# INSIDE OUT

### Jefferies Virtual Healthcare Conference

June 4, 2020

## **sc**Pharmaceuticals

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
  - FUROSCIX<sup>®</sup> in Heart Failure (HF)
    - NDA resubmission expected mid-2020; anticipate 6-month review
  - scCeftriaxone a potentially novel delivery of a broad spectrum antibiotic
- High barriers to competitive entry
  - Patent coverage of drug formulation and methods of treatment until 2034
- Ended 1Q20 with cash of \$75; 2020 annual burn of \$36-40M
  - Raised additional ~\$50M in May follow-on

#### scPharmaceuticals Senior Management & Board of Directors

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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 reason for hospitalization<sup>4</sup>
- \$4.3 B 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. <u>http://us.milliman.com/insight/2017/The-cost-burden-of-worsening-heart-failure-in-the-Medicare-fee-for-service-population-An-actuarial-analysis/</u>

#### 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.

## 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]

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## 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  $\Psi$  efficacy

Decompensation leads to  $\psi$  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. Neuenschwander 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

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## Hospitalization for HF is associated with disease progression and poor outcomes



## Oral absorption of furosemide is poor and further diminished in HF with congestion

Representative serum concentration time profile after



Guidelines recommend IV loop diuretics during episodes of worsening congestion in heart failure

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1. Ellison DH and Felker GM, NEJM. 2017; 377(20): 1964-1975. 2. Vasko MR, et al. Ann Int Med. 1985;102(3):314-8. 3. Mullens W, et al. Eur J of Heart Fail. 2019;21(2):137-55.

#### Primary opportunities for intervening 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 of Treating Heart Failure — FUROSCIX<sup>®</sup>

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### 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
- Delivered by an On-Body Infusor
  - SmartDose<sup>®</sup> Gen II 10 mL on-body delivery system
  - Developed to deliver fixed dose of 80mg of Furoscix subcutaneously through a preprogrammed, 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.

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#### 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

- Pre-filled drug cartridge
- Single-use, fully disposable Infusor
- Visual, tactile, and audible feedback
- Electromechanical drive
  - Delivery volume up to 10mL
- Delivery profile pre-programmed
- Patient-centric design
- Wireless connectivity capability



#### 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



Sica DA, et al. JACC Basic to Transl Sci. 2018;3(1):25-34

Mean Plasma Furosemide Concentration (ng/mL)

.000

#### FUROSCIX pharmacodynamics are IV equivalent

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



#### **Human Factors Summative Validation Study**

- In this summative study the On-Body Infusor and Instructions For Use (IFU) were 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
- Based on this study "we believe the On-Body Infusor and IFU can be safely and effectively used"
  - No patterns of preventable use errors observed

#### Human Factors Summative 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

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Data on file. scPharmaceuticals, Burlington, MA.
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#### 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 summative human factors study
- 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

### **FUROSCIX Value Proposition**

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#### FUROSCIX annual U.S. market opportunity

Potential paradigm shift in how HF is treated



## Prevention of admissions and readmissions are targeted opportunities for HF intervention

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



- 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>
- 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 providers based on readmission penalty risk
- HF in-patient care represents multimillion dollar loss for targeted hospitals

