

TURNING PATIENT CARE  
**INSIDE**OUT

# 11th Annual LifeSci Partners Corporate Access Event

January 5 – 6, 2022

scPharmaceuticals

*Innovative outpatient solutions that  
bring care closer to home*



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# Investment Highlights

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

- Two late-stage programs addressing multi billion-dollar markets
  - FUROSCIX® for Heart Failure (HF)
    - A \$5.9B total US market opportunity
    - PDUFA date targeted for Q3 2022
  - scCeftriaxone, a potentially novel delivery of a broad-spectrum antibiotic
    - A \$4.5B total US market opportunity
- Clear value proposition and established-reimbursement model for FUROSCIX
- Well defined development plan leveraging FDA's 505(b)(2) pathway
- Strong intellectual property coverage for FUROSCIX through 2034
- Strong financial position with cash, cash equivalents, restricted cash and investments of \$85.0 million as of September 30, 2021

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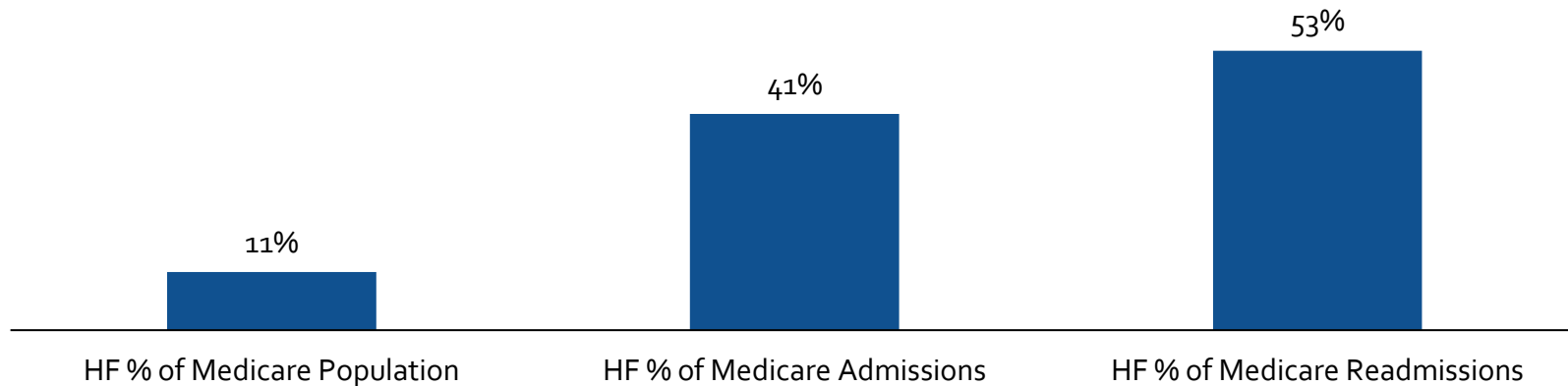
# Large Unmet Need in Heart Failure (HF)

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

- Prevalence of HF is 7.2 million adults in the US<sup>1</sup> and 15.8 million adults in the G7<sup>1</sup>
- In the US 4.0 million HF events occur annually<sup>1,2,3</sup>
  - Congestion is the most common cause of hospitalization<sup>4</sup>
- \$5.9B accessible 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 savings for payers and hospitals by reducing patient hospital admission/readmission rates

1. Decision Resource Group Report 2020 HF Disease Landscape & Forecast, Table 6 pg 52: forecast of ~3.3M diagnosed events of Acute HF in the US for 2022 and HF prevalence of 7.2M cases note: G7=US, Germany, France, UK, Italy, Spain, Japan equals 15.8M cases .2. Virani, et. al. Circulation 2020;e374 HF clinic visits. 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/>

