

TURNING PATIENT CARE  
**INSIDE**OUT

# SVB Leerink 10th Annual Global Healthcare Conference

February 24, 2021



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
  - 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
- Cash runway through anticipated FUROSCIX resubmission, potential approval and launch

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# Large Unmet Need in Heart Failure (HF)

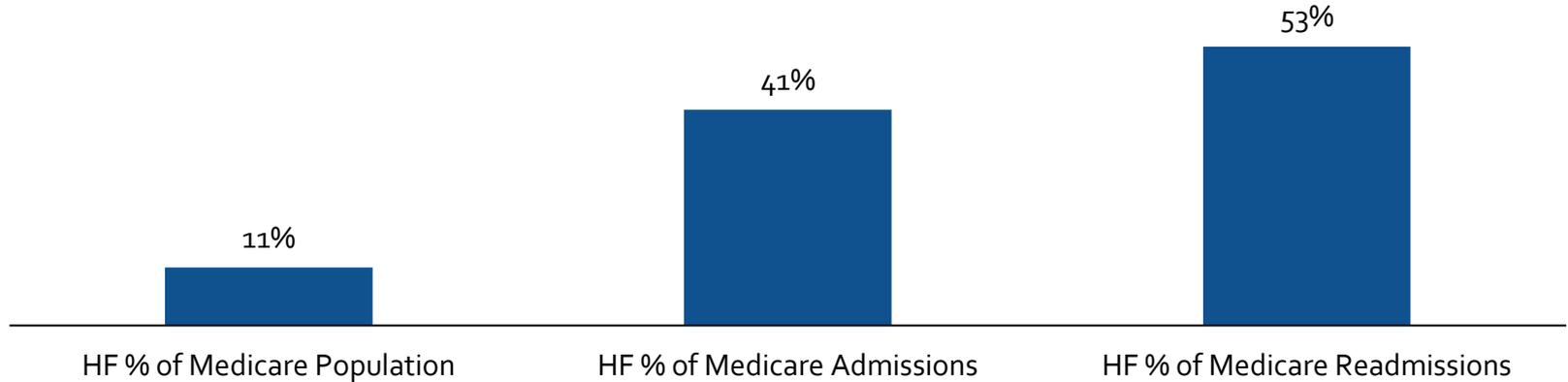
## Lead program targets HF — a large global market opportunity with a clear value proposition

- Prevalence of HF is 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 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. 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/>

