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Monday, October 27, 2025
02:30 PM - 02:45 PM

Lasix® ONYU – A New Chapter for a Legendary Drug Name

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Sponsored by Ligand: How Captisol® enabled the development of a high-concentration furosemide formulation — starting the next chapter in the life of a legendary drug

Forward-looking Statement

This presentation may contain "forward-looking" statements within the meaning of the safe harbor provisions of the U.S. Private Securities Litigation Reform Act of 1995. Forward-looking statements can be identified by words such as: "anticipate," "intend," "plan," "goal," "seek," "believe," "project," "estimate," "expect," "strategy," "future," "likely," "may," "should," "will" and similar references to future periods. These statements are subject to numerous risks and uncertainties that could cause actual results to differ materially from what we expect. Examples of forward-looking statements include, among others, timing or outcomes of communications with the FDA, our expectations about safety and efficacy of our product candidates and timing of clinical trials and its results, our ability to commence clinical studies or complete ongoing clinical studies, and to obtain and maintain regulatory approvals for Lasix® ONYU and other candidates in development, and the success of any efforts to commercialize and market Lasix® ONYU. We undertake no obligation to publicly update any forward-looking statement, whether written or oral (including any forward-looking statements on the Website) that may be made from time to time, whether as a result of new information, future developments, or otherwise.

Important Safety Information

What is Lasix® ONYU (furosemide injection) for subcutaneous use?

Lasix® ONYU is a prescription drug-device combination that treats edema caused by fluid build-up in a person with heart failure. Lasix ONYU comes with a special device that delivers the medicine under the skin. Follow the instructions provided by your healthcare provider when using Lasix ONYU.

IMPORTANT SAFETY INFORMATION

Before using Lasix® ONYU, read the Instructions for Use and tell your healthcare provider about all your medical conditions, including if you are allergic to furosemide or any of the ingredients in Lasix ONYU, have trouble urinating, or if you are allergic to medical adhesives.

Tell your healthcare provider about all of the medicines you take, including prescription and over-the-counter medicines.

Warning: Only use the Lasix ONYU Prefilled Cartridge with the Lasix ONYU Infusor. Do not use insulin cartridges or other medicine cartridges in the Lasix ONYU Infusor. Doing so could cause severe injury.

What are the possible side effects of Lasix ONYU?

Dehydration: Lasix® ONYU is a diuretic that can make you lose a lot of fluid and with it electrolytes. You may get a dry mouth, have increased thirst, get muscle pains or cramps, have reduced urine output or your urine may be more yellow than normal, you may get a headache, get dry skin, or have nausea or vomiting. Your healthcare provider may check your electrolytes while receiving Lasix® ONYU.

Low Blood Pressure: Lasix® ONYU may lower your blood pressure temporarily. You may feel lightheaded or dizzy. This usually happens when you stand. Getting up slowly may help.

High Blood Sugar: Lasix® ONYU may increase blood sugar (glucose) levels if you have diabetes mellitus.

Loss of Hearing: Lasix® ONYU can cause ringing in your ears. If so tell your healthcare provider.

Risk of Sunburn: Your skin may be more sensitive to sunlight while taking Lasix® ONYU.

Infusion Site Reactions: Lasix® ONYU can cause infusion site pain, bruising and temporary swelling or redness at the site of the Infusor.

Incomplete Dosing: Make sure the Infusor does not get wet during use. Also limit your physical activities. Some movements or when it gets wet may stop the infusion and you may not get all the medication.

These are not all the possible side effects of Lasix® ONYU. For more information, ask your healthcare provider or pharmacist.

Call your healthcare provider for medical advice about side effects. You may report side effects to the FDA at 1-800-FDA-1088.

