

**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): **January 8, 2024**

**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	Trading Symbol(s)	Name of each exchange on which registered
Common Stock, par value \$0.0001 per share	NUWE	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.**

On January 8, 2024, Nuwellis, Inc. (the “*Company*”) posted an updated corporate presentation to its website at ir.nuwellis.com, which the Company may use from time to time in communications or conferences. A copy of the corporate presentation is attached as Exhibit 99.1 to this Current Report on Form 8-K (this “*Report*”).

The information in this Report, including Exhibit 99.1 hereto, is furnished pursuant to Item 7.01 and shall not be deemed “filed” for purposes of Section 18 of the Securities Exchange Act of 1934, as amended (the “*Exchange Act*”), or otherwise subject to the liabilities of that Section, nor shall it be deemed incorporated by reference in any filing under the Securities Act of 1933, as amended, or the Exchange Act, except as expressly set forth by specific reference in such a filing. The Company’s submission of this Report shall not be deemed an admission as to the materiality of any information required to be disclosed solely to satisfy the requirements of Regulation FD.

Exhibit 99.1 hereto contains forward-looking statements within the meaning of the federal securities laws. These forward-looking statements are based on current expectations and are not guarantees of future performance. Further, the forward-looking statements are subject to the limitations listed in Exhibit 99.1 and in the other reports of the Company filed with the Securities and Exchange Commission, including that actual events or results may differ materially from those in the forward-looking statements.

**Item 9.01 Financial Statements and Exhibits.****(d) Exhibits**

<b>Number</b>	<b>Description</b>
<a href="#">99.1</a>	Corporate Presentation, dated January 8, 2024
104	Interactive Data File (embedded within the Inline XBRL document)

**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: January 8, 2024

**NUWELLIS, INC.**

By: /s/ NESTOR JARAMILLO, JR.

Name: Nestor Jaramillo, Jr.

Title: President and Chief Executive Officer

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# Investor Presentation

January 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, 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.

## 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.



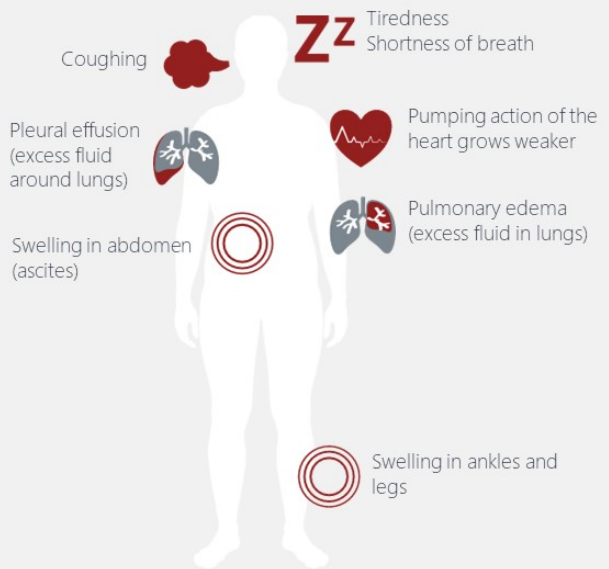
## The Problem

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



## What is Fluid Overload?

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



# 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 **the leading cause of hospital readmission** post 30 days following cardiac surgery<sup>2</sup>



## Heart Failure

**90% of all heart failure hospitalizations** are due to symptoms of Fluid Overload<sup>1</sup>



## Critical Care

Fluid Overload is the **leading cause of death** for critically ill patients in the ICU within 90 days<sup>3</sup>



## Pediatric

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 Nephrol. 2004; 19(12): 1394-99.

