

# **Investor Presentation**

July 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 quarantees 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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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.

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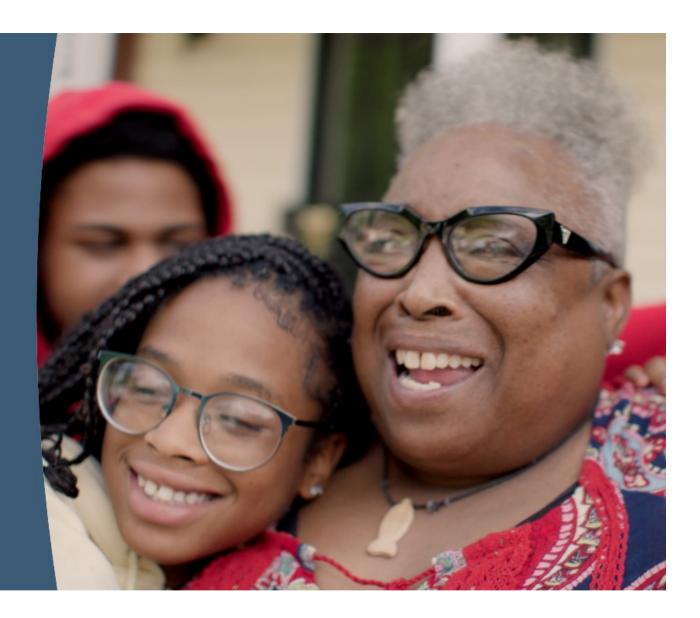
# **Overview**

- The Problem: Fluid Overload
- The Market Opportunity
- Nuwellis Solutions
- Market Validation
- Growth Strategy
- Financial Snapshot
- Team



# **Our Mission**

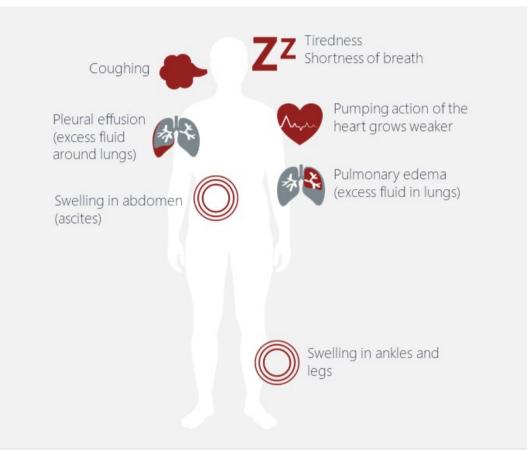
Nuwellis is dedicated to transforming the lives of patients suffering from Fluid Overload through science, collaboration, and innovation.