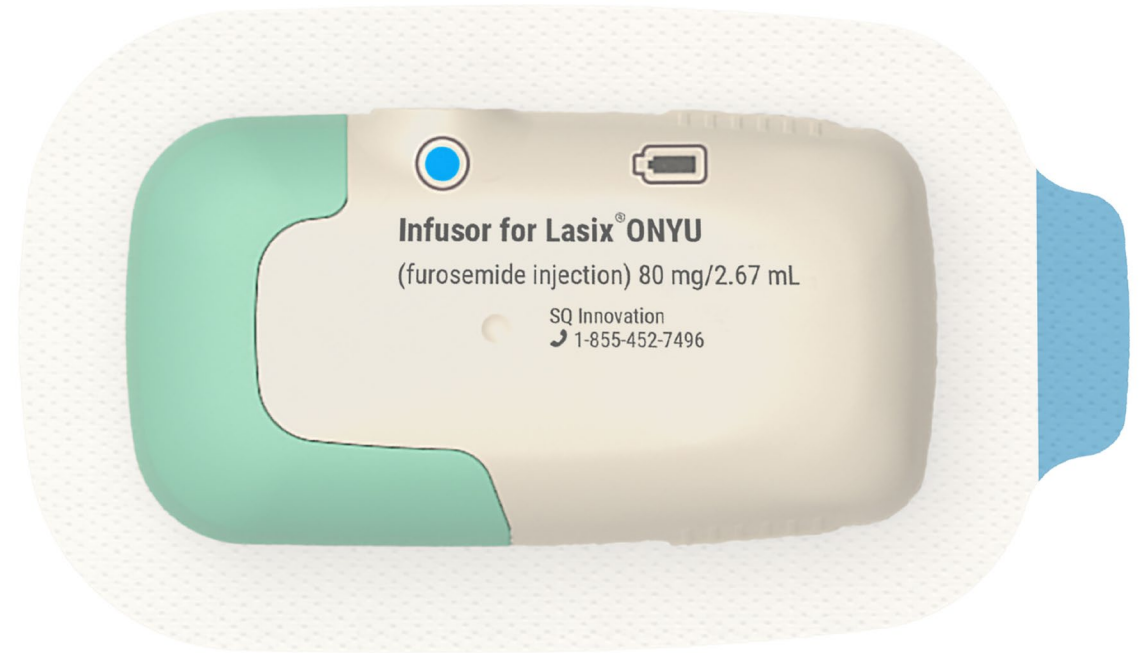
Please see the full [Prescribing Information](#) and [Instructions for Use](#).

For Important Safety Information and Instructions for Use visit www.lasix-onyu.com

FDA Approved Oct 7, 2025

Lasix[®] ONYU

(furosemide injection)
80 mg/2.67 mL for subcutaneous use



Furosemide 30mg/mL concentration at pH 7.5 enabled by Betadex (Captisol[®])

The trademark LASIX[®] is registered for Validus Pharmaceuticals L.L.C. in the United States and used by SQ Innovation under license.

For Important Safety Information and Instructions for Use visit www.lasix-onyu.com

Formulation Credentials

- Four patent families of issued formulation patents
- Two FDA approved products

Patent Family	Basis	Product	FDA Approval
US 6278824	Furosemide Cyclodextrin	Lasix® ONYU (30mg/mL)	10/7/2025
US 61808962	Furosemide Tris	Furoscix® (8mg/mL)	10/7/2022
US 62788306	Torsemide Cyclodextrin		
US 62777384	pH 8.0-8.5		



The trademark Furoscix® is registered for scPharmaceuticals

Why new formulations of loop diuretics?

- **Enable subcutaneous infusion:**
 - Get pH down to avoid the burning/stinging that may occur with pH 9+ (furosemide USP)
 - Reduce volume to below 3mL, so we could operate in the “insulin-pump ecosystem” (Lasix ONLY)

