



Making Aquadex the Standard of Care for Fluid Management

**Investor Presentation
October 2024**



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.

Financial and Statistical Data

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.

Trademarks

The trademarks included herein are the property of the owners thereof and are used for reference purposes only. Such use should not be construed as an endorsement of such products.

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

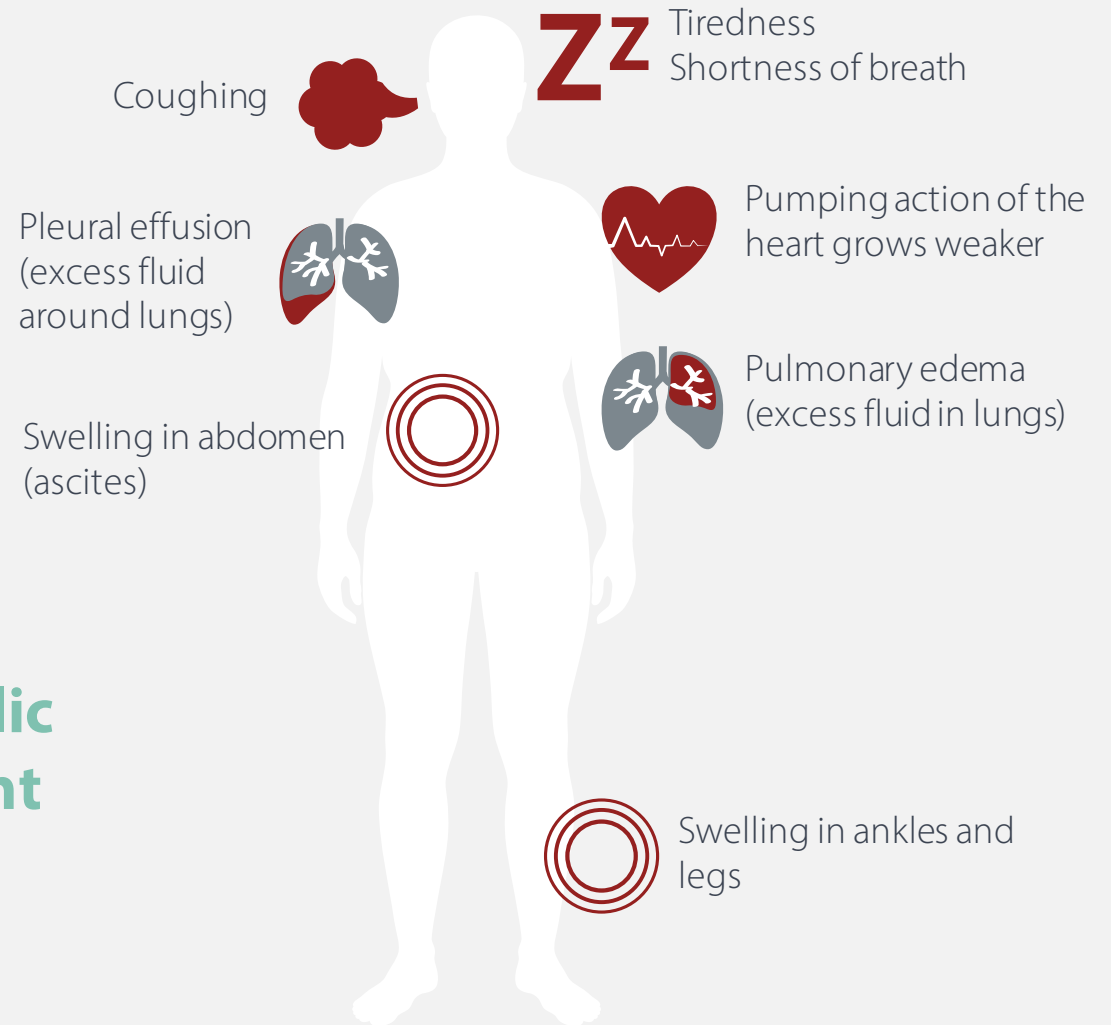
Nuwellis is dedicated to transforming the lives of patients suffering from Fluid Overload through science, collaboration, and innovation.



