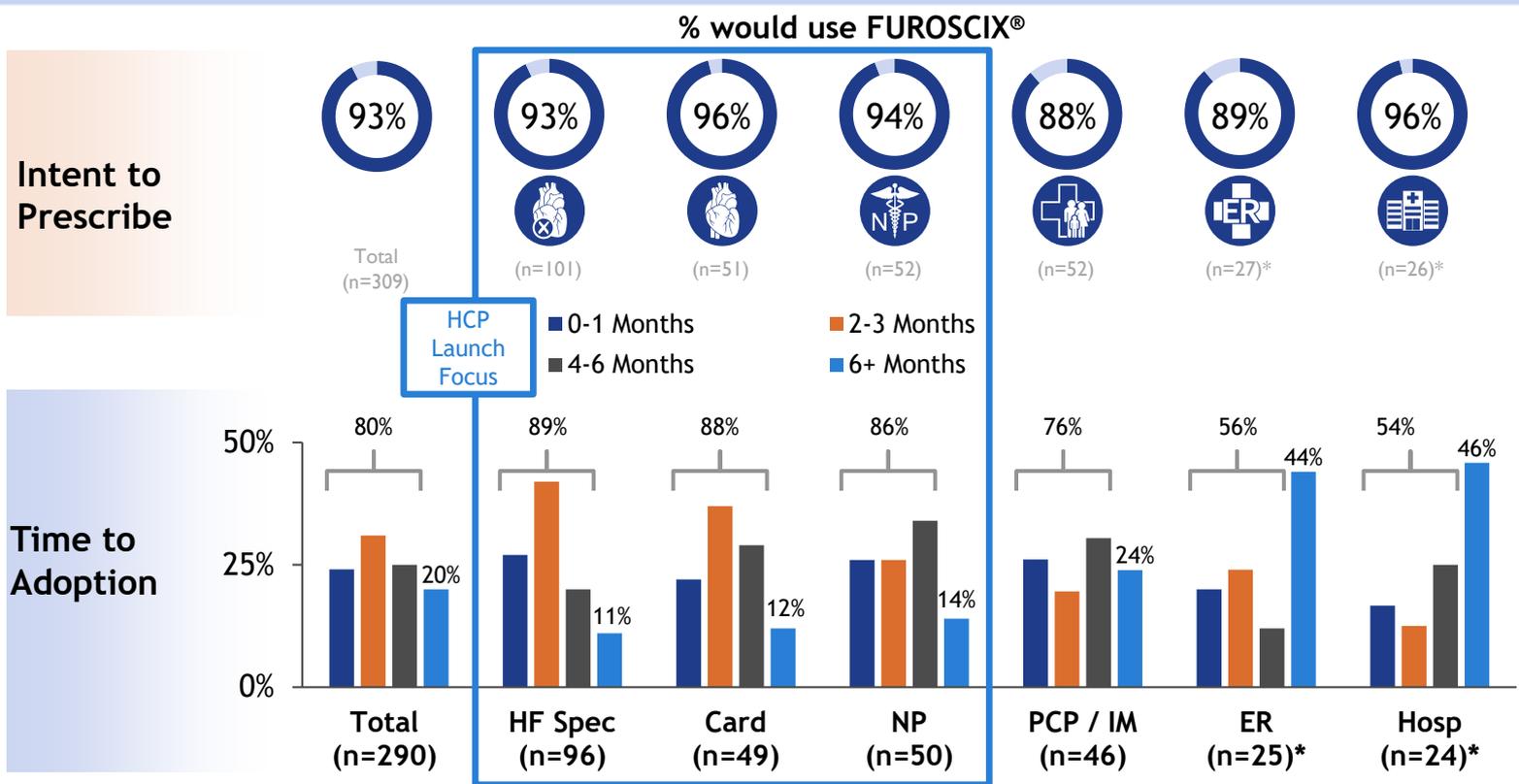


**Stay Home**  
Avoid admission  
Avoid readmission

1. Decision Resources HF landscape and Forecast Dec 2016 adjusted HCUP all listed 2014 number down based on chart abstraction, KOL interviews, and ARIC study