# HF Patients are a Significant Financial Burden to Medicare

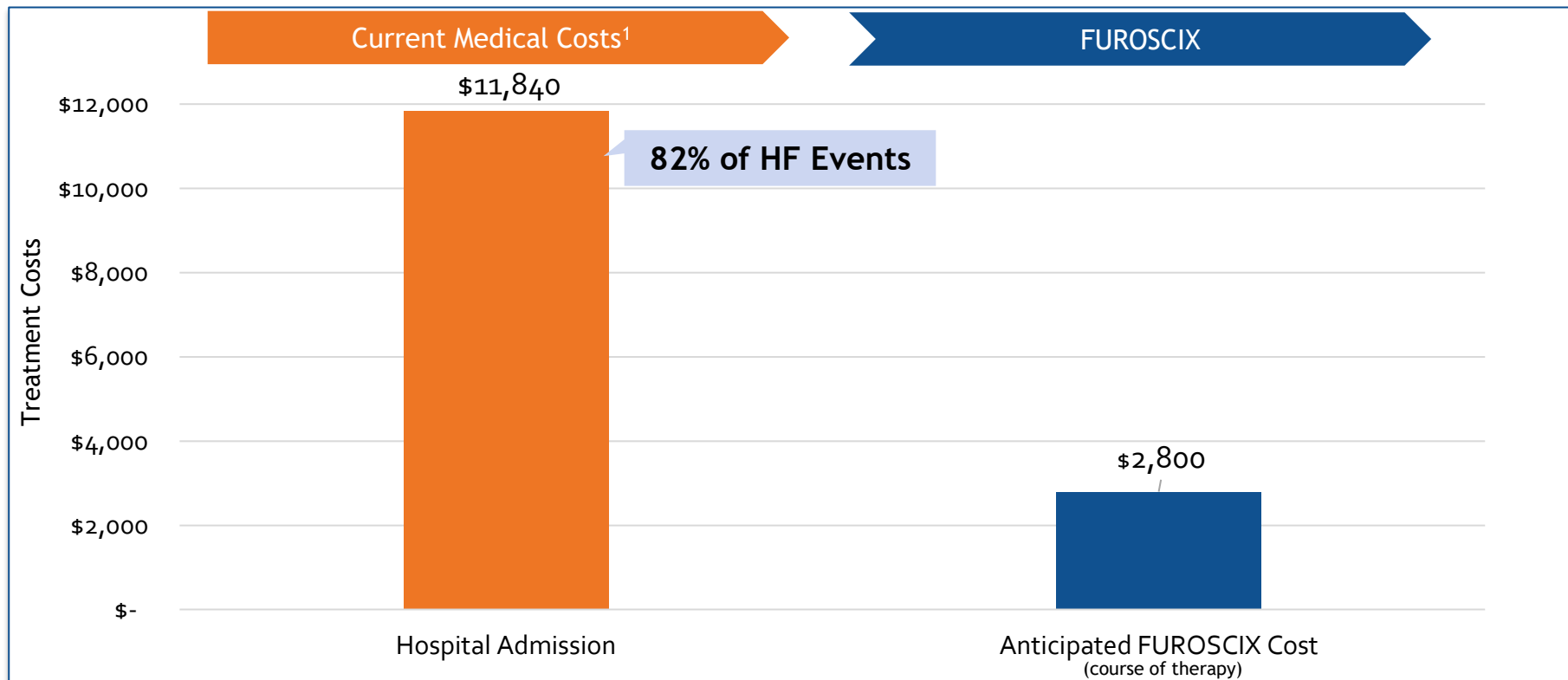


**HF patients represent 33% (\$123B) of annual Medicare Part A and B spending<sup>1</sup>**

**Average cost of a heart failure hospitalization is \$11,840<sup>1</sup>**

**80% of HF costs is attributed to the hospitalization cost<sup>1</sup>**

# Opportunity to decrease medical costs associated with HF treatment



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]