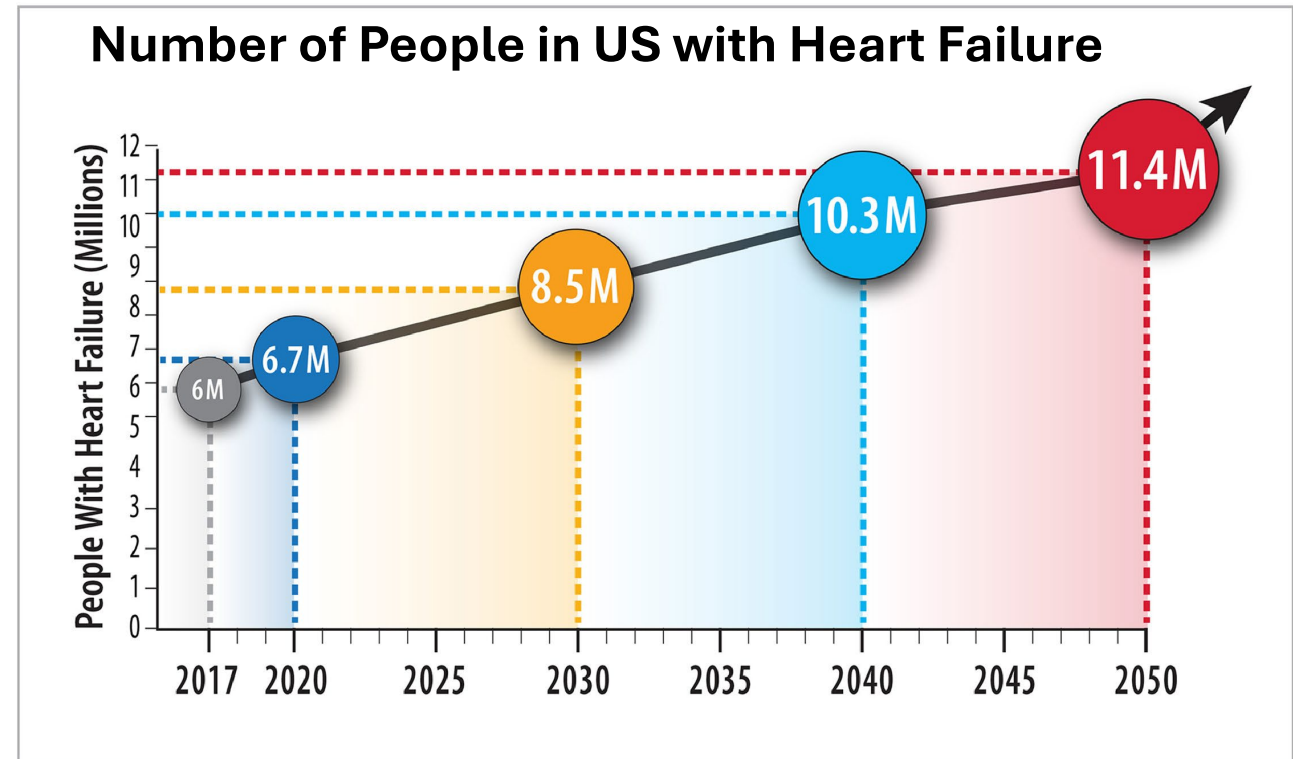
Our Goal:

Cost-effective, hospital-strength diuretic treatment option as an alternative to hospitalization for select patients as directed by their healthcare provider



The Crisis:

- The burden of heart failure is rapidly increasing
- We already do NOT have enough:
 - Beds
 - Providers
 - Money