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





6.7 million US adults with Heart Failure and ~50% will die within five years of their diagnosis^{5,6}

With Fluid Overload as a leading cause of HF readmissions, it also presents a considerable economic burden on hospitals

PATIENT	HOSPITAL
<ul style="list-style-type: none"> Over 1 million HF hospitalizations occur annually in the US¹ Efficacy of diuretic use in HF & CV surgery patients <ul style="list-style-type: none"> 10-40%⁵ are refractory 68%⁵ show sub-optimal response 	<ul style="list-style-type: none"> Decompensated HF admission drives economic loss per admission High readmission rates lead to Medicare penalties⁴

The Healthcare Burden of Heart Failure/Fluid Overload

90%

of Heart Failure (HF) hospitalizations are due to signs and symptoms of Fluid Overload¹

Unresolved congestion

Poor clinical outcomes¹



Long Lengths of Stay & High Costs of Care



8 Days

Average HF Length of Stay²

\$24,027

Total True Inpatient Cost per Encounter²

Low Reimbursement

High Loss per HF Hospitalization



DRG 291

\$8,283³

\$15,744

Loss per visit

DRG 292

\$5,708³

\$18,319

Loss per visit

DRG 293

\$3,901³

\$20,126

Loss per visit

High Readmission Rates



24%

30-Day Readmission rate¹

50%

90-Day Readmission rate¹

Related Costs/Penalties

\$24,027

Non-reimbursable cost estimate for readmission encounter²

Opportunity Cost of occupied bed

Up to 3%

of ALL Medicare reimbursements⁴

1. Costanzo MR, et al. *J Am Coll Cardiol*. 2017 May 16;69(19):2428-2445. 2. From Premier Applied Sciences database. 3. 2021 DRG National Average Payment Table Update 4. <https://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/AcuteInpatientPPS/Readmissions-Reduction-Program> 5. Testani, *Circ Heart Failure*, 2016;9:e002370. 6. Kazory A, Sgarabotto L, Ronco C: Extracorporeal Ultrafiltration for Acute Heart Failure. *Cardiorenal Med* 2023;13:1-8. doi: 10.1159/000527204

**Differentiated
Solution**

Aquadex[®]

**A clinically superior
solution for
Fluid Overload**

The *only* device of its kind
in the market



Aquadex

A proven and predictable solution for Fluid Overload.



1.74 fewer hospitalizations¹

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 days¹

\$3,975 in average savings

Reduces length of hospital stay when initiated early, resulting in average savings of \$3,975 (14%)⁶⁻⁷

Over \$2B addressable market

Reintroduced in 2016

- An estimated 25,700 patients treated across all three of our customer categories⁹
- 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