# Cycle of Decompensation and Hospitalization is the Primary Burden for Patients Suffering from HF

Stable patient treated with oral diuretic

Fluid retention (Congestion) – hallmark of HF

Decompensation leads to ↓ oral bioavailability diuretics

Worsening symptoms is the most common reason patients contact their provider

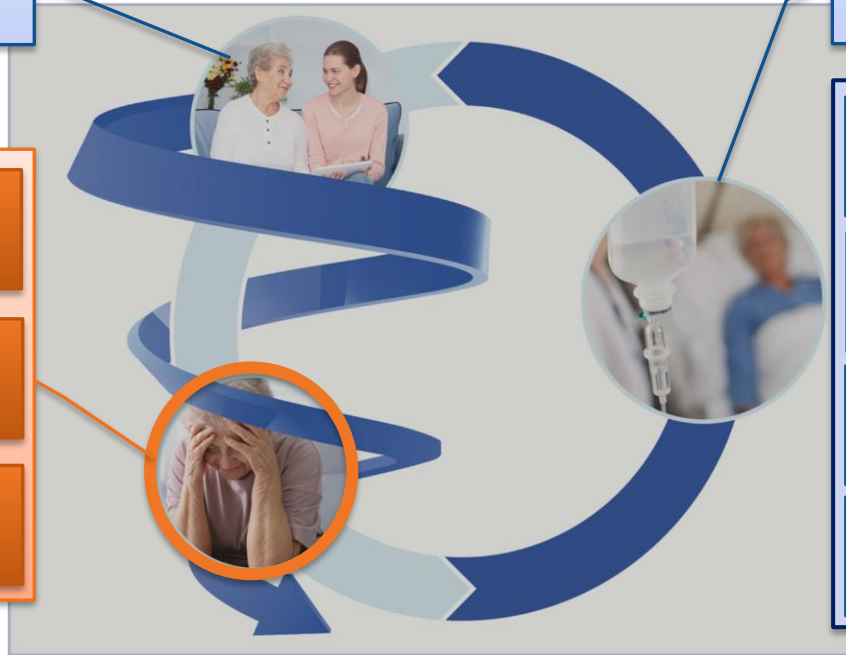
Hospitalized patient treated with IV diuretic

59% of hospital admission directly attributed to volume overload<sup>1</sup>

Up to 50% of HF hospital admissions may be avoidable<sup>2</sup>

30 – 50% patients discharged still congested<sup>3-5</sup>

25-30% of patients readmitted to the hospital after discharge within 30 days<sup>6,7</sup>