# HF Patients Present a Significant Burden to Medicare

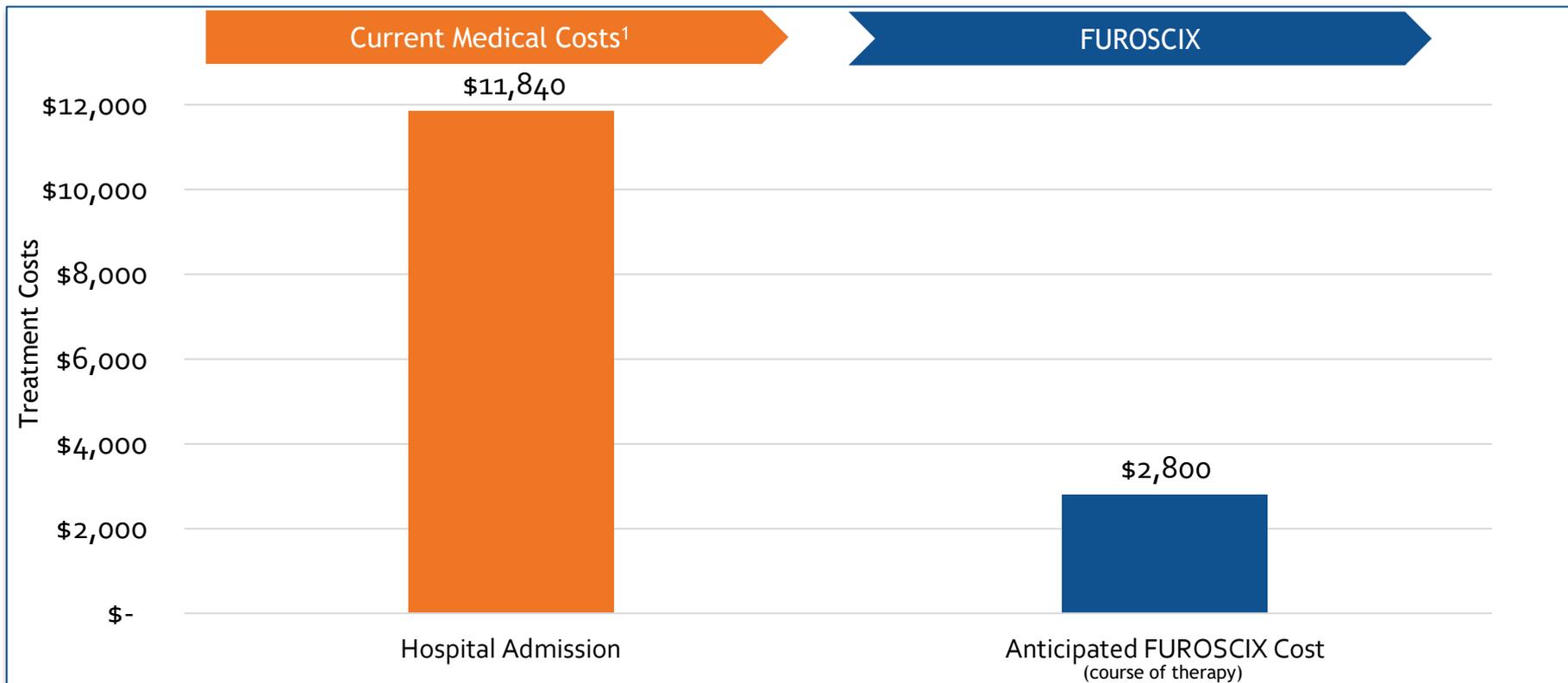
## HF Prevalence and In-Patient Admissions



**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.

# Opportunity to Decrease Medical Costs Associated with HF Hospitalizations



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

Start of fluid retention – hallmark of HF

Worsening fluid status - oral therapies ↓ efficacy

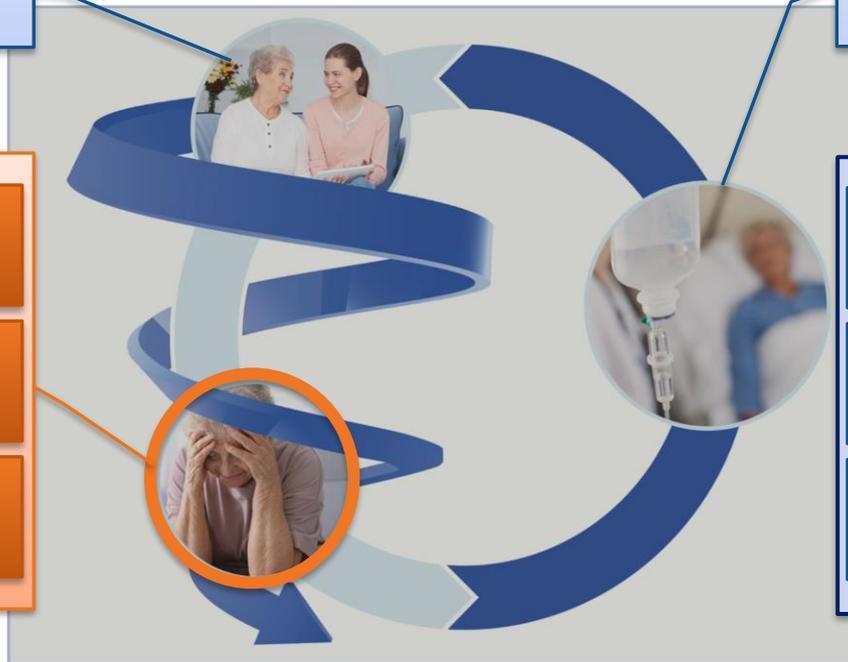
Decompensation leads to ↓ oral bioavailability