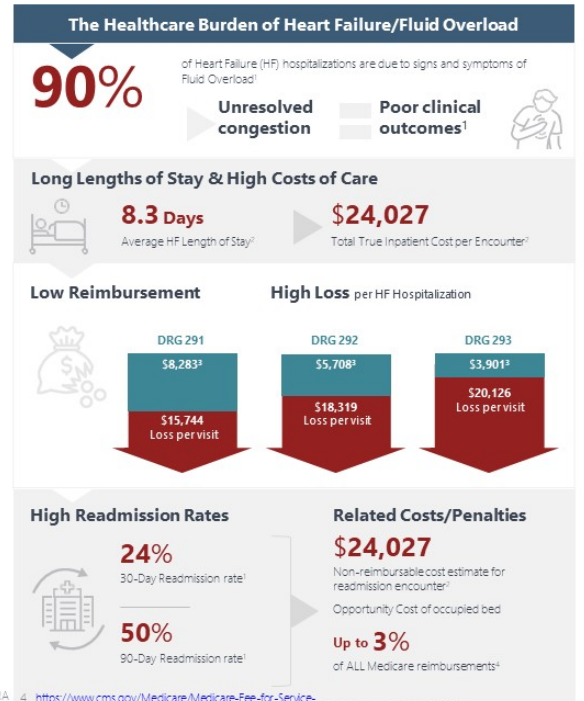


# 6.5 million US adults with Heart Failure and 40-45% will die within five years of their diagnosis.

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

PATIENT	HOSPITAL
<ul style="list-style-type: none"> <li>Over 1 million HF hospitalizations occur annually in the US<sup>1</sup></li> <li>Efficacy of diuretic use in HF &amp; CV surgery patients               <ul style="list-style-type: none"> <li>10-40%<sup>5</sup> are refractory</li> <li>68%<sup>5</sup> show sub-optimal response</li> </ul> </li> </ul>	<ul style="list-style-type: none"> <li>Decompensated HF admission drives ~\$16K loss per admission<sup>3</sup></li> <li>Non-reimbursed 30-day readmissions can cost up to \$15.2M annually<sup>2</sup></li> <li>High readmission rates lead to Medicare penalties<sup>4</sup></li> </ul>

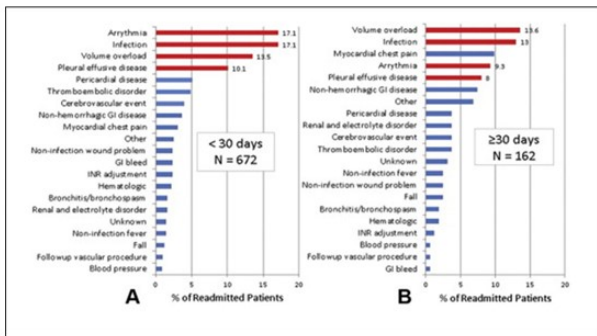
1. Costanzo MR, et al. *J Am Coll Cardiol*. 2017 May 16;69(19):2428-2445. 2. From Premier Applied Sciences database. 3. Reimbursement estimates from MCRA. 4. <https://www.cms.gov/Medicare/Medicare-Fee-for-Service-Payment/AcuteInpatientPPS/Readmissions-Reduction-Program> 5. Testani, *Circ Heart Failure*,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





## Nearly 1 of 5 patients who undergo cardiac surgery require readmission

In a multi-center study, volume overload was among the top 3 most prevalent causes for first readmission within 30 days and beyond 30 days



- 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>

Source: Iribarne A, et al. Ann Thorac Surg. 2014 Oct; 98(4): 1274-80. 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. Costanzo MR, et al. J Am Coll Cardiol. 2017 May 16; 69(19): 2428-2445.



## Pediatric patients that experience Fluid Overload are vulnerable and have an increased mortality rate

In a pediatric study, a 3% increase in mortality was observed for every 1% increase in fluid overload<sup>1,2</sup>

FO is an independent risk factor for acute kidney injury in critically ill patients<sup>3,4</sup>

Children with more than 20% FO had an odds ratio for mortality of 8.5 compared with children with less than 20% FO.<sup>1,2</sup>

Diuretics and adult CRRT devices can be poorly tolerated by pediatric patients<sup>5-8</sup>

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. Salahuddin et al. *BMC Nephrology*, 2017;18:45. 4. Raina, R et al. *Frontiers in Pediatrics*, Vol 6, Article 306, Oct 2018. 5. Wang S, et al. *Perfusion*, vol. 27, no. 5, pp. 438-446, Sep 2012. 6. Askhenazi D, et al. *Pediatr Nephrol*, vol. 31, no. 5, pp. 853-860, May 2016. 7. Chakravarti S, et al. *Pediatr Rep*, vol. 8, no. 2, p. 6596, 23 Jun 2016. 8. Raina R, et al. *PLoS ONE*, vol. 12, no. 5, p. e0178233, 30 May 2017.