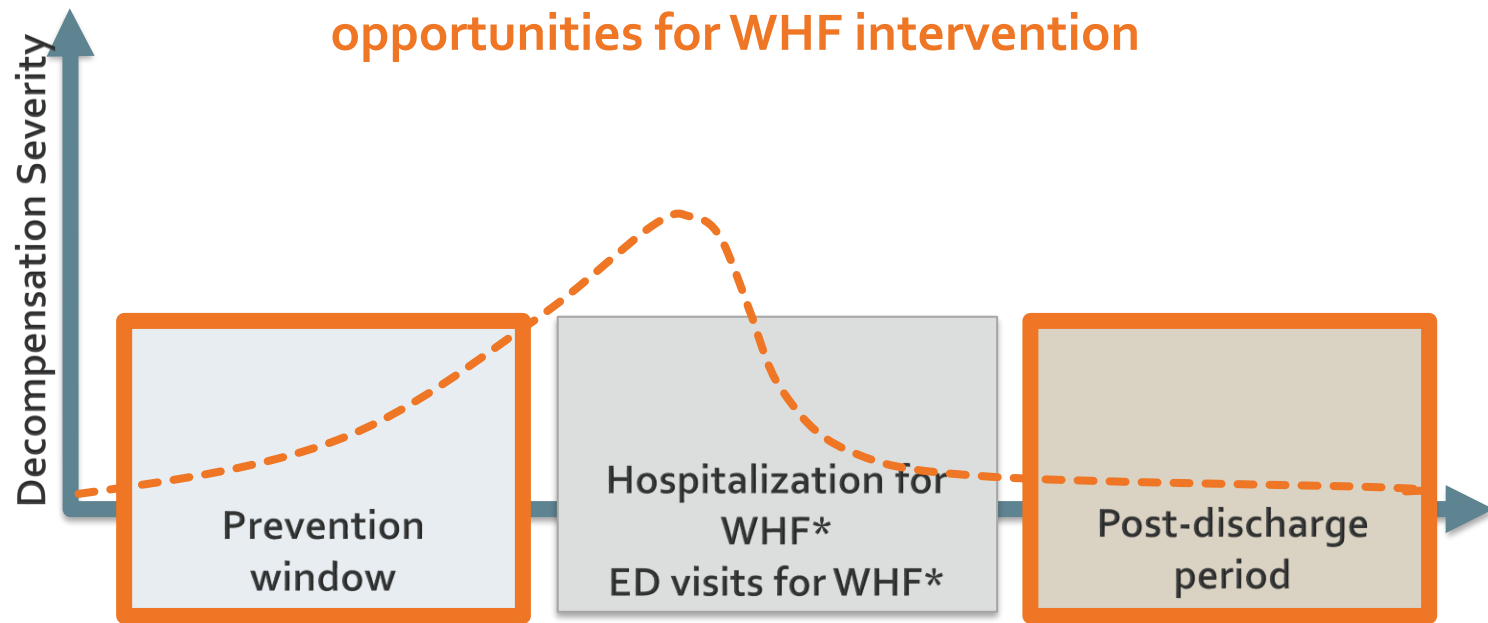


1. Bennett S, et al. American Journal of Crit Care. 1998;7(3):168-174. 2. Collins et al. J Am Coll Cardiol. 2013 January 15; 61(2): 121-126. 3. Neuenschwander JF, et al. Crit Care Clin. 2007;23(4):737-58. 4. Costanzo MR, et al. Am Heart J. 2007;154(2):267-77. 5. Fonarow GC, et al. JAMA. 2005;293(5):572-80. 6. Kilgore M et al. Risk Manag Healthc Policy. 2017;10:63..7. Fitch K, et al (2017) The cost burden of worsening heart failure in the Medicare fee for service population: an actuarial analysis [white paper]



# Primary Opportunities for Intervention in Worsening Heart Failure (WHF)

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



\*WHF: Worsening Heart Failure

# A New Model for Treating Heart Failure — FUROSCIX®

# FUROSCIX — a Subcutaneous Formulation of Furosemide

- **FUROSIX** – 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

# FUROSCIX Delivery System Incorporates an Easy-to-use On-Body Infusor

## Incorporates West Pharmaceutical Services, Inc.'s SmartDose® Gen II 10ml platform technology

*Technology is FDA and EMA approved as part of a combination product*

- Pre-filled Crystal Zenith® disposable cartridge
- Delivers fixed 80mg sc dose through pre-programmed, biphasic profile (30mg first hour + 12.5mg/hour for next 4 hours)
- Visual, tactile, and audible feedback
- Electromechanical drive
- Patient-centric design
- Wireless connectivity capability

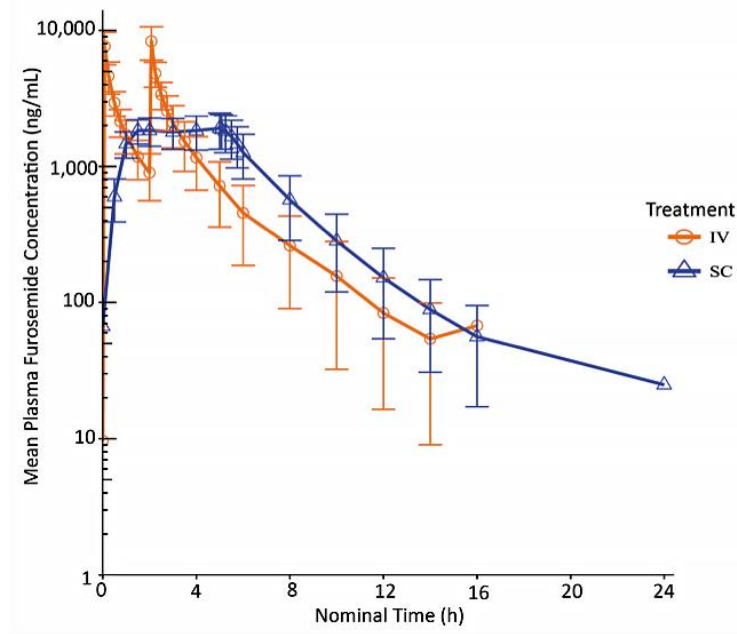


SmartDose® and the external product configuration of West's SmartDose® drug delivery platform are the intellectual property of West Pharmaceutical Services, Inc. or one of its subsidiaries, in the United States and other countries.