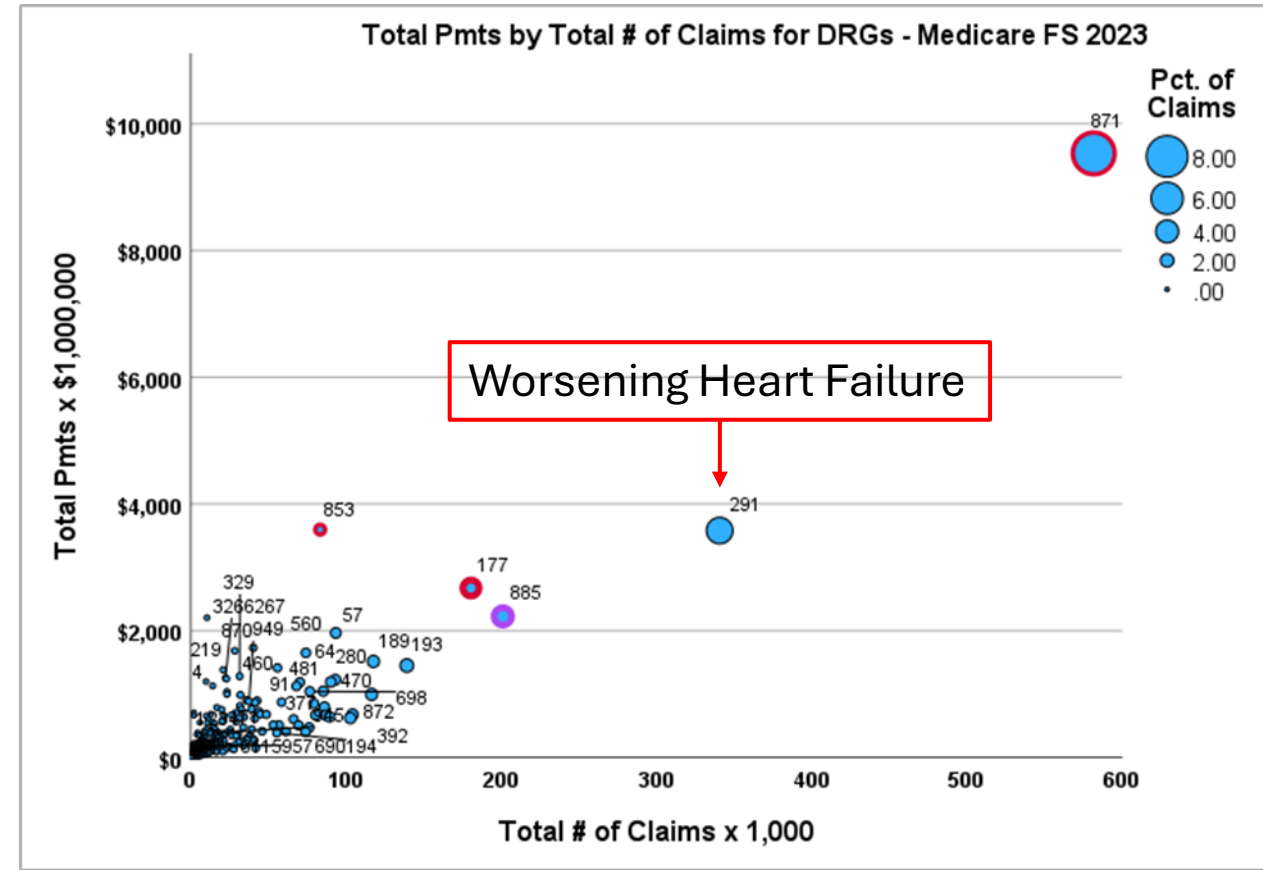


Data from Joynt Maddox KE, Elkind MSV, Aparicio HJ, Commodore-Mensah Y, de Ferranti SD, Dowd WN, et al. Forecasting the burden of cardiovascular disease and stroke in the United States through 2050: prevalence of risk factors and disease: A Presidential Advisory from the American Heart Association. *Circulation*. 2024 Jun 4; Van Nuys KE, Xie Z, Iysinger B, Hlatky MA, Goldman DP. Innovation in heart failure treatment: life expectancy, disability, and health disparities. *JACC Heart Fail*. 2018; 6:401–9.; and Heidenreich PA, Albert NM, Allen LA, Blumenthal DA, Butler J, Fonarow GC, et al. Forecasting the impact of heart failure in the United States: A policy statement from the American Heart Association. *Circ Heart Fail*. 2013; 6:606–19.

Leading Cause of Hospital Admissions

Worsening Heart Failure (DRG 291) is the 2nd most common reason for hospital admissions in the elderly

- Out of 773 identified Medicare admission reasons, DRG 291 ranks second
- The top 5 DRGs account for approximately 20% of all Medicare inpatient admissions
- Adoption of Lasix ONYU can have a measurable and material impact on Medicare Part A spending