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

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

- Diuretics do not remove sodium predictably, which causes fluid retention
- 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.

# \$2B+ Addressable 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)

## \$2B+ TAM



### Heart Failure

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

~30% of current sales



### Critical Care

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

~40% of current sales



### Pediatric

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

~30% of current sales

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



# In addition to the ongoing pediatric and HF segments, we will expand our use cases to address new critical care needs

## Near-term opportunities (U.S.)



## Mid to Long-term opportunities (U.S.)



**Pediatric Patients**  
16,000 patients/year<sup>7</sup>

**Heart Failure Patients**  
360,000 patients/year<sup>8</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/statistics/spl17-Operating-Room-Procedure-Trends.pdf> 2. Derived from: <https://www.healthline.com/health/liver-transplant-survival> and this for growth rate: <https://www.marketwatch.com/press-release/organ-transplantation-market-size-to-grow-at-3.94-pace-during-the-forecast-period-of-2022-2027-100-report-pages-2022-09-23> 3. Derived from: <https://www.grandviewresearch.com/industry-analysis/ventricular-assist-device-market> (3 billion 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/PMC6557150/> 5. Derived from: <https://www.ncbi.nlm.nih.gov/pubmed/25591948> 6. Derived from: <https://www.ucihealth.org/medical-services/heart-ecmo/research/statistics> and growth rate from same source. 7. AKI in Hospitalized Children Epidemiology and Clinical Associations in a National Cohort, Sutherland, B, Costanzo MR, et al. J Am Coll Cardiol. 2017 May 16;69(19):2428-2445.

# Differentiated Solutions

Nuwellis has been in the business of fluid management since 2016, and we're only getting started.

# We have strategically built a robust foundation, positioning the company to effectively address a significant market opportunity

Robust clinical foundation reinforces strategic technology expansion and collaboration



Our hero therapy:

# Aquadex<sup>®</sup>

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.