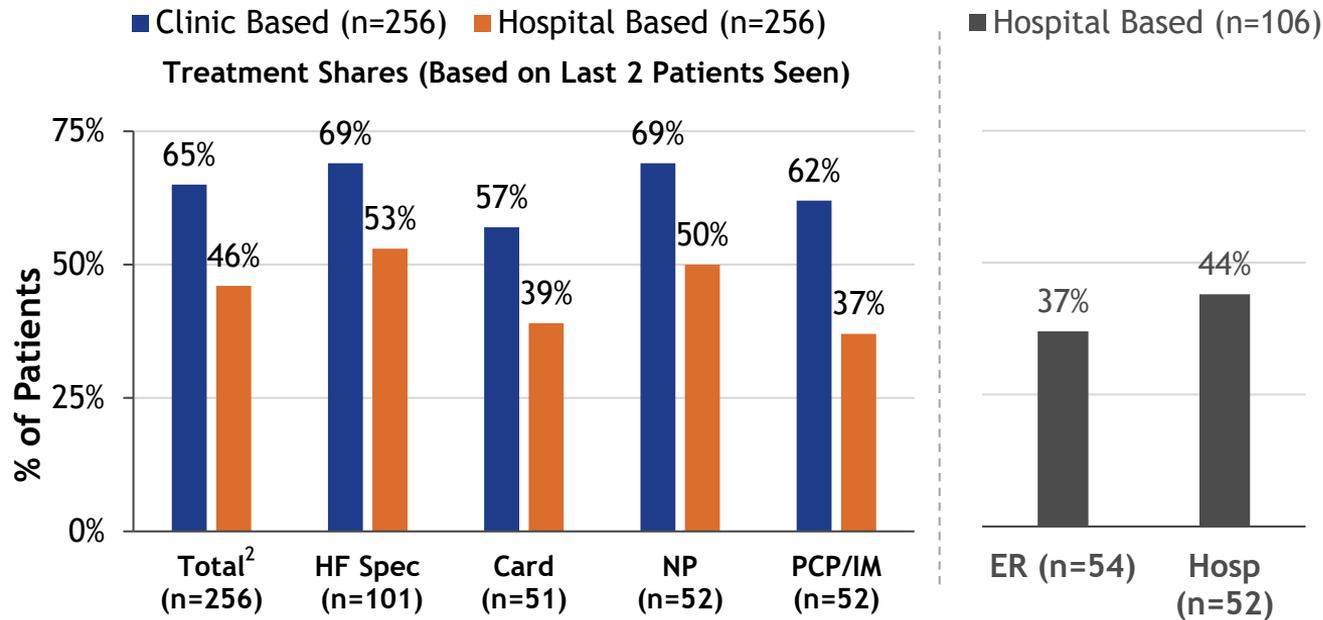
2. Benjamin E, et al. Circulation. 2017;135:e146-e603

# HCPs have a high willingness to prescribe FUROSCIX® and a rapid time to adoption



1. scPharmaceuticals data on file: Reason Research quantitative study (n=309 HCPs)

