



# Making Aquadex the Standard of Care for Fluid Management

Investor Presentation  
January 2025



# Safe Harbor Statement

## Forward Looking Statement

This presentation contains forward-looking statements within the meaning of Section 27A of the Securities Act of 1933, as amended and Section 21E of the Securities and Exchange Act, as amended regarding our plans, expectations, beliefs, estimates, goals and outlook for the future that are intended to be covered by the Private Securities Litigation Reform Act of 1995. Except for statements of historical fact, all forward-looking statements are management's present expectations and are not guarantees of future events and are subject to a number of known and unknown risks and uncertainties and other factors that may cause actual results to differ materially from those expressed in, or implied by, such forward-looking statements. In some cases, you can identify forward-looking statements by terminology such as "may," "will," "could," "would," "should," "plan," "predict," "potential," "project," "promising," "expect," "estimate," "anticipate," "intend," "goal," "strategy," "milestone," and similar expressions and variations thereof. Various factors could cause actual results to differ materially from these statements including our ability to execute on our commercial strategy and to grow our Aquadex® business, the possibility that we may be unable to raise sufficient funds necessary for our anticipated operations, our-clinical data collection activities, benefits of our products to patients, our expectations with respect to product development and commercialization efforts, our ability to increase market and physician acceptance of our products, potentially competitive product offerings, intellectual property protection, our expectations regarding anticipated synergies with and benefits of the Aquadex business, our business strategy, market size, potential growth opportunities and the other risks set forth under the caption "Risk Factors" and elsewhere in our periodic and other reports filed with the U.S. Securities and Exchange Commission ("SEC"), including our Annual Report on Form 10-K for the fiscal year ended December 31, 2023 and subsequent reports. We are providing this information as of the date of this presentation, and we undertake no obligation to update any forward-looking statements contained in this presentation as a result of new information, future events or otherwise. Although the Company believes that the forward-looking statements are reasonable and based on information currently available, it can give no assurances that the Company's expectations are correct. All forward-looking statements are expressly qualified in their entirety by this cautionary statement.

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This presentation also contains estimates and other statistical data made by independent parties and by us relating to market shares and other data about our industry. These data involve a number of assumptions and limitations and have not been reviewed or audited by our independent registered accounting firm. You are cautioned not to give undue weight to such estimates. In addition, projections, assumptions and estimates of our future performance and future performance of the markets in which we operate are necessarily subject to a high degree of uncertainty and risk. Neither we nor our advisors or representatives makes any representations as to the accuracy or completeness of that data or undertake to update such data after the date of this presentation.

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## Additional Information

You should read the documents that we have filed with the SEC for more complete information about us. We encourage you to read such documents in full for more detailed information, statistics, reports and clinical trials referenced in this presentation. You may access these documents for free by visiting EDGAR on the SEC website at <http://www.sec.gov>.

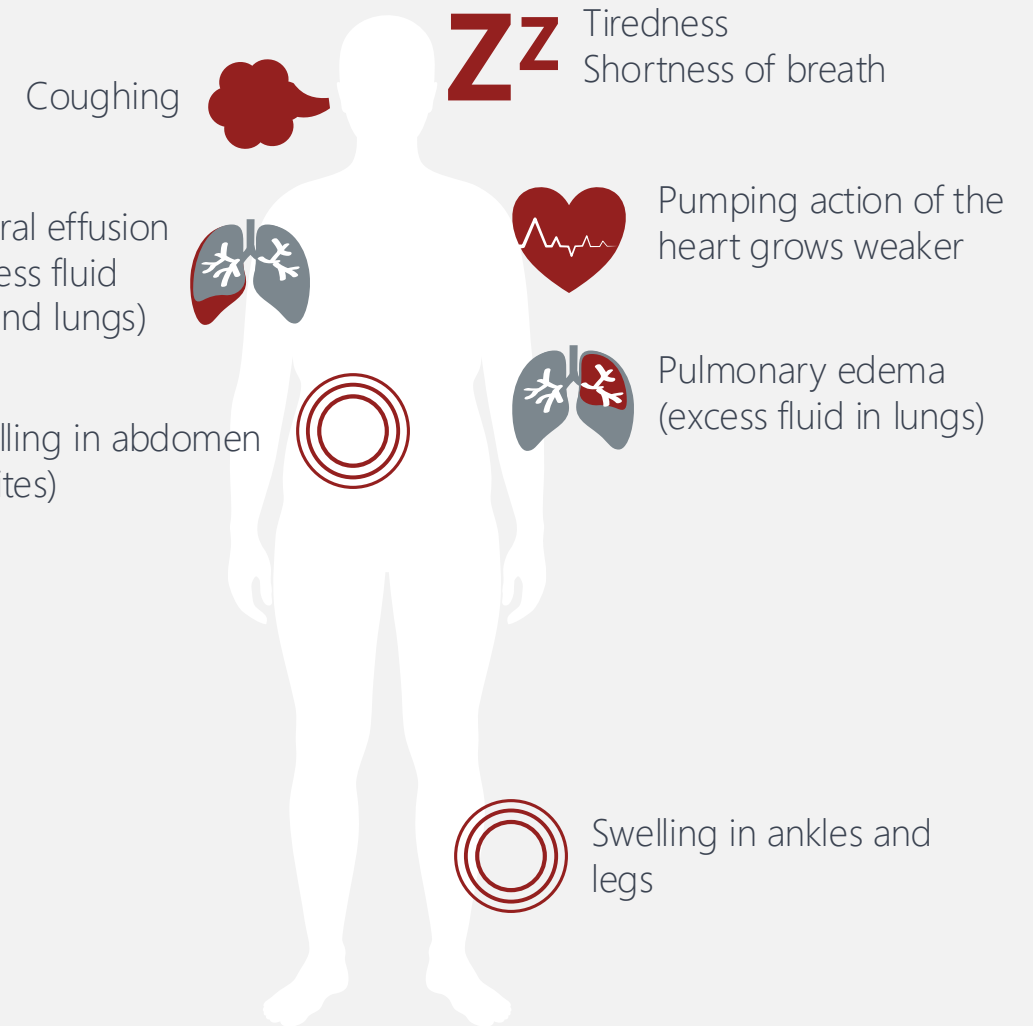
## Our Mission

Nuwellis is dedicated to transforming the lives of patients suffering from Fluid Overload through science, collaboration, and innovation.