# 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

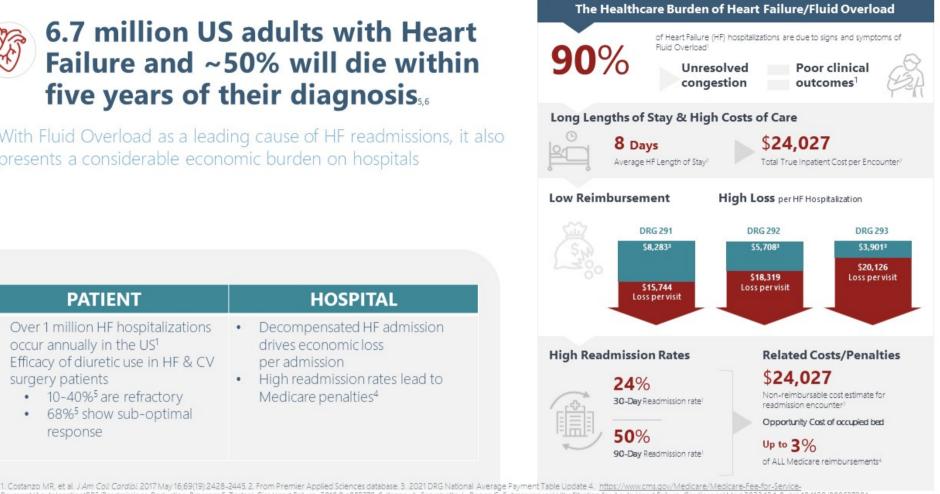




# 6.7 million US adults with Heart Failure and ~50% will die within five years of their diagnosis,

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

#### **PATIENT** HOSPITAL Over 1 million HF hospitalizations Decompensated HF admission occur annually in the US1 drives economic loss Efficacy of diuretic use in HF & CV per admission · High readmission rates lead to surgery patients • 10-40%5 are refractory Medicare penalties4 • 68%5 show sub-optimal response







# 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 post 30 days following cardiac surgery<sup>2</sup>



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



For critically ill patients in the ICU, Fluid Overload was associated with a markedly increased risk for 90-day mortality<sup>3</sup>



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

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.



# 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."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



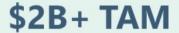
Market Opportunity

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



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

Outpatient market opportunity adds \$0.5B+ to addressable market (heart failure and advanced liver disease)

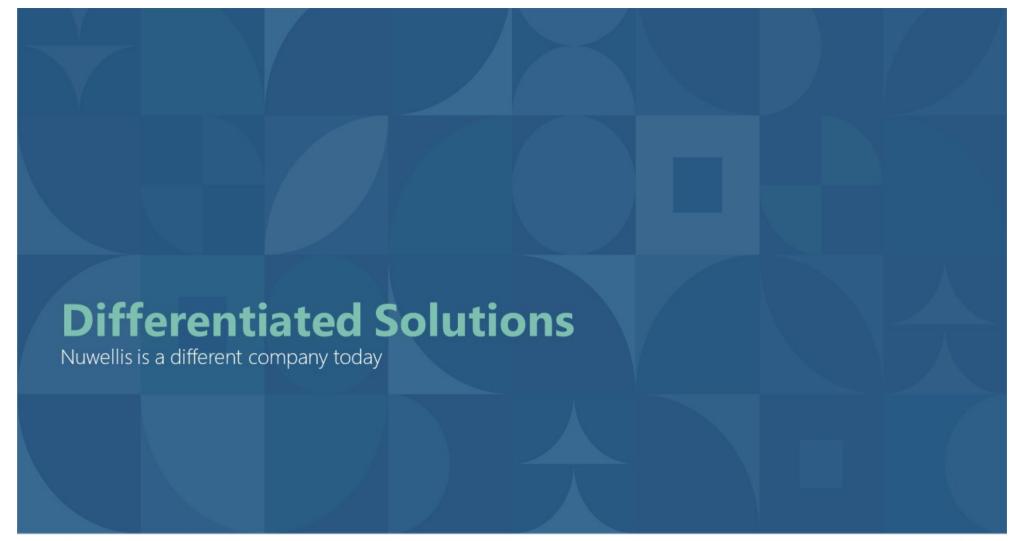






<sup>1.</sup> See Appendix.

<sup>2.</sup> Approved for use in pediatric patients weighing 20 kg or more.



# Aquadex represent our foundation, positioning the company to effectively address significant market opportunities

Robust clinical foundation reinforces strategic technology expansion and collaboration





