

**UNITED STATES  
SECURITIES AND EXCHANGE COMMISSION  
Washington, D.C. 20549**

**FORM 8-K**

**Current Report Pursuant to Section 13 or 15(d) of  
the Securities Exchange Act of 1934**

Date of Report (Date of earliest event reported): **March 14, 2023**

**Nuwellis, Inc.**

(Exact Name of Registrant as Specified in its Charter)

**Delaware**  
(State or Other Jurisdiction of Incorporation or Organization)

**001-35312**  
(Commission File Number)

**No. 68-0533453**  
(I.R.S. Employer Identification No.)

**12988 Valley View Road, Eden Prairie, MN 55344**  
(Address of Principal Executive Offices) (Zip Code)

**(952) 345-4200**  
(Registrant's Telephone Number, Including Area Code)

Securities registered pursuant to Section 12(b) of the Act:

Title of each class  
Common Stock, par value \$0.0001 per share

Trading Symbol(s)  
NUWE

Name of each exchange on which registered  
Nasdaq Capital Market

Check the appropriate box below if the Form 8-K filing is intended to simultaneously satisfy the filing obligation of the registrant under any of the following provisions:

- Written communications pursuant to Rule 425 under the Securities Act (17 CFR 230.425)
- Soliciting material pursuant to Rule 14a-12 under the Exchange Act (17 CFR 240.14a-12)
- Pre-commencement communications pursuant to Rule 14d-2(b) under the Exchange Act (17 CFR 240.14d-2(b))
- Pre-commencement communications pursuant to Rule 13e-4(c) under the Exchange Act (17 CFR 240.13e-4(c))

Indicate by check mark whether the registrant is an emerging growth company as defined in Rule 405 of the Securities Act of 1933 (§230.405 of this chapter) or Rule 12b-2 of the Securities Exchange Act of 1934 (§240.12b-2 of this chapter).

Emerging growth company

If an emerging growth company, indicate by check mark if the registrant has elected not to use the extended transition period for complying with any new or revised financial accounting standards provided pursuant to Section 13(a) of the Exchange Act.

**Item 7.01 Regulation FD Disclosure**

The management of Nuwellis, Inc. (the “*Company*”) will give a presentation at the Oppenheimer Annual Healthcare Conference taking place virtually, on Tuesday, March 14, 2023 at 9:20 a.m. Eastern Time. A copy of the presentation slide deck that will be presented at the conference is being furnished as Exhibit 99.1 to this Current Report on Form 8-K.

The information furnished under Item 7.01 of this Current Report on Form 8-K, including Exhibit 99.1, is being furnished and shall not be deemed to be “filed” for the purposes of Section 18 of the Securities Exchange Act of 1934, as amended (the “*Exchange Act*”), or incorporated by reference in any filing under the Securities Act of 1933, as amended, or the Exchange Act, except as shall be expressly set forth by specific reference in such a filing. The information on this Current Report on Form 8-K will not be deemed as an admission as to the materiality of any information that is required to be disclosed solely by Regulation FD.

**Item 9.01 Financial Statements and Exhibits**

(d) Exhibits

<b>Exhibit No.</b>	<b>Description</b>
<a href="#">99.1</a>	Company Presentation, dated March 14, 2023.
104	Cover Page Interactive Data File (embedded within the Inline XBRL document).

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**SIGNATURES**

Pursuant to the requirements of the Securities Exchange Act of 1934, the registrant has duly caused this report to be signed on its behalf by the undersigned hereunto duly authorized.

Date: March 14, 2023

**NUWELLIS, INC.**

By: /s/ NESTOR JARAMILLO, JR.

Name: Nestor Jaramillo, Jr.

Title: Chief Executive Officer

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# Investor Presentation

March 2023



## 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 post-market 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, 2022 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>.

Aquadex FlexFlow® and Aquadex SmartFlow® are registered trademarks of Nuwellis, Inc.  
Aquadex® is a trademark of Nuwellis, Inc.

## Our Mission



nuwellis®

is dedicated to transforming the lives of patients suffering from fluid overload through science, collaboration, and innovation.