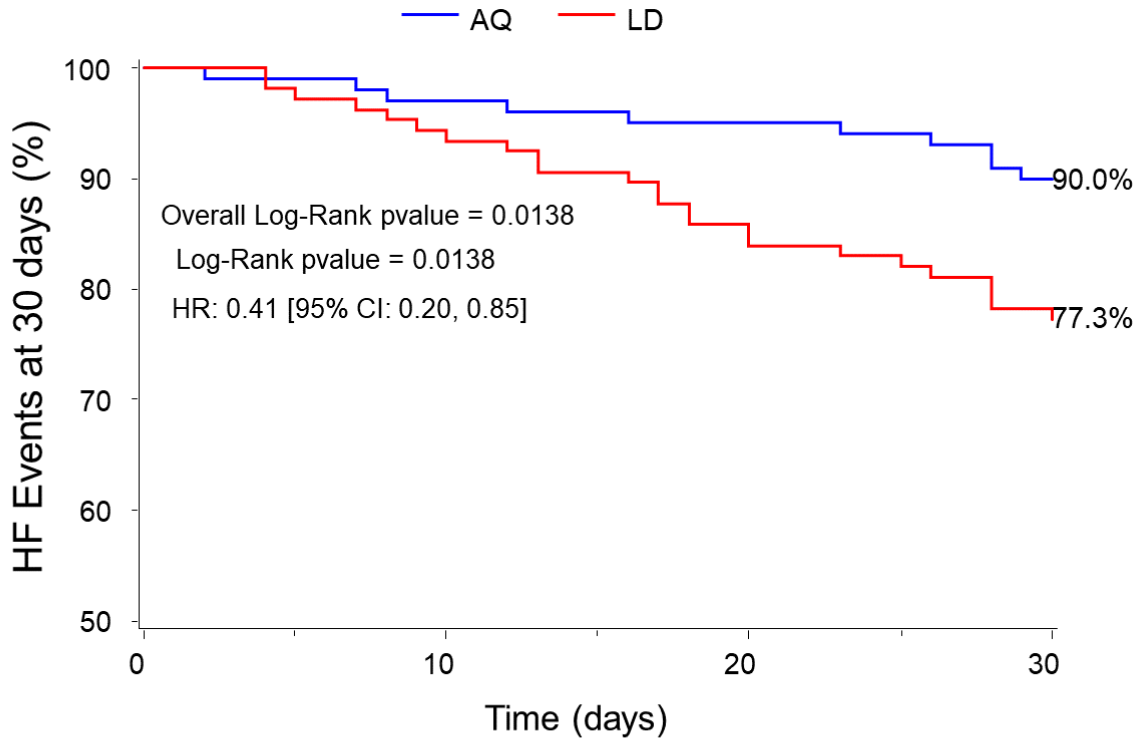
- More effective in decongesting resulting in stabilized or improved cardiac hemodynamics²⁻⁵
- Easier to set-up than CRRT; built-in Hematocrit sensor allows real-time measurement of blood volume changes
- Designed for multiple settings: ICU, Stepdown Unit, Telemetry Unit, HF Floor, and Outpatient – versus ICU only for CRRT
- Predictably removes excess isotonic fluid (water and sodium)⁸
- No significant changes to kidney function¹

1. Watson R, et al. *J Cardiac Fail.* 2020; 26(10): s56-2. Kiziltepe, U, et al. *Ann Thorac Surg.* 2001;71(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.



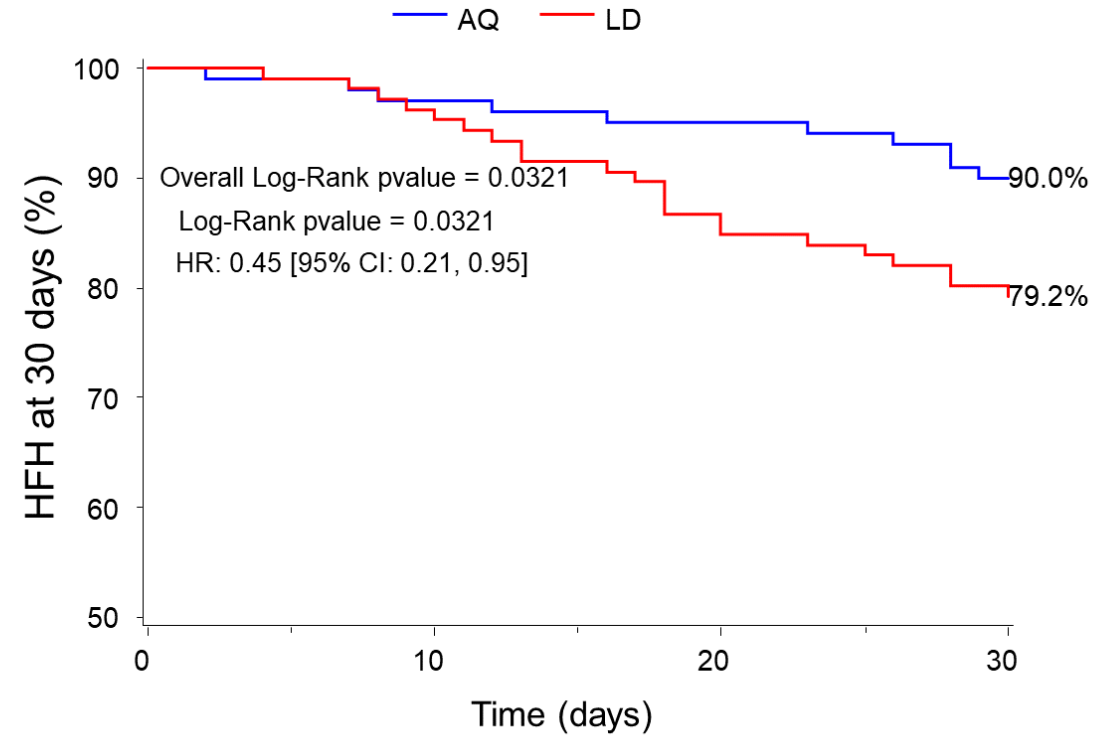
At a Recent Late Breaking Clinical Trials, Significant Reduction in HF Events and HF Hospitalization