# **Our hero therapy:**

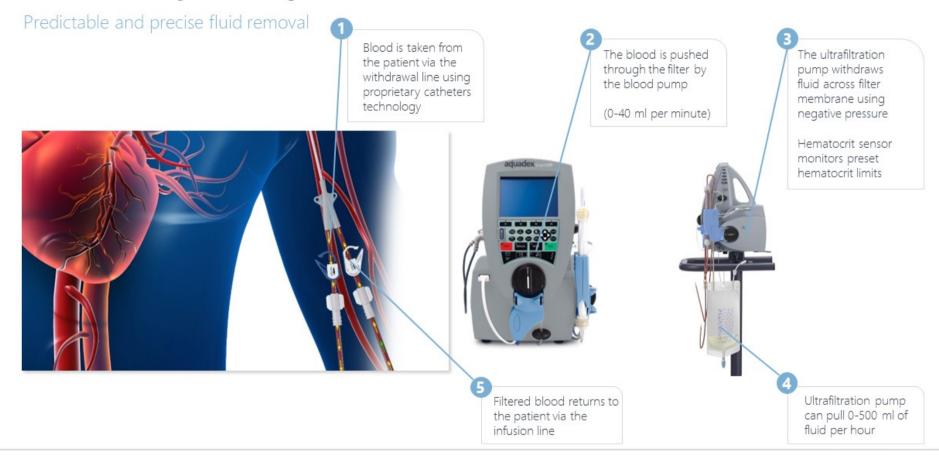
# Aquadex®

A clinically superior solution for Fluid Overload

The <u>only</u> device of its kind in the market



# **How the Aquadex system works**

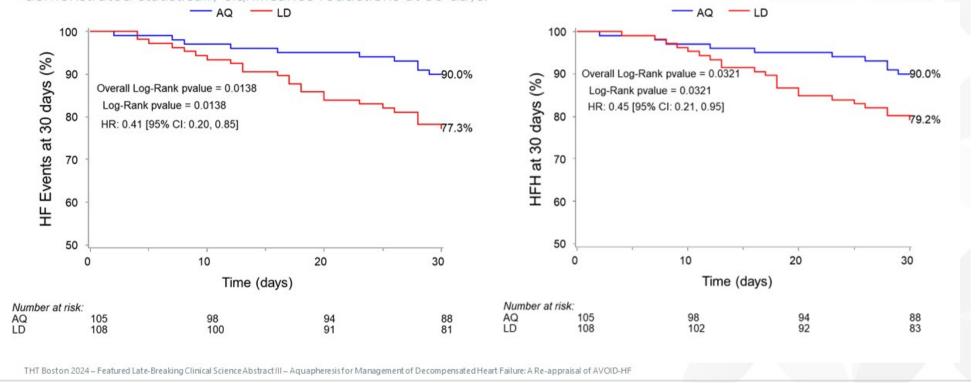






# At a Recent Late Breaking Clinical Trials, Significant Reduction in HF Events and HF Hospitalization at 30 Days

Presented at THT 2024 in early March, a re-appraisal of a 224-patients randomized controlled trial (AVOID-HF) demonstrated statistically significance reductions at 30 days.





# **Aquadex**

A proven and predictable solution for Fluid Overload.



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 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. Wattom R. et al. J Cardiac Fail. 2020; 26(10): \$56. 2. Kizilhepe, U. et al. Ann Thorac Surg. 2007;7(2): 684-93. 3. Sahoq, TK, et al. Indian J Thorac Cardiavas Surg. 2007;2(2): 16-24. 4. Boga et al. Perfusion. 2001;16(37-42-65. 6. Contanzo MRet al. JACC. 2005; 46(11): 2457-51. 7. Contanzo, et al. Perfusion. 2001;16(37-42-65. 6. Contanzo MRet al. JACC. 2005; 46(11): 2457-51. 7. Contanzo, et al. Perfusion. 2001;16(37-42-65. 6. Contanzo MRet al. JACC. 2005; 46(11): 2457-51. 7. Contanzo, et al. Perfusion. 2001;16(37-42-65. 6. Contanzo MRet al. JACC. 2005; 46(11): 2457-51. 7. Contanzo, et al. Perfusion. 2001;16(37-42-65. 6. Contanzo MRet al. JACC. 2005; 46(11): 2457-51. 7. Contanzo, et al. Perfusion. 2001;16(37-42-65. 6. Contanzo MRet al. JACC. 2005; 46(11): 2457-51. 7. Contanzo MRet al.