# Investment Highlights

- \$2B+ and growing addressable market
- Outpatient market opportunity adds \$0.5B+ to addressable market (heart failure and advanced liver disease)
- Positive ROI and attractive clinical + economic benefits to hospitals and healthcare system
- Robust body of clinical evidence
- Scalable consumables driven growth
- Commercial infrastructure leverage
- Novel product pipeline
- Experienced leadership

# Executive Leadership Team



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



**Lynn Blake**  
Chief Financial Officer



**Sandra Eayrs**  
Chief Human Resources  
Officer



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



**John Kowalczyk**  
Senior Vice President  
of Sales & Marketing



**John Jefferies, M.D.**  
Chief Medical Officer



**Vitaliy Epshteyn**  
Senior Vice President of  
Operations & Engineering



**Megan Cease**  
Vice President of  
Clinical Research and  
Reimbursement



**Laurent Duhoux**  
Vice President of International  
Business Development

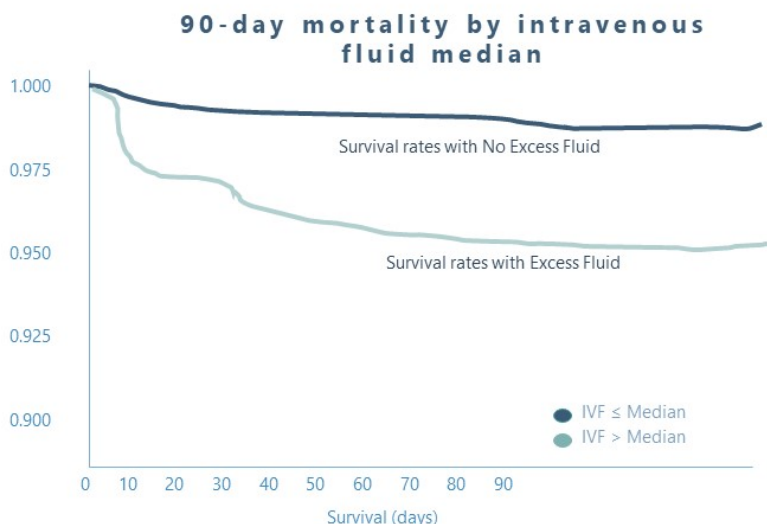


**Al Saalabi**  
Vice President of  
Quality and Regulatory

- Over 200 years' collective experience in clinical practice and the medical device industry, working with companies including Medtronic, Boston Scientific and Abbott/St. Jude Medical
- Management team with proven success commercializing many therapies
- John Jefferies, M.D., joined as Chief Medical Officer



# Fluid Overload is Associated with Greater Mortality

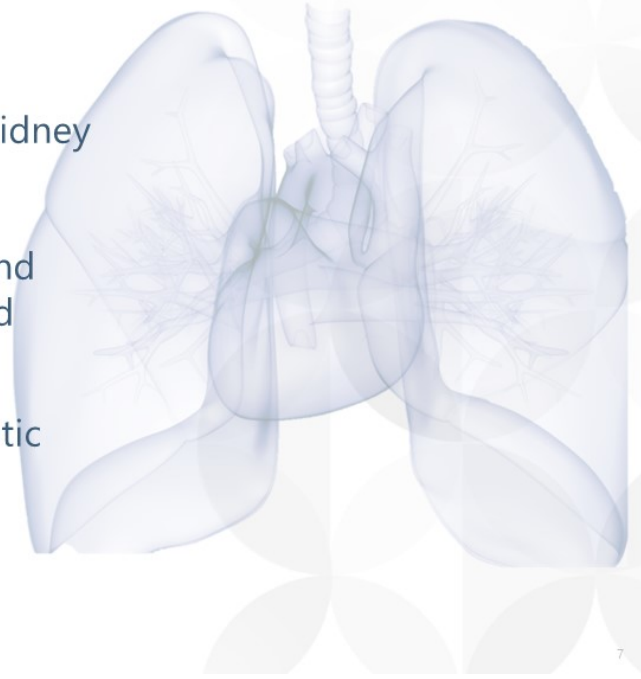


- Fluid overload is the leading cause of death for critically ill patients in the ICU within 90 days<sup>1</sup>
- Excess fluid following cardiac surgery leads to three-fold increase in mortality at 90 days<sup>2</sup>
- 90% of heart failure hospitalizations are due to signs and symptoms of fluid overload<sup>3</sup>

1. Vaara ST et al. *Crit Care*.2012; 16: 1-11.  
 2. Pradeep, A. et al. *HSR Proc IC and Car An*. 2010 Mar; 2(4): 287-296.  
 3. CostanzoMR, et al. *J Am Coll Cardiol*. 2017 May 16;69(19):2428-2445.