**81%<sup>1</sup>** hospitalization reduction  
Compared to diuretics

**48%** lower readmission  
than the 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

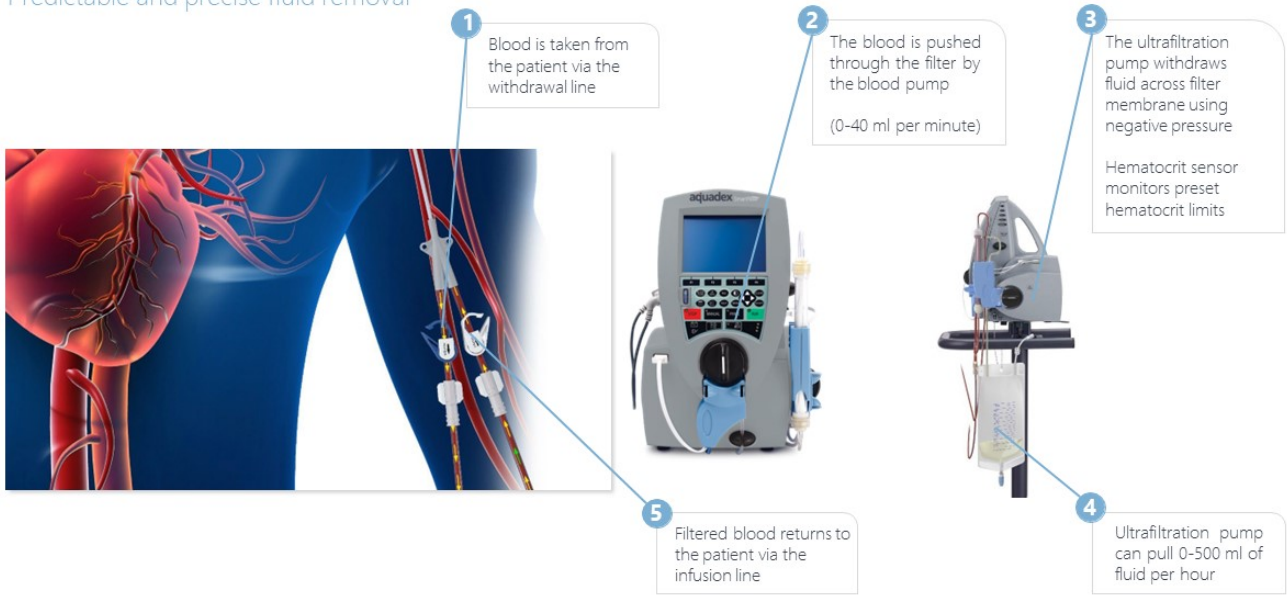
Product Strategy & Differentiation

- More effective in decongesting resulting in stabilized or improved cardiac hemodynamics<sup>2-5</sup>
- Easier to set-up than CRRT with a higher, 4:1 nurse to patient monitoring ratio; 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. Woson R, et al. / *Catheter* Fall 2020; v56: 2. Kallinger, U, et al. *Ann Thorac Surg* 2001;71(2): 684-93. 3. Sahay, TK, et al. *Indian J Thorac Cardiovasc Surg* 2007;27(2): 116-24. 4. Baga, et al. *Perfusion* 2000;15:143-50. 5. Chawla, et al. *Perfusion* 2009;16:37-42. 6. Costanzo, MB, et al. *JACC* 2005; 46(1): 2457-59. 7. Costanzo, et al. *ESOR 23rd Annual Int'l Mtg*, May 19-23, 2010, Baltimore, MD, USA. 8. Kazory, A, Sgarbato, L, Rocco, C. *Extracorporeal Ultrafiltration for Acute Heart Failure*. *Cardiovasc Med* 2023;13:5-8. doi: 10.1155/2023/27204. 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 procedure, such that patients served equals total number of units sold divided by a per procedure estimate of circuit used per adult and pediatric patients.

# How the Aquadex system works

Predictable and precise fluid removal



# While the competitive landscape does address Fluid Overload, Aquadex is the only device in the market that gently and predictably removes fluid

Indicated for use in hospital, ambulatory, and physician office; Aquadex, with a flow rate of up to 40 ml/minute and 35ml extracorporeal volume, removes isotonic fluid



## Heart Failure

More flexible and predictable treatment (UF) with Aquadex



## Critical Care

Potential for more timely/effective treatment (UF) with Aquadex



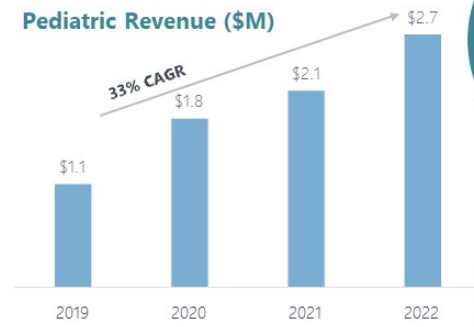
## Pediatric

Draw less blood, more predictably with Aquadex



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

Pediatrics represents a \$130M TAM



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	N = 72	N = 13	N = 34
Primary disease	43% kidney	54% kidney	38% kidney
	29% cardiac	31% other	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



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<sup>1,2</sup>

66% 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

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

16 novel patents with protection to 2043+

- Robust and evolving portfolio of patents circling the technology
- 21 Nuwellis patent applications (US & EU) in addition to licensed IP from Baxter
- 1 pending patent application, expected to issue January 9, 2024
- 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

## Strategic Collaborations

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

# 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



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

2,500+ clinic<sup>1</sup>

6,500+ employees<sup>1</sup>

11.6B in revenue in 2022<sup>1</sup>

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 outpatient clinics
- Enable accelerated commercial expansion of Aquadex
- Provides DaVita the option to acquire up to 19.9% of Nuwellis

