

TURNING PATIENT CARE  
**INSIDE**OUT



Piper Jaffray 31<sup>st</sup> Annual  
Healthcare Conference

December 5, 2019

scPharmaceuticals

*Innovative outpatient solutions that  
bring care closer to home*

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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 programs in large markets utilizing 505(b)(2) pathway
  - Heart failure (HF)
    - FUROSCIX® NDA expected 2020
  - Broad spectrum antibiotics
    - Ceftriaxone NDA expected 2021
- High barriers to competitive entry
  - Patent coverage of drug formulation and methods of treatment until 2034
- Ended 3Q19 with cash of \$83.7; 2019 quarterly burn of \$8-10M

# scPharmaceuticals Senior Management & Board of Directors

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# Large unmet need in HF

## Lead program targets HF — a large global market opportunity with a clear value proposition

- Prevalence of HF is 6.5 million adults in the US<sup>1</sup> and 10.5 million adults in the G7<sup>2</sup>
- In the US ~3.8 million HF events occur annually<sup>1,3</sup>
  - Congestion is the most common reason for hospitalization and patients seeking medical care<sup>4</sup>
- \$8B total addressable market opportunity in the US
- HF patients represent 33% (\$123B) of annual Medicare Part A and B spending<sup>5</sup>
- Potential for significant cost reductions for payers and hospitals by reducing patient hospital admission/readmission rates

1. Benjamin, et al. Circulation 2018; 137(12):e67-e492. 2. Decision Resources 2014 Cardium report, note: G7=US, Germany, France, UK, Italy, Spain, Japan 3. Data on file. scPharmaceuticals, Burlington, MA. 4. Mullens W, et al. Eur J Heart Fail 2019; 21(2):137-155. 5. Fitch, et al. Cost Burden of Worsening Heart Failure in the Medicare fee for service population, Milliman, 2017. <http://us.milliman.com/insight/2017/The-cost-burden-of-worsening-heart-failure-in-the-Medicare-fee-for-service-population-An-actuarial-analysis/>

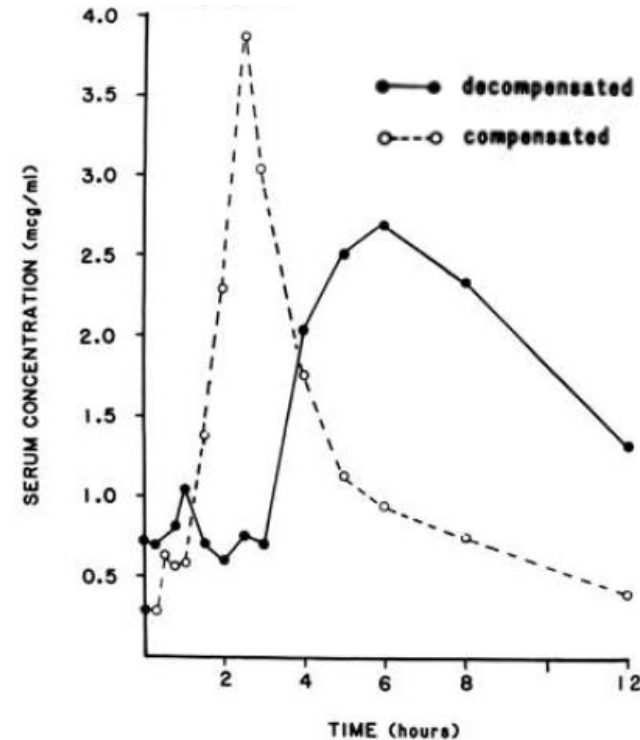
# Cycle of decompensation and hospitalization is the primary burden for patients suffering from HF



1. HCUP National Inpatient Sample (NIS), 2014, Agency for Healthcare Research and Quality (AHRQ) based on ICD-9 codes 2. Data on file. scPharmaceuticals, Burlington, MA.

# Reduced oral absorption of furosemide in decompensated congestive heart failure<sup>1</sup>

- Delayed absorption time
- Reduced peak serum levels
- Guidelines recommend IV loop diuretics for acute HF<sup>2</sup>
  - Gut edema