Present at THT 2024 in early March, a re-appraisal of a 224-patients control randomized trial (AVOID-HF) demonstrated significant statistical significance when using Aquadex



Number at risk:

	0	10	20	30
AQ	105	98	94	88
LD	108	100	91	81

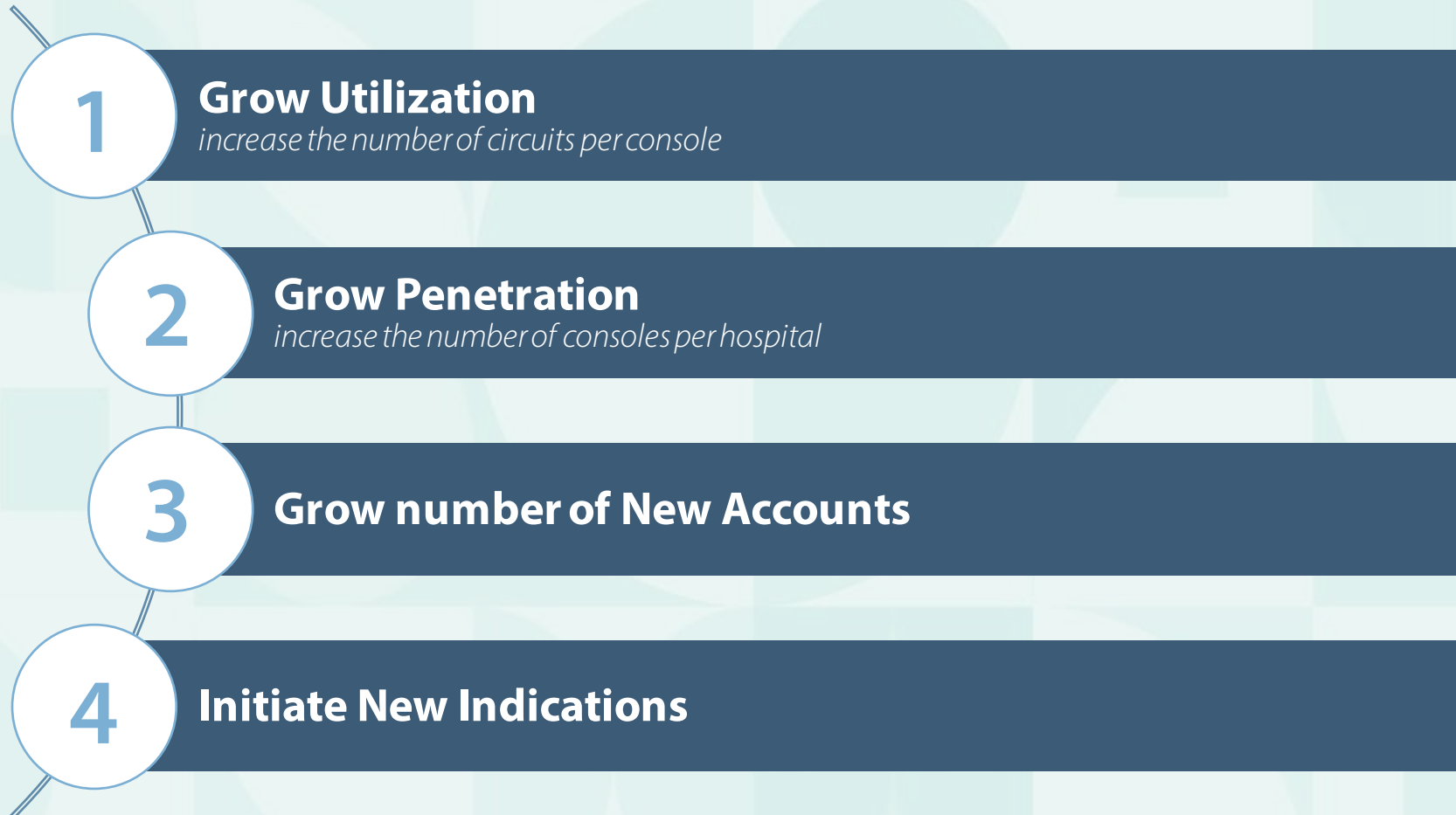


Number at risk:

	0	10	20	30
AQ	105	98	94	88
LD	108	102	92	83

Our strategic growth plan emphasizes four key efforts

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



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 discharge¹

- High risk of readmissions¹
- Long-term use of diuretics is associated with kidney damage¹⁻⁴
- Efficacy of diuretic use in HF & CV surgery patients
 - **10-40%**⁵ have poor diuretic response
 - **68%**⁵ show sub-optimal response

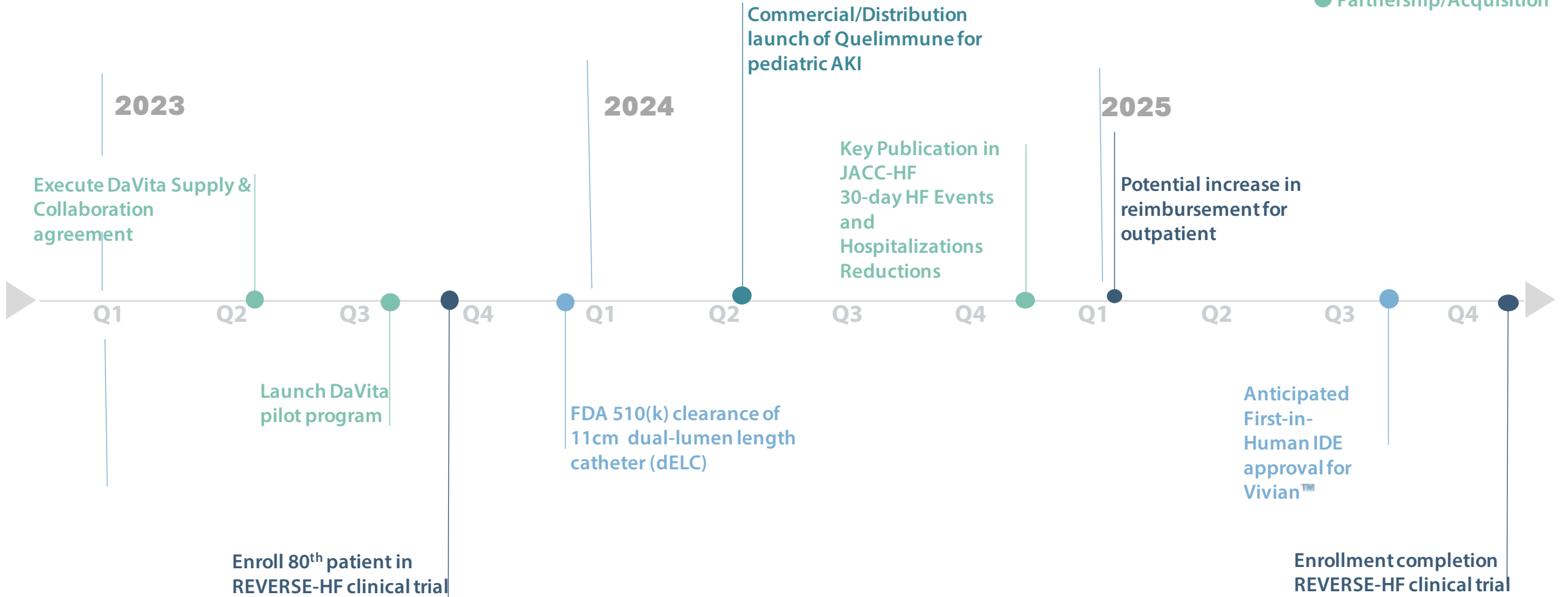
“Diuretic resistance has been a well-known challenge in the care of these patients, and not surprisingly is tied to worse prognosis.”⁶

“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.