# What is Hypervolemia (Fluid Overload)?

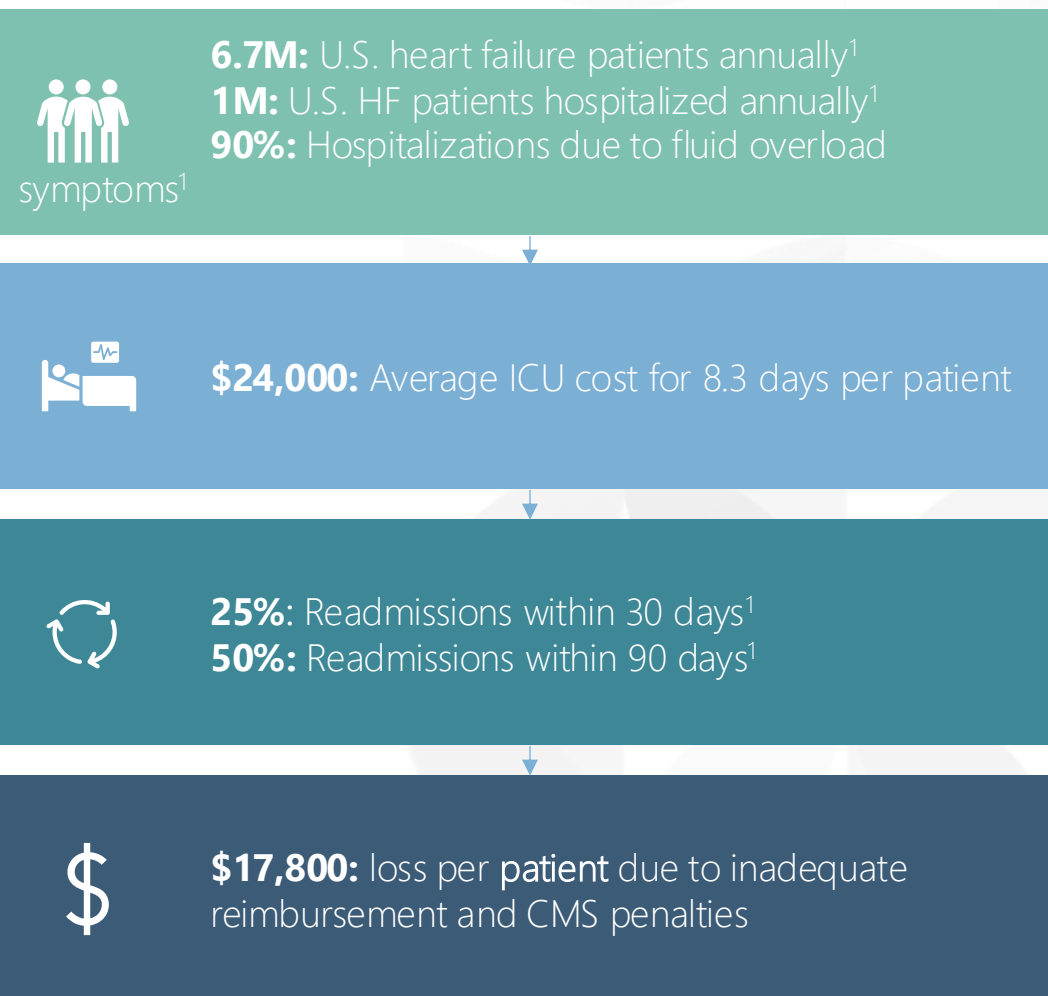
**Hypervolemia** is an excess of fluid in the bloodstream, vital organs and interstitial space that results in an array of patient symptoms



Fluid Overload presents a significant public health challenge that impacts both patient outcomes and hospital resources

# There are 6.7 million US adults with Heart Failure and ~50% will die within five years of their diagnosis<sup>2,3</sup>

With Fluid Overload as the leading cause of hospitalizations, it also presents a considerable economic burden on hospitals.



**Heart failure's high hospitalization rates and costs present urgent financial and health challenges, highlighting the need for innovative solutions.**

1: <https://pmc.ncbi.nlm.nih.gov/articles/PMC5632523/> 2. Testani, Circ Heart Failure, 2016;9:e002370. 3. Kazory A, Sgarabotto L, Ronco C: Extracorporeal Ultrafiltration for Acute Heart Failure. Cardiorenal Med 2023;13:1-8. doi: 10.1159/000527204

# Diuretics, the current standard of care, have significant limitations leaving a gap in clinical care

Diuretics provide insufficient symptom relief and are **associated with in hospital worsening heart failure and increased mortality** after discharge<sup>1</sup>

- High risk of readmissions <sup>1</sup>
- Long-term use of diuretics is associated with kidney damage<sup>1-4</sup>
- Efficacy of diuretic use in HF & CV surgery patients
  - 10-40%<sup>5</sup> have poor diuretic response
  - 68%<sup>5</sup> show sub-optimal response

***“Diuretic resistance has been a well-known challenge in the care of these patients, and not surprisingly is tied to worse prognosis.”<sup>6</sup>***

**“Extracorporeal Ultrafiltration for Acute Heart Failure”**  
Cardiorenal Medicine Journal

1. Costanzo MR, et al. *JACC*. 2017;69(19):2428-2445. 2. Felker MG & Mentz RJ. *JACC*. 2012;59(24):2145-53. 3. Al-Naher et al. *Br J Clin Pharmacol*. 2018 Jan; 84(1): 5-17. 4. Butler J et al. *Am Heart J*. 2004 Feb;147(2):331-8. 5. Testani JM, et al. *Circ Heart Fail*. 2016;9(1):e002370. 6. Kazory et al. *Cardiorenal Med* 2023;13:1-8. doi: 10.1159/000527204.

Differentiated Solution

# Aquadex<sup>®</sup>

A clinically superior  
solution for  
Fluid Overload<sup>1</sup>

The *only* device of its kind  
in the market



# Aquadex

A proven and predictable solution for Fluid Overload.



**1.74** fewer hospitalizations<sup>1</sup>

At one year after Aquadex therapy treatment, compared to 2.14 before treatment

**12.4%** readmission rate

Compared to the 24% national average at 30 days<sup>1</sup>

**\$3,975** in average savings

Reduces length of hospital stay when initiated early, resulting in average savings of \$3,975 (14%)<sup>6-7</sup>

**Over \$2B** addressable market

## Reintroduced in 2016

- An estimated 25,700 patients treated across all three of our customer categories<sup>9</sup>
- From proprietary technology to unmatched advantages in Fluid Overload therapy, Aquadex has the potential to be the standard of care for diuretic resistant patients

## Product Strategy & Differentiation

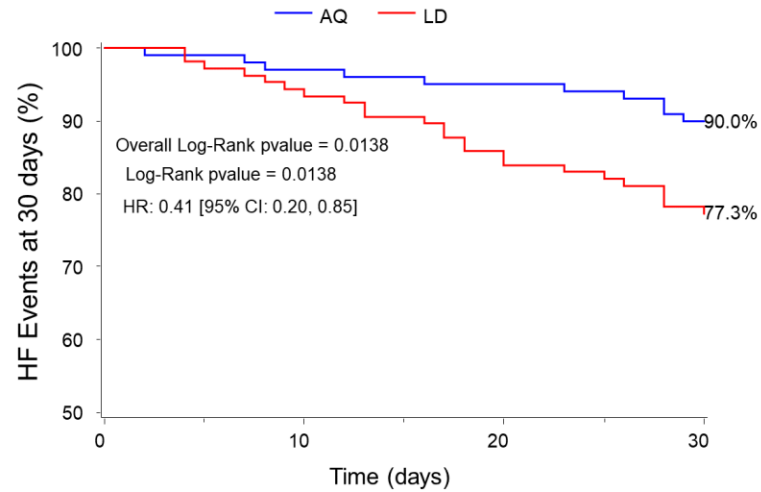
- More effective in decongesting resulting in stabilized or improved cardiac hemodynamics<sup>2-5</sup>
- Easier to set-up than CRRT; built-in Hematocrit sensor allows real-time measurement of blood volume changes
- Designed for multiple settings: ICU, Stepdown Unit, Telemetry Unit, HF Floor, and Outpatient – versus ICU only for CRRT
- Predictably removes excess isotonic fluid (water and sodium)<sup>8</sup>
- No significant changes to kidney function<sup>1</sup>

1. Watson R et al. *J Cardiac Fail.* 2020; 26(10): s56. 2. Kiziltepe, U, et al. *Ann Thorac Surg.* 2007;23(2): 684-93. 3. Sahoo, TK, et al. *Indian J Thorac Cardiovas Surg.* 2007;23(2): 116-24. 4. Boga et al. *Perfusion.* 2000;15:143-50. 5. Onoe et al. *Perfusion.* 2001;16:37-42. 6. Costanzo MR et al. *JACC.* 2005; 46(11): 2457-51. 7. Costanzo, et al, ISPOR 23rd Annual Int'l Mtg., May 19-23, 2018, Baltimore, MD, USA. 8. Kazory A, Sgarabotto L, Ronco C. Extracorporeal Ultrafiltration for Acute Heart Failure. *Cardiorenal Med* 2023;13:1-8. doi: 10.1159/000527204. 9. Utilization figures are based upon Company estimates, including certain good faith assumptions of the number of blood circuits used per adult and per pediatric procedures, such that patients served equals total number of units sold divided by a per procedure estimate of circuit used per adult and pediatric patients.