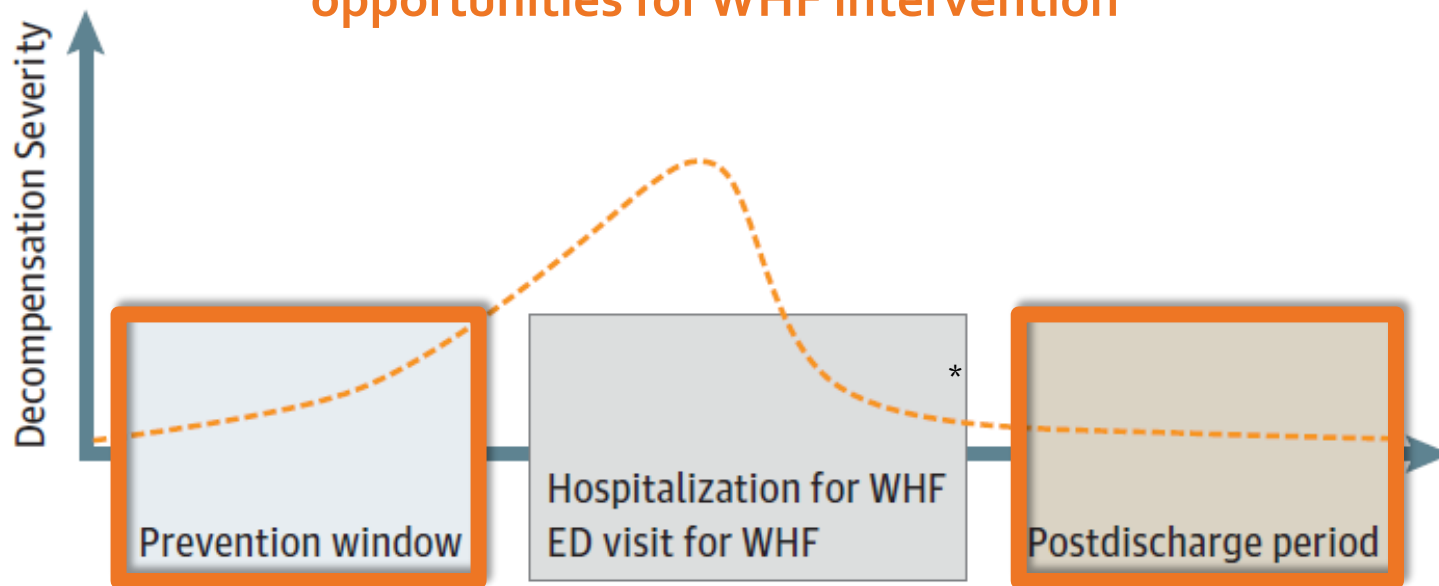


Representative serum concentration time profile after oral administration of 160 mg furosemide

1. Vasko MR, et al. Ann Int Med. 1985;102(3):314-8. 2. Mullens W, et al. Eur J of Heart Fail. 2019;21(2):137-55.

# Primary opportunities for intervening in worsening HF

Pre-admission and post-discharge are targeted opportunities for WHF intervention



\*WHF: Worsening Heart Failure

Greene SJ, et al. JAMA Cardiol. 2018;3(3):3029-3039.



# A New Model of Treating Heart Failure — FUROSCIX<sup>®</sup>

# FUROSCIX — a subcutaneous formulation of furosemide

## Enabling IV-equivalent diuresis at home

- Drug: FUROSCIX
  - Proprietary formulation of furosemide
    - Furosemide is the most widely used oral and parenteral diuretic in treatment of edema associated with congestive heart failure
    - Physiologic pH formulation enables subcutaneous administration; eliminates skin irritation
- Device: On-Body Infusor
  - SmartDose® Gen II 10 mL on-body delivery system
  - Developed to deliver fixed dose of 80mg of scFurosemide subcutaneously through a pre-programmed, biphasic delivery profile with 30 mg administered over the first hour, followed by 12.5 mg/hour for the subsequent 4 hours
  - Pre-filled, Crystal Zenith® cartridge

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.

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

## Incorporates West Pharmaceutical Services, Inc.'s (West) SmartDose platform technology

*This platform technology has been previously approved by FDA and EMEA as part of a combination product*

