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

FORM 8-K/A

(Amendment No. 1)

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

Date of Report (Date of earliest event reported): **July 16, 2024**

Nuwellis, Inc.

(Exact Name of Registrant as Specified in its Charter)

Delaware	**001-35312**	**No. 68-0533453**
(State or Other Jurisdiction of Incorporation or Organization)	**(Commission File Number)**	**(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. ☐

Explanatory Note

This Current Report on Form 8-K/A (the ***"Amendment"***) amends the Current Report on Form 8-K (the ***"Original Report"***) of the Company (as defined below) filed on July 17, 2024. The sole purpose of this Amendment is to provide an updated version of the corporate presentation furnished as Exhibit 99.1 thereto. The updated corporate presentation is furnished as Exhibit 99.1 hereto and replaces and supersedes Exhibit 99.1 to the Original Report in its entirety. No other revisions have been made to the Original Report, and other than mentioned in the foregoing sentence, this Amendment does not amend, update, or change any other items or disclosures contained in the Original Report.

Item 8.01. Other Events.

Corporate Presentation

On July 17, 2024, Nuwellis, Inc. (the ***"Company"***) posted an updated corporate presentation to its website at https://ir.nuwellis.com/, which the Company may use from time to time in communications with potential investors or conferences. A copy of the corporate presentation is attached as Exhibit 99.1 to this Current Report on Form 8-K (this ***"Report"***).

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 U.S. Securities and Exchange Commission (***"SEC"***), including that actual events or results may differ materially from those in the forward-looking statements.

Risk Factor Update

On May 8, 2024, the Company filed its Quarterly Report on Form 10-Q for the quarter ended March 31, 2024 (the ***"Form 10-Q"***) with the SEC. This Report is being filed in part to revise Item 1A to include the risk factor included below.

Except as described below, no other changes have been made to the Form 10-Q, and this Report does not otherwise amend, update or change the financial statements or other disclosures in the Form 10-Q. This Report speaks as of the filing date of the Form 10-Q and does not (i) reflect events, results or developments that occurred or facts that became known after the filing date of the Form 10-Q or (ii) modify or update those disclosures affected by subsequent events, results, developments or facts. Among other things, forward-looking statements made in the Form 10-Q have not been revised to reflect events, results or developments that occurred or facts that became known to us after the date of the Form 10-Q, and such statements should be read in conjunction with our filings with the SEC subsequent to the Form 10-Q. This Report should be read in conjunction with the Company's other filings with the SEC subsequent to May 8, 2024.

If we fail to comply with federal and state laws regarding off-label use of our products, we could face substantial civil and criminal penalties and our business, financial condition, results of operations, and prospects could be adversely affected.

Healthcare professionals may choose to use and prescribe medical devices for uses that are not described in the product's labeling and for uses that differ from those tested in clinical trials and approved or authorized by the regulatory authorities. Medical device companies, however, are prohibited from marketing and promoting products for indications and uses that are not specifically approved or authorized by FDA. Such "off-label" uses are common on the medical world and often are appropriate treatments for some patients. Regulatory authorities in the U.S. generally do not restrict or regulate the treatment choices of healthcare professionals. Regulatory authorities do, however, restrict communications by companies concerning off-label uses of their products. Any FDA approval or marketing authorization that we have or may obtain in the future permits us to promote the subject medical device only for the specific use(s) cleared, approved, certified or otherwise authorized. We are prohibited from marketing or promoting any medical devices for off-label use.

Notwithstanding the regulatory restrictions on off-label promotion, the FDA and other regulatory authorities allow companies to engage in truthful, non-misleading, and non-promotional speech concerning their products. Accordingly, we engage in medical education activities and communicate with healthcare professionals about many aspects of our products and clinical trials. In addition, we are aware that the Aquadex System, which is cleared by FDA solely for use in adults and pediatric patients weighing 20 kg or more, is being used off-label uses to treat patients who weigh under 20 kg, including being modified by children's hospitals so that it can provide dialysis to neonates and other premature infants who were born either without kidneys or without normal kidney function. These patients typically have very few other treatment options given the large extracorporeal blood volume required by standard dialysis machines, the need for blood priming of the dialysis circuit and the use of large catheters.

Although we believe that all of our communications regarding off-label uses are in compliance with the relevant regulatory requirements, the FDA or another regulatory authority may disagree, and characterize such communications as marketing and promotion of an off-label use.

If the FDA determines that we have marketed or promoted our products for off-label use by us or our commercial partners, it could request that we or our commercial partners modify those promotional materials. We also could be subject to regulatory or enforcement actions, including the issuance of an untitled letters or warning letters, injunctions, seizures, civil fines and criminal penalties.