## Diuretics: Significant Limitations as Current Standard of Care

- High risk of rehospitalization<sup>1</sup>
- Long-term use of diuretics is associated with kidney damage<sup>1-4</sup>
- Diuretics provide insufficient symptom relief and are associated with worsening heart failure and increased mortality after discharge<sup>1</sup>
- >40% of heart failure patients have poor diuretic response<sup>5</sup>



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.

## Clinically Superior Solution for Fluid Overload



**SIMPLE**



**FLEXIBLE**



**SMART**

- Reduces hospitalization by 81%<sup>1</sup> compared to diuretics
- Rehospitalizations with Aquadex were 48% lower than the national average at 30 days<sup>1</sup>
- Reduces length of hospital stay when initiated early, resulting in average savings of \$3,975 (14%)<sup>6-7</sup>
- No significant changes to kidney function<sup>1</sup>
- Stabilizes or improves cardiac hemodynamics<sup>2-5</sup>
- Predictably removes excess fluid
- Safe, easy to use and flexible in application

**The only device of its kind in the market:  
Saving lives, time & money**

# Multiple Growth Opportunities

Moving Aquadex to standard of care in fluid overload

\$2B+ TAM



**\$1B Market<sup>1</sup>**  
*~30% of sales*



**\$900M Market<sup>1</sup>**  
*~40% of sales*



**\$130M Market<sup>1</sup>**  
*~30% of sales*

## TREATING THE MOST VULNERABLE

From children<sup>2</sup> to the elderly, our therapy is critical to improving care and outcomes

1. See Appendix.

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

**Expanding Use of Ultrafiltration Across Hospital Specialty Units**  
 Improves outcomes for fluid overloaded patients

**NEAR-TERM OPPORTUNITIES (In the U.S.)**

**Cardiac Surgery**

550,000 patients/year<sup>1</sup>

**Liver Transplants**

12,000 patients/year<sup>2</sup>

**VAD**

6,000 patients/year<sup>3</sup>

**MID to LONG-TERM OPPORTUNITIES (In the U.S.)**

**Sepsis**

1.8M patients/year<sup>4</sup>

**Advanced Liver Disease**

700,000 patients/year<sup>5</sup>

**Adult ECMO**

15,000 patients/year<sup>6</sup>

1. Derived from: <https://www.grandviewresearch.com/industry-analysis/coronary-artery-bypass-graft-cabg-market> and growth rate from: <https://www.hcup-us.ahrq.gov/reports/statbriefs/sb171-Operating-Room-Procedure-Trends.pdf>. 2. Derived from: <https://www.healthline.com/health/liver-transplant-survival> and this for growth rate: <https://www.marketsandmarkets.com/press-releases/organ-transplantation-market-size-to-grow-at-9.4-cagr-during-the-forecast-period-of-2022-2027-100-report-pages-2022-09-23>. 3. Derived from: <https://www.grandviewresearch.com/industry-analysis/ventricular-assist-devices-market> (\$600m estimated market in 2018 / Avg cost per procedure of \$200k = 3k procedures) and growth rate from same source. 4. Derived from: <https://www.ncbi.nlm.nih.gov/pmc/articles/PMC6537150/>. 5. Derived from: <https://www.ncbi.nlm.nih.gov/pubmed/25291348>. 6. Derived from: <https://www.ucsfhealth.org/medical-services/heart/ecmo/research/statistics> and growth rate from same source.

# Diuretic Limitations Create Significant Burden to Hospitals & Healthcare Systems

High patient readmission rates and related costs/penalties

- *HF Case Study: National data suggests the current standard of care for managing fluid overload in HF patients is challenging and costly for patients and hospitals*