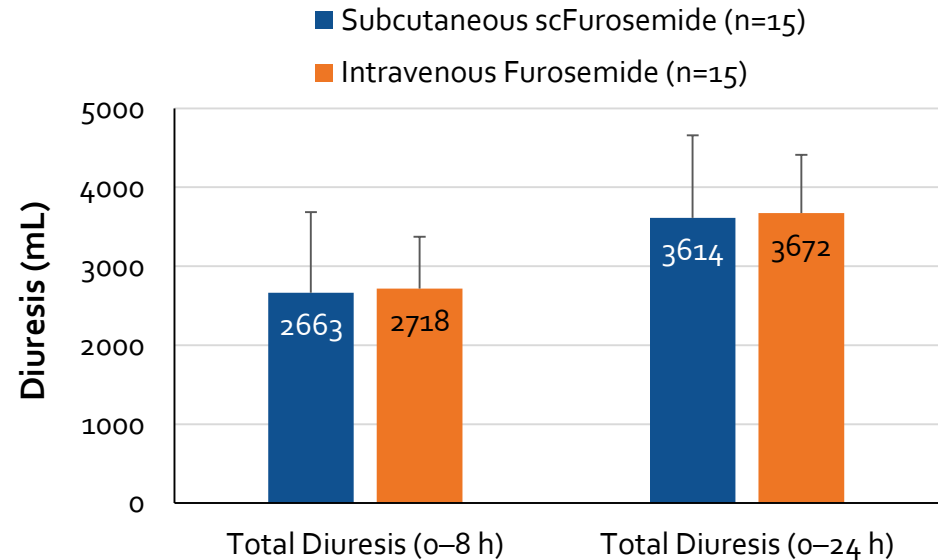
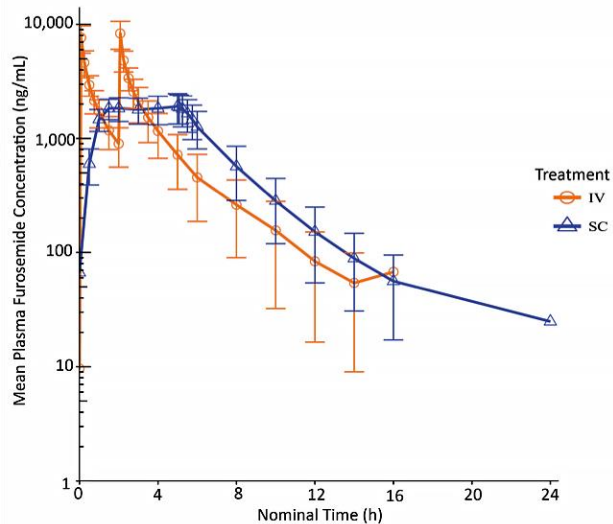
- Single-use, pre-filled cartridge
- Visual, tactile, and audible feedback
- Electromechanical drive
  - Delivery volume up to 10mL
- Pre-programmable injection time
- Patient-centric design
- Wireless connectivity



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.

# Subcutaneous furosemide drug exposures and diuresis observed to be comparable to IV furosemide

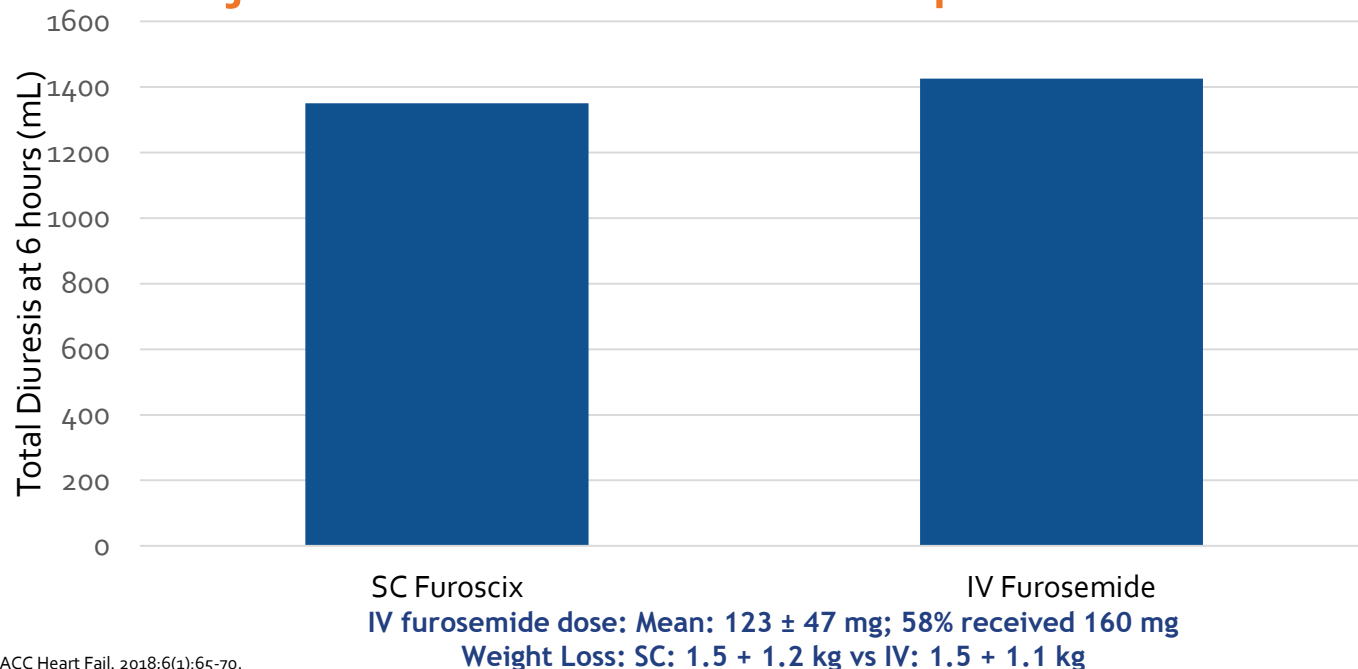
- Subcutaneous: 80 mg over 5 hours
- Intravenous: 40 mg x 2 doses over 2 hours



**Absolute bioavailability: 99.6% (90% CI: 94.8-104.8%)**

# FUROSCIX pharmacodynamics are IV equivalent

SC infusion of FUROSCIX produced comparable pharmacodynamics to IV bolus injections of furosemide in clinic patients with WHF



Gilotra NA, et al. JACC Heart Fail. 2018;6(1):65-70.