# Pivotal PK/PD Study (scP-01-002)

## Pharmacokinetic Overview

	<b>FUROSCIX SC</b> 5-hour, 80 mg infusion (n = 15) <sup>a</sup>	<b>IV bolus furosemide</b> 2-40 mg injection (n = 15) <sup>a</sup>
<b>C<sub>max</sub>, ng/mL</b> <b>Mean ± SD</b>	2040 ± 449	8580 ± 2540
<b>t<sub>max</sub>, h</b> <b>Median (min–max)</b>	4.00 (1.00–5.08)	2.08 (0.08–2.08)
<b>AUC<sub>last</sub>, h*ng/mL</b> <b>Mean (SD)</b>	13000 ± 4000	13000 ± 4050
<b>AUC<sub>∞</sub>, h*ng/mL</b> <b>Mean (SD)</b>	13100 ± 4010	13200 ± 4170



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

<sup>a</sup>One subject was excluded from analysis due to high pre-dose concentration.  
Sica DA, Muntendam P, Myers RL, et al. JACC Basic Transl Sci. 2018;3(1):25-34

# FUROSCIX — Regulatory Path

- NDA resubmission target – Q1 2022
  - 6-month NDA review
- No additional efficacy, PK ,safety data, human factors or device modifications are required by FDA
- All additional testing of devices will be required to be on devices manufactured on the planned commercial line
- Pre-Approval Inspection required at the West Pharmaceuticals Scottsdale location
  - Triggered by resubmission

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# FREEDOM-HF Top Line Results

# FREEDOM-HF

## Study Overview

- Goal
  - To evaluate the economic impact of hospital avoidance and safety with management of worsening HF due to congestion in patients initially presenting to the emergency department with FUROSCIX administered outside the hospital setting
- Objectives
  - Compare the differences in healthcare resource utilization and direct medical costs for patients treated with FUROSCIX outside the hospital with matched patients receiving IV furosemide inside the hospital
  - Evaluate the safety of FUROSCIX administered outside the hospital
  - Describe the quality of life and patient satisfaction for patients who receive FUROSCIX outside the hospital
- Study Design
  - Open-label, comparative study with an adaptive sample size
  - 34-75 patients presenting to ED for worsening HF
    - Interim analysis to be conducted after first 10 subjects complete 30-day follow up to confirm sample size.
  - Patients discharged from the ED and received FUROSCIX at home
  - Cost differences derived and calculated based on matched comparators from Truven Health Analytics Database



# FREEDOM-HF

## Primary Outcome: Healthcare Costs

Outcome	Furoscix <sup>[b]</sup> (N=24)	Control (N=66)	Difference (95% CI)	P-value <sup>[a]</sup>
HF-related health care costs, mean (SD)	\$2920.30 (7073.20)	\$19,915.60 (10,666.60)	-\$16,995.30 (-22,187.90, -11,802.70)	<0.0001
Overall health care costs, mean (SD)	\$7512.30 (11,905.50)	\$35,352.80 (31,662.00)	-\$27,840.50 (-41,581.10, -14,100.00)	<0.0001

Abbreviations: Heart Failure (HF); Standard Deviation (SD)

[a] P-value was obtained from the t-test statistic.

[b] Costs in Furoscix arm does not include a cost for Furoscix

- Analyses of additional secondary endpoints provide additional insights into the clinical effectiveness of FUROSCIX
  - Patients who received FUROSCIX had a median reduction of heart failure peptide biomarkers from study entry (day 0) to first visit (day 2 – 4), and to last visit (day 30), of 42.3% and 28%, respectively (p<0.01)
  - Patients who received FUROSCIX had a 12.8-point improvement in the Kansas City Cardiomyopathy Questionnaire (KCCQ-12) Summary Score 30 days after study entry