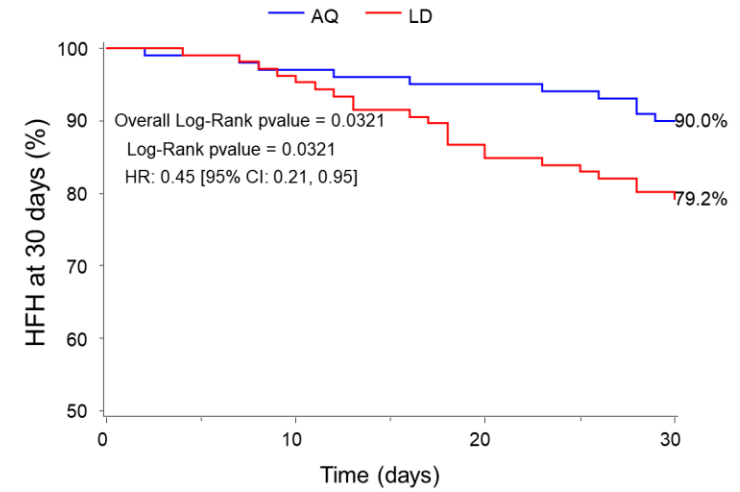
# Recent clinical trials presented at THT 2024 demonstrated that Aquadex significantly reduces heart failure hospitalizations

This re-evaluation of a 224-patient randomized controlled trial (AVOID-HF) shows statistically significant results.



Number at risk:  
 AQ 105  
 LD 108

	105	98	94	88
	108	100	91	81



Number at risk:  
 AQ 105  
 LD 108

	105	98	94	88
	108	102	92	83

	HF Event Free at 30 days	HF Hospitalization Free at 30 days
<b>Aquadex</b>	90%	90%
<b>Diuretics</b>	77.3%	79.2%

# Addressing fluid overload across critical and pediatric specialties, Nuwellis opens doors to a multi-billion dollar market opportunity

Fluid Overload is a **leading cause of hospital readmission** 30 days following cardiac surgery<sup>2</sup>

## \$2B+ TAM



### Heart Failure

**\$1B Market<sup>1</sup>**

~20% of current  
Nuwellis sales

**90% of all heart failure hospitalizations** are due to symptoms of Fluid Overload<sup>2</sup>



### Critical Care

**\$900M Market<sup>1</sup>**

~40% of current  
Nuwellis sales

As many as **80%** of cardiac surgery patients may have stage 1 or greater CSA-AKI according to the strict, consensus-based guidelines published by the KDIGO.<sup>3</sup>



### Pediatric

**\$130M Market<sup>1</sup>**

~40% of current  
Nuwellis sales

In pediatric patients, Fluid Overload is associated with **significant increases in mortality**<sup>4-5</sup>

1. See Appendix. 2. Costanzo, et. al., ISPOR 23rd Annual Int'l Mtg., May 19-23, 2018, Baltimore, MD, USA. 3. <https://doi.org/10.1016/j.athoracsur.2022.10.022> 4. Sutherland SM, et al. Am J Kidney Disease. 2010; 5(2): 316-25. 5. Gillespie RS, et al. Ped Nephro. 2004; 19(12): 1394-99.

# Our Strategic Growth Plan Emphasizes Four Key Efforts

We've structured our sales and marketing team to ensure seamless execution

- 1 Grow Penetration and Utilization**
- 2 Outpatient Initiative**
- 3 Grow New Accounts in Cardiac Surgery**
- 4 Continue Development and Commercialize Vivian**

# CPT 0692T has been reassigned to a higher-paying category, enhancing outpatient Aquadex therapy reimbursement.

## Changes:

- **Code Reassignment:** From APC 5241 to higher-paying APC 5242 for outpatient Aquadex services.
- **Increased Rates:** Daily reimbursement rate increased from \$413 to \$1,639.
- **Operational Efficiency:** Encourages shift from inpatient to outpatient care, by reducing costs and improving resource use.

## Benefits:

- ✓ **Cost Savings:** Lowers healthcare costs while maintaining quality care.
- ✓ **Improved Patient Experience:** Provides treatment in scheduled and more comfortable settings.
- ✓ **Market Expansion:** Opens new avenues for leadership in heart failure management.

## The Big Picture:

### HOSPITALS

Financially  
Viable  
Therapy

### PATIENTS

Improved  
Quality of  
Life

### PAYOR

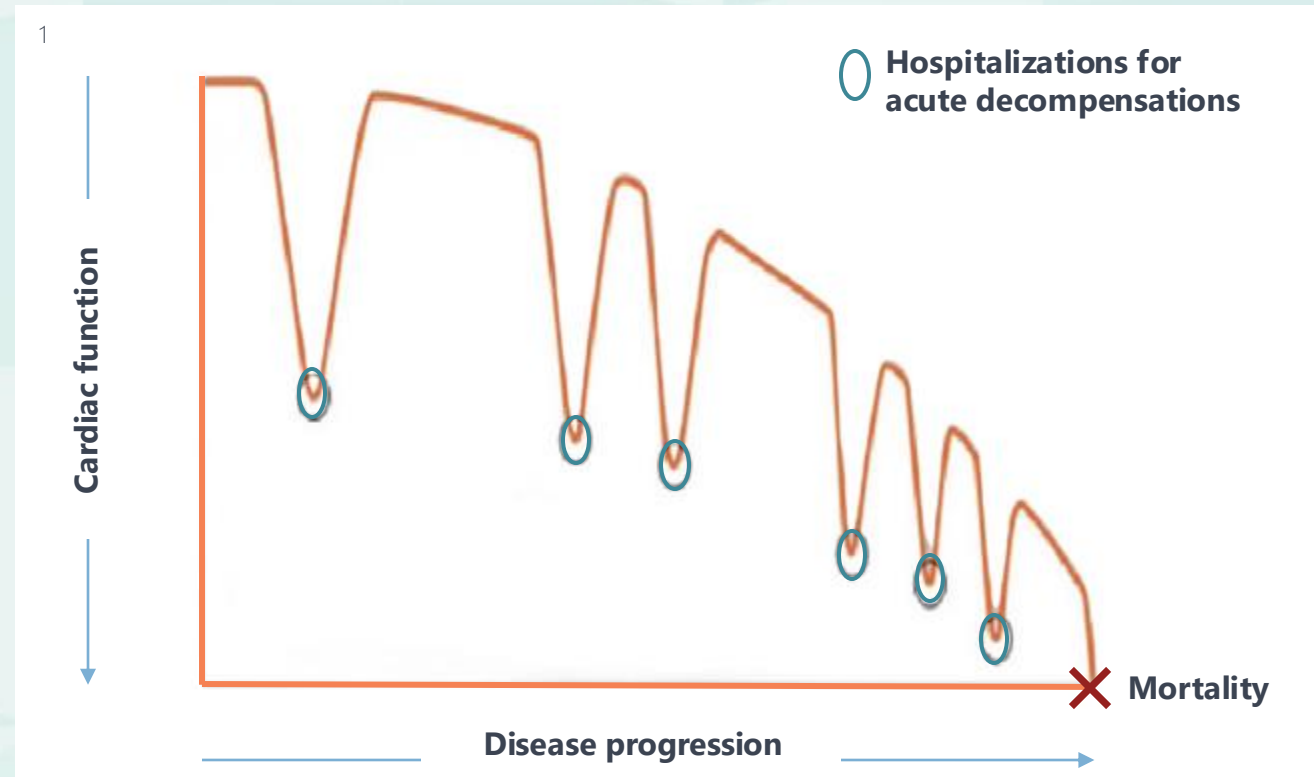
Cost  
Reduction

### NUWELLIS

Business  
Expansion

# The Human Impact of Readmissions

- **Prolonged Recovery:** Rehospitalizations delay patient stabilization and strain caregivers.
- **Increased Mortality:** Fluid overload is associated with a **2.38x higher risk of death** for readmitted patients.<sup>2</sup>
- **Reduced Quality of Life:** Frequent hospitalizations disrupt lives, causing mental and physical decline.