# FUROSCIX — regulatory path

## Anticipate the resubmission of FUROSCIX NDA with the U.S. Food and Drug Administration (FDA) by mid-year 2020

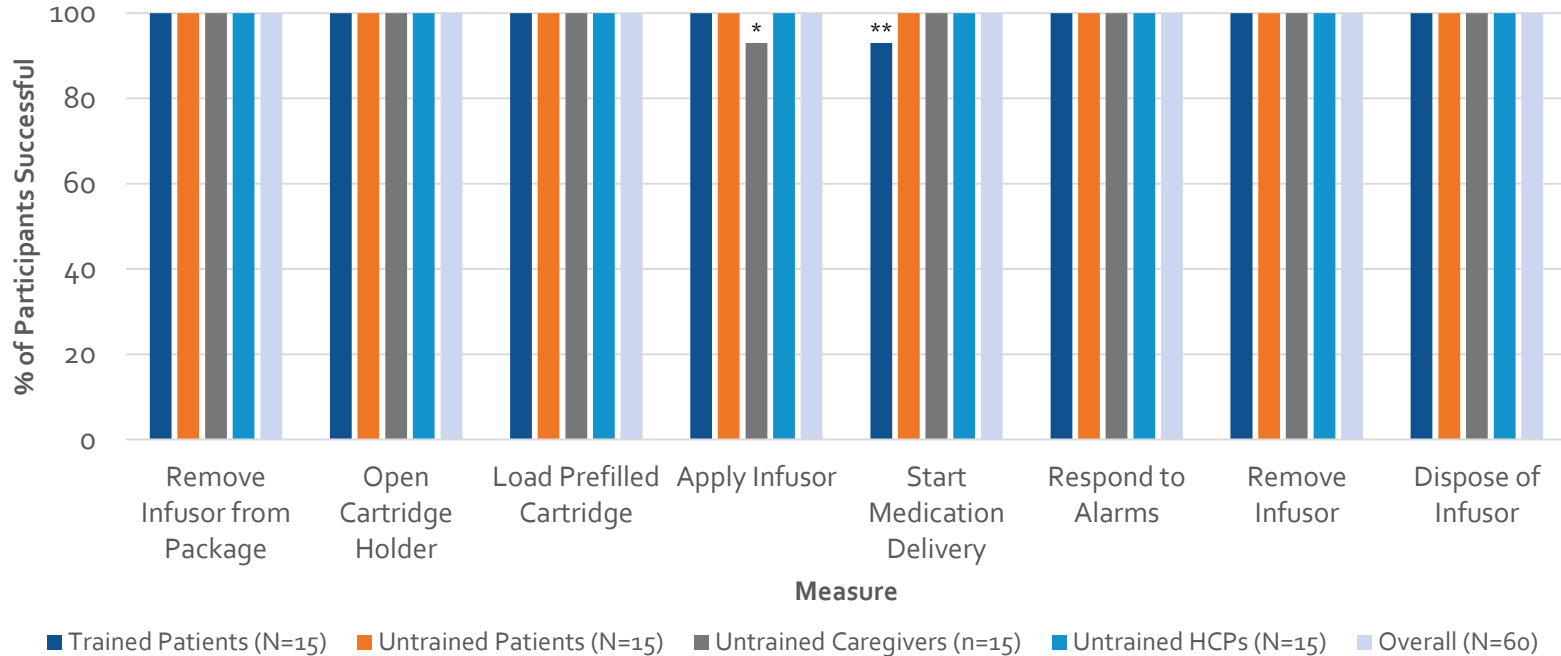
- Completed clinical safety, efficacy, and pharmacology studies
- Completed human factors studies supporting the new FUROSCIX Infusor
- Completed preliminary feasibility with SmartDose delivery; device validation testing in process
- Product (drug and device) stability program in process
- Anticipate a Type 2 resubmission with a 6-month review period

# Human Factors Validation Study

- The On-Body Infusor and Instructions For Use (IFU) have been successfully validated with the intended user populations (HF Patients, Caregivers, and HCPs)
  - Over 99% success rate for 900 observational use tasks (including critical tasks)
  - Over 99.5% success rate for 2,200 knowledge task/comprehension metrics
- The On-Body Infusor and IFU can be safely and effectively used
  - No patterns of preventable use errors observed
- Two minor edits to the IFU were suggested based on results:
  - Move a green check mark denoting application site
  - Rewording of 1 sentence for clarity
- No further testing required

# Human Factors Validation Study

## Observational Use Task Highlights



\* 1 untrained caregiver removed and reapplied adhesive liner to On-Body Infusor

\*\* 1 trained patient did not press the blue start button

Data on file. scPharmaceuticals, Burlington, MA.