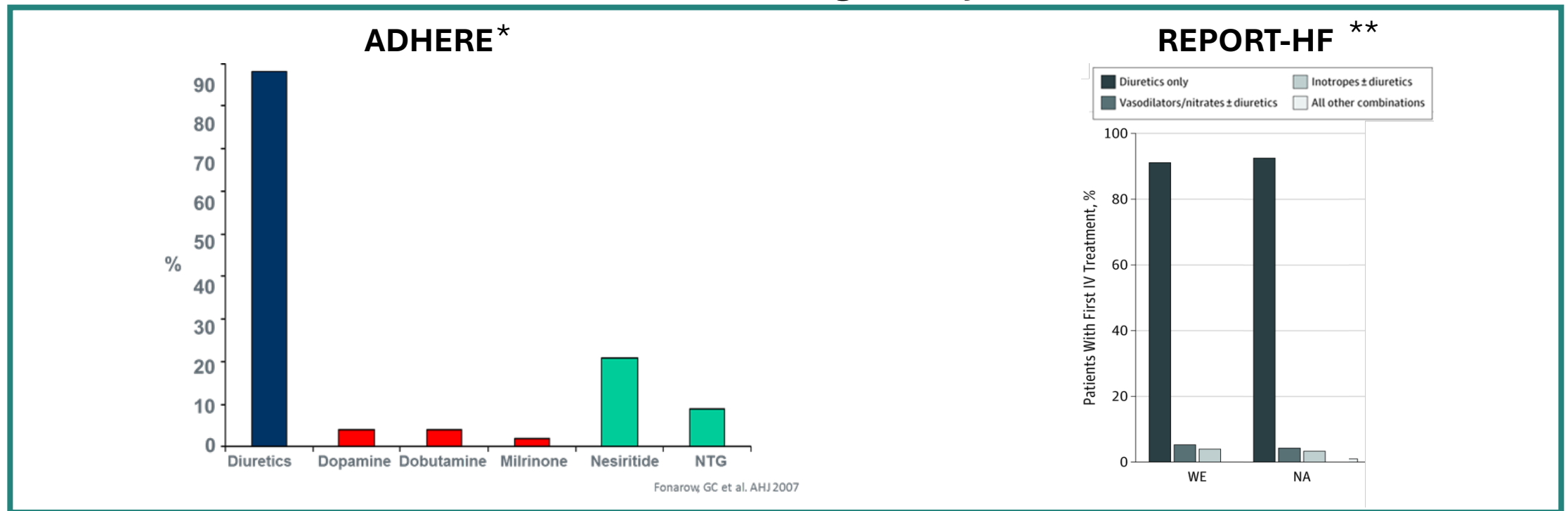


Source: DEFINITIVE HEALTHCARE

Parenteral Diuretics are the Cornerstone

For around 95% of patients hospitalized for worsening HF, diuretics are the only treatment they receive

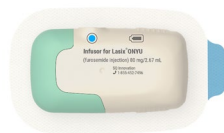
- Furosemide is the diuretic of choice globally



*Am Heart J. 2007 Jun;153(6):1021-8. doi: 10.1016/j.ahj.2007.03.012.
**JAMA Cardiol. 2020;5(4):401-410. doi:10.1001/jamacardio.2019.5108

Loop Diuretic Products for SC Administration

	Lasix® ONYU	Furoscix®	SCP-111*
Furosemide – 80mg	30mg/mL	8mg/mL	80mg/mL
Administration	5hr Infusion	5hr Infusion	Injection
Dose	1-2 units/day (no limit)	1-2 units/day (no limit)	[UNK]
Solubilizer/Solvent	Betadex (Captisol®)	TRIS	[UNK]
FDA Status	Approved -2025	Approved - 2022	NDA Pending
Shelf-life	24 months RT	12 months RT (due to device)	[UNK]

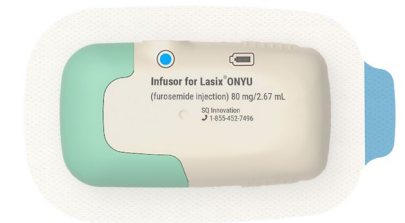


*A previous slide used at the PODD contained an error – SCP-111 does not use NMP as an excipient
Furoscix is a registered trademark for scPharmaceuticals

No Small Task:

Removing 8-10L (2 gallons) of edema requires an intense multi-day course of therapy at moderate to high doses

- Typical patient in an inpatient setting receive 500 to >1000mg of furosemide-equivalent over a course of treatment¹
- Initial treatment often involves two 80mg units/day for 1-3 days
- Average number of 80mg doses to replace an admission: ~ 10
- Milder/earlier cases may require fewer units



