



A LIFELONG SOLUTION  
**FOR A CHRONIC  
CONDITION**

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and Restricted to the Direct Recipient of the Enclosed Materials



**Dr. Yair Feld**  
Medical Director & Founder



**Nitai Hanani**  
CEO & Co-founder

# Snapshot

Founded 2016, Haifa, Israel,

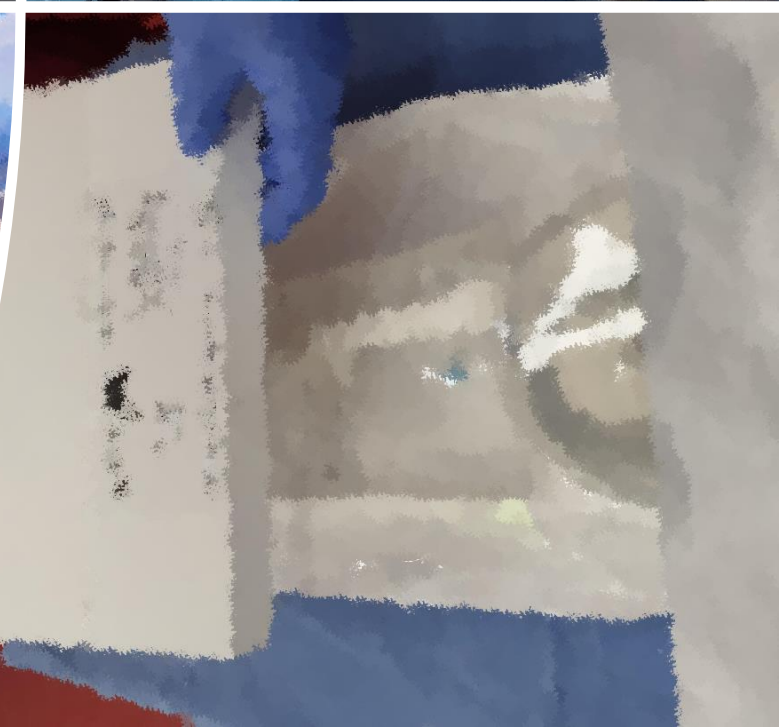
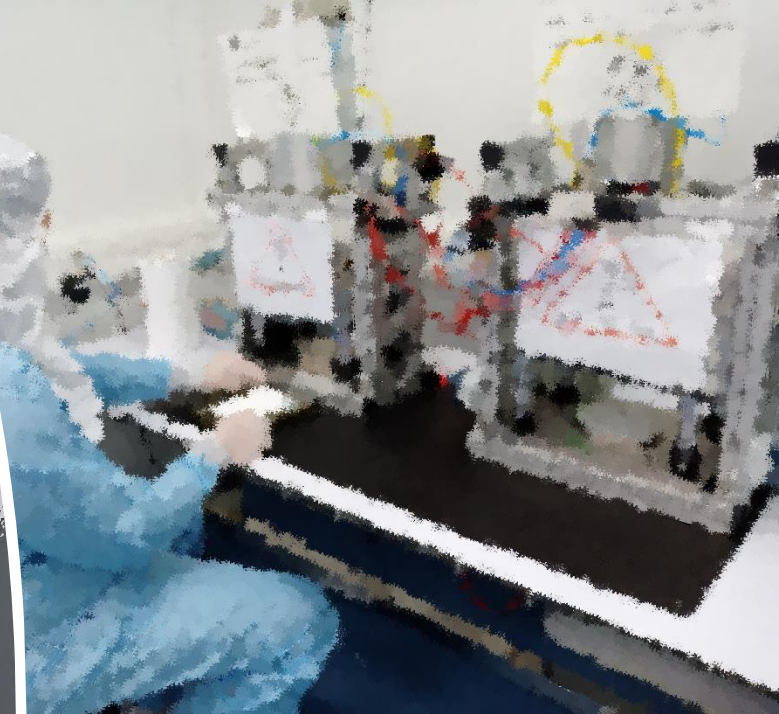
7 employees

\$4.5mn funding to date  
(including prestigious €2mn H2020 grant)

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## Status:

Preparing for first clinical trial



## Mission



**To prevent fluid overload in Chronic Heart & Kidney Failure patients**



**To shift weight of chronic disease treatment towards home-based care**



Severe heart failure fills your  
lungs with fluid until you

**can't breathe.**

Time and time again.