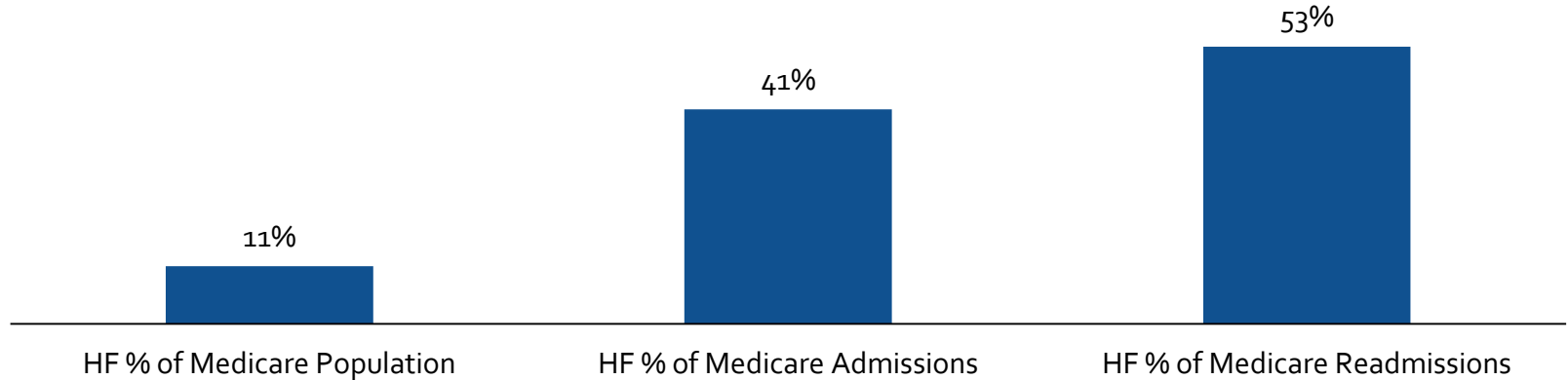


# FUROSCIX Value Proposition

# HF patients present a significant burden to Medicare



## HF Prevalence and In-Patient Admission



**59% of admissions directly attributed to volume overload<sup>1</sup>**

1. 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 associated treatment costs



## Payer

- Average cost to Medicare for a HF admission 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

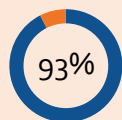
- Average length of stay is 5.2<sup>4</sup> days with DRG only reimbursing 3.9 days<sup>5</sup>
- Increased financial exposure for providers based on readmission penalty risk
- HF in-patient care represents multi-million dollar loss for targeted hospitals

1. Fitch, et al. Cost Burden of Worsening Heart Failure in the Medicare fee for service population, Milliman, 2017. <http://us.milliman.com/insight/2017/The-cost-burden-of-worsening-heart-failure-in-the-Medicare-fee-for-service-population-An-actuarial-analysis/> 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. Data on file. scPharmaceuticals, Burlington, MA.

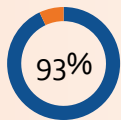
# HCPs have a high willingness to prescribe FUROSCIX and a rapid time to adoption

## Percent Would Use FUROSCIX

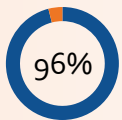
Intent to Prescribe



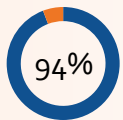
Total  
(n=309)



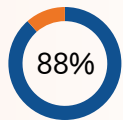
(n=101)



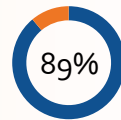
(n=51)



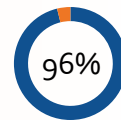
(n=52)



(n=52)