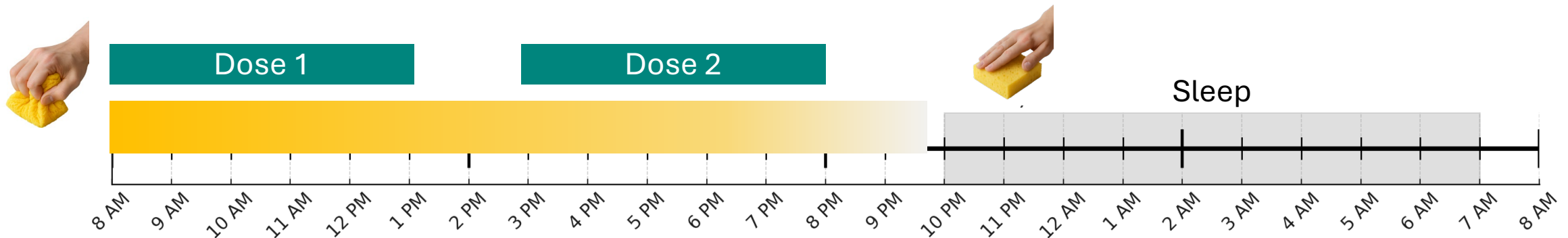
Guidance in our trial - ClinicalTrials.gov identifier NCT05419115

Total oral (pre-hospital) or IV daily dose (prior to randomisation) of loop diuretic	SQIN-Furosemide
≤ 80mg furosemide or ≤ 2mg bumetanide	SC 80mg ONCE daily
> 80mg furosemide or > 2mg bumetanide	SC 80mg TWICE daily

¹N Engl J Med. 2011 Mar 3;364(9):797-805.

Why 5hr Infusion?

- Delivery Profile 80mg over 5-hours: 30mg in first hour and 12.5mg/hour over the remaining 4 hours:
 - Objective: Tempered diuretic response over $\pm$ 8hrs
 - Aimed to reduce risk of orthostatic hypotension, falls, incontinence, prostatism*
 - Reduce period of post diuretic sodium retention (keep sponge squeezed)
 - Dry night



* Based on pharmacological considerations. No evidence exists that the tempered diuretic response is associated with these clinical benefits

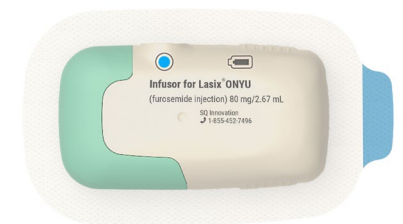
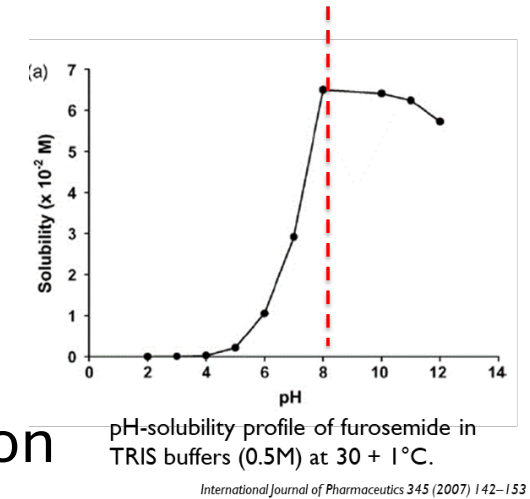
Our Requirements and Goals:

Pharmaceutical Side

- Neutral pH – effective solubilizer
- 24 month RT stability
- Favorable skin safety profile - pain, skin irritation, resolution