1. Fitch, et al. Cost Burden of Worsening Heart Failure in the Medicare fee for service population, Milliman, 2017. <u>http://us.milliman.com/insight/2017/The-cost-burden-of-worsening-heart-failure-in-the-Medicare-fee-for-service-population-An-actuarial-analysis/</u> 2. Readmission Reduction Program (HRRP) (updated 2018, April 27) Retrieved from <a href="https://www.cms.gov/medicare-fee-for-service-payment/acuteinpatientpps/readmissions-reduction-program.thml">http://www.cms.gov/medicare-fee-for-service-payment/acuteinpatientpps/readmissions-reduction-program.thml</a> Quality Payment Program from CMS <a href="https://cms.gov/medicare-fee-for-service-payment/acuteinpatientpps/readmissions-reduction-program.thml">https://cms.gov/medicare-fee-for-service-payment/acuteinpatientpps/readmissions-reduction-program.thml</a> Quality Payment Program from CMS <a href="https://cms.gov/medicare-fee-for-service-payment/acuteinpatientpps/readmissions-reduction-program.thml">https://cms.gov/medicare-fee-for-service-payment/acuteinpatientpps/readmissions-reduction-program.thml</a> Quality Payment Program from CMS <a href="https://cms.gov/medicare-fee-for-service-payment/acuteinpatientpps/readmissions-reduction-program.thml">https://cms.gov/medicare-fee-for-service-payment/acuteinpatientpps/readmissions-reduction-program.thml</a> Quality Payment Program from CMS <a href="https://cms.gov/medicare-fee-for-service-payment-failure-in-the-Medicare-fee-for-service-payment-failure-in-the-Medicare-fee-for-service-payment-failure-in-the-Medicare-fee-for-service-payment-failure-in-the-Medicare-fee-for-service-payment-failure-in-the-Medicare-fee-for-service-payment-failure-in-the-Medicare-fee-for-service-payment-failure-in-the-Medicare-fee-for-service-payment-failure-in-the-Medicare-fee-for-service-payment-failure-in-the-Medicare-fee-for-service-payment-failure-in-the-Medicare-fee-for-service-payment-failure-in-the-Medicare-fee-for-service-payment-failure-in-the-Medicare-fee-for-service-payment-failure-in-the-Medicare-fee-for-service-payment-fa

### Hospital Readmission Reduction Program (HRRP)

- Medicare aims to reduce HF excessive readmissions by administering financial penalties under HRRP as part of the larger Medicare Shared Savings Program
  - Supports national goal of linking payment to quality of hospital care
  - Maximum penalty is a 3% reduction in payments
  - CMS calculates the penalty adjustment for each hospital based on performance over 3yrs
- In fiscal 2020, CMS will penalize 2,583 hospitals for too many Medicare readmissions in 30 days<sup>1</sup>
  - CMS will withhold~ \$563M in Medicare payments to hospitals under HRRP
  - 83% of 3,129 hospitals evaluated received a penalty
  - Hospitals on the penalty list include large safety-net hospitals and academic medical centers
  - Heart failure is one of the original 3 conditions tracked to determine penalties

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1. Kaiser Health News report citing federal data released Sept. 30, 2019 Readmission numbers and penalty information provided by CMS: https://www.cms.gov/Medicare/Medicare-Feefor-Service-Payment/AcuteInpatientPPS/Downloads/FY2018-CMS-1677-FR-Table-15.

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



Percent Would Use FUROSCIX

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

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#### 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 2, would you change your previous treatment choice to Product X?

#### Target Top Hospital Accounts with Affiliated Clinics

IV Furosemide and Discharge Volume Captured Based on Covered Deciles						
Decile	Hospital Count	Normalized Discharge Volume	Normalized IV Furosemide Volume	% Cumulative Hospital Count	% Cumulative Discharge	% Cumulative IV Furosemide
10	57	7,202	13,047	1%	7%	13%
9	93	8,991	11,090	3%	16%	24%
8	125	9,978	9,940	5%	26%	34%
7	160	10,601	9,378	7%	37%	43%
6	198	10,816	9,187	11%	48%	53%

Covering deciles 7 and above hospitals (435) and their affiliated outpatient facilities captures 37% of the HF discharge volume and 43% of the IV furosemide volume used in affiliated HF community

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

### HF payer mix and FUROSCIX value proposition

#### 2017 Medicare Part D Insights

#### 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.

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## **Anti-infective Program**

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### 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



#### **Ceftriaxone Outpatient Days of Therapy**

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

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#### Pivotal study confirms scCeftriaxone comparable to IV

- Similar drug exposures (AUC o-∞) between IV ceftriaxone and scCeftriaxone
- Complete bioavailability (107.7%) with subcutaneous administration
- Pharmacodynamic profile (%T>MIC24) 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 \$4.3B US market opportunity
  - scCeftriaxone represents \$4.5B US market opportunity
- Clear value proposition
- Established reimbursement model
- 505(b)(2) regulatory pathway
- High barriers to entry
  - IP on FUROSCIX to 2034, provisional patent 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



## Thank you

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Innovative outpatient solutions that bring care closer to home