# #1 Healthcare Burden



**9 out of 10**

HF admissions are due to congestion

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**24%**

< 1-month readmissions

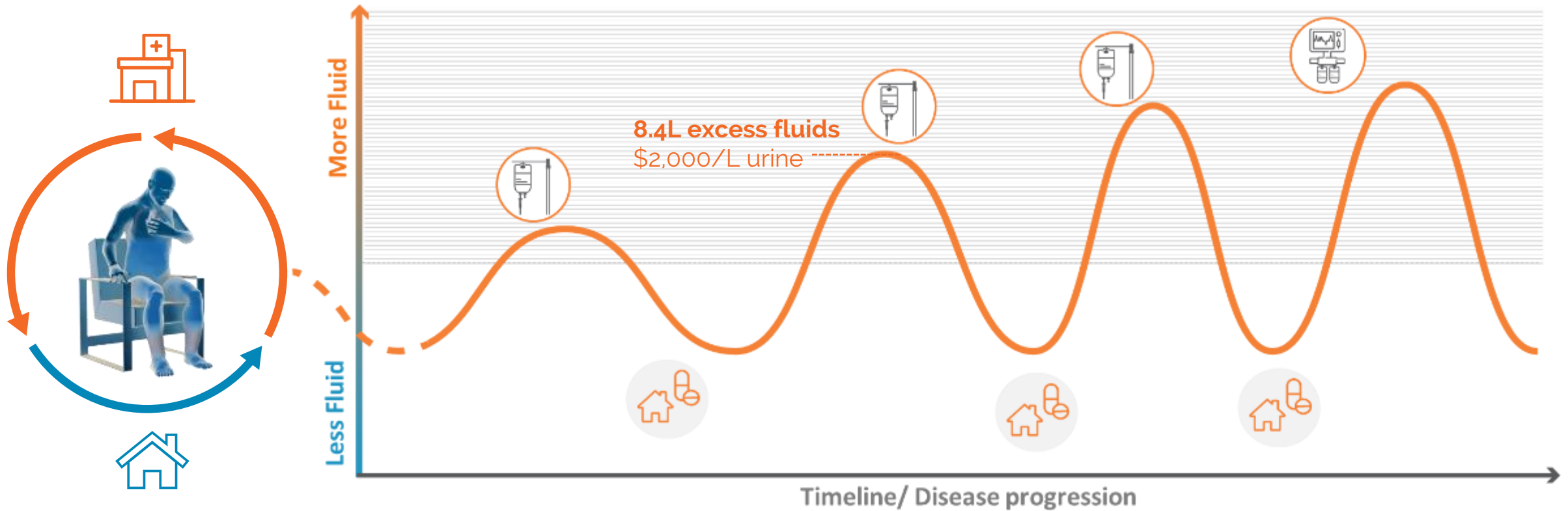
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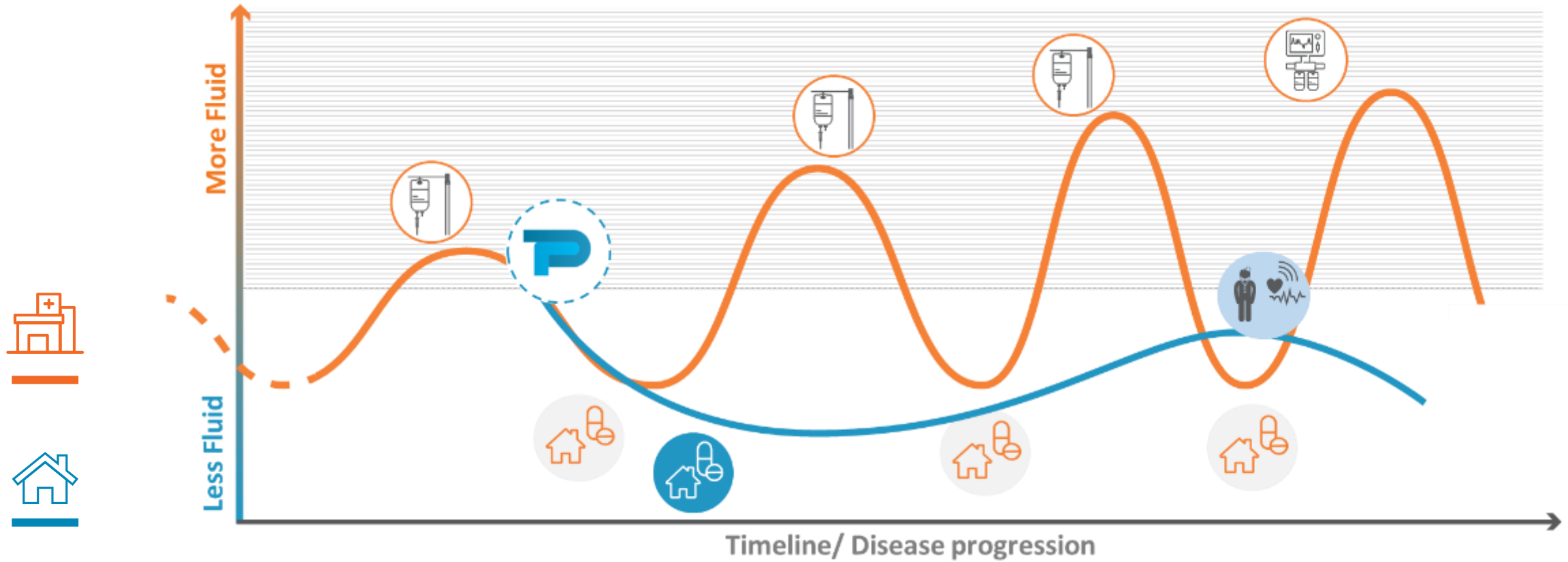
**\$17B**