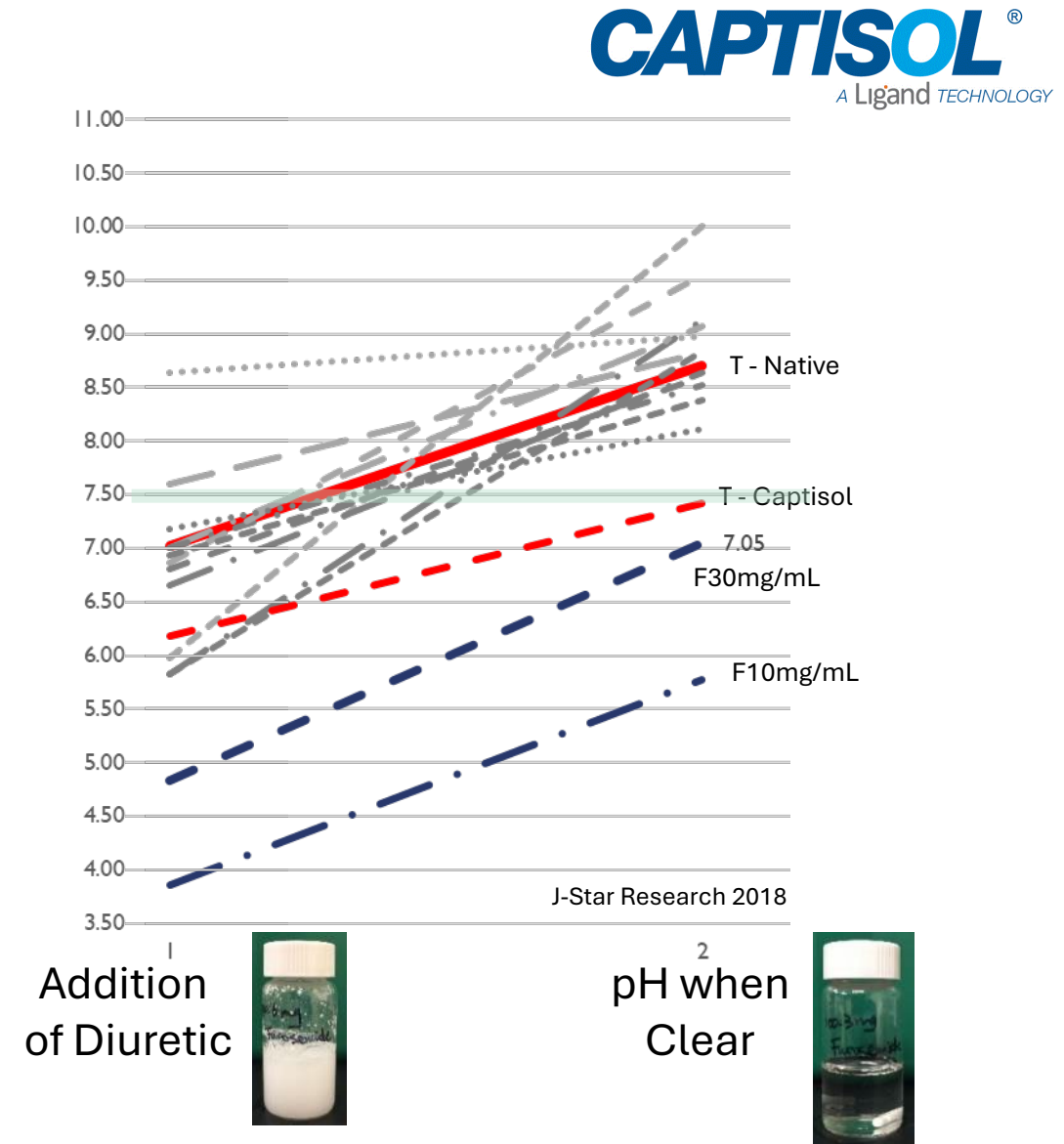
Device Side

- Reuse of electromechanical components
 - Reduce COGS and environmental impact
 - Manufacturability
- Include features requested by the clinical community
 - “Travel home” feature (option to start at home after placement in clinic)