# FUROSCIX® HCP research—treatment share<sup>1</sup>

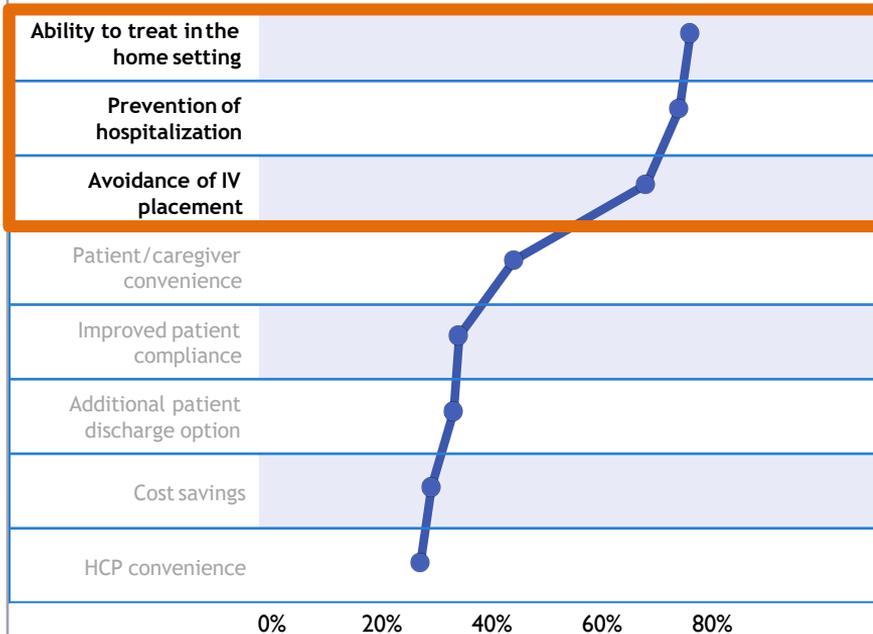


1. scPharmaceuticals data on file: Reason Research quantitative study (n=309 HCPs)

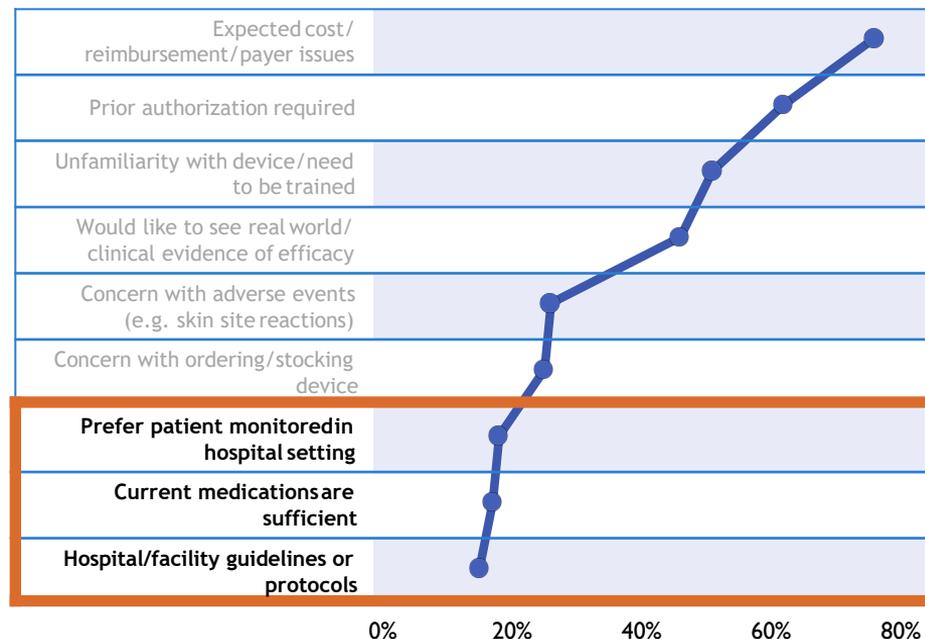
2. Total = HF Spec, Card, NP and PCP/IM patients; No ER or Hospitalist/ER and Hospitalists were only asked about their last 2 patients, while HF Spec, Cards, NPs, and PCP/IM were asked for their last pre-acute and last post-acute patient/Q71. Assume Product X were available (without insurance coverage issues) for long enough for you to begin prescribing. If you were to treat adult patients with fluid overload with the same characteristics as your last Pre-Acute Patient and your last Post-Acute Patient/Patient 1 and Patient 2, would you change your previous treatment choice to Product X?