cost of "frequent flyers" admissions in US alone

# No Chronic Solution for the "Frequent Flyers"



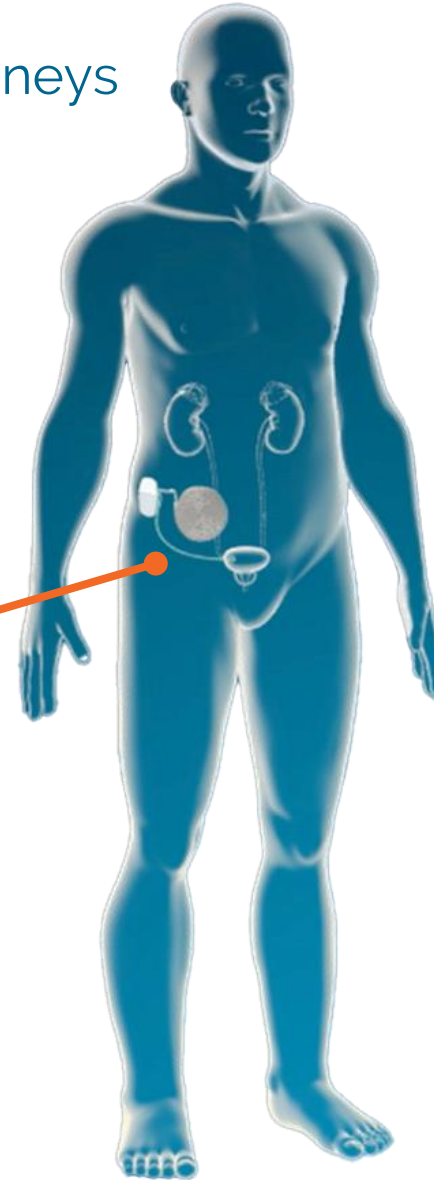
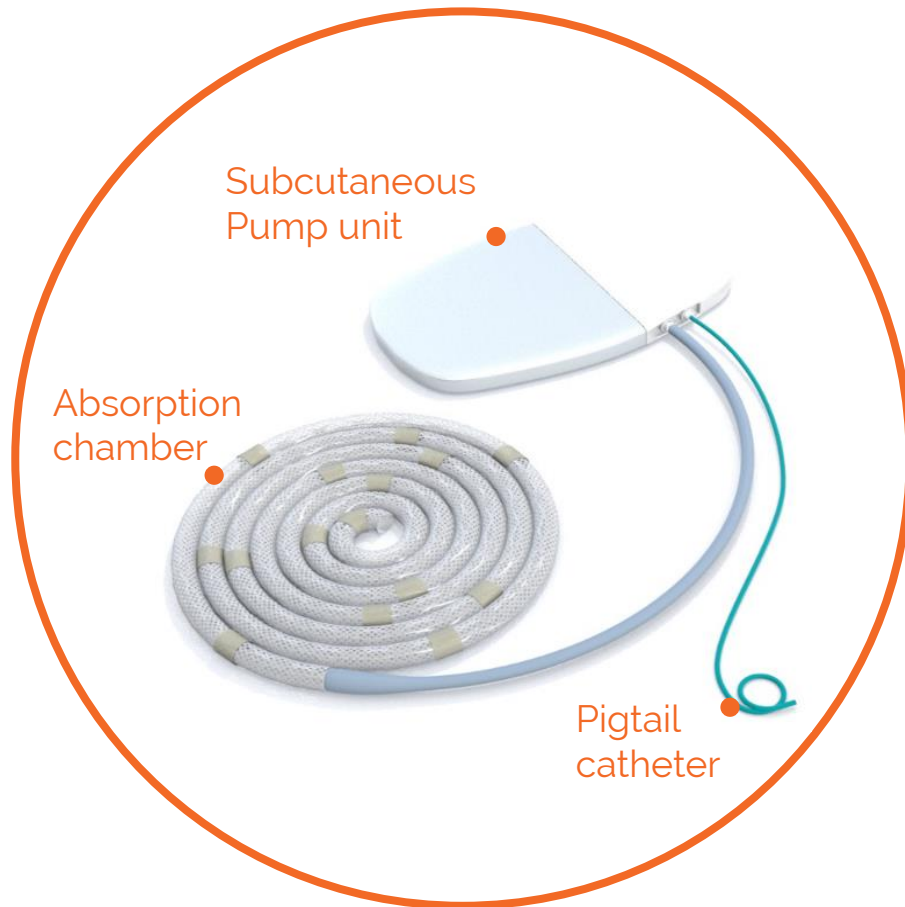
# Approach: Just Don't Let the Fluids Accumulate





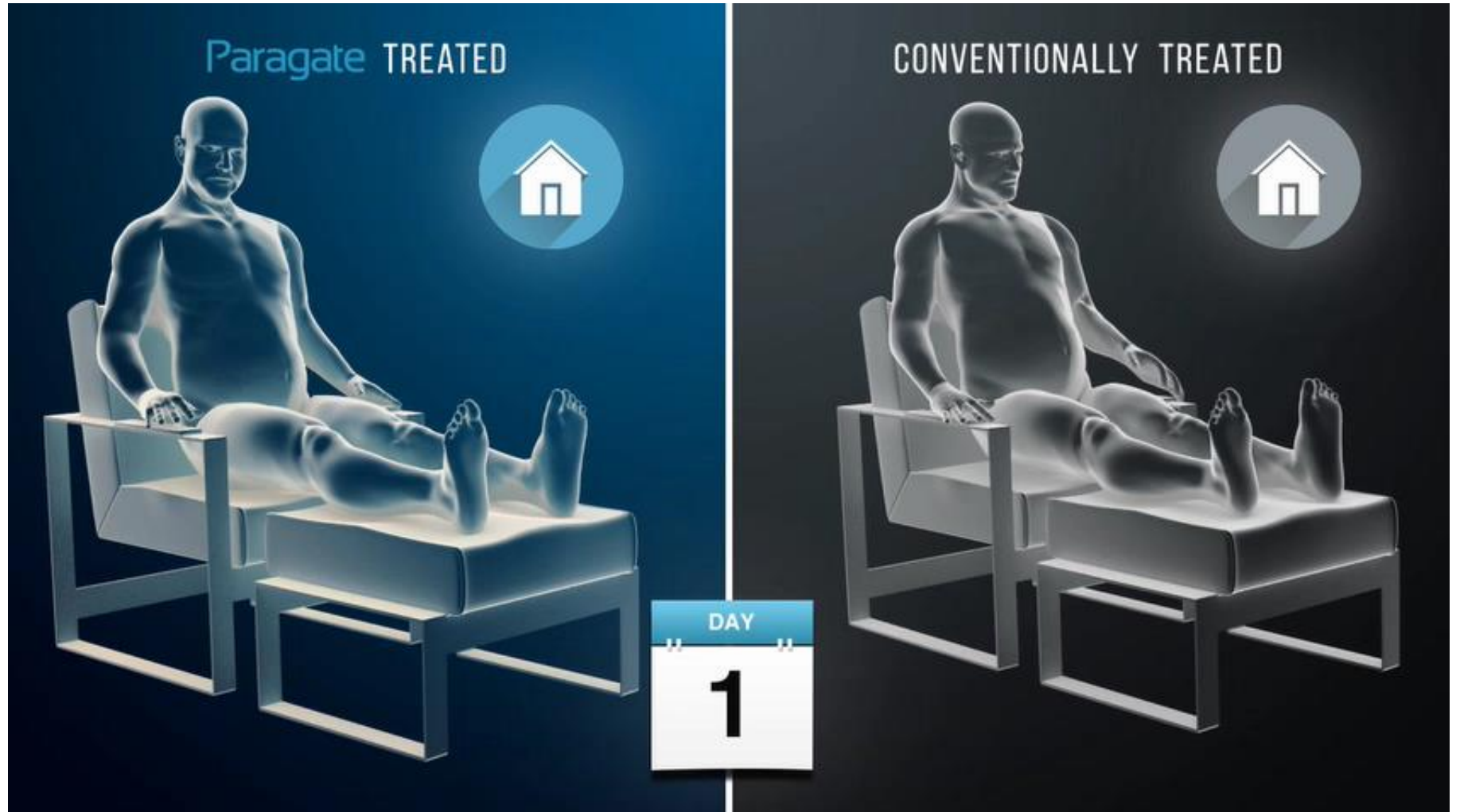
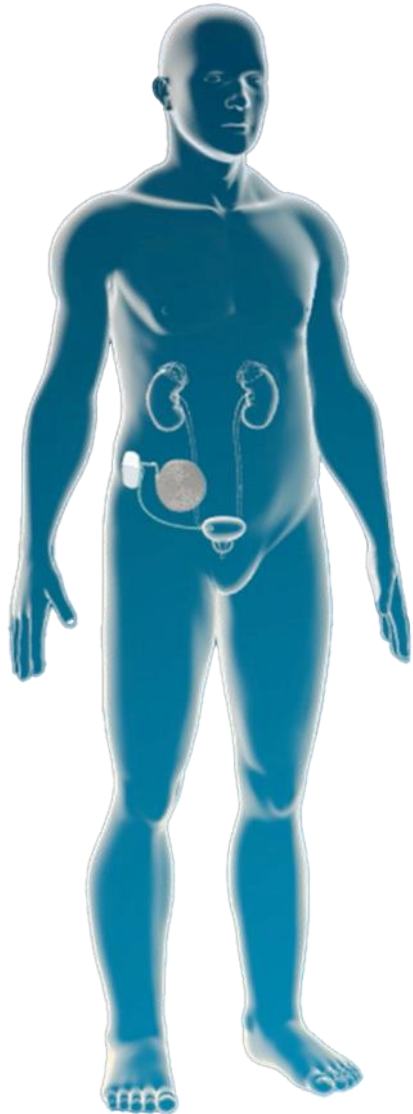
# The IPUD System