Key milestones

- Legend:
- Clinical Milestone
 - Commercial Milestone
 - Product Milestone
 - Partnership/Acquisition



The market faces an urgent challenge as three patient categories grapple with the debilitating impact of Fluid Overload across multiple hospital specialty units

Fluid Overload is a **leading cause of hospital readmission** 30 days following cardiac surgery²



Heart Failure

90% of all heart failure hospitalizations are due to symptoms of Fluid Overload ¹



Critical Care

For critically ill patients in the ICU, Fluid Overload **was associated with a markedly increased risk** for 90-day mortality³



Pediatric

In pediatric patients, Fluid Overload is associated with **significant increases in mortality**⁴⁻⁵

1. Costanzo MR, et al. JACC. 2017 May 16;69(19):2428-2445. 2. Iribarne A, et al. Ann Thorac Surg. 2014; 98(4): 1274-80. 3. Vaara ST et al. Crit Care.2012; 16: 1-11. 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.

**Differentiated
Solution**

Aquadex[®]

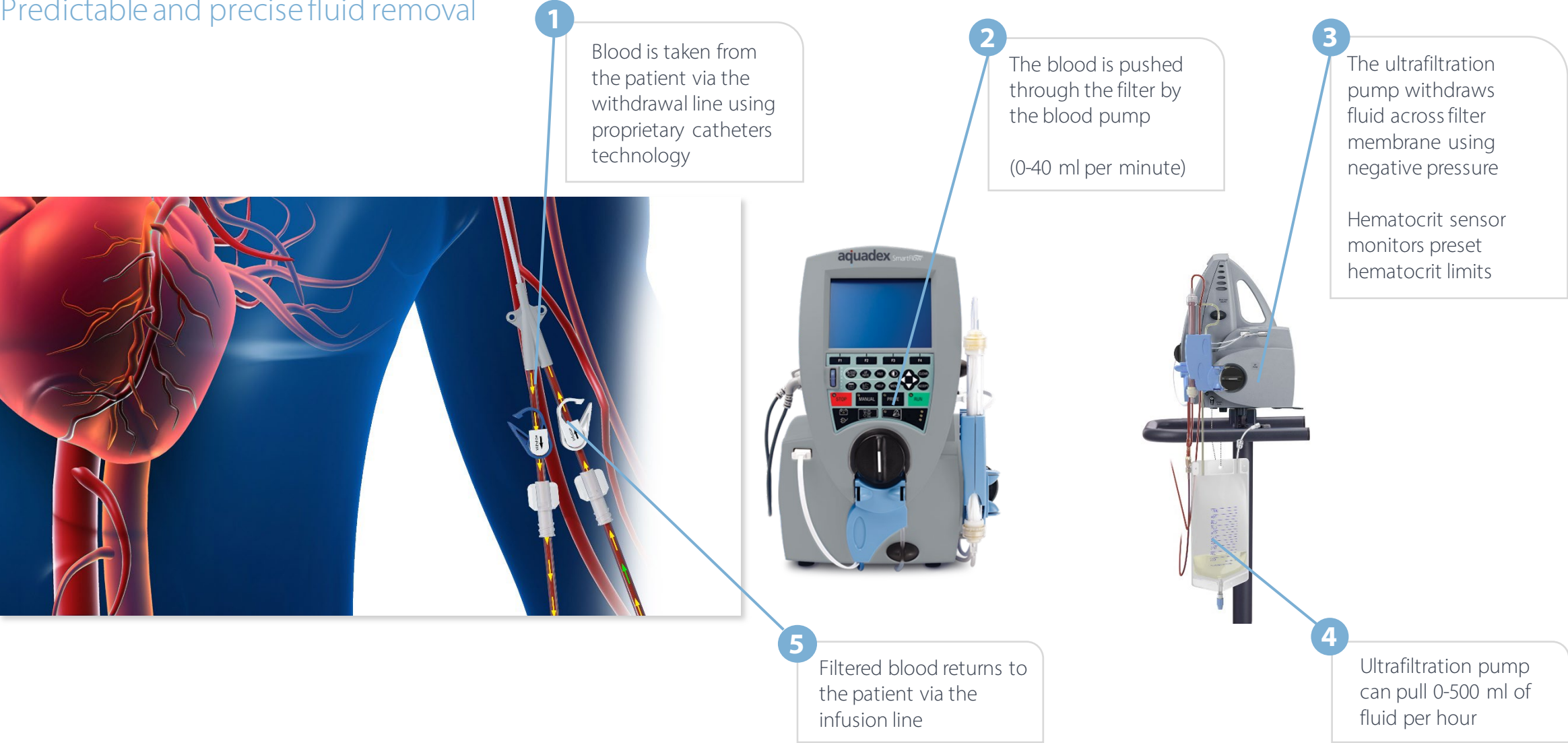
**A clinically superior
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The *only* device of its kind
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How the Aquadex system works