# FREEDOM-HF

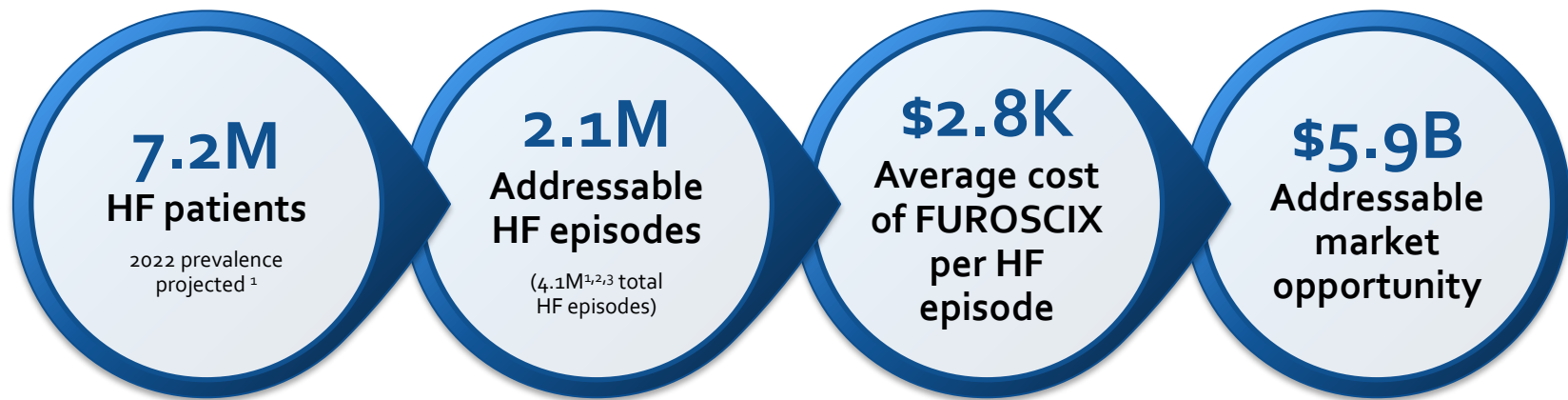
## Conclusions

- Use of FUROSCIX allowed for outpatient treatment of HF patients presenting to the ED with worsening congestion despite oral diuretic use
- Initial HF hospitalization was avoided and persisted across the subsequent 30-days
- Significant reduction in 30-day HF related costs compared to matched comparator group
- The most common adverse events with FUROSCIX were infusion site pain, bruising and dizziness

# FUROSCIX Commercial Overview

# NEW - FUROSCIX Multi-billion-dollar Annual U.S. Market Opportunity

Potential paradigm shift in how HF is treated



Prevention of admissions and readmissions are targeted opportunities for HF intervention

1. Decision Resource Group Report 2020 HF Disease Landscape & Forecast, Table 6 pg 52: forecast of ~3.3M diagnosed events of Acute HF in the US for 2022 and HF prevalence of 7.2M cases 2. Virani, et. al. Circulation 2020;e374 HF clinic visits 3. H-CUP 2017 Inpatient Stays HF principal diagnosis 4. Market Research Data on file. scPharmaceuticals, Burlington, MA

# Stakeholders are Aligned on the Need to Reduce Hospitalizations and Treatment Costs



## Payer

- Average cost to Medicare for a HF admission is \$11,840<sup>1</sup>
- HF is top condition targeted by CMS Hospital Readmission Reduction Program<sup>2</sup> (HRRP)
- Medicare Advantage plans bear both medical and pharmacy costs



## 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 hospitals and providers based on readmission penalty risk
- HF in-patient care represents multi-million-dollar loss for targeted hospitals
- HRRP<sup>2</sup> introduces potential for substantial financial penalties

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.

# Positioning and Messages

## Positioning:







Only FUROSCIX, a new subcutaneous infusion of furosemide, enables IV-caliber diuresis at home for heart failure patients with reduced responsiveness to oral therapy – breaking the cycle of hospitalization, by regaining control of fluid

- FUROSCIX provides IV-equivalent diuresis at home, when it's needed and where it's wanted, to reduce heart failure hospitalizations and lower costs
- When oral diuretic bioavailability declines, regain fluid control with FUROSCIX treatment at home
- Avoid heart failure admissions and reduce readmissions due to fluid overload by intervening with FUROSCIX at home

**FUROSCIX**<sup>®</sup>  
(furosemide) 80mg/10mL for  
subcutaneous administration

FUROSCIX<sup>®</sup> is an investigational drug that is not approved for use by any regulatory agency. The safety and effectiveness of FUROSCIX have not been established. All positioning statements are aspirational.