# **Coming soon:**

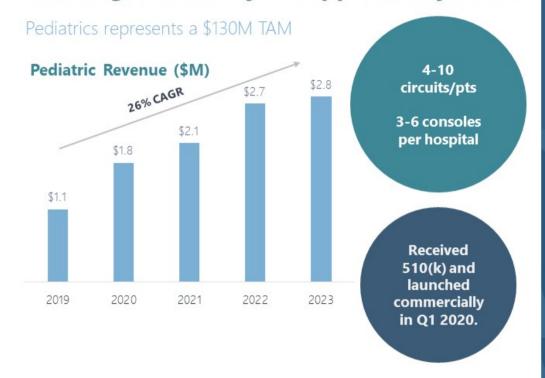
# Vivian™

Our pediatric solution

On track for H1 2027 launch



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



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.

#### Improved patient survival at end of treatment

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

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



# **Introducing Vivian**<sup>™</sup>

Therapy to fill crucial gaps, offering 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 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, H1 2027

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

#### 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. CJSAN, vol 14, October 2019,



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

13 issued patents with protection up to 2043

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

Console	Circu
Transport Mode	Filter Clo
Self-loading/ Self-emptying Bags	Prevent Source L
Open vs. Closed Loop	Connect

#### **Peripheral Access** Peripheral Flow tting Improvements tion line Dual Lumen Catheter tion

### **Accuracy & Safety** External Pump Detection Hemolysis/ Blood Leak Detector Accounting for Density Auto Clamp

# **Guided Therapy** Plasma and Blood Volume Measurement Physiological Parameters Guidance

# Strategic Collaborations Our collaborations with DaVita and SeaStar are expanding market access, bolstering technology offerings, and accelerating Nuwellis growth trajectory.



In June of 2023, we launched a supply and collaboration agreement with DaVita to expand the access of Aquadex therapy for heart failure

790+ hospital partnerships<sup>1</sup>

2,500+ clinic1

65,000+ employees<sup>1</sup>

11.6B in revenue in 20221

1. Used with permission from DaVita



SeaStar distribution and licensing agreement to offers a new Selective Cytopheretic Device (SCD-PED) for pediatric patients with AKI

77% survival rate<sup>1</sup> At day 60

NO dialysis dependency<sup>2</sup> At day 60

2X length of stay in ICU for patients with AKI

(8 days vs. 4 days) as ICU patients without AKI3

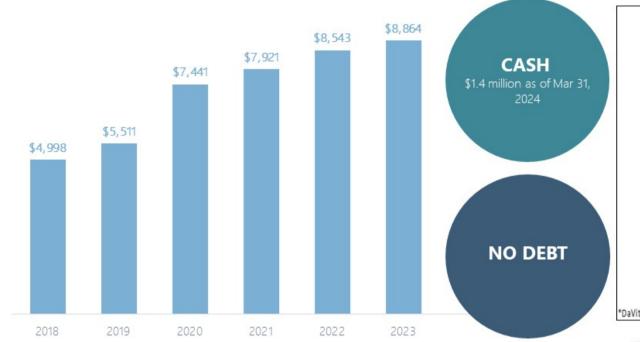
1) Use of the Selective Cytopheretic Device to Support Critically III Children Requiring Continuous Renal Replacement Therapy: A Probable Benefit-Risk Assessment Stuart L. Goldstein, Nicholas J. Oliberding, David J. Askenazi, Rajit K. Basu, David T. Selewski, Kelli Krallman, Lenar Yessayan, H. David Humesmed Rxiv 2023.08.22.23294378; doi: https://doi.org/10.1101/2023.08.22.23294378 2) SL Goldstein et al.: The Selective Cytopheretic Devicein Children; Kidney International Reports (2021) 3) De Zan F, Amigoni A, Pozzato R Pettenazzo A, Murer L, Vidal E. Acute Kidney Injury in Critically III Children: A Retrospective Analysis of Rish Fators Well's 2020;49(1-2):1-7. doi:10.1159/000502081. Epub 2019 Aug 5. PMID: 31382259.