Predictable and precise fluid removal



aquadex SmartFlow®
System

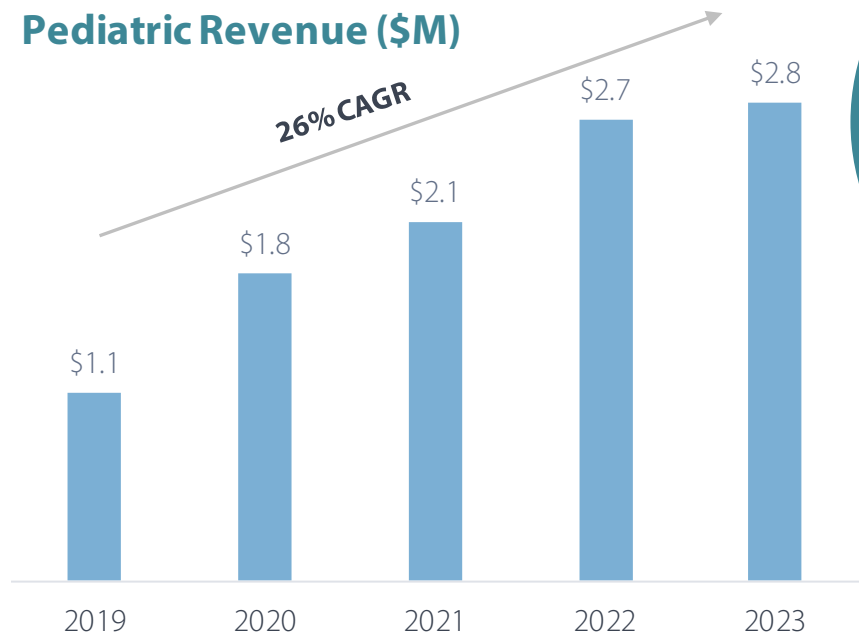
Mechanism of Action

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

We've seen a steady increase in our pediatric business, providing patients with high mortality an opportunity at life¹

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.

Coming soon:

Vivian™

**Our pediatric
solution**

On track for H1 2025 launch



Introducing Vivian™

Therapy to fill crucial gaps, offering a lifeline to critically ill neonates and children



Ultrafiltration
Hemofiltration
Hemodialysis

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^{1,2}

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)³

\$130m addressable pediatric market

Launch best-in-class pediatric CRRT system, 1H 2025

- 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 large and expanding addressable market, Nuwellis stands at the forefront of a transformative healthcare opportunity

Outpatient market opportunity adds \$500M+ to addressable market (heart failure and advanced liver disease)

\$2B+ TAM



Heart Failure

\$1B Market¹

~30% of current
Nuwellis sales



Critical Care

\$900M Market¹

~40% of current
Nuwellis sales



Pediatric

\$130M Market¹

~30% of current
Nuwellis sales

Across our three strategic patient categories, we have an enormous opportunity to improve outcomes for Fluid Overload patients across multiple hospital specialty units