## 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 offers a new Selective Cytopheretic Device (SCD-PED) for pediatric patients with AKI

**77%** mortality reduction<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 AKI<sup>3</sup>

## 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 2025
- Explore Nuwellis manufacturing viability for SCD
- Strengthen Nuwellis pediatric product portfolio

## Expected Collaboration Benefits

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

<sup>1</sup> Use of the Selective Cytopheretic Device to Support Critically Ill 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 Krallman, Lenar Yessajyan, 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 Ill 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>

AHJ  
American Heart Journal

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

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.



### 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

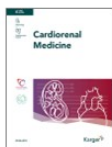


# Peer-reviewed publication advocates for early clinical application of ultrafiltration in diuretic resistant patients

## 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"

Cardioresenal 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

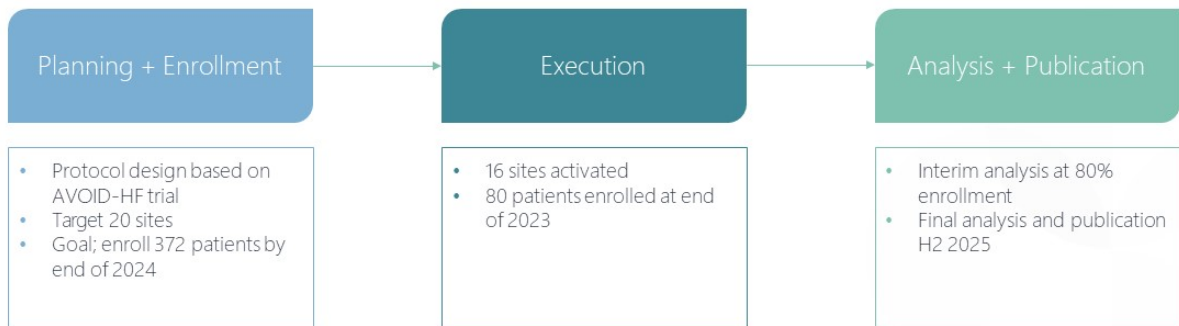
Kazory A, Sgarabotto L, Ronco C: Extracorporeal Ultrafiltration for Acute Heart Failure. Cardioresenal Med 2023;13:1-8. doi:10.1159/000527204.

30 | FOR INVESTOR PURPOSES ONLY: NOT FOR PRODUCT PROMOTION ©2024 Nuwellis, Inc.

 nuwellis

# With over 16 sites and 80+ 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



As of December 31, 2023

# 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

- 1 Grow Utilization**  
*increase the number of circuits per console*
- 2 Grow Penetration**  
*increase the number of consoles per hospital*
- 3 Grow number of New Accounts**
- 4 Initiate New Indications**

# We will implement tactics aligned to our growth plan to drive revenue for 2024 to 2026, focusing on sales and marketing efforts