# With a track record of revenue growth, we believe our strategy will lead to continued revenue growth

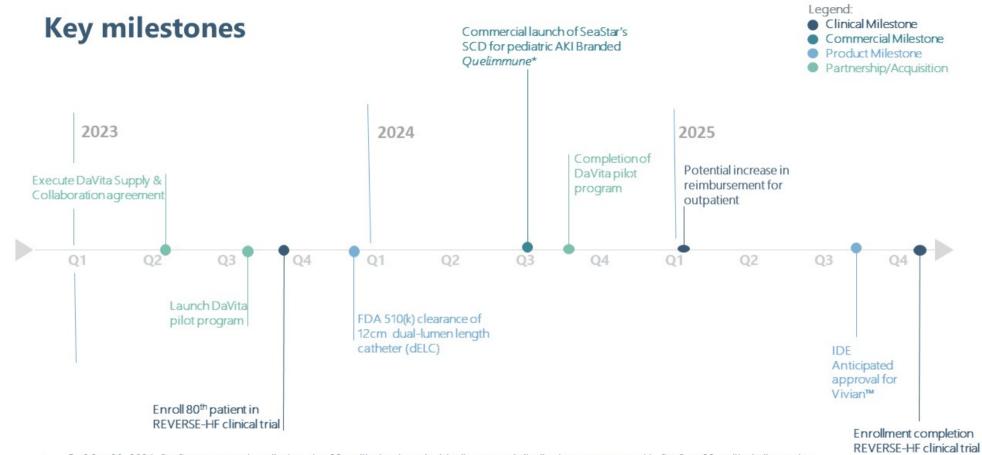
Annual Revenue (\$000)



Common Share Equivalents:		
Preferred Shares:		
Preferred F: 127 units		
Preferred J: 88 units		
Warrants:		
Historical Warrants		
Preferred J Warrants: 67, 168 units		
April 2024 Warrants: 16,875,000 units		
DaVita Warrants*: 1,289,081 units		
Employee & Director Options:		
Options Issued & Outstanding		
Total Common Share Equivalents		
Total Common Share & Share Equivalents		
s: ts		

Capitalization Table as of June 30th, 2024





On May 20, 2024, SeaStar sent a notice alleging that Nuwellis has breached its license and distribution agreement with SeaStar. Nuwellis believes that the alleged breach allegation is without merit and that Nuwellis has fully complied with the terms of the license and distribution agreement. Nonetheless, the license and distribution agreement provides Nuwellis with a ninety-day cure period. As of the date hereof, SeaStar has honored Nuwellis' most recent purchase orders under the license and distribution agreement.



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



Nestor Jaramillo, Jr. President & Chief Executive Officer Chief Financial Officer



Rob Scott



Sandra Eayrs Chief Human Resources Officer



Megan Cotts VP of Clinical Research and Reimbursement



John Kowalczyk Senior Vice President of Sales & Marketing



John Jefferies, M.D. Chief Medical Officer



Neil P. Ayotte General Counsel, SVP & Chief Compliance Officer

- Seasoned Leadership: Over 200 years' of 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.