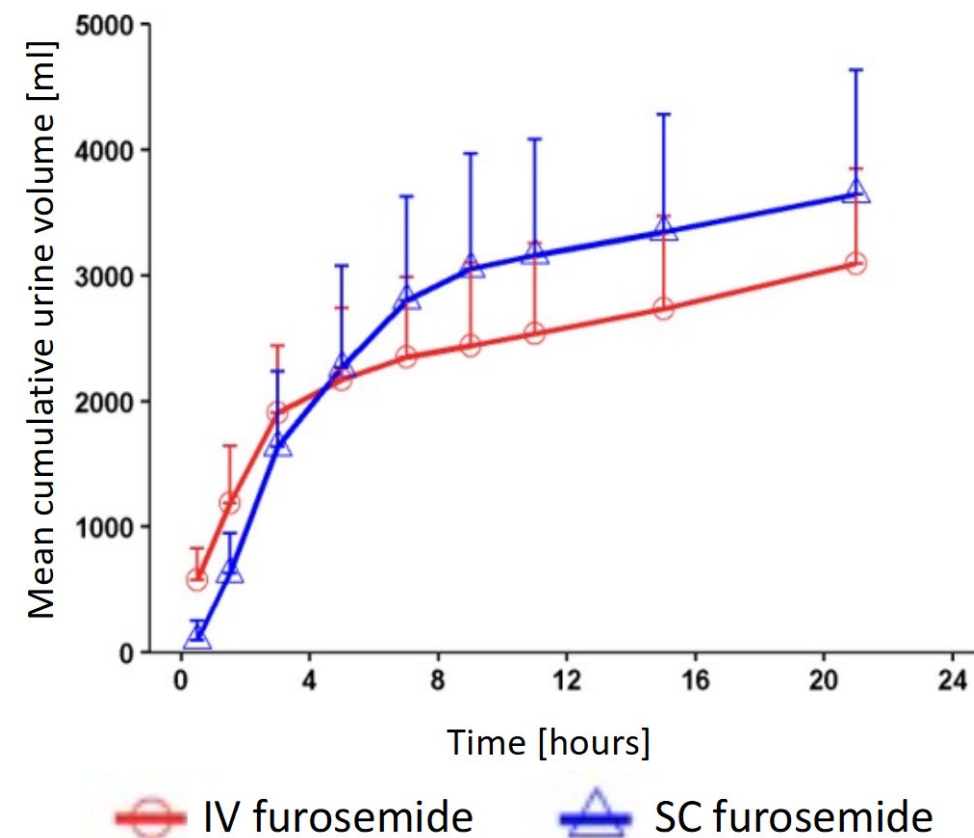
Our Formulation Research

- We screened a long list of buffers and solubilizers (grey lines)
- None had noticeable effect except 40% Captisol which reduced pH at solubility from 8.7 to 7.4
- The Furosemide line was even more dramatic with solubility of 10mg at pH 5.8
- Additional experiments confirmed stability of solution at 30mg/mL with pH of 7.4
- Two patent families related to SBECD



Clinical Evidence Summary

- Complete bioavailability (112%)
- Diuretic response similar to standard IV hospital treatment (80mg IV bolus)
 - Diuresis (24h): 3.650 L (115%)
 - Natriuresis (24h): 8.8 gr. (117%)
- Tempered diuretic response over 8 hours
- Well tolerated
 - No SAEs, no bruising



Eur Heart J Cardiovasc Pharmacother.
2024;10: 35–44.

Lasix[®] ONYU – Combination Product

Lasix ONYU is a combination product delivering pH-neutral furosemide formulation subcutaneously via a pre-programmed patch pump Infusor.

Drug Constituent

- Novel furosemide formulation
 - pH of 7.5 for skin tolerance
 - 30mg/mL to reduce infusion volume (80mg/2.67mL)
- Prefilled standard (3mL) glass cartridge
- Shelf-life: 24 months 20-25 C



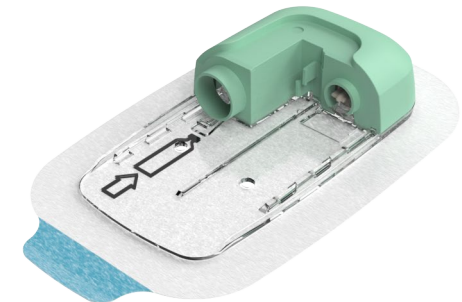
Full Unit



Drug Cartridge



Reusable Unit



Disposable Unit

Device Constituent (Infusor)

- Two component design
 - Single-use sterile Disposable Unit
 - Electromechanical multi-use component rated for 48 infusions (one user - no DME)
- 2nd generation design to reduce cost and offer advanced features

Summary:

Lasix[®] ONYU
(furosemide injection)
80 mg/2.67 mL for subcutaneous use

CAPTISOL[®]
A Ligand TECHNOLOGY

- **Lasix[®] ONYU** FDA approved on Oct 7, 2025
 - Providing hospital-strength diuresis
 - Up to two doses/day
 - Average number of doses to replace a hospital stay is ~ 10 over 5-8 days
 - Some patients present with massive fluid overload and may require >20 units for an episode
 - Betadex (Captisol) enabled high concentration neutral pH formulation without limitation of number of doses
 - Global product developed in collaboration with Ligand

Thank you