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>

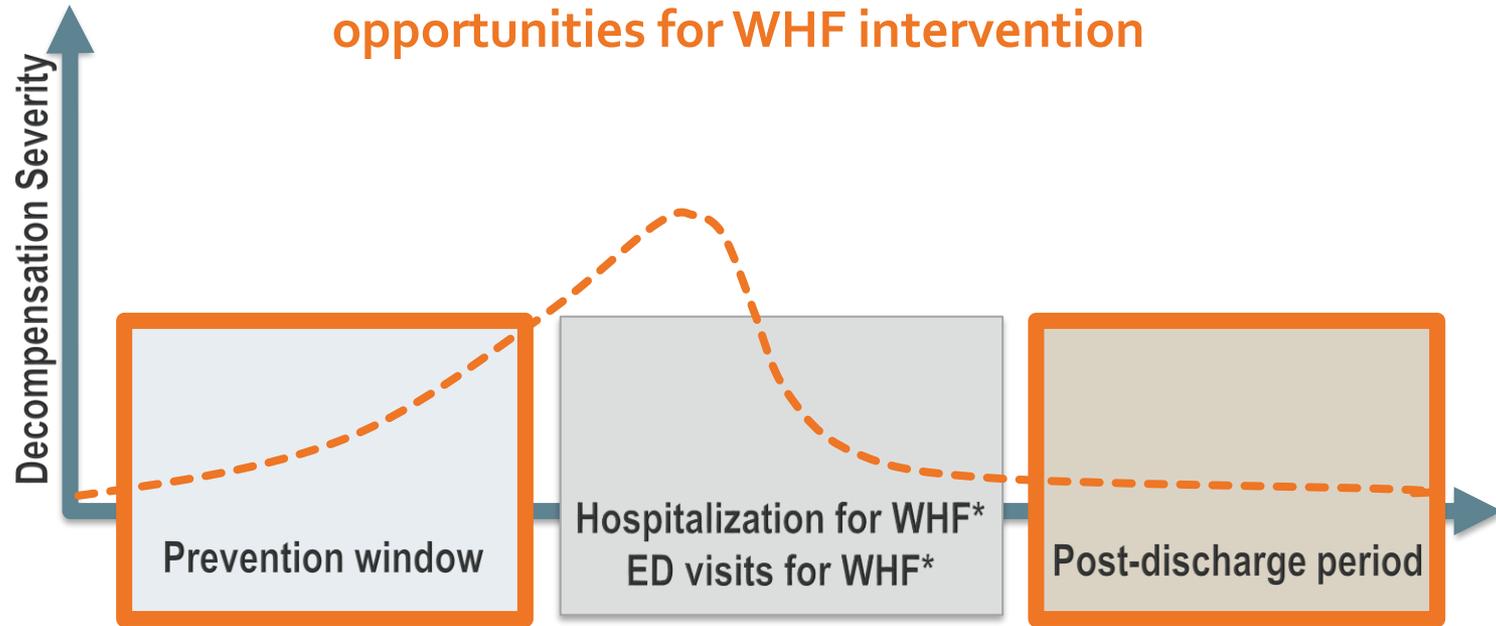
High rate of readmissions 30 – 50% patients discharged wet<sup>3</sup>



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. 3. Neuweschwander JF, et al. Crit Care Clin. 2007;23(4):737-58. Costanzo MR, et al. Am Heart J. 2007;154(2):267-77. Fonarow GC, et al. JAMA. 2005;293(5):572-80

# 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

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

# A New Model for Treating Heart Failure — FUROSCIX®

# FUROSCIX — a Subcutaneous Formulation of Furosemide

## Enabling IV-equivalent diuresis at home

- 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



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 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