**Frequent readmissions lead to worsened health outcomes, prolonged recovery, and increased mortality.**

# Introducing New Outpatient Reimbursement Rate for Aquadex

With the reassignment of CPT 0692T, daily reimbursement rates have significantly increased, making Aquadex a sustainable option for hospitals to provide essential outpatient care without financial loss.



**Hospitals can now obtain up to \$1,639 per day for Aquadex in outpatient care, improving accessibility and financial viability.**

# Comparative Overview of Inpatient vs. Outpatient Care Pathways

Understanding patient journeys with Aquadex treatment.

## Inpatient Care with Diuretics/ICU Path

High Costs, High Readmissions



ER admission



Avg. Stay: 8.3 Days Overnight<sup>1</sup>



25% Readmission at 30 Days<sup>2</sup>  
50% Readmission at 90 Days<sup>2</sup>



Extended hospital stays, high readmission rates, increased chance of mortality<sup>2</sup>

## Outpatient Care with Aquadex/Observational Unit Path

Positive Profitable Outcomes



ER admission →  
decongested



Outpatient registration



Schedule 3-5 treatments



Reduced Readmission by 40% at 30 Days<sup>3,4</sup>

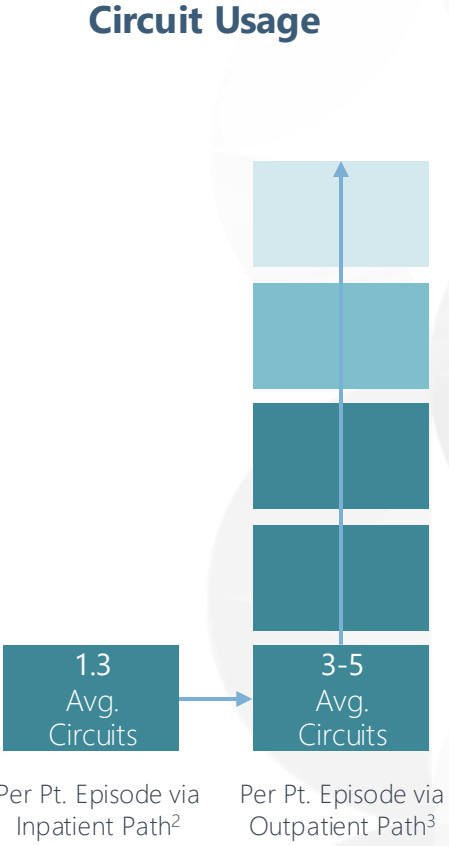
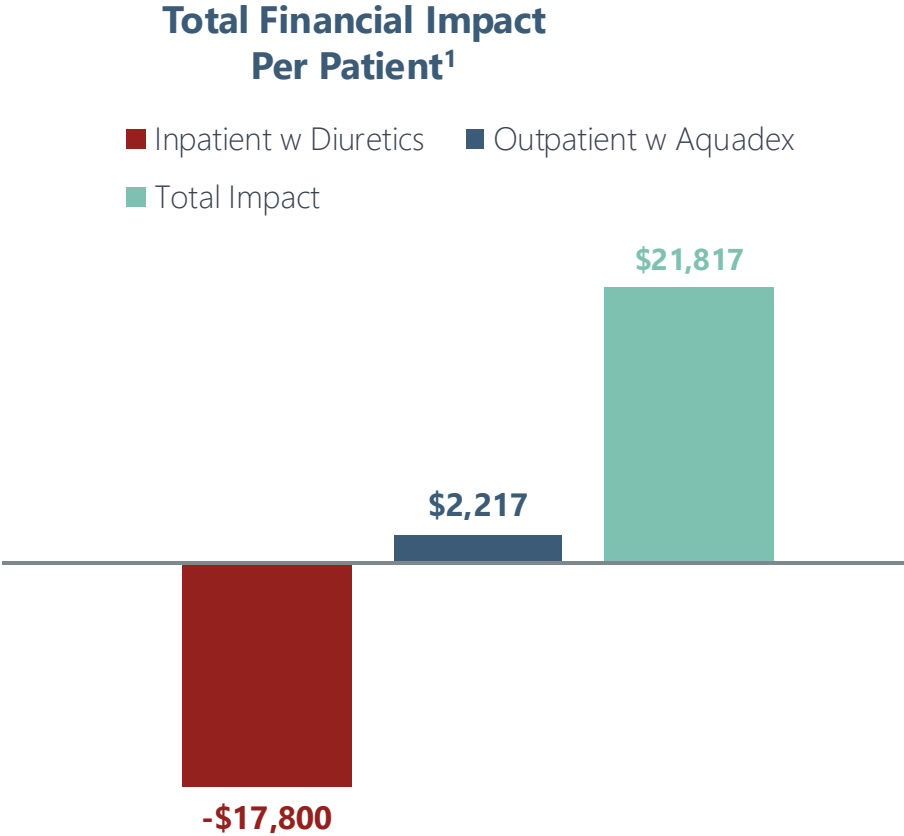
Reduced Readmission by 59% at 60 days<sup>3,4</sup>



Quick recovery, lower readmission<sup>5</sup>,  
discharge to home

# Turning Higher Reimbursement into Better Hospital and Business Outcomes

Higher CMS reimbursement enables outpatient care, reducing costs and driving viability.



**The new reimbursement model opens the door to expand Aquadex usage, increasing outpatient adoption and driving growth.**



# Strategic Focus on Critical Care for 2025

We are prioritizing cardiac surgery as a key focus area due to the significant, immediate benefits Aquadex offers, which aligns with our commitment to pioneering patient care.

## Immediate Clinical Impact

Reduces complications and speeds recovery.

## Attracting Top Surgeons

Appeals to innovators in cardiac care.

## Enhancing Treatment Protocols

Sets new standards with advanced fluid management.

# Critical Care Commercialization Plan

## GOAL

Generate & Accelerate Revenue Growth

## STRATEGY

Promote Aquadex as a Superior Alternative to Traditional Diuretics

Position Aquadex through targeted marketing and sales efforts that emphasize its clinical benefits, cost-effectiveness, and support services to drive adoption in cardiac surgery units.

## TACTICS



### Enhanced Digital Marketing

- Targeted digital ads
- SEO driven content
- Grow organic social presence

### Strategic Outreach

- Direct emails
- Data-Driven Personalization
- Advanced Analytics for Custom Engagement
- Cross-Industry Symposiums

### Highlight Early Adopters

- Create a program in existing cardiac centers showing them as innovators
- Build and share case study results
- Establish centers of excellence

### Expand Strategic Partnership Development

- Medical Society engagement and events
- Collaborate with Healthcare Providers
- Joint Marketing Initiatives
- Active partnership with ERAS