- **A Fully Implantable** Mechanical Bypass of the Kidneys



- ✓ **Systemic Isotonic Fluids**
- ✓ **Wirelessly Configurable**
- ✓ **Monitoring features**
- ✓ **No circulation contact**
- ✓ **Low infection risk**

# Home Based Solution

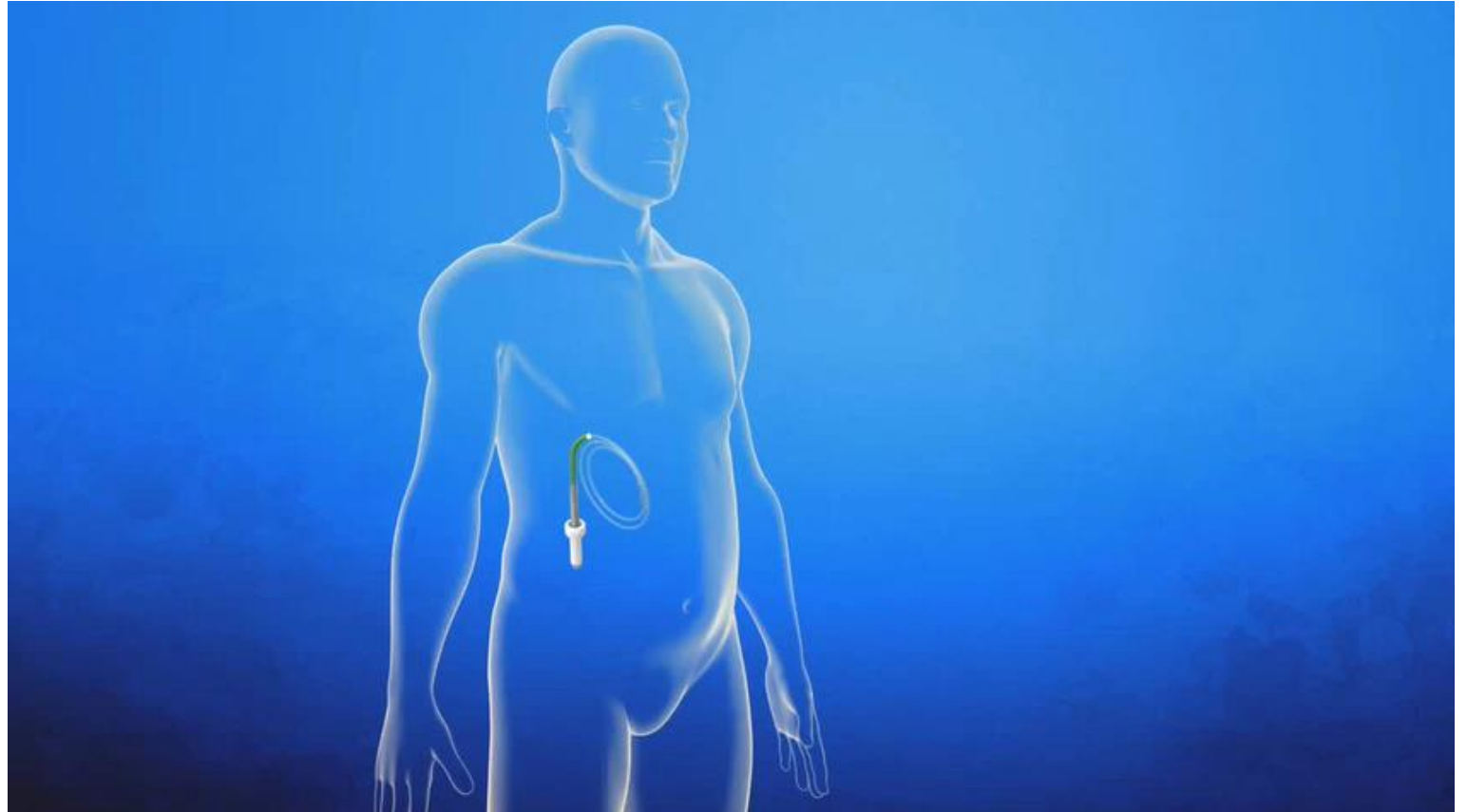
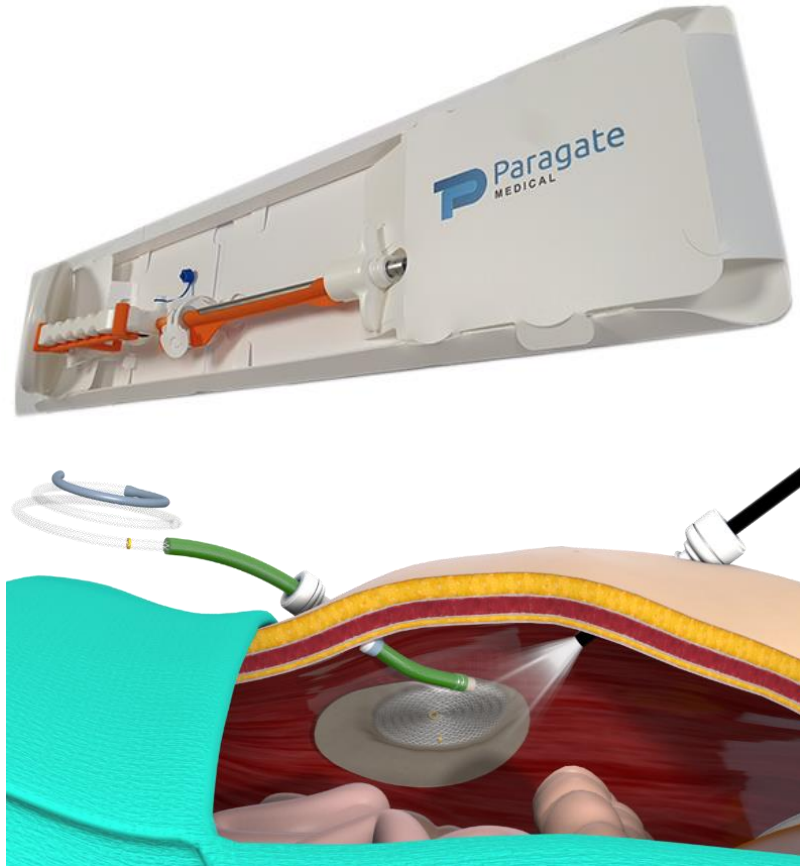