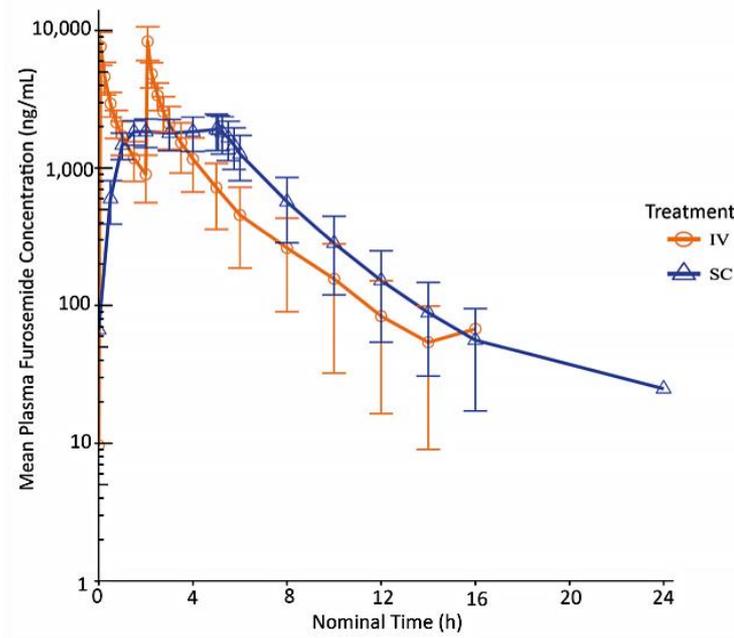


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# Pivotal PK/PD Study (scP-01-002)

## 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> Mean ± SD	2040 ± 449	8580 ± 2540
<b>t<sub>max</sub>, h</b> Median (min–max)	4.00 (1.00–5.08)	2.08 (0.08–2.08)
<b>AUC<sub>last</sub>, h*ng/mL</b> Mean (SD)	13000 ± 4000	13000 ± 4050
<b>AUC<sub>∞</sub>, h*ng/mL</b> Mean (SD)	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 — FDA Type A Meeting Feedback & Regulatory Path

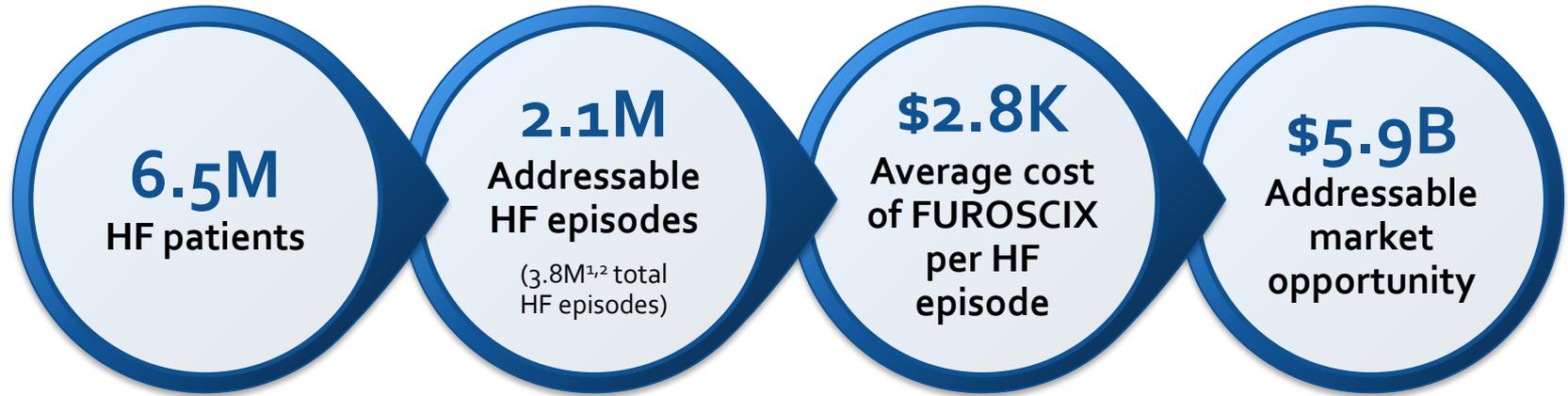
- Received Complete Response Letter from FDA on December 3, 2020
- No additional clinical efficacy, PK or safety data required
- No device modifications required
- Pre-Approval Inspections required at the following sites:
  - West Pharmaceuticals, Inc.
  - Sharp Packaging Services
  - Third-party manufacturer of the off-the-shelf alcohol swabs
- Modified bench tests required on aged commercial units of the SmartDose® Gen II on-body infusor