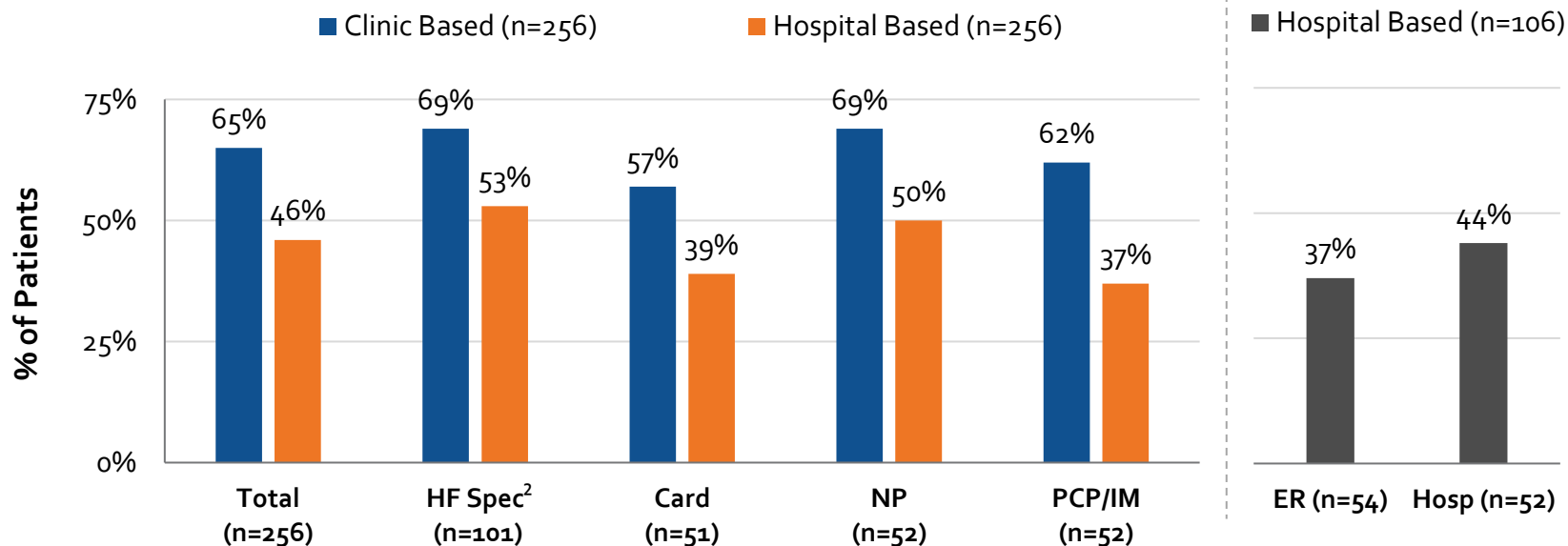
# HCPs Have a High Willingness to Prescribe FUROSCIX and a Rapid Time to Adoption

							
	Total n=309	HF Spec n=101	Card n=51	NP n=52	PCP/IM n=52	ER n=27	Hosp. n=26
Intent to prescribe	93%	93%	96%	94%	88%	89%	96%
	n=290	n=96	n=49	n=50	n=46	n=25*	n=24*
Intent to prescribe within 6 mos.	80%	89%	88%	86%	76%	56%	54%
HCP launch focus							

\*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?