**Vivian™**

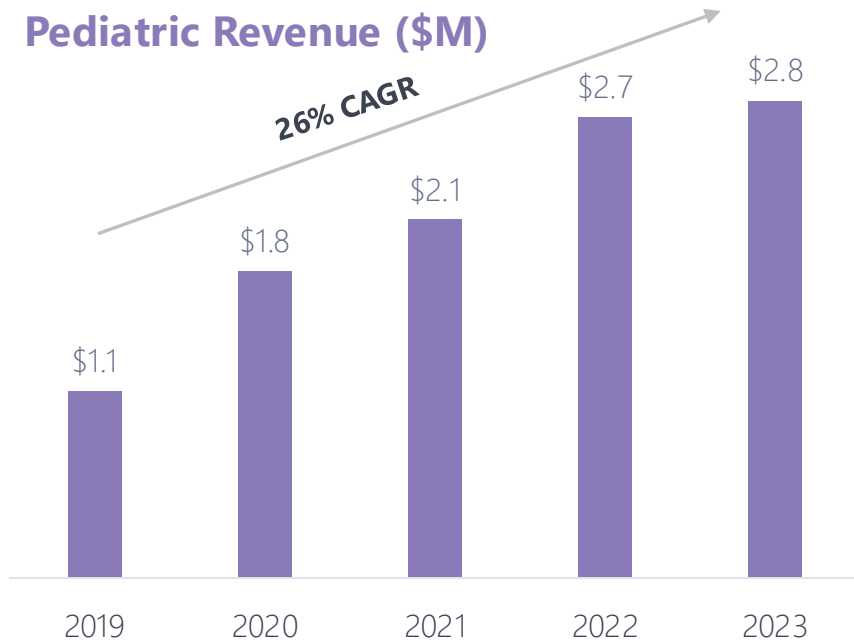
**Our pediatric  
solution**



# We've seen a steady increase in our pediatric business, providing patients with high mortality an opportunity at life<sup>1</sup>

Pediatrics represents a \$130M TAM

## Pediatric Revenue (\$M)



**4-10**  
circuits/pts

**3-6 consoles**  
per hospital

**Received 510(k) and launched commercially in Q1 2020.**

## Improved patient survival at end of treatment

Attributes	Group 1: <10kg	Group 2: 10-20kg	Group 3: >20kg
# of Patients	N = 72	N = 13	N = 34
Primary disease	43% kidney 29% cardiac	54% kidney 31% other	38% kidney 28% cardiac
Survival at end of treatment (Aquadex)	43 (60%)	13 (100%)	33 (97%)

Group 1 patients traditionally do not receive any kind of therapy

*"For our babies born with diseased or absent kidneys, Aquadex has given them a chance at life because in the past, there were no options to treat these patients."*

Kara Short  
MSN, CRNP, NICU nurse practitioner at Alabama Children's Hospital

1. Source: Menon S, et al. CJSN, 2019; 14: 1432-40. Aquadex is currently cleared for use in pediatric patients weighing 20 kg or more

# Therapy to fill crucial gaps

Offer a lifeline to critically ill neonates and children

**8.5x** mortality

Fluid Overload drives pediatric morbidity and mortality risk in critically ill patients

Children with >20% fluid overload had an odds ratio for mortality of 8.5 compared to children with <20% FO<sup>1,2</sup>

**60%** survival to end therapy

Providing renal support and hemodynamic stability can be life-saving

In patients <20 kg who primarily received Slow Continuous Ultrafiltration (SCUF)<sup>3</sup>

**\$130m** addressable pediatric market



Ultrafiltration  
Hemofiltration  
Hemodialysis

Launch best-in-class pediatric CRRT system ~Q1 2027

Early feedback from pediatric nephrologists: "This will be a game-changer for us." Nuwellis Pediatric Advisory Board member

## Product Strategy & Differentiation

- Integrates Ultrafiltration with Hemofiltration and Hemodialysis capabilities
- Expected broadest weight indication: 2.5 kg +
- Safety features: lowest extracorporeal blood volume; built-in hematocrit sensor
- Clinician-driven UX design
- Product name: "Viv" Latin root means life; Vivian – Lady of the Lake in King Arthur, allusion to Land of 10,000 Lakes

1. Sutherland SM, et al. American Journal of Kidney Diseases, vol. 55, no. 2, pp. 316-325, February 2010, 2. Gillespie RS, et al. Pediatric Nephrology, vol. 19, no. 12, pp. 1394-1399, December 2004., 3. Menon S, et al. CJASN, vol 14, October 2019.

# We are keenly focused on developing novel technology with a strong IP portfolio

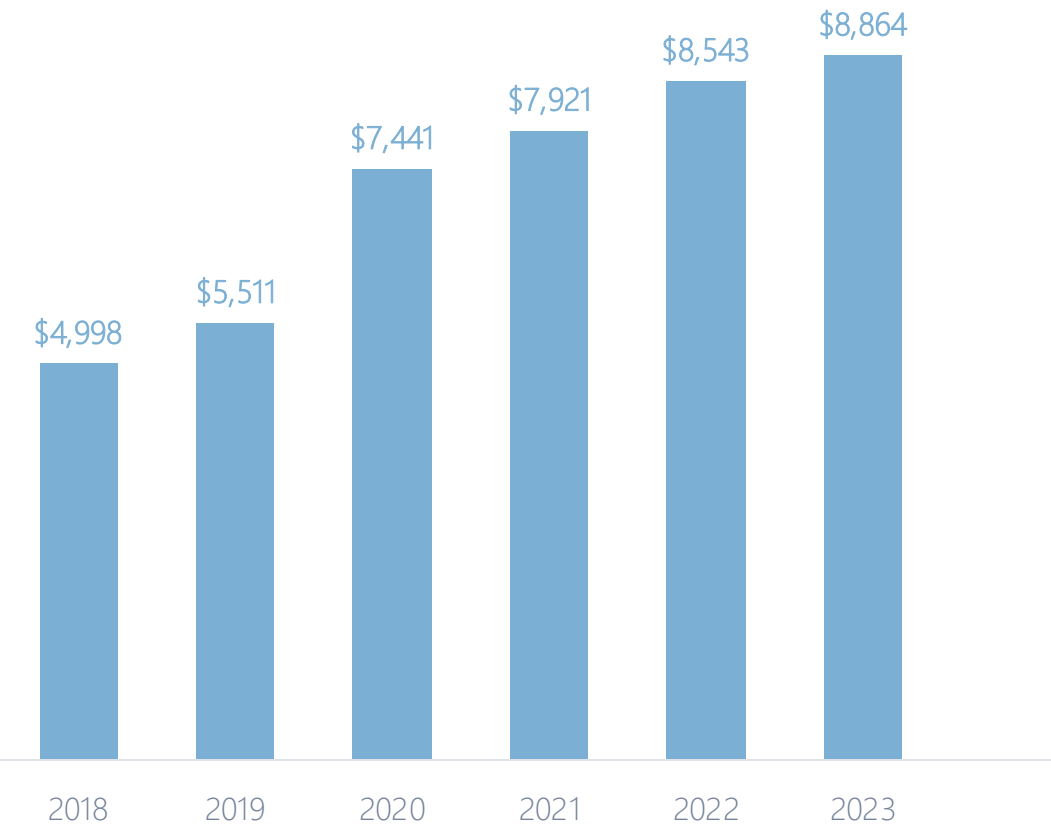
11 novel patents with last to expire protection to 2043

- Robust and evolving portfolio of patents circling the technology
- 20 Nuwellis patent applications (US & EU) in addition to licensed IP from Baxter
- Wide technology scope coverage

Console	Circuit	Peripheral Access	Accuracy & Safety	Guided Therapy
Transport Mode Self-loading/ Self-emptying Bags Open vs. Closed Loop	Filter Clotting Prevention Source Line Connection	Peripheral Flow Improvements Dual Lumen Catheter	External Pump Detection Hemolysis/ Blood Leak Detector Accounting for Density Auto Clamp	Plasma and Blood Volume Measurement Physiological Parameters Guidance

# With a track record of consistent financial success, we're confident that our growth strategy will lead to meaningful revenue expansion and cash flow

Annual Revenue (\$000)



**CASH**  
\$1.9 million as of Sept. 30, 2024

**RAISED**  
\$5.1 million In Nov. 2024<sup>1</sup>

**NO DEBT**

Common Shares Outstanding	1,866,890
Common Share Equivalents:	
Preferred Shares:	
Preferred F: 127 units	68,961
Preferred J: 95 units	67
Warrants:	
Historical Warrants	477
Preferred J Warrants: 67,168 units	23,762
April 2024 Warrants: 13,919,955 units	2,651,426
July 2024 Warrants: 938,680 units	938,680
August 2024 Warrants: 483,351 units	497,852
Employee & Director Options:	
Options Issued & Outstanding	3,890
<b>Total Common Share Equivalents</b>	<b>4,185,115</b>
<b>Total Common Share &amp; Share Equivalents</b>	<b>6,052,005</b>

Capitalization Table as of September 30, 2024

1. In early November, Nuwellis raised \$5.1 million in gross proceeds from warrant exercises and through a warrant inducement solicitation.