**Company expects to address all issues raised by FDA and resubmit FUROSCIX NDA in Q3 2021**

# FUROSCIX Commercial Overview

# 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. Benjamin, et. al. Circulation 2018; 137(12):e67-e492. 2. 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:

FUROSCIX significantly reduces the burden of a fluid overload exacerbations in worsening heart failure patients, by providing next level diuresis, when it's needed and where it's wanted, to regain fluid control and avoid hospitalizations.

- 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

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

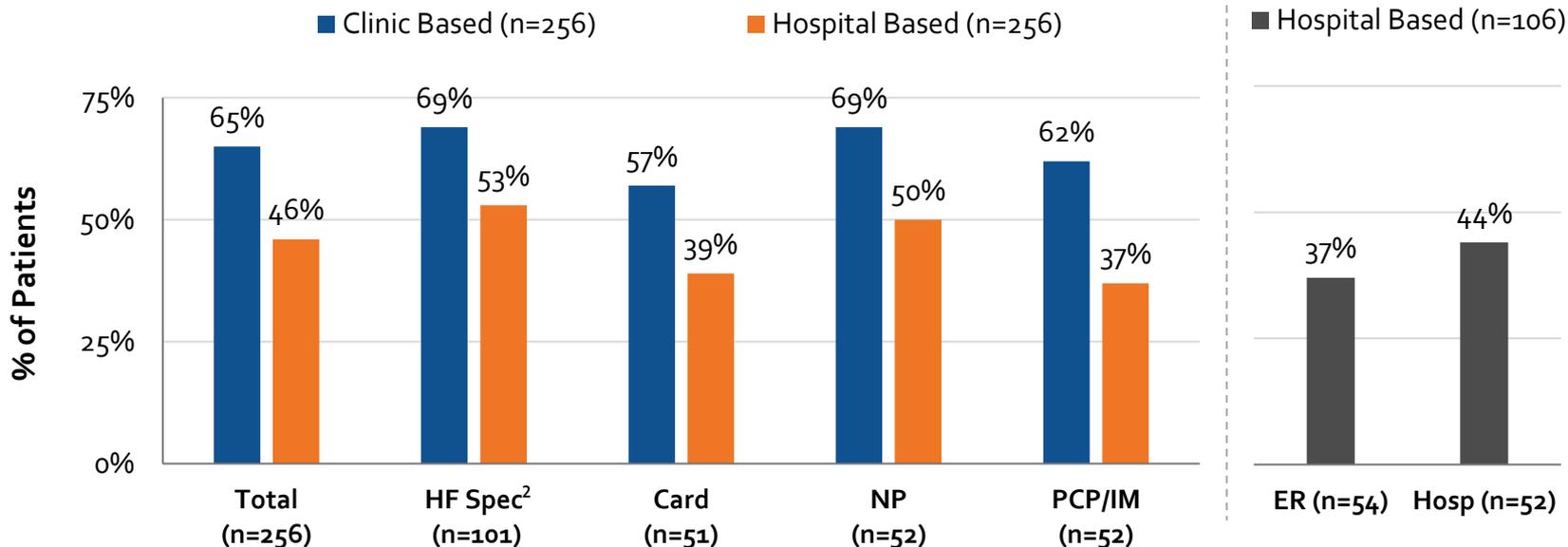
	Total n=309	 HF Spec n=101	 Card n=51	 NP n=52	 PCP/IM n=52	 ER n=27	 Hosp. n=26
Intent to prescribe	93%	<b>93%</b>	<b>96%</b>	<b>94%</b>	88%	89%	96%
	n=290	n=96	n=49	n=50	n=46	n=25*	n=24*
Intent to prescribe within 6 mos.	80%	<b>89%</b>	<b>88%</b>	<b>86%</b>	76%	56%	54%