# HCPs clearly identify advantages of FUROSCIX® and believe it has the ability to improve HF treatment

## What are the advantages of FUROSCIX®?



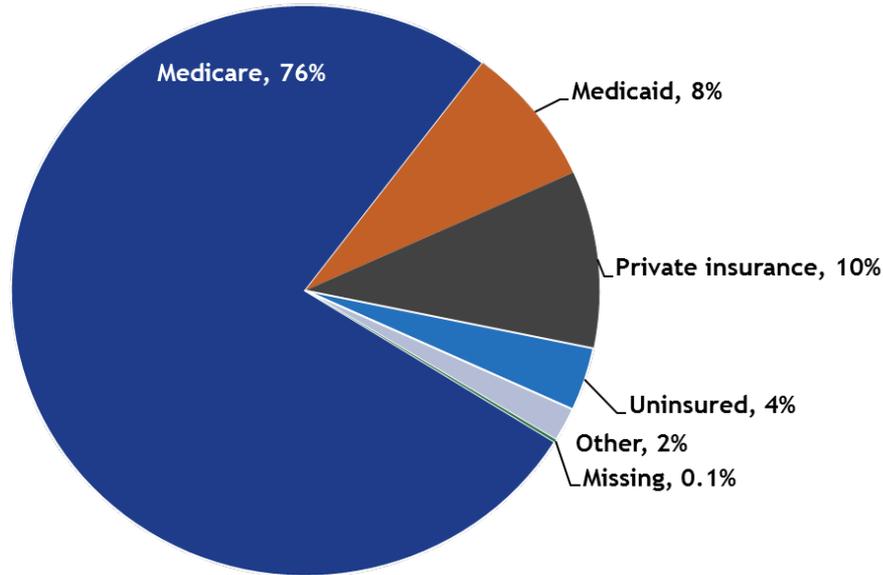
## What are the barriers to adopting FUROSCIX®?



Reason Research Quantitative study (n=309 HCPs)