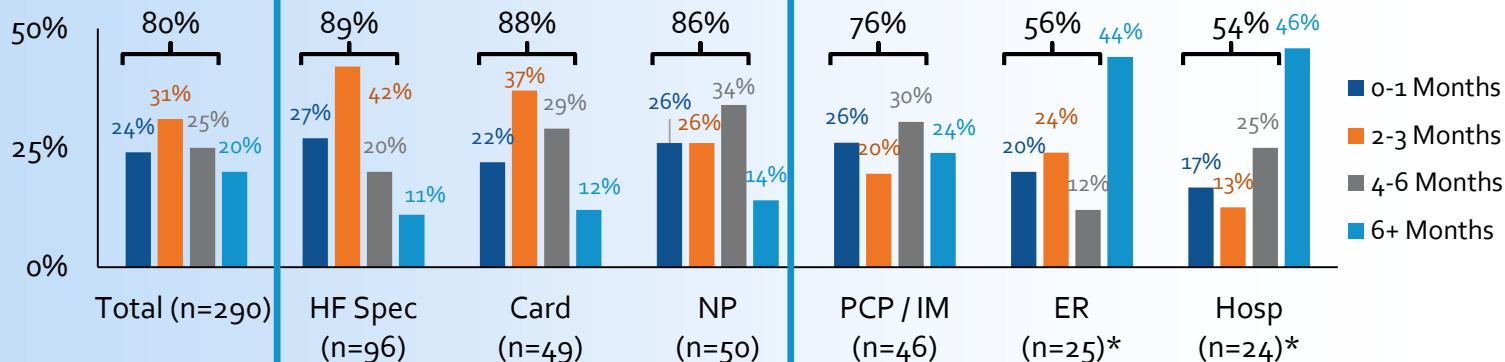
(n=27)\*



(n=26)\*

### HCP Launch Focus

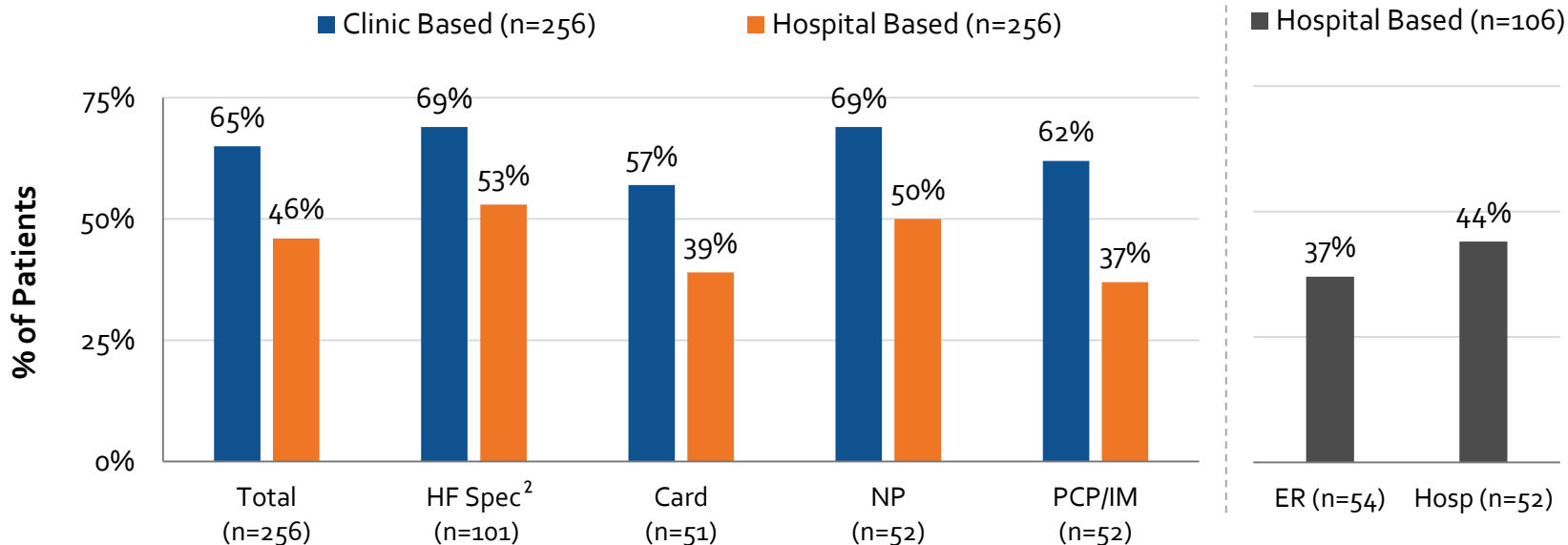
Time to Adoption



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

# FUROSCIX HCP Research—Treatment Share<sup>1</sup>

## Treatment Shares (based on last 2 patients seen)



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?