## BACKGROUND

Over 1 million HF hospitalizations occur annually in the US<sup>1</sup>

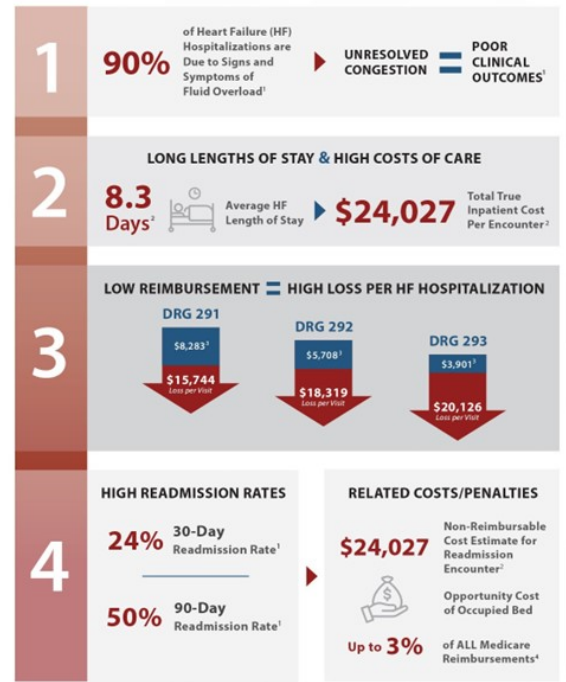
### Efficacy of Diuretic Use in HF & CV Surgery Patients

- 30-40%<sup>5</sup> are refractory
- 68%<sup>5</sup> show sub-optimal response



Sources:  
1. Costanzo MR, et al. *J Am Coll Cardiol*. 2017 May 16;69(19):2428-2445.  
2. From Premier Applied Sciences database.  
3. Reimbursement estimates from MCRA.

4. <https://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/AcuteInpatientPPS/Readmissions-Reduction-Program>  
5. Testani, *Circ Heart Failure*, 2016;9:e002370.



# Aquadex Ultrafiltration: A Safe and More Effective Therapy Than Diuretics

## Aquapheresis Versus Intravenous Diuretics and Hospitalizations for Heart Failure (AVOID-HF) Trial



Results					
Primary Endpoint	Clinical results favored AUF with 81% more wins	Win Ratio	Secondary Analyses	Clinical results favored AUF with 109% more wins	Win Ratio
		<b>1.81</b>			<b>2.09</b>
<ul style="list-style-type: none"> <li>CV mortality within 90 days</li> <li>HF event within 30 days</li> <li>Time to first HF event within 90 days</li> </ul>			<ul style="list-style-type: none"> <li>CV mortality within 30 days</li> <li>HF event within 30 days</li> <li>Time to first HF event within 90 days</li> </ul>		
<b>Number (%) of Winners</b> Aquapheresis IV Diuretics Win Ratio* 95% CI P-value 29 (29.6%) 16 (16.3%) 1.81 (1.02, 3.64) 0.0429			<b>Number (%) of Winners</b> Aquapheresis IV Diuretics Win Ratio* 95% CI P-value 23 (23.5%) 11 (11.2%) 2.09 (1.08, 5.01) 0.0278		

**Adjustable Ultrafiltration “won” more times than Adjustable IV Loop Diuretics, resulting in Win Ratios that all favored Ultrafiltration over diuretics in reducing CV mortality and HF events in congested HF patients**

Finkelstein-Schoenfeld Method of Win Ratios Analysis Provides **New Insights Into Clinical Data Favors Adjustable Ultrafiltration (AUF) over Adjustable Loop Diuretics (ALD) in Treating Fluid Overloaded Heart Failure Patients**

\*Sean Pinney<sup>1</sup>, Maria DeVita<sup>2</sup>, Maria Rosa Costanzo<sup>3</sup>

1. University of Chicago Medicine, Division of Cardiology, Chicago, IL (through February 2023). Mount Sinai Morningside, Division of Cardiology, New York, NY (March 2023 to present); 2. Lenox Hill Hospital, Division of Nephrology, New York, NY. 3. Midwest Cardiovascular Institute, Division of Cardiology, Naperville, IL

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81% reduction in heart failure hospitalizations per year

## 10-Year, Real-World Experience with Ultrafiltration<sup>1</sup>

**ABINGTON HOSPITAL  
JEFFERSON HEALTH**



**Newly  
published**

- 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** 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 and 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.

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HOSPITAL NAME	Actual Hospital Account
<b>INPATIENT TREATMENT WITH DIURETICS ONLY</b>	
<b>ESTIMATED HEART FAILURE (HF) 30-DAY READMISSION COSTS</b>	
Est Annual HF Admissions <sup>1</sup>	7,537
30-Day Readmission Rate <sup>1</sup>	23%
Est Annual HF Readmissions	1,734
Est Cost Per HF Patient Readmission (Inpatient) <sup>2</sup>	\$24,027
Est Reimbursement Per HF Readmission (Inpatient)	\$0
Est Loss Per HF Patient (Inpatient)	\$24,027
<b>EST LOSS FOR ALL 30-DAY READMISSIONS</b>	<b>(\$41,662,818)</b>