1. See Appendix.

2. Approved for use in pediatric patients weighing 20 kg or more.

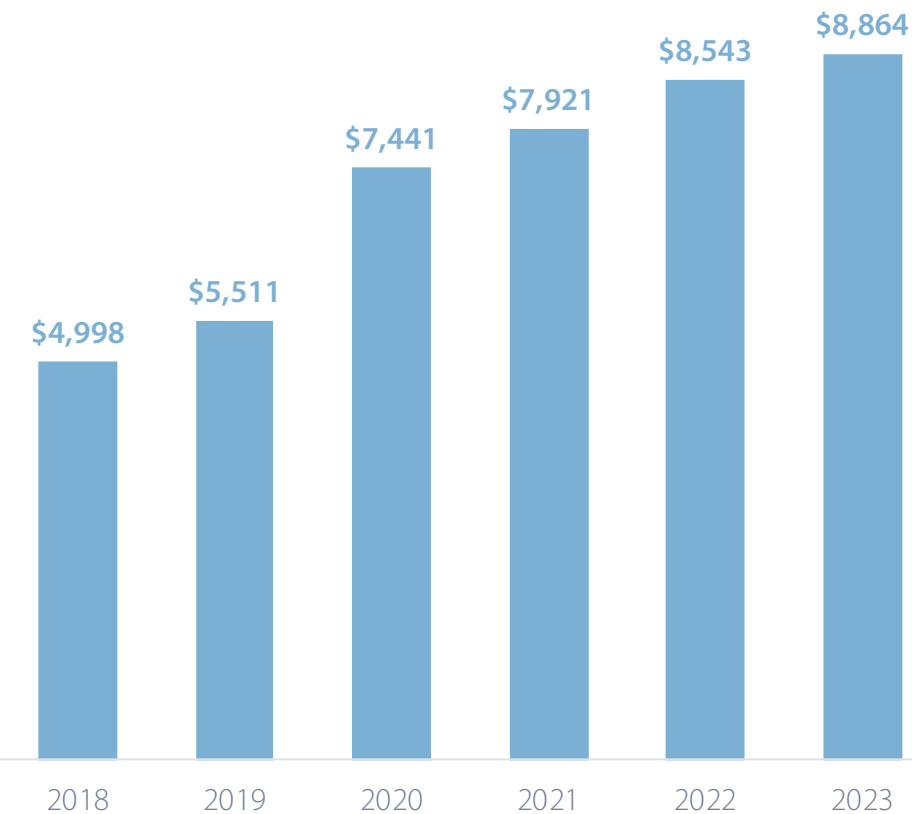
Investment Highlights

We're confident that the key catalysts we will pursue in 2024 should support a valuation of 3-5x revenue.

\$2B+ TAM	Positive ROI	Clinical Evidence	Scalable Consumables	Commercial Infrastructure	Product Pipeline	Leadership Team
\$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	Scalable consumables driven growth	Commercial infrastructure leverage	Novel product pipeline along with an expanding IP Portfolio for continued expansion	Highly experienced leadership perfectly positioned to drive our growth strategy

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
\$1.0 million as of Jun 30, 2024

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	495
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: 497,852 units	497,852
Employee & Director Options:	
Options Issued & Outstanding	3,906
Total Common Share Equivalents	4,185,149
Total Common Share & Share Equivalents	6,052,039

Capitalization Table as of August 31st, 2024

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 Eayrs
Chief Human Resources Officer

Seasoned Leadership: Over 200 years' collective experience in clinical practice and the medical device industry, with significant tenures at industry leaders such as Medtronic, Boston Scientific, and Abbott/St. Jude Medical.

Commercialization Prowess: Demonstrated success in commercializing various therapies, showcasing the team's ability to bring innovative medical devices to market effectively.

Strategic Industry Involvement: In-depth industry knowledge and strategic insights gained from working with major players in the medical device sector.

Adaptive Management: Dynamic management style with a history of successfully navigating challenges and adapting to evolving market dynamics.

Innovative Contribution: Track record of contributing to the growth and success of previous ventures through innovation and product development.

Thank you!

Appendix

Market Validation

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

Ultrafiltration: Positive ROI, clinical and economic benefits

81% reduction in heart failure hospitalizations per year

10-Year, real-world experience with ultrafiltration¹



Newly published

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 days²

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

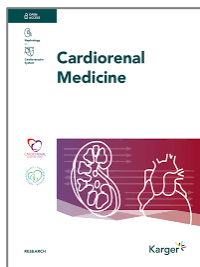
1. Watson R et al. *J Cardiac Fail.* 2020; 26(10): s56. 2. Costanzo MR, et al. *JACC.* 2017 May 16;69(19):2428-2445.

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 $-0.26, 0.23$).