# Highly concentrated hospital targets

## Hospital Account Universe

	IV Furosemide Segment	Number of Accounts*	Total IV Doses <sup>1</sup>
Launch Target	High / Very High	349	7,041,506
	Medium	473	3,515,214
	Low / Very Low	22,565	7,032,129
	<b>Total</b>	<b>23,387</b>	<b>17,588,849</b>

Coverage of 349 hospital accounts, representing 40% of the annual IV doses, will require a specialty sales force of approximately 40 representatives

IMS DDD

\*Accounts defined by hospitals and clinics

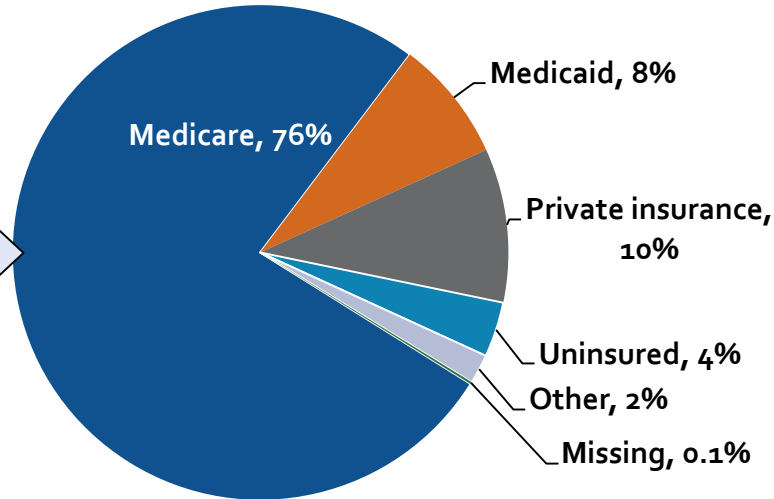
1. Data on file. scPharmaceuticals, Burlington, MA.

# HF payer mix and FUROSCIX value proposition

## 2017 Medicare Part D Insights

- 42 million Medicare with Part D coverage
  - 60% PDP; 40% MA-PDP
  - 29% receive full or partial LIS subsidies
- 17% (10 million) are active workers or have employer/retiree coverage, VA, FEHB
- 12 million LIS/Dual Eligible patients with Part D coverage
- 90% concentrated in 7 payers

## Payer Mix for HF Patients (2013)



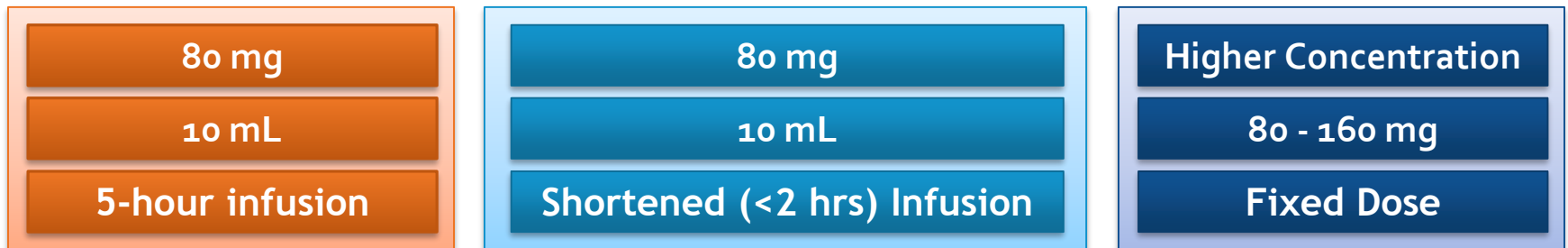
HCUP National Inpatient Sample (NIS), 2013, Agency for Healthcare Research and Quality (AHRQ)

**FUROSCIX Value: Reduction in PMPM costs when FUROSCIX is utilized**

1. Data on file. scPharmaceuticals, Burlington, MA.

# FUROSCIX life cycle management and development planning

- Enhancing FUROSCIX to continually improve the patient experience
  - Prefilled cartridge with West
  - Potential with device and drug development to shorten infusion time
  - Potential with higher concentration to create future dose flexibility
- Increasing barriers to entry
  - Patent application for concentrated furosemide formulation could extend protection through 2040



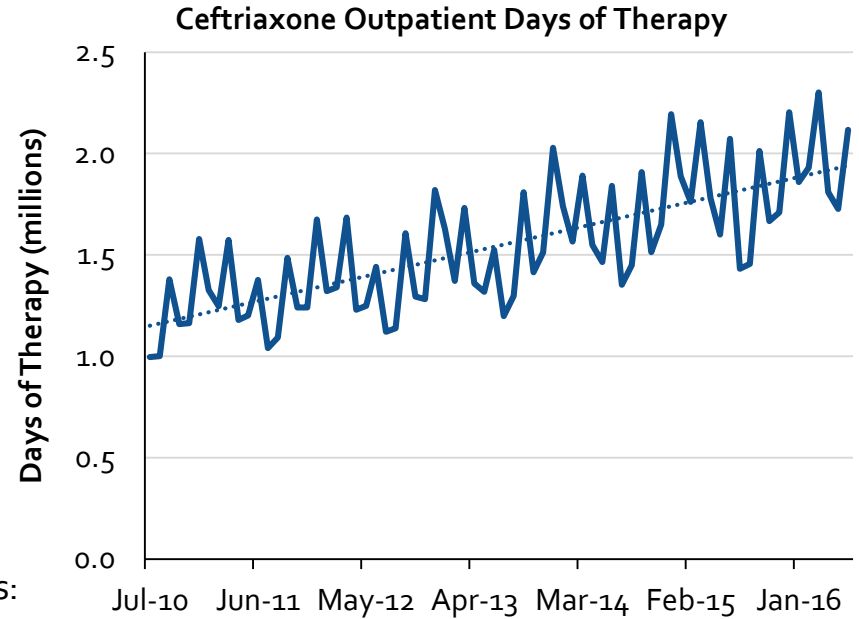
SmartDose® and the external product configuration of West's SmartDose® drug delivery platform are the intellectual property of West Pharmaceutical Services, Inc. or one of its subsidiaries, in the United States and other countries.