# 24/7 Treated, 24/7 Monitored



# ○ Laparoscopic Procedure

Short, Minimally Invasive, No Anchoring, Single Access



**2<sup>nd</sup> Gen** – Percutaneous, local anesthesia

# Development Status

## Lap Procedure



Simple, intuitive and quick laparoscopic procedure, without intervention with circulation

## Implantable, Wireless



Wireless Fully Implantable System  
2 mo. Follow up, large animals  
200-400ml/day of isotonic fluid (salts, toxins)

## First in Human Prep.



Design Freeze of Gen.1 (partially implantable) for FIH trial. Ongoing GLP safety trial (12 animals) and validations

# Value Proposition



Re-hospitalization ▲  
Quick Breakeven

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Quality of Life ▲  
HF Exacerbation ▼

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Burden of Care ▼  
Patient Engagement

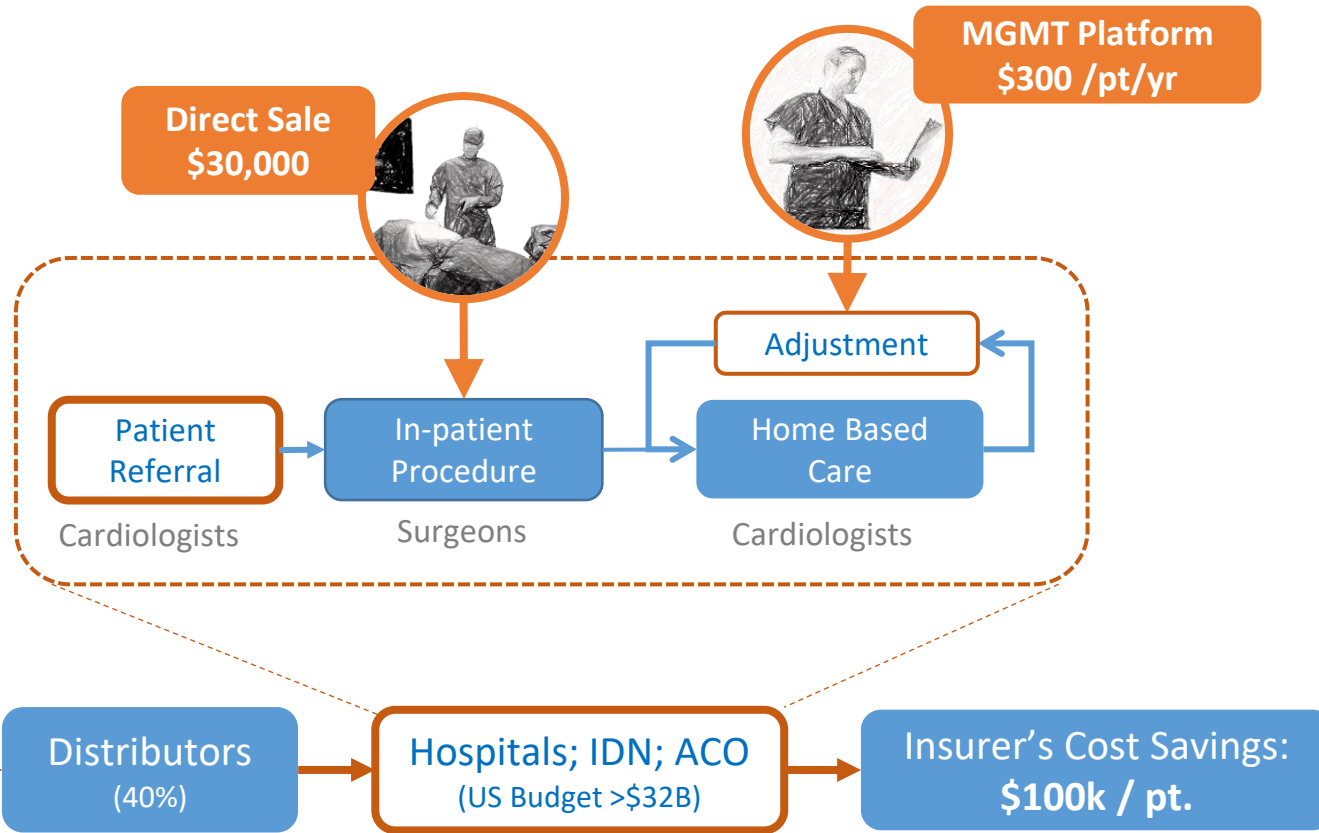
Cost Savings of  
**\$100k**

per patient, billions to  
healthcare system



# Business Model & Value Chain

## Dual Revenue Stream:



## Market:

### Total Addressable Market

Advanced and wet heart failure pts.  
4m pts. (15%) worldwide  
→ **\$120 billion**