- With inpatient therapy only:
  - 23% HF patient readmission rate
  - \$41.7M non reimbursable loss
- With outpatient Aquadex:
  - 12% HF patient readmission rate
  - 35% cost savings over inpatient therapy only

ESTIMATED PER PATIENT REIMBURSEMENT FOR OUTPATIENT AQUADEX	
Outpatient Facility Payment	\$1,216
Venous Access Payment	\$1,436
Physician Payment	\$366
<b>TOTAL ESTIMATED REIMBURSEMENT (PER PATIENT)</b>	<b>\$3,018</b>
<b>NET OUTPATIENT AQUADEX COSTS (PER PATIENT)</b>	<b>(\$3,490)</b>

ESTIMATED COSTS FOR OUTPATIENT AQUADEX	
Total Costs (All Patients)	(\$11,284,433)
Total Reimbursement (All Patients)	\$5,233,472
<b>NET OUTPATIENT AQUADEX COSTS (ALL PATIENTS)</b>	<b>(\$6,050,961)</b>

30-DAY READMISSIONS (AQUADEX TREATED PATIENTS)	
% Readmission Reduction	50%
Readmission Reduction (Number of Patients)	867
<b>READMISSION REDUCTION COST</b>	<b>(\$20,831,409)</b>

30-DAY READMISSIONS (NON-AQUADEX TREATED PATIENTS)	
% Readmission Reduction	0%
Readmission Reduction (Number of Patients)	0
<b>READMISSION REDUCTION SAVINGS</b>	<b>\$0</b>

ADJUSTED REACTIONS AND COSTS	
<b>ADJUSTED READMISSIONS (NUMBER OF PATIENTS)</b>	<b>867</b>
<b>ADJUSTED COSTS FOR READMISSIONS</b>	<b>(\$20,831,409)</b>
<b>NET COSTS FOR ADMINISTRATION OF OUTPATIENT AQUADEX</b>	<b>(\$6,050,961)</b>
<b>TOTAL COSTS FOR OUTPATIENT AQUADEX</b>	<b>(\$26,882,370)</b>
<b>NET SAVINGS OVER INPATIENT THERAPY ONLY</b>	<b>\$14,780,448</b>
<b>% COST SAVINGS</b>	<b>35%</b>
<b>ADJUSTED READMISSION RATE</b>	<b>12%</b>

\*Figures above are not guaranteed, are used for illustrative purposes only and actual results can and will vary by location

1. Definitive Health Database for year 2019. 2. Premier Applied Sciences database.



# Driving Use of Ultrafiltration in the Outpatient Setting

Prevents hospitalization and lowers readmission rates

## NEAR-TERM OPPORTUNITY (U.S.)

### Heart Failure

400,000 patients/year<sup>1</sup>

## MID-TERM OPPORTUNITY (U.S.)

### Advanced Liver Disease

700,000 patients/year<sup>2</sup>

1. Derived from: <https://www.grandviewresearch.com/industry-analysis/coronary-artery-bypass-graft-cabg-market> and growth rate from: <https://www.hcup-us.ahrq.gov/reports/statbriefs/sb171-Operating-Room-Procedure-Trends.pdf>.  
2. Derived from: <https://www.ncbi.nlm.nih.gov/pubmed/25291348>.

# Making Aquadex the Standard of Care in Fluid Overload



Growing body of clinical evidence; Advocating for medical society guidelines and improved provider reimbursement

- New clinical evidence in Heart Failure: Finkelstein-Schoenfeld Win Ratio (WR) analysis favored ultrafiltration in reducing cardiovascular mortality and heart failure rehospitalization as compared to intravenous diuretics at 30 days and 90 days<sup>1</sup>
- New peer-reviewed publication: Data from ten-year, real-world experience demonstrated 81% reduction in heart failure hospitalizations per year and 48% decrease in 30-day hospital readmission rates, as well as improvements in renal function response, with ultrafiltration<sup>2</sup>
- New clinical evidence in Critical Care: *100% survival at 30 days following use of ultrafiltration in high-risk postoperative coronary artery bypass grafting (CABG) patients*<sup>3</sup>
- Recent peer-reviewed publication of promising clinical data demonstrating 71% survival with kidney replacement therapy with ultrafiltration to treat, low weight preterm neonates with end-stage kidney disease<sup>4</sup>
- 2023 peer-reviewed publication of a turnkey order set for cardiac-surgery associated acute kidney injury, viewed as a template to guide clinicians in creating institution-specific, evidence-based protocols for patient care, that provides a recommendation to consider ultrafiltration if unresponsive to diuretics<sup>5</sup>
- Ongoing REVERSE-HF randomized controlled trial to support driving ultrafiltration to standard of care