# Anti-infective Program

# Subcutaneous delivery of ceftriaxone has the potential to transform the outpatient antibiotic market

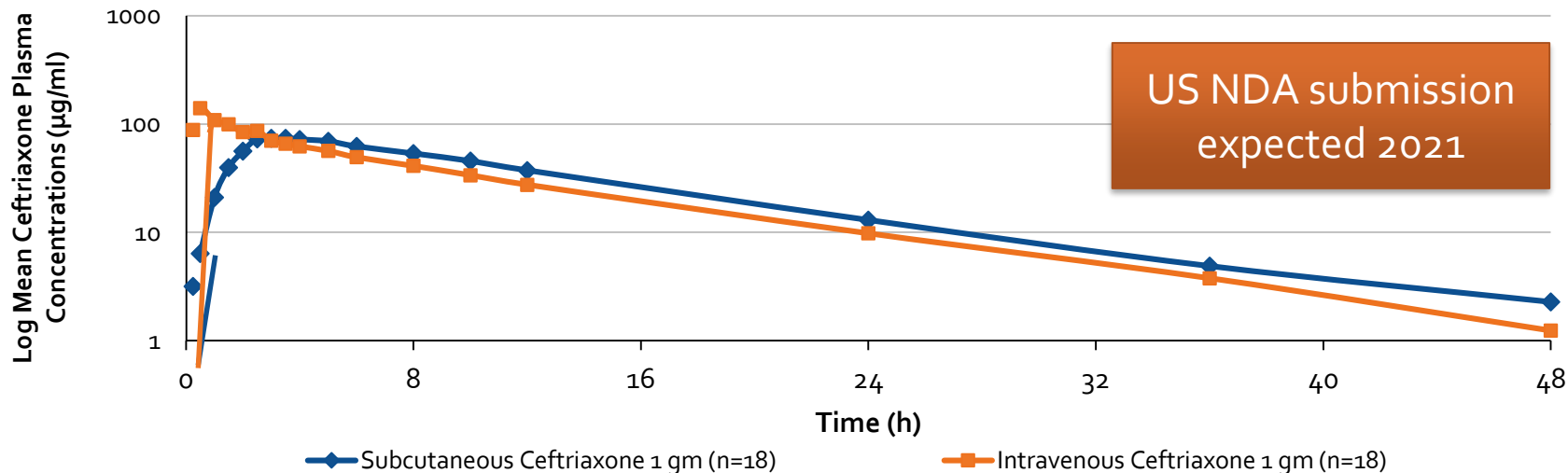
- ~15 million US ceftriaxone doses<sup>1</sup> in outpatient setting projected for 2021
- \$4.5B total addressable market opportunity in the US projected for 2021
- Clear clinical and economic value proposition
  - Eliminate the reliance on intravenous catheters/ PICC lines
  - Avoid the need for coordination of home infusion services which often delays discharge
  - Provide patients an alternative to hospitalization or driving to an infusion center daily
  - Alternative to suboptimal oral agents (fluoroquinolones)
- Subcutaneous option benefits multiple stakeholders: patients, hospitals, physicians, payers



<sup>1</sup> Data on file. scPharmaceuticals, Burlington, MA.

# 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>MIC<sub>24</sub>) of scCeftriaxone is non-inferior to IV infusion



1. Muntendam P, et al. Abstract 1966. Presented at ID Week; October 26-30, 2016; New Orleans, Louisiana. 2. Data on file. scPharmaceuticals, Burlington, MA.

# Corporate Summary

# Opportunity summary

- Pipeline includes products with large global market opportunity
  - FUROSCIX represents \$8B addressable US opportunity
  - scCeftriaxone represents \$4.5B addressable US opportunity in 2021
- Clear value proposition
- Established reimbursement model
- 505(b)(2) regulatory pathway
- High barriers to entry
  - Provisional patent of FUROSCIX filed that would extend protection through 2040

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

TURNING PATIENT CARE  
**INSIDE** **OUT**



**Thank you**

**scPharmaceuticals**

*Innovative outpatient solutions that  
bring care closer to home*