### Serviceable Available Market

200,000 new incidents a year  
in EU, US  
→ **\$6 billion annually, 5% CAGR**

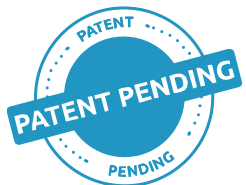
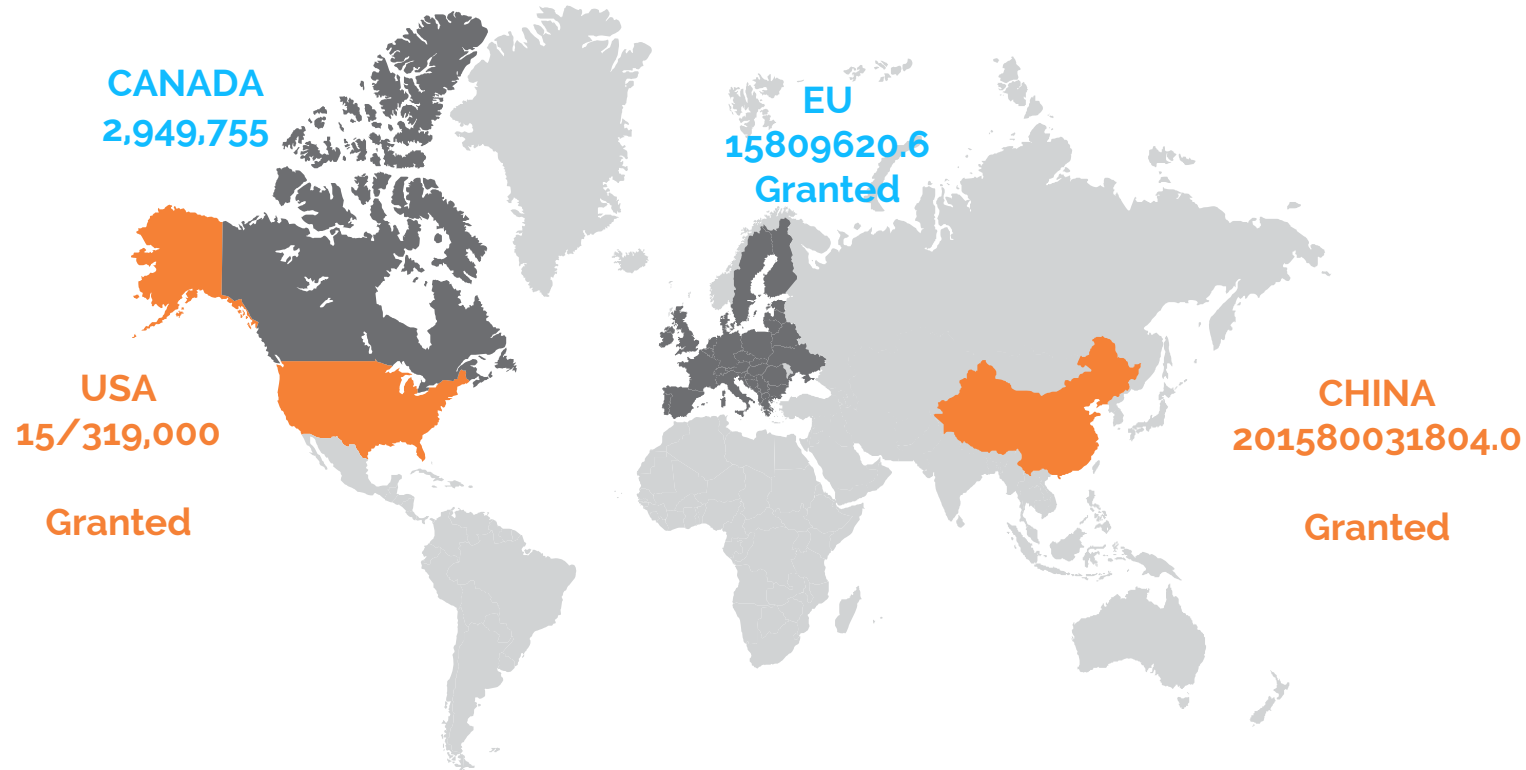
### Projected Sales

5,000 systems annually  
15,000 licenses  
→ **\$155 million annually**

# Granted IP



WO2015193880 "Continuous Implantable Peritoneal Dialysis", priority June 2014



NP: IL2018/050525 (USP 62/505.931) "Implantable Fluid Extraction Systems"  
EU, US, CA, **JP**, CN; for particular designs & operation modes, priority May 2017