**Change practice guidelines to Ultrafiltration  
Reimbursement expansion into outpatient setting**

1. Pinney S et al Poster presented HFSA Annual Meeting 2022. 2. Haas D et al. Ten year real world experience with ultrafiltration for the management of acute decompensated heart failure. *American Heart Journal*, 2022. 3. Beckles DL et al. The Use of Simple Ultrafiltration Technology as a Fluid Management Strategy for High-Risk Coronary Artery Bypass Grafting Surgery. *J Cardiac Surg*. 2022. DOI: 10.1111/jocs.16867  
4. Sutherland SM, Davis AS, Powell D, Tanaka J, Woo M, Josephs S, Wong CJ. Kidney Replacement Therapy in Low Birth Weight Preterm Newborns. *Pediatrics*. 2022 Sep 1;150(3):e2022056570. doi:10.1542/peds.2022-056570. PMID: 35945293. 5. Engelman DT, Shaw AD. A Turnkey Order Set for Prevention of Cardiac Surgery-Associated Acute Kidney Injury. 2023 Jan 1. *The Annals of Thoracic Surgery*. doi.org/10.1016/j.athoracsur.2022.10.022.

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# Driving Penetration and Increased Utilization Across Territories



Scaling up field sales organization, education programs and social platforms



- Aquadex in Hospital Specialty Units
- Target Outpatient Accounts

Looking for a better way to manage your #HeartFailure patients with fluid overload?  
<https://nhd.in/gz28M/hk>

**WEBINAR: SAFETY AND EFFICACY OF ULTRAFILTRATION IN REDUCING MORTALITY & HEART FAILURE EVENTS**  
 A REVIEW OF THE AVOID-HF STUDY WIN RATIO ANALYSIS

DATE: Nov. 29, 2022 | TIME: 10:00 AM CT / 11:00 AM ET | REGISTER NOW

MARIA DEVITA, MD (Northwell Health) | SEAN PINNEY, MD (University of Chicago)

**nuwellis WEBINAR SERIES**

**Breaking the Cycle of Heart Failure Readmissions: Outpatient Ultrafiltration Therapy**

Tuesday, June 21 | 9 a.m. PT • 10 a.m. MT • 11 a.m. CT • 12 p.m. ET

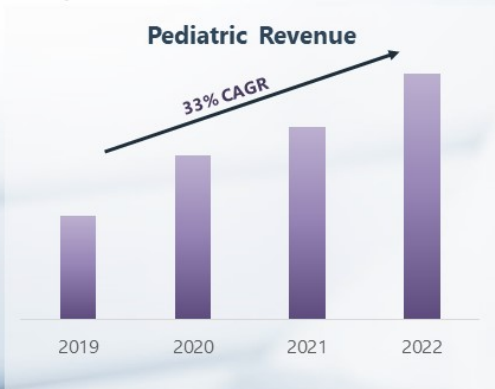
**SPEAKERS:** Daryl Wenzler, MD (AdventHealth South Central Texas), Sitaramesh Emami, MD (Memorial Hermann), Patrick Cornell, PA-C (Cardiologist, Professor, Associate Director of Outpatient Outpatient/Comprehensive Heart Failure at the University of Maryland)

**WELCOME**



## Growing Pediatric Business

Pediatric revenue has outpaced total growth over past two years



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

Development of novel pediatric pipeline product on track. Growing patent portfolio supporting pediatric products.

*"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

# Market-Driven Demand to Improve Pediatric Therapy

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

1% → 3%

With every 1% increase in fluid overload...

A 3% increase in pediatric mortality was observed <sup>1,2</sup>

8.5x mortality

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

Providing renal support and hemodynamic stability can be life-saving

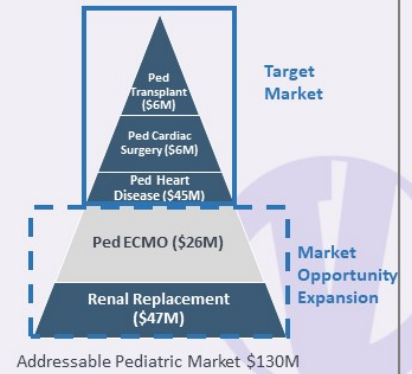
66% survival to end therapy

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

Yet clinical gaps exist in current competitive offerings

- Adult therapies unsafe for children
- Competitive pediatric therapies meet only a subset of the clinical needs
  - Narrow indicated weight ranges
  - High extracorporeal volumes
  - Less than optimal ease of use

Large current market opportunity, Nuwellis technology can address multiple pediatric conditions



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.