 <p><b>Execute Strategies</b></p> <p>CV Surgery / CC / HF / Peds</p> <p>Physical presence and productive days readmission</p> <p>Leverage Proforma and Evidence to drive earlier intervention for diuretic resistance or Invest in Highest Opportunity Territories</p> <p>Build 2:1 CES to AM ratio</p>	 <p><b>Maximize Go To Market Model</b></p> <p>Leverage DaVita footprints, network, contracts and resources</p> <p>Grow Organically with direct team</p> <p>Leverage SeaStar as revenue driver</p> <p>Add additional indirect distribution partnerships</p>	 <p><b>Penetration / Growth Drivers</b></p> <p>Drive utilization across multiple departments and customer categories</p> <p>Build Pediatric presence for Vivian and Aquadex coexistence</p> <p>Drive Therapy Adoption and New Indications</p>	 <p><b>Leverage DaVita and SeaStar Partnerships</b></p> <p>Successful DaVita pilot leads to broader adoption</p> <p>Solution to nursing or hospital capital shortage</p> <p>SeaStar drives revenue while building relationships for Vivian opportunity</p>
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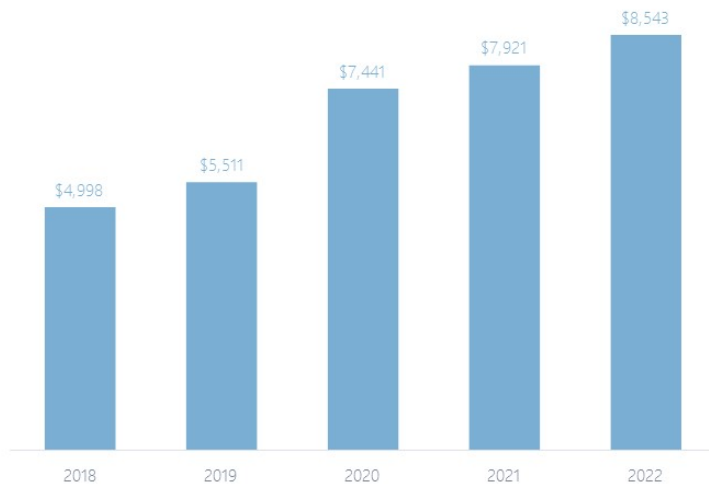
<b>Outpatient Reimbursement</b>		
<p><b>1. Leverage</b> outpatient reimbursement data for improved coverage</p>	<p><b>2. Explore and drive</b> Apheresis APC code change</p>	<p><b>3. Continue to drive</b> Category III CPT Code (0692T)</p>

# Financial Snapshot

Nuwellis forecasts a financially robust future, aligning our funding ask with our strategic growth plan.

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

Annual Revenue (\$'000)



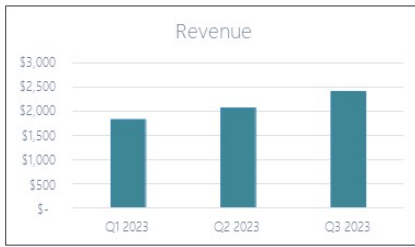
**CASH**  
\$4.9 million as of Sept 30, 2023

**NO DEBT**

# Our 2023 quarterly results reflect improving operational efficiencies

We've increased revenue and become more efficient in spend, resulting in a decrease in net loss

(\$'000)