# Our diverse leadership team boasts extensive industry experience and a successful history of commercialization



Nestor Jaramillo, Jr.  
President & Chief Executive Officer



Rob Scott  
Chief Financial Officer



Megan Catts  
Vice President of Clinical Research  
and Reimbursement



John Kowalczyk  
Senior Vice President of  
Sales & Marketing



John Jefferies, M.D.  
Chief Medical Officer



Sandra Eays  
Chief Human Resources Officer

**Seasoned Leadership:** Over 200 years of combined experience in clinical practice and the medical device industry, including major tenures at Medtronic, Boston Scientific, and Abbott/St. Jude Medical.

**Commercialization Prowess:** Proven success in bringing innovative medical devices to market.

**Strategic Industry Involvement:** Extensive knowledge and strategic insights from engagements with top industry players.

**Adaptive Management:** Known for a dynamic approach in overcoming industry challenges and adapting to market changes.

**Innovative Contribution:** Strong history of enhancing company growth and success through innovative product development.



# Investment Highlights

We're confident that the key catalysts we will pursue in 2025 should support a valuation of 3-5x revenue.

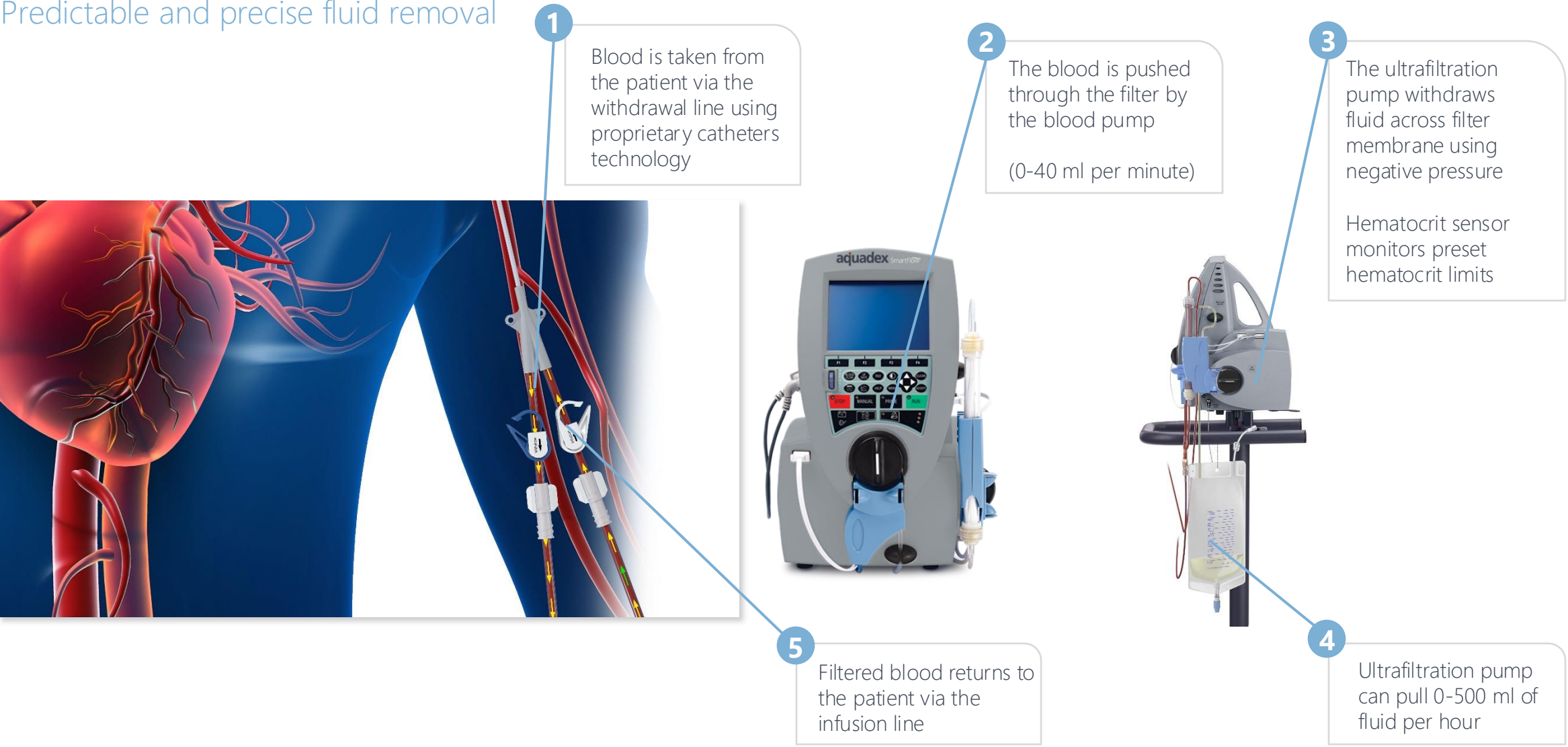
<b>\$2B+ TAM</b>	<b>Positive ROI</b>	<b>Clinical Evidence</b>	<b>Scalable Consumables</b>	<b>Commercial Infrastructure</b>	<b>Product Pipeline</b>	<b>Leadership Team</b>
\$2B+ and growing addressable market in critical need	Attractive clinical + economic benefits to hospitals and healthcare system	Robust body of clinical evidence demonstrating the success of our products	With the new outpatient reimbursement model, we can scale circuit usage	Leveraging one sales organization for all three patient categories	Novel product pipeline along with an expanding IP Portfolio for continued expansion	Highly experienced leadership perfectly positioned to drive our growth strategy