# Small specialized force can target top hospitals/clinics efficiently

Decile	# hospitals	% total hospitals	Normalized discharge volume	% normalized discharge volume	Normalized IV Furosemide volume	% normalized Furosemide volume
7 - 10	435	7%	36,772	37%	43,815	43%

Covering ~40% of the IV furosemide and HF discharge opportunity requires a sales force size of 40 territories

Launch starts with 6,000 health care providers (HCPs)

~ 150 HCPs and 10 hospitals per territory

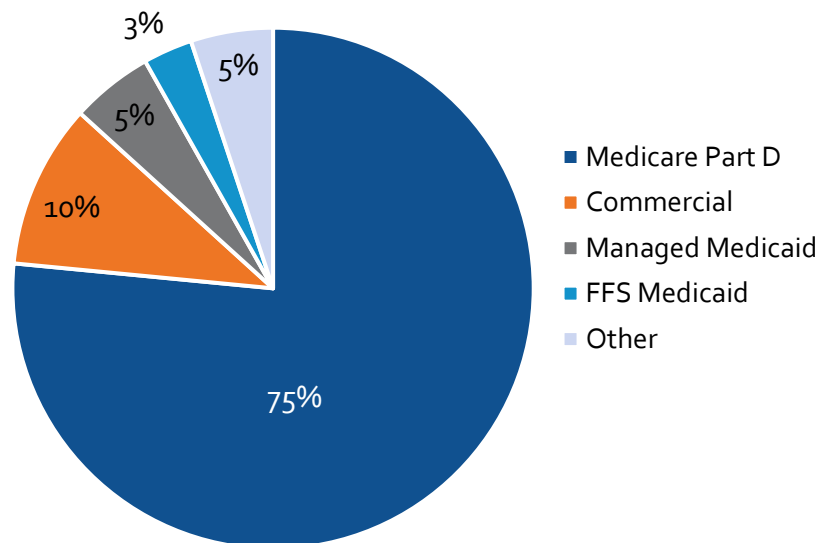
Expect spill-over coverage to reach 50% of opportunity from med group reach to non-targeted hospitals and IDN affiliations

\*From Sales Force sizing project conducted by consultant Trinity partners

# Heart Failure Drug Coverage

- 47 million lives will be covered by Medicare Part D in 2021
- Medicare D will be the predominant payer segment for FUROSCIX® (75%)
- In 2020, 55% of Medicare D lives were covered by PDP plans while 45% were covered under Medicare Advantage plans
- It is anticipated this split will continue to trend toward a 50-50 split in 2021
- 52% of potential patients will have reduced co-pay
  - 42% LIS and Medicaid will have low copays
  - 10% Commercial can use copay offset cards

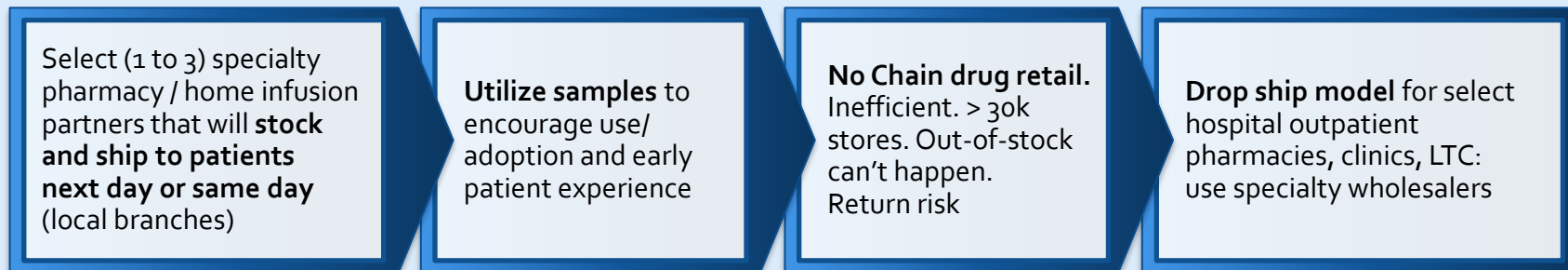
## HF Lives Drug Coverage



# Patient Support and Distribution



## Distribution Strategy



# Financial Snapshot

- September 30, 2021 cash, cash equivalents, restricted cash and investments \$85.0 million
  - Sufficient to fund operations into 2023
- Venture debt - \$20M (SVB and Solar Capital)
  - Term through September 2023
  - Amortization commencing 4Q21
- Shares outstanding on September 30, 2021: 27,355,454

# scPharmaceuticals Investment Highlights Summary

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Thank you

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