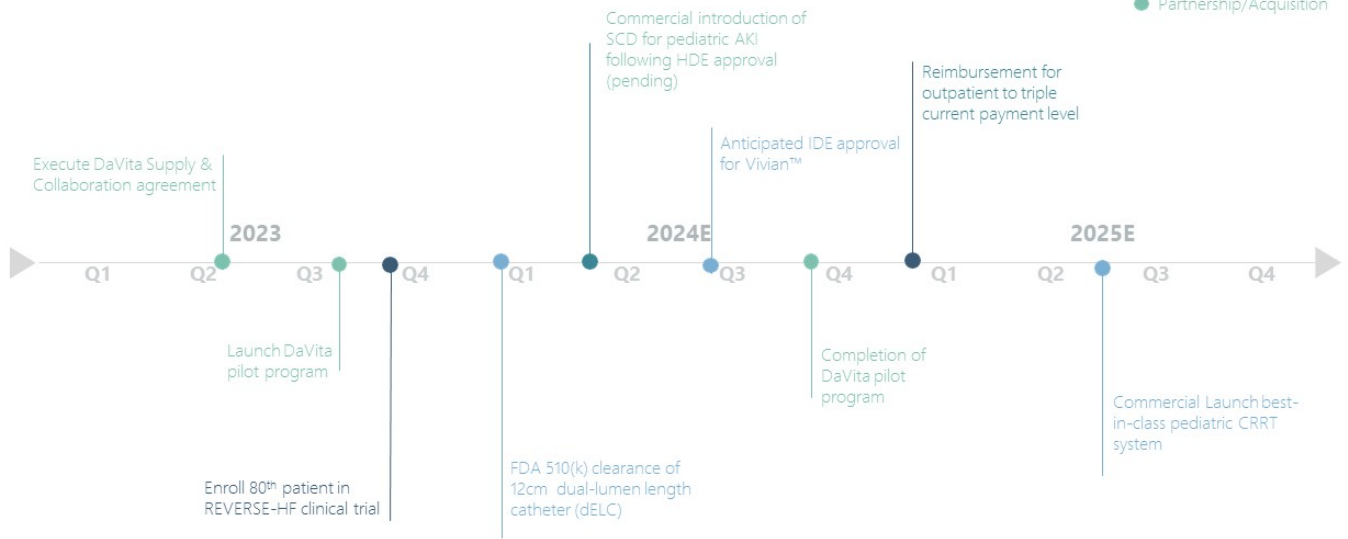


Unaudited\*



# Key milestones

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



## Team

Led by industry veterans, our team is well positioned to grow Nuwellis to meet the market need.

# 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



Vitaliy Epshteyn  
Senior Vice President of  
Operations, Engineering & QA/RA

**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.

# Investment Overview

Nuwellis is committed to making Aquadex the standard of care for fluid management.

# Investment Highlights

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

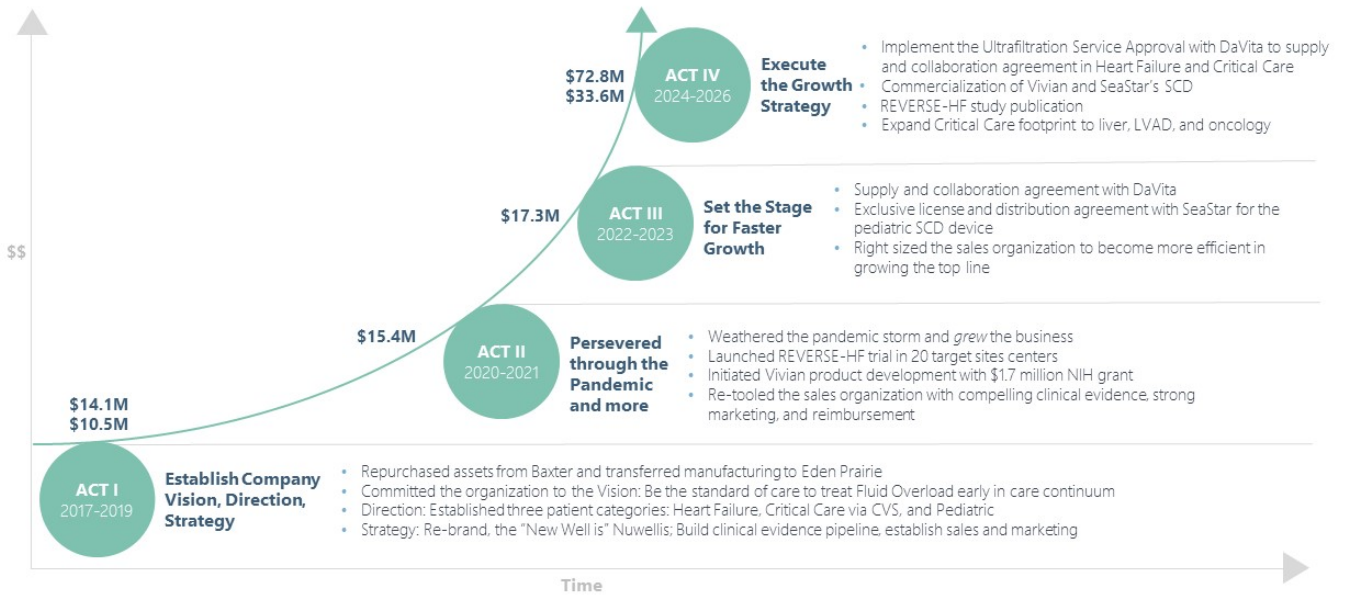
<b>\$2B+ TAM</b>	<b>Positive ROI</b>	<b>Clinical Evidence</b>	<b>Scalable Consumables</b>	<b>Commercial Infrastructure</b>	<b>Product Pipeline</b>	<b>Leadership Team</b>
\$2B+ and growing addressable market in critical need	Attractive clinical + economic benefits to hospitals and healthcare system	Robust body of clinical evidence demonstrating the success of our products	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