# The Nuwellis Solution – Introducing Vivian™



## Business Objectives

- Launch best-in-class pediatric Continuous Renal Replacement Therapy (CRRT) system in 1H 2025
  - IDE approval anticipated in 1Q 2024
- Continuously expand pediatric therapy value proposition with planned roadmap of product enhancements

## Product Strategy & Differentiation

- Deliver a solution that provides the broadest pediatric indication on the market
- Drive adoption and penetration with user experience (UX) design principles
- Uncompromising focus on patient safety

## Vivian System Details

- Integrates Ultrafiltration with Hemofiltration and Hemodialysis capabilities
- Broadest weight indication: 2.5 kg +
- Safety features: lowest extra-corporeal blood volume; built-in hematocrit sensor
- Clinician-driven UX design

## Clinical & Regulatory Plan

- 15 patient IDE to support 510(k) submission
- To be confirmed with FDA via pre-submission in May 2023
- IDE submission anticipated in late 2023

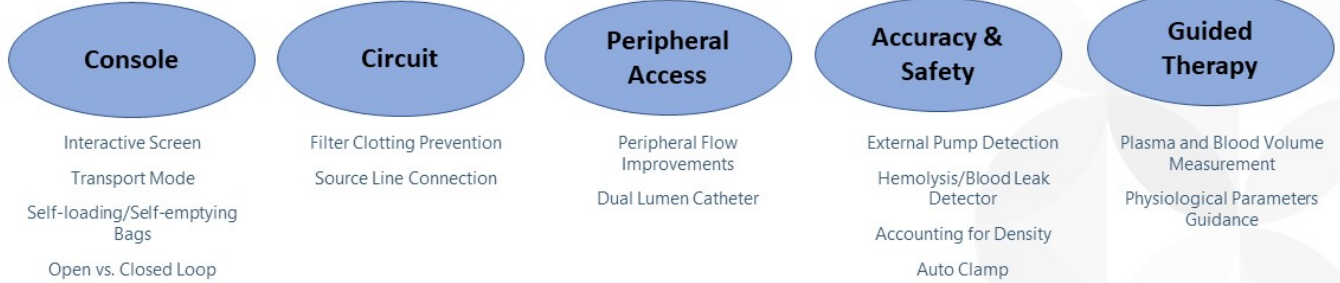
## Commercialization Plan

- Distribute with established Nuwellis field force
- Grow from current pediatric customer base
- Offer competitive pricing

# Novel Technology with Strong IP Portfolio

17 novel patents with protection to 2043+

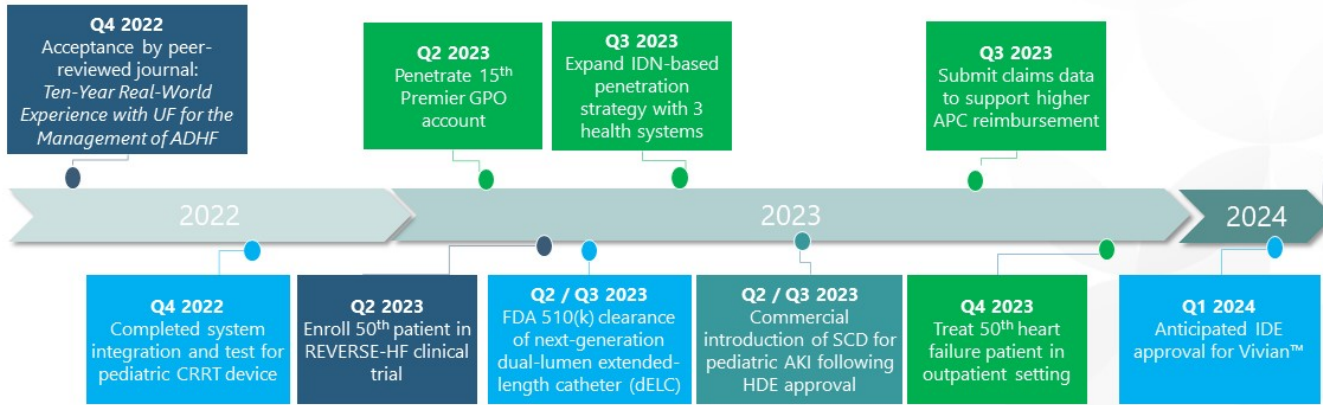
- Robust and evolving portfolio of patents circling the technology
- 17 Nuwellis patent applications in addition to licensed IP from Baxter
  - 1 granted, 1 allowed, 15 pending
- Wide technology scope coverage