**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

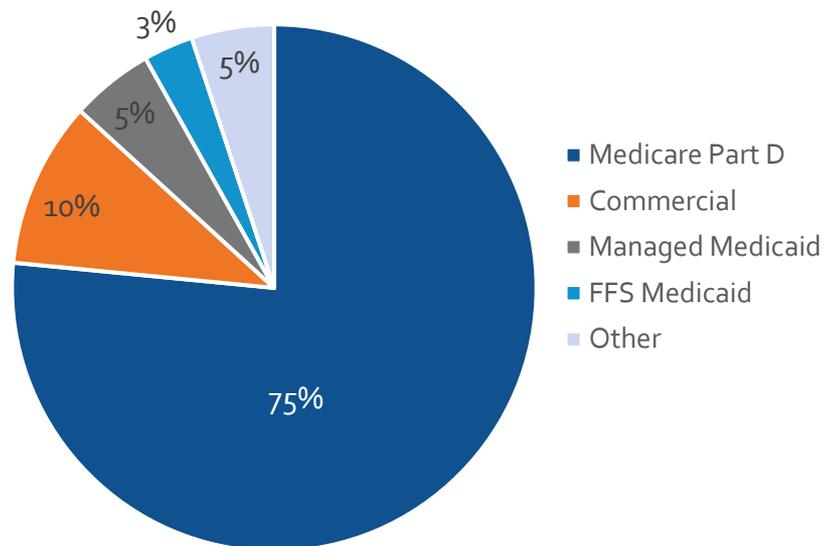
Expect spill-over coverage to reach 50% of opportunity from med group reach to non-targeted hospitals and IDN affiliations

\*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
- 55% of potential patients will have reduced co-pay
  - 41% LIS plus Medicaid and commercial

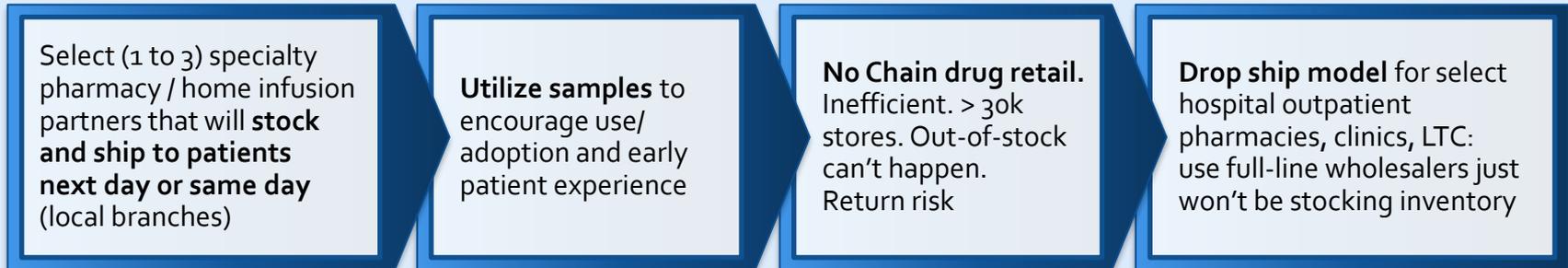
## HF Lives Drug Coverage



# Patient Support and Distribution



## Distribution Strategy



# Financial Snapshot

- December 31, 2020 cash, cash equivalents, restricted cash and investments estimated to be \$105 million
  - Sufficient to fund operations through potential FUROSCIX® approval and launch and into 2023
- Venture debt - \$20M (SVB and Solar Capital)
  - Term through September 2023
  - Amortization commencing 4Q21
- Shares outstanding on December 31, 2020 = 27,325,959

# scPharmaceuticals Investment Highlights Summary

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**Thank you**

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