# FUROSCIX® provides a clear value proposition to Medicare that will facilitate unrestricted market access

HF Payer Mix



## FUROSCIX® Value

Reduction in PMPM costs when FUROSCIX® is utilized

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**Anti-infective Program**

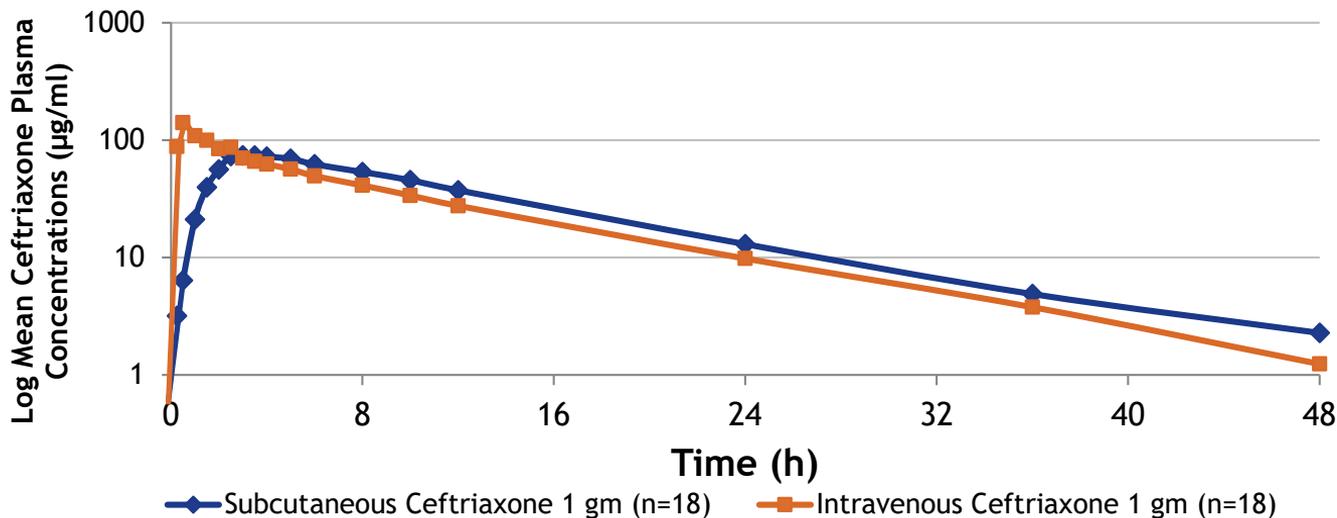
# Anti-infective commercial summary

- Clinical and economic value proposition
  - Reduce need for IV access/eliminate PICC lines
  - Oral agents available at discharge are suboptimal to IV therapy
- The potential main source of business is hospital discharge
  - Majority of Outpatient Antimicrobial Therapy (OPAT) days result from a hospitalization
  - Ability to reduce LOS and provide Medicare patients with home option
- 15M days of outpatient ceftriaxone therapy<sup>1</sup> annually
  - Several additional candidates identified

1. IMS kg Ceftriaxone data

# Pivotal study confirms scCeftriaxone comparable to IV

- Similar drug exposures (AUC 0-∞) between IV ceftriaxone and scCeftriaxone
- Complete bioavailability (107.7%) with subcutaneous administration
- Pharmacodynamic profile (%T>MIC24) of scCeftriaxone is non-inferior to IV infusion



US NDA submission expected 2021

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## Corporate Summary

# scPharmaceuticals senior management & board of directors

**John H. Tucker**

PRESIDENT AND CHIEF EXECUTIVE OFFICER

**Troy Ignelzi**

CHIEF FINANCIAL OFFICER

**Michael Hassman**

SENIOR VICE PRESIDENT, MANUFACTURING AND TECHNICAL OPERATIONS

**John Mohr, Pharm. D.**

SENIOR VICE PRESIDENT, CLINICAL DEVELOPMENT AND MEDICAL AFFAIRS

**Rachael Nokes**

SENIOR VICE PRESIDENT, FINANCE

## Board of Directors

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Lundbeckfond Ventures

**Minnie Baylor-Henry**

B-Henry & Associates, J&J

**Dorothy Coleman**

EVP & CFO, Excellus BCBS

**Mason Freeman, MD**

MGH & 5AM Ventures

**Fred Hudson**

Former partner, KPMG

**Jack Khattar**

Supernus Pharmaceuticals

**Leonard Schaeffer**

Founding Chairman & CEO, WellPoint

**Klaus Veitinger**

OrbiMed Advisors

**John H. Tucker**

CEO, scPharmaceuticals

# Opportunity summary

- Large global market opportunity
- Clear value proposition
- Established reimbursement model
- 505(b)(2) regulatory pathway
- High barriers to entry

**Alignment of patients/caregivers, HCPs and payers in a life science innovation that can transform and reduce cost of care**

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**Thank you**

# SmartDose® : The Next-Generation FUROSCIX® Infusor

## New FUROSCIX® delivery system incorporates an easy to use patient-centric wearable device

- FDA-approved, commercially available proprietary platform
  - Self-administered
  - Easy to use and intuitive design
  - Pre-filled cartridge
  - Visual, tactile and audible feedback to boost user confidence
- SmartDose® design will allow heart failure patients to self-load and pre-program the device to deliver FUROSCIX® in accordance with their prescribed treatment
  - Facilitates customized, pre-scheduled delivery times
    - Adheres to the patient's body, enabling the patients to be hands-free during administration
  - Will use Gen. II Smartdose® device, which can deliver up to 3.5mL of FUROSCIX®
  - Onboarding and training solutions ensure that patients know how to properly set up the device
- First combination product that incorporated Smartdose® technology, the Repatha® *Pushtronex*<sup>tm</sup> system, was approved by FDA and EMEA in 2016 with Amgen
  - Single-dose administration option for Amgen's Repatha® for treatment of high cholesterol allowed Repatha® to become first and only PCSK9 inhibitor to offer monthly single-dose delivery option

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