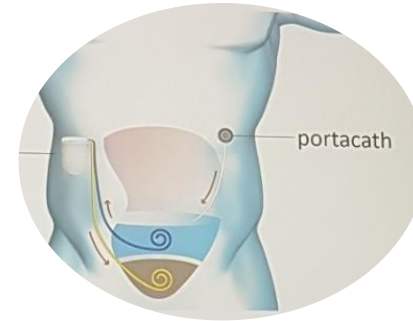
# HF Decongestion Competitive Landscape



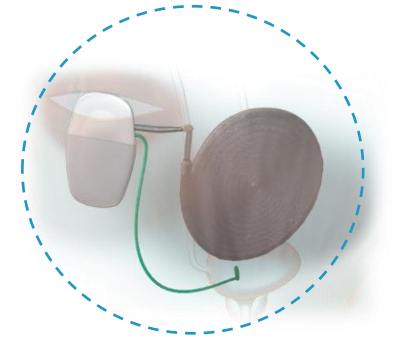
chf solutions



FRESENIUS MEDICAL CARE

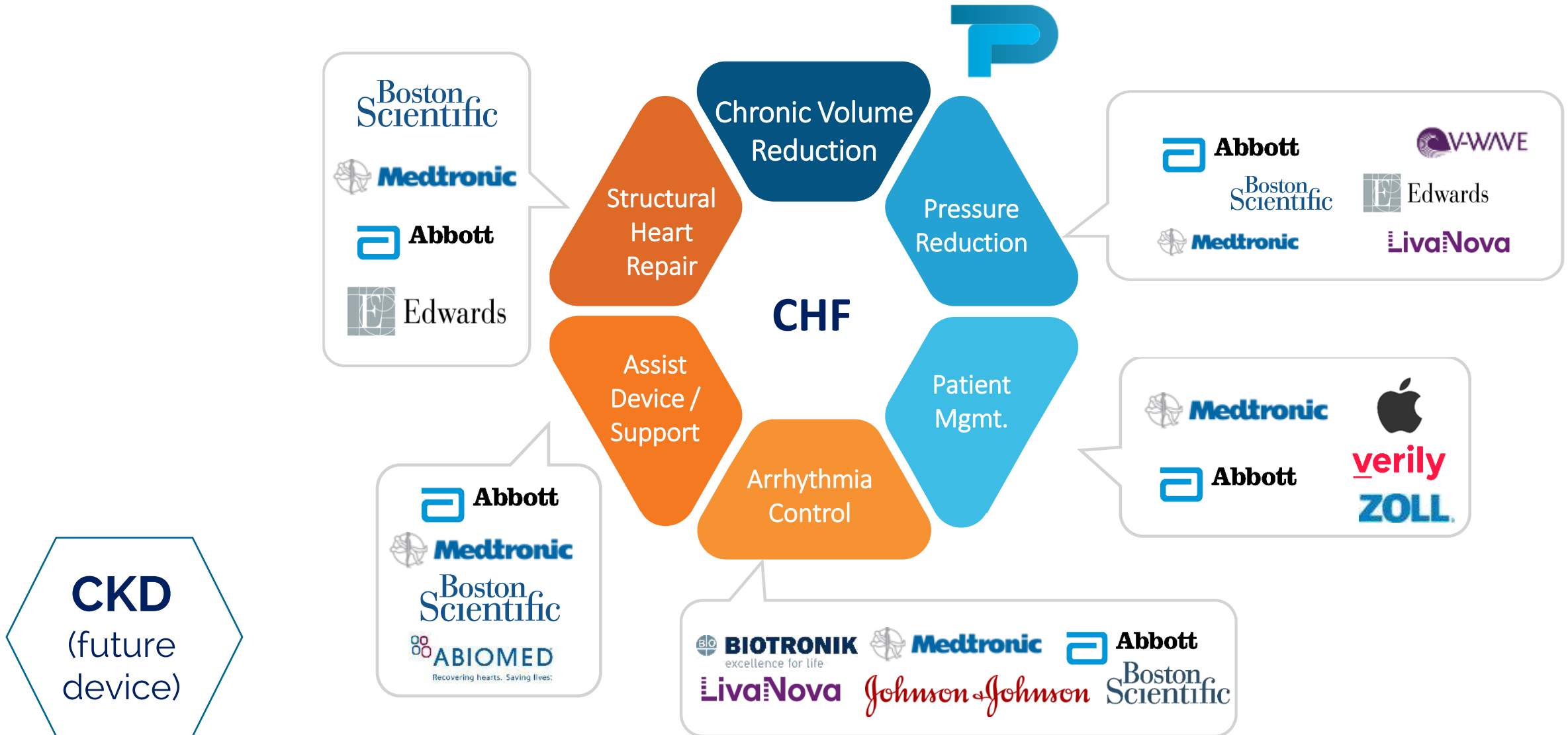


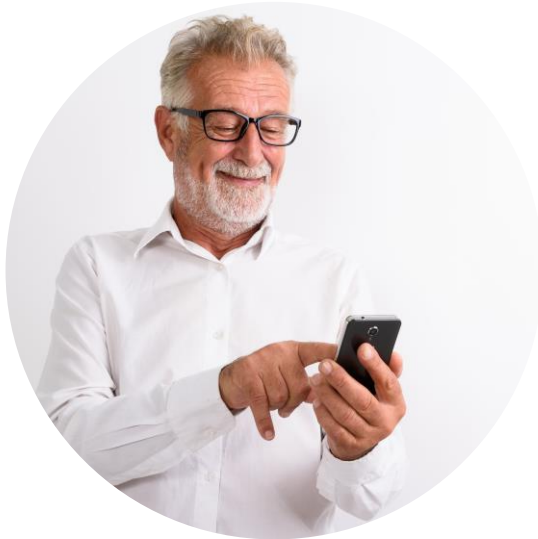
sequana medical



Paragate MEDICAL

	Ultrafiltration, etc.	Peritoneal Dialysis	Semi-Implantable Dialysis	Implantable Ultrafiltration
<i>Setting</i>	<b>Acute</b>	<b>Sporadic</b>	<b>Intermittent</b>	<b>Continuous</b>
<i>Patient Burden Free</i>	xx	xx	x	✓
<i>Admissions Reduction</i>	x	✓	✓	✓✓
<i>Infection Risk Free</i>	✓	xx	x	✓
<i>Blood Contact Free</i>	x	✓	✓	✓





## Chronic Heart Failure

**Continuous, home based, active solution**

Prevents frequent readmissions



## End Stage Renal Disease

**Solving the Inter-Dialytic Weight Gain (IDWG)**

Shortens dialysis sessions & Improves throughput by 50%

# Acknowledgement

Horizon 2020 EIC Grant

2018 Top 25 Emerging Companies

Acceleration Programs

Featured on..

ePCR Innovators Day | HFA / ICI / TCT Selected Abstract | A-Cure Scholars

ICI MAXIS Innovation Award & Best Abstract Winners

TCT Shark Tank Competition's Top-3

## – Lead Team



### **Yair Feld, MD PhD, Founder, Medical Director**

Cardiologist (Rambam, Sunnybrook) & Physicist  
Serial Entrepreneur

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### **Nitai Hanani, MSc, CEO and Co-founder**

15 years in R&D, Eng. and Mgmt. positions  
Led development of world's 1<sup>st</sup> intravascular stimulator

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### **Zohar Gendler, MSc MBA, Chairman of BoD**

CEO NGT3 VC (Seed investor)  
Former CEO Technion's Incubator (**Mazor, Corindus, Prolor**)

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### **Nizar Mishael, CPA, CFO**

18 years experience handling the finance in over 20  
companies as managing partner of NGT3VC

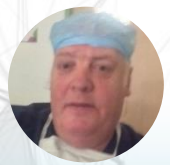
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### **Hernan Altman, BSc MBA, Director**

Director of Ophthalmic Programs, Lumenis  
Led development of #1 TAVI, Led FDA trials of >1,000 pts.