**Thank you!**

# Appendix

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# History of Nuwellis: from restart to growth





## Company history

- Incorporated in Delaware on August 22, 2002
- In January 2010, Gambro, a Denver-based medical device company, purchased CHF Solutions
- In September 2013, Baxter International completed its acquisition of Gambro
- Prior to 2016, the current Nuwellis entity was Sunshine Heart, a company focused on the development of the C-Pulse System for treatment of Class III and ambulatory Class IV heart failure
- In August 2016, Sunshine Heart acquired the Aquadex Business from Baxter International
- In September 2016, Sunshine Heart announced a strategic re-focus, halting all clinical evaluations of the C-Pulse System to focus entirely on the Aquadex Business, under the name CHF Solutions, Inc.
- On April 27, 2021, CHF Solutions announced a name change to Nuwellis, Inc. to reflect its expansion to include critical care and pediatrics applications
- Currently, Nuwellis has approximately 60 full-time employees as of December 31, 2023

# 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.

# Selling strategy & account targeting tools

**GOAL: Increase total number of active accounts & drive utilization**

## 1. Top 10 Accounts: Maintain



Use *Top 10 Account Analysis* to plan support activities to ensure these accounts maintain current levels of utilization or grow.

- Leverage success across IDN healthcare system

CES / AM Responsibility

## 2. 11-30 Accounts: Pull-through



Use *11-30 Account Analysis* to plan launch/support activities to ensure good on-boarding/on-going experiences and pull-through

- Expand within the Account to new Rxers, Departments and Specialties

CES Responsibility

## 3. Identify: New Accounts



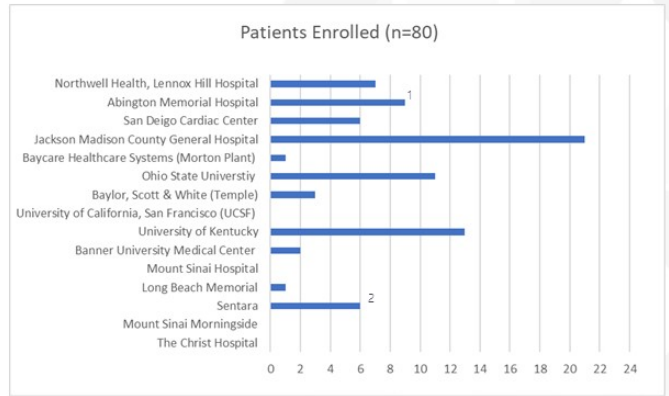
Use *Account Targeting Tool* to help identify new accounts to focus selling efforts on greatest/most-sustainable opportunities and markets (incl. Premier)

- Standardize across IDNs.

AM Responsibility

# REVERSE-HF Activated Study Sites & Enrollment

Site	Activation Date
Northwell Health, Lennox Hill Hospital	20 May 2022
Abington Memorial Hospital	<b>11 Aug 2022</b>
University of California, San Francisco (UCSF)	<b>06 Sep 2022</b>
BayCare Healthcare Systems (Morton Plant)	13 Sep 2022
San Diego Cardiac Center	02 Nov 2022
Jackson Madison County General Hospital	12 Dec 2022
Baylor Scott & White (Temple)	<b>12 Dec 2022</b>
Ohio State University	<b>22 Dec 2022</b>
University of Kentucky	13 Jan 2023
Banner University Medical Center	13 Apr 2023
Mount Sinai Hospital	02 Jun 2023
Long Beach Memorial	11 Sep 2023
Sentara	20 Sep 2023
Mount Sinai Morningside	09 Oct 2023
Christ Hospital	20 Nov 2023
Henry Ford	SIV scheduled 25 Jan 2023



<sup>1</sup>1 patient is a screen failure

<sup>2</sup>1 patient was withdrawn prior to randomization

*Closing St Joe's – PI left institution*

# 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
- 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)

## 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
- 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://idatasearch.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>