# Key Near-Term Milestones

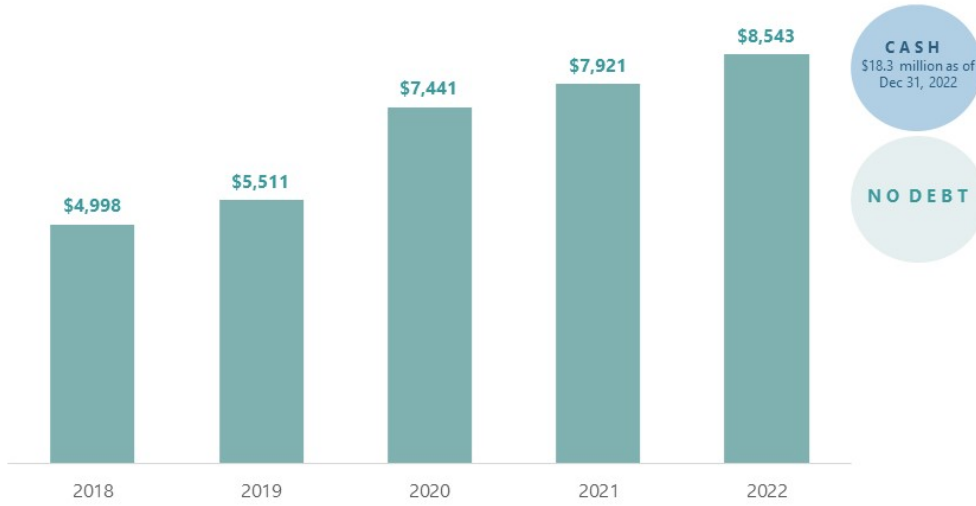
## KEY MILESTONES



Legend
Clinical Milestone
Commercial Milestone
Product Milestone
Partnership/Acquisition

# Financial Snapshot

Annual Revenue (\$'000)



## Growth Agenda

1. Increase utilization of Aquadex therapy
  - Focused sales strategy and expansion of field organization
  - Expanding utilization of Aquadex therapy in the outpatient setting
2. Grow body of clinical evidence to change practice guidelines and make Aquadex the standard of care
  - Leverage Healthcare economic benefits data
3. New product development; continued progress on pediatric renal replacement therapy device
4. Corporate development
  - Selective pursuit of strategic partnerships, e.g., SeaStar Medical

## Investment Highlights

- \$2B+ and growing addressable market
- Outpatient market opportunity adds \$0.5B+ to addressable market (heart failure and advanced liver disease)
- Positive ROI and attractive clinical + economic benefits to hospitals and healthcare system
- Robust body of clinical evidence
- Scalable consumables driven growth
- Commercial infrastructure leverage
- Novel product pipeline
- Experienced leadership



nuwellis®

dedicated to transforming the  
lives of patients suffering from  
fluid overload through science,  
collaboration, and innovation

## **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
- Insufficient diuretic response: [https://www.ahajournals.org/doi/10.1161/CIRCHEARTFAILURE.115.002370?url\\_ver=Z39.88-2003&rft\\_id=ori:rid:crossref.org&rft\\_dat=cr\\_pub%20%20pubmed](https://www.ahajournals.org/doi/10.1161/CIRCHEARTFAILURE.115.002370?url_ver=Z39.88-2003&rft_id=ori:rid:crossref.org&rft_dat=cr_pub%20%20pubmed)

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- Diuretic resistance rate: [https://www.ahajournals.org/doi/10.1161/CIRCHEARTFAILURE.115.002370?url\\_ver=Z39.88-2003&rft\\_id=ori:rid:crossref.org&rft\\_dat=cr\\_pub%20%20pubmed](https://www.ahajournals.org/doi/10.1161/CIRCHEARTFAILURE.115.002370?url_ver=Z39.88-2003&rft_id=ori:rid:crossref.org&rft_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>