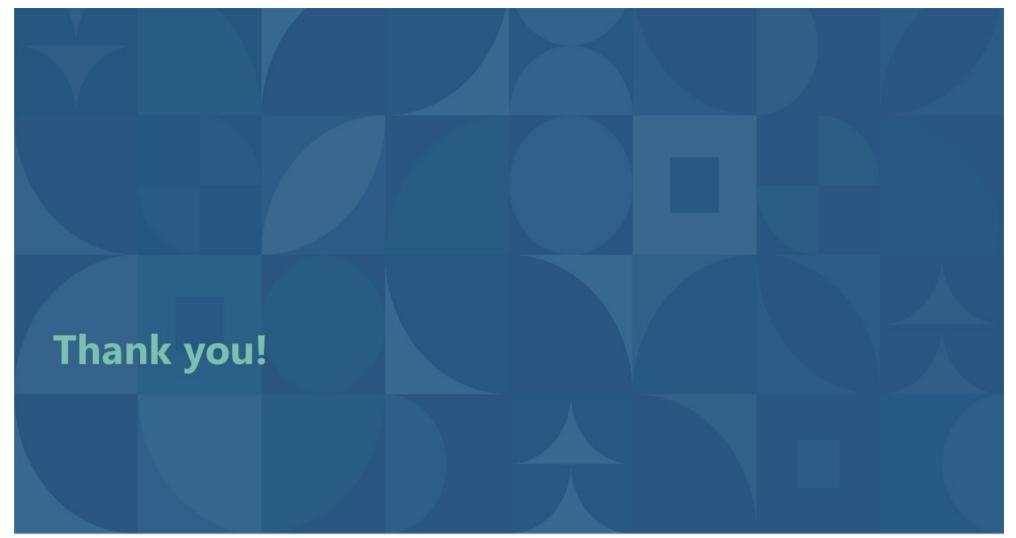


# **Investment Highlights**

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







# **DaVita pilot to commercialization**



In June of 2023, we launched a supply and collaboration agreement with DaVita to expand the access of Aquadex therapy for Fluid Overload patients

11.6B in revenue in 20221

1. Used with permission from DaVita

#### Collaboration Strategy

- Pilot Aquadex to treat adult patients with congestive heart failure in select U.S. markets
- · Offer Aquadex to patients across a network of hospitals and
- Enable accelerated commercial expansion of Aquadex
- · Provides DaVita the option to acquire up to 19.9% of

#### **Expected Collaboration Benefits**

- Improved patient outcomes and lower long-term cost of care for hospitals and health care system
- Reduce related healthcare costs for providers and payers
- · Accelerated Aquadex market penetration
- · Provides DaVita with a new therapy offering



# **SeaStar Distribution and Licensing Agreement**



SeaStar distribution and licensing agreement offers a new Selective Cytopheretic Device (SCD-PED) for pediatric patients with AKI

77% survival rate<sup>1</sup>

dialysis dependency<sup>2</sup> At day 60

2X length of stay in ICU for patients with AKI (8 days vs. 4 days) as ICU patients without AKI3

#### Collaboration Strategy

- Launch market-first SCD-PED device (2024)
- Offer new product to existing Nuwellis pediatric customers
- Develop relationships at new pediatric accounts to support Vivian launch in 2027
- Explore Nuwellis manufacturing viability for SCD
- Strengthen Nuwellis pediatric product portfolio

#### **Expected Collaboration Benefits**

- New revenue stream
- Therapeutic diversification
- Strong strategic fit with Vivian

1) Use of the Selective Cytopheretic Device to Support Critically III Children Requiring Continuous Renal Replacement Therapy: A Probable Benefit-Risk Assessment Stuart L. Goldstein, Nicholas J. Ollberding, David J. Askenazi, Rajit K. Basu, David T. Selewski, Kelli K. Basu, David T. Selewski, Kelli Lenar Yessayan, H. David HumesmedRxiv 2023.08.22.23294378; doi: https://doi.org/10.1101/2023.08.22.23294378 2) SL Goldstein et al.: The Selective Cytopheretic Device in Children; Kidney International Reports (2021) 3) De Zan F, Amigoni A, Pozzato R, Pettenazzo A, Murer L, Vidal E. Acute Kidney Injury in Critically III Children: A Retrospective Analysis of Risk Factors. Blood Purif. 2020;49(1-2):1-7. doi: 10.1159/000502081. Epub 2019 Aug 5. PMID: 31382259



# **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 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

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

Kazory A, Sgarabotto L, Ronco C: Extracorporeal Ultrafiltration for Acute Heart Failure. Cardiorenal Med 2023;13:1-8. doi:10.1159/000527204



# With 15 sites and 125 patients enrolled, we are in the midst of executing our REVERSE-HF Clinical Study with Aquadex

Ongoing REVERSE-HF randomized controlled trial to support driving ultrafiltration to standard of care





# Growth Strategy We aim to achieve sustainable expansion and market leadership through strategic growth plans and tactics.

# Our strategic growth plan emphasizes four key efforts

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

**Grow Utilization** increase the number of circuits per console

> **Grow Penetration** increase the number of consoles per hospital

**Grow number of New Accounts** 

**Initiate New Indications** 