**Thank you!**

# Appendix

# How the Aquadex system works

Predictable and precise fluid removal



**aquadex** SmartFlow®  
System

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**Mechanism of Action**

<https://www.youtube.com/watch?v=RnODf5uL9oI>

# Higher CMS reimbursement enables outpatient care, reducing costs and driving viability.

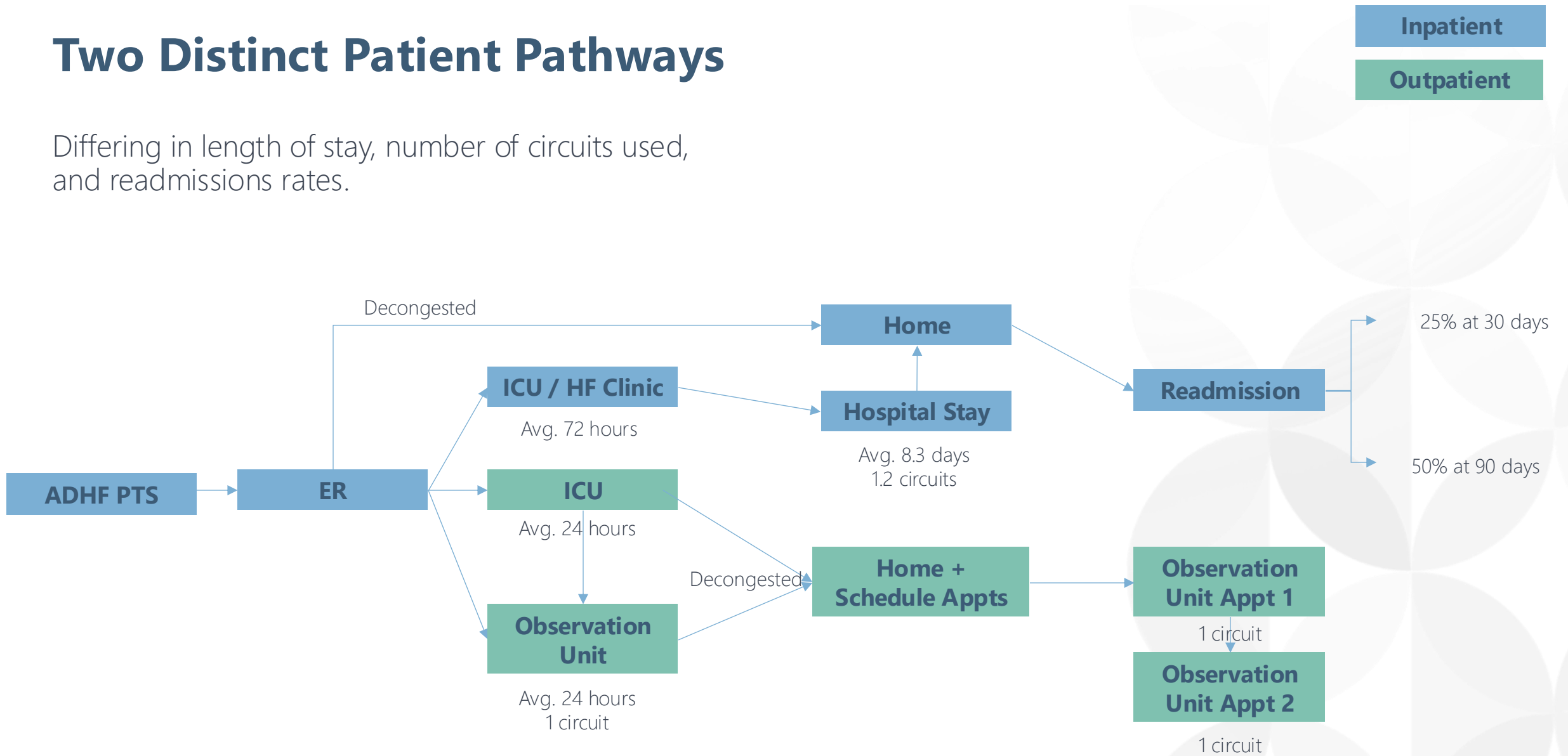
Inpatient	Cost
ICU Cost	\$24,000
DRG Reimbursement	- \$8,000
CMS Penalty	+ \$1,800
<b>Total Loss per Patient</b>	<b>-\$17,800</b>

Outpatient/Observational Unit	Cost Per Treatment	x3 Treatments
Cost of Therapy (x3 treatments)	\$900	\$2,700
APC 5242 Reimbursement (x3 treatments)	\$1,639	\$4,917
<b>Total Profit per Patient</b>	<b>\$739</b>	<b>\$2,217</b>

Total Financial Impact	Cost
Avoided CMS Penalty	\$1,800
Avoided ICU Losses	\$17,800
Profit per Patient	\$2,217
<b>Total Financial Benefit</b>	<b>\$21,817</b>

# Two Distinct Patient Pathways

Differing in length of stay, number of circuits used, and readmissions rates.



# Delivering Value Across the Healthcare Ecosystem

Nuwellis' Aquadex drives profitability for hospitals, reduces costs for payers, and grows shareholder value.

## Financial benefits

- Higher margins and profitability in outpatient care.
- Broader hospital adoption driven by financial viability.

## Market leadership potential

- Positioned to become the **standard of care** in fluid management.
- Unique solution for diuretic-resistant heart failure patients.

## Long-term growth

- Commitment to innovation and product development for the HF community.
- Supporting adoption through clinical evidence (e.g., REVERSE-HF study).



# Market Validation

Real-world testimonials and clinical studies provide meaningful validation for Nuwellis' products.

# Case Study<sup>2</sup>:



A prospective, single center study of 23 patients treated with the Aquadex FlexFlow<sup>®</sup> System to manage heart failure (HF) related fluid overload in an **outpatient setting**

## RESULTS:



### **50% DECREASE** IN MEDIAN HOSPITAL ADMISSION RATES

- **6 months prior** to outpatient therapy = **2 admissions**
- **6 months after** outpatient therapy = **1 admission**



### **69% DECREASE** IN HOSPITALIZATION DAYS

- **Before** outpatient therapy = **16 days**
- **After** outpatient therapy = **5 days**

Source: 2. O'Brien TM et al. The 17th Annual HFSA Scientific Meeting, 2013.



**Dr. Thomas O'Brien**

With appropriate patient selection, **outpatient Aquadex therapy may be an additional therapeutic option** for patients with chronic HF and fluid overload plus diuretic resistance

# Case Study<sup>1</sup>:



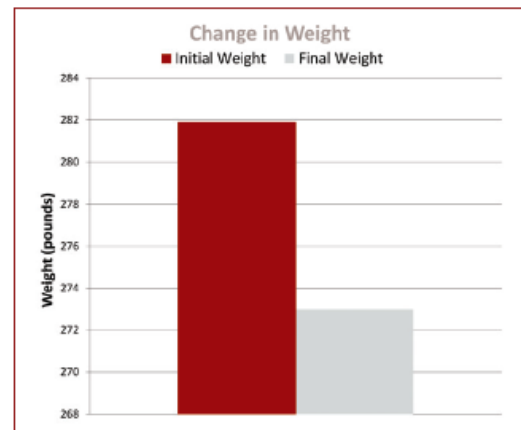
**THE OHIO STATE UNIVERSITY**  
WEXNER MEDICAL CENTER

A retrospective, single center analysis of 14 patients treated with the Aquadex FlexFlow<sup>®</sup> System to manage heart failure (HF) patients in an **outpatient setting in order to avoid hospital admissions**

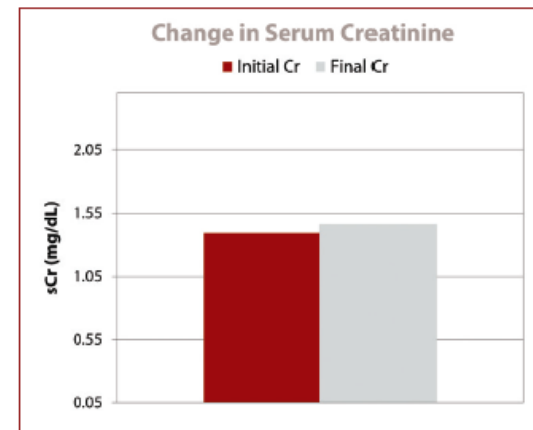
## RESULTS:

Average days per treatment	2.35
Average fluid removed per day	2.06 L
Average total fluid removed per treatment	4.83 L
Access via dual-lumen UF catheter	60%
Freedom from unplanned 30 day presentation	79%
Adverse events	0

**Significant Change in Average Weight Loss (8.9 pounds)**  
(281.9±54.2 vs. 273±53.3, p<0.05)



**No Significant Change in Serum Creatinine with Therapy**  
1.39±0.48 vs 1.46±0.57, p NS)



**Dr. Sitaramesh Emani**

***"We believe the use of outpatient UF may reduce the number of unplanned admissions for this high-risk population"***

Source: 1. Emani S, et al. Poster from The 16th Annual Scientific Meeting of HFSA. 2012.