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### **Steve Whittaker, PhD, Clinical Affairs Lead**

Former VP CA/RA for Sequana Medical  
>20 years in LVAD applications (Heartware, Thoratec)

## – Scientific Board



### **Prof. Piotr Ponikowski**

Head of Dep. of Heart Diseases, Medical University,  
Wroclaw, Poland. **Chairman of ESC HF 2016 guidelines**  
Former president of HF Association

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### **Dr. Maria Rosa Costanzo**

Dir. of Heart Failure Program, Midwest Heart Specialists.  
Dir. of Edwards Center for Advanced HF, Naperville, Illinois.  
**Worldwide Leading Researcher in Ultrafiltration Therapy**

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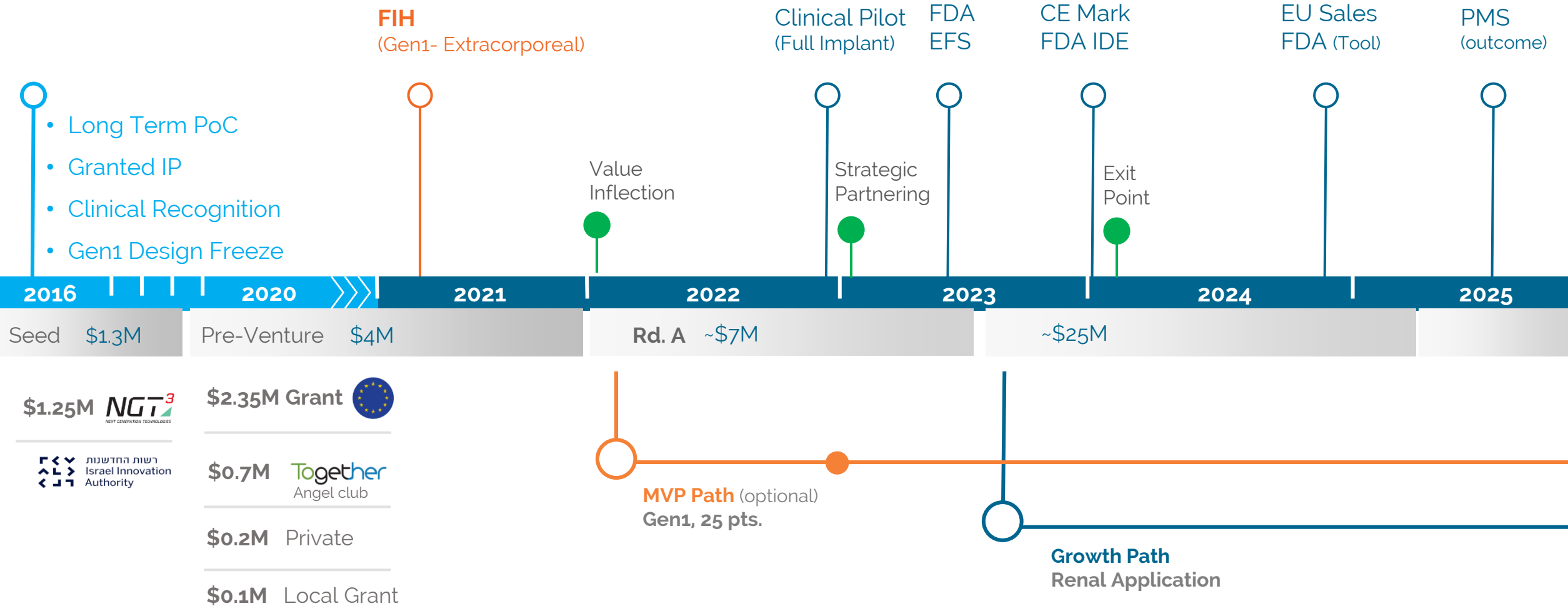


### **Prof. Uri Elkayam**

MD Professor of Medicine, Cardiac Care Unit, USC  
**Executive Council of the Heart Failure Society of America**



# Roadmap



Option to reach directly Rd. A and expedite product development  
 Forward Looking Information for 2021 and on

# Notable Exits in Heart Failure Space

Company	HF Focus	Exit value	Investments	Yrs. to exit	To	Exit MS
Cardiomems	Monitoring, Implantable	\$463M	\$231M in 9 rds.	13	St. Jude	FDA, CMS
Corventis	Monitoring, Wearable	\$150M	\$27M in 2 rds.	7 from round B	Medtronic	FDA
BioControl	Treatment, Neuromodulation	\$550M*	\$90M	4** / 9	Medtronic	IDE (FDA trial) completion
Heartware	Treatment, Ventricular Assist Devices (VAD)	\$1,255M	N/A	5 to IPO 12 to Exit	Medtronic	Multiple Portfolio, FDA, Marketing
Valtech	Treatment, Structural, Mitral and Tricuspid valve replacement	\$990M	\$70M	10	Edwards	CE
CardiAQ	Treatment, Structural, Mitral	\$400M	\$44.5M in <u>3 rds</u>	8	Edwards	Pre-IDE
Symetis	Treatment, Structural, TAVI	\$700M	\$77M in 3 rounds	8	Boston Scientific	CE (30 patients)
Twelve	Mitral Valve	\$458M	\$75M	6	Medtronic	10 patients study

# Exits in Medical Devices

	<b>PMA</b> heavy regulation	<b>510(k)</b> simple regulation
Exists stage	Pre-FDA/Revenue	Post-FDA/Revenue
Median Selling Price	\$353M	\$135M
Median ROI	6.8x	3.6x
Median Exit Time	5.5 yrs.	9.1 yrs.





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