# Ultrafiltration: Positive ROI, clinical and economic benefits

81% reduction in heart failure hospitalizations per year

## 10-Year, real-world experience with ultrafiltration<sup>1</sup>




### Abington Hospital Jefferson Health

- Retrospective, single center analysis
- **334 consecutive** acutely decompensated heart failure patients
- Cohort of patients in study were sicker than those in other clinical trials
- Treated with adjustable-rate UF using Aquadex
- Weight loss due to fluid removal
- Unchanged kidney function

 **HF Hospitalizations**

Average 2.14 hospitalizations per year before Aquadex Ultrafiltration

1 Year after Aquadex ultrafiltration Average 0.4 hospitalizations

 **Hospital Readmissions**

National Average

24% at 30 days<sup>2</sup>

50% at 6 months

12.4% at 30 days

14.9% at 90 days

27.3% at 1 year

Significant quality of life improvement for the patients as well as savings to the healthcare system and to the individual hospitals

1. Watson R et al. *J Cardiac Fail.* 2020; 26(10): s56. 2. Costanzo MR, et al. *JACC.* 2017 May 16;69(19):2428-2445.

# Aquadex UF vs. Renal Replacement Therapy proves positive patient outcomes with real time hospital advantages

“This small retrospective pilot study shows the **safety of using UF technology** alone and in combination with other existing RRT modes to remove excess isotonic plasma water effectively in a highly monitored setting in the **postoperative phase of cardiac surgery care with great outcomes.**”



**EDITORIAL**  
**The use of simple ultrafiltration as a fluid management strategy for high-risk coronary artery bypass grafting surgery**

Daniel L. Beckles MD, PhD, Giuseppe Tavilla MD, PhD, Nikki E. Williams PA-C, Tamara Jackson BSN ... See all authors  
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*“The use of simple ultrafiltration technology as a fluid management strategy for high-risk coronary artery bypass grafting surgery”*  
 Journal of Cardiac Surgery

Study of 17 cardiac surgery patients treated with Aquadex UF

*“The 30-day survival rate was 100% [for patients in the UF group]”*

	Simple ultrafiltration (Aquadex)	Renal replacement Therapy/CVVH
Nurse staffing	No change required	Increased
Venous access	Peripheral/Central	Central
Immediate need for renal consult	No	Yes
Earliest time from request to start of fluid removal	Within minutes (15–60 min)	Within hours (3–48 h)
Ease of use/set-up	Simple	Complex
Dialysate fluid	None	Yes
Treatment location	Ambulatory/Stepdown/ICU	ICU/Monitored/HD unit

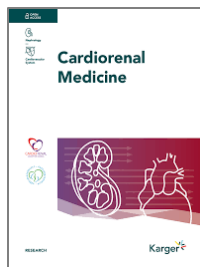
Baylor Scott & White Health (Temple, TX)

# Peer-reviewed publication advocates for early clinical application of ultrafiltration in diuretic resistant patients

## Diuretic shortcomings leave a gap in clinical care

*"The efficacy of diuretics gradually decreases as (heart failure) progresses in a significance subset of patients."*

*"Diuretic resistance has been a well-known challenge in the care of these patients, and not surprisingly is tied to worse prognosis."*



### **"Extracorporeal Ultrafiltration for Acute Heart Failure"**

Cardiorenal Medicine Journal

Pooled data from seven randomized controlled trials of ultrafiltration, 771 patient participants

***"Extracorporeal ultrafiltration has emerged as an option to overcome shortcomings of diuretics"***



Predictable, adjustable, and more efficient fluid removal with ultrafiltration compared to diuretics



Applicability in other clinical settings, such as cardiac surgery, burn and other specialty units



Potential to expand use of ultrafiltration into outpatient centers and other ambulatory settings

# Proven superior outcomes with Aquadex in real-world clinical use

## *“Outcomes of Ultrafiltration in community-based hospitals” Current Problems in Cardiology (October 2024)*

Key findings from a retrospective analysis of 30 acute decompensated heart failure patients:



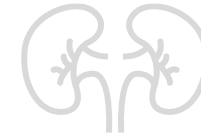
### **Significant Volume Loss and Weight Reduction:**

Patients experienced significant volume loss and weight reduction without adverse renal effects.



### **Significant Reduction in Heart Failure Readmissions:**

Statistically significant reduction in rehospitalization rates for heart failure at 60 days from the initiation of ultrafiltration therapy compared to the pre-ultrafiltration period (16.7% vs. 26.7%,  $p=0.013$ ). The total number of ADHF readmissions in the 30 days following ultrafiltration therapy decreased by 40%, and by 59% in the subsequent 60 days.



### **Stable Renal Function:**

Serum creatinine levels at 72 hours post-ultrafiltration did not change significantly ( $-0.01$  mg/dL, 95% CI  $-0.26, 0.23$ ).

# Market size sources

## Heart Failure – Inpatient (\$1B+)

- Incidence of HF: <https://www.ncbi.nlm.nih.gov/pmc/articles/PMC5494150/>
- Annual HF Hospitalizations: [Costanzo MR, et al. J Am Coll Cardiol. 2017 May 16;69\(19\):2428-2445](https://doi.org/10.1161/CIRCULATION.2017.05.001)
- Insufficient diuretic response: [https://www.ahajournals.org/doi/10.1161/CIRCHEARTFAILURE.115.002370?url\\_ver=Z39.88-2003&rfr\\_id=ori:rid:crossref.org&rfr\\_dat=cr\\_pub%20%20pubmed](https://www.ahajournals.org/doi/10.1161/CIRCHEARTFAILURE.115.002370?url_ver=Z39.88-2003&rfr_id=ori:rid:crossref.org&rfr_dat=cr_pub%20%20pubmed)

## Heart Failure – Outpatient (\$0.5B+)

- Incidence of HF: <https://www.ncbi.nlm.nih.gov/pmc/articles/PMC5494150/>
- Annual HF Hospitalizations: [Costanzo MR, et al. J Am Coll Cardiol. 2017 May 16;69\(19\):2428-2445](https://doi.org/10.1161/CIRCULATION.2017.05.001)
- Diuretic resistance rate: [https://www.ahajournals.org/doi/10.1161/CIRCHEARTFAILURE.115.002370?url\\_ver=Z39.88-2003&rfr\\_id=ori:rid:crossref.org&rfr\\_dat=cr\\_pub%20%20pubmed](https://www.ahajournals.org/doi/10.1161/CIRCHEARTFAILURE.115.002370?url_ver=Z39.88-2003&rfr_id=ori:rid:crossref.org&rfr_dat=cr_pub%20%20pubmed)

## Critical Care (\$900m)

- VADs: <https://www.grandviewresearch.com/industry-analysis/ventricular-assist-devices-market>
- CABG: <https://www.grandviewresearch.com/industry-analysis/coronary-artery-bypass-graft-cabg-market>
- Valves: <https://idataresearch.com/over-182000-heart-valve-replacements-per-year-in-the-united-states/>
- Liver Transplants: <https://www.healthline.com/health/liver-transplant-survival>
- Liver Disease: <https://www.ncbi.nlm.nih.gov/pubmed/25291348>
- Kidney Disease: <https://www.kidney.org/news/newsroom/factsheets/KidneyDiseaseBasics>
- Sepsis: <https://www.ncbi.nlm.nih.gov/pmc/articles/PMC6557150/>
- ECMO: <https://www.uclahealth.org/medical-services/heart/ecmo/research/statistics>

## Pediatrics (\$130m)

- Renal Replacement/AKI: <https://www.ncbi.nlm.nih.gov/pmc/articles/PMC3789331/#:~:text=The%20hospitalized%20population%20at%20risk,are%20shown%20in%20Table%201>
- Heart Disease: <https://www.cdc.gov/ncbddd/heartdefects/data.html#:~:text=Congenital%20heart%20defects%20are%20conditions,the%20United%20States%20each%20year>
- Pediatric Transplantations: <https://www.organdonor.gov/about/donors/child-infant.html>
- Pediatric ECMO: <https://www.ncbi.nlm.nih.gov/pubmed/23246046>