In addition to FDA, we may be subject to significant enforcement actions from other federal and state enforcement authorities, such as the Department of Justice and the Office of the Inspector General of the Department of Health and Human Services, if they consider our communications, including promotional and training materials, to constitute promotion of an uncleared, uncertified or unapproved use of a medical device. In the U.S., engaging in the impermissible promotion of our products, following approval, for off-label uses can also subject us to false claims and other litigation under federal and state statutes, including fraud and abuse and consumer protection laws, which can lead to civil and criminal penalties and fines, agreements with governmental authorities that materially restrict the manner in which we promote or distribute therapeutic products and do business through, for example, corporate integrity agreements, suspension or exclusion from participation in federal and state healthcare programs, and debarment from government contracts and refusal of future orders under existing contracts. These laws include the federal False Claims Act, which allows any individual to bring a lawsuit against a company on behalf of the federal government alleging submission of false or fraudulent claims or causing others to present such false or fraudulent claims, for payment by a federal program such as Medicare or Medicaid. If the government decides to intervene and prevails in the lawsuit, the individual will share in the proceeds from any fines or settlement funds. If the government declines to intervene, the individual may pursue the case alone. Many False Claims Act lawsuits against, and preceding investigations of, manufacturers of healthcare products are brought every year, leading to several substantial civil and criminal settlements related to off-label uses. In addition, False Claims Act lawsuits may expose manufacturers to follow-on claims by private payors based on fraudulent marketing practices. This growth in litigation has increased the risk that a company will have to defend a false claim action, pay settlement fines or restitution, as well as criminal and civil penalties, agree to comply with burdensome reporting and compliance obligations, and be excluded from Medicare, Medicaid, or other federal and state healthcare programs. If we or our collaborators do not lawfully promote our approved products, we may become subject to such investigations and litigation and, if we do not successfully defend against such actions, those actions may have a material adverse effect on our business, financial condition, results of operations and prospects.

Additionally, we must have adequate substantiation for the claims we make for our products and services. If any of our claims are determined to be false, misleading or deceptive, our products and services could be considered misbranded under the FDCA or in violation of the Federal Trade Commission Act. We could also face lawsuits from our competitors under the Lanham Act alleging that our marketing materials are false or misleading.

Foreign jurisdictions have their own laws and regulations concerning medical devices, including marketing authorizations and certifications, communications about off-label uses, and substantiation of advertising and promotional claims. Failure to comply with those laws and regulations could result in actions against us, including fines, penalties and exclusion from the market. Any such actions could adversely affect our ability to market new products and services or continue to market existing products and services in those jurisdictions.

Item 9.01. Financial Statements and Exhibits.

(d) Exhibits

Exhibit Number	Exhibit Description
99.1	Corporate Presentation, dated July 17, 2024
104	Cover Page Interactive Data File (embedded within 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: July 17, 2024

NUWELLIS, INC.

By: /s/ Nestor Jaramillo, Jr
Name: Nestor Jaramillo, Jr.
Title: President and Chief Executive Officer

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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 guarantees of future events and are subject to a number of known and unknown risks and uncertainties and other factors that may cause actual results to differ materially from those expressed in, or implied by, such forward-looking statements. In some cases, you can identify forward-looking statements by terminology such as "may," "will," "could," "would," "should," "plan," "predict," "potential," "project," "promising," "expect," "estimate," "anticipate," "intend," "goal," "strategy," "milestone," and similar expressions and variations thereof. Various factors could cause actual results to differ materially from these statements including our ability to execute on our commercial strategy and to grow our Aquadex® business, the possibility that we may be unable to raise sufficient funds necessary for our anticipated operations, our clinical data collection activities, benefits of our products to patients, our expectations with respect to product development and commercialization efforts, our ability to increase market and physician acceptance of our products, potentially competitive product offerings, intellectual property protection, our expectations regarding anticipated synergies with and benefits of the Aquadex business, our business strategy, market size, potential growth opportunities and the other risks set forth under the caption "Risk Factors" and elsewhere in our periodic and other reports filed with the U.S. Securities and Exchange Commission ("SEC"), including our Annual Report on Form 10-K for the fiscal year ended December 31, 2023 and subsequent reports. We are providing this information as of the date of this presentation, and we undertake no obligation to update any forward-looking statements contained in this presentation as a result of new information, future events or otherwise. Although the Company believes that the forward-looking statements are reasonable and based on information currently available, it can give no assurances that the Company's expectations are correct. All forward-looking statements are expressly qualified in their entirety by this cautionary statement.

Financial and Statistical Data

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

Trademarks

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

Additional Information

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

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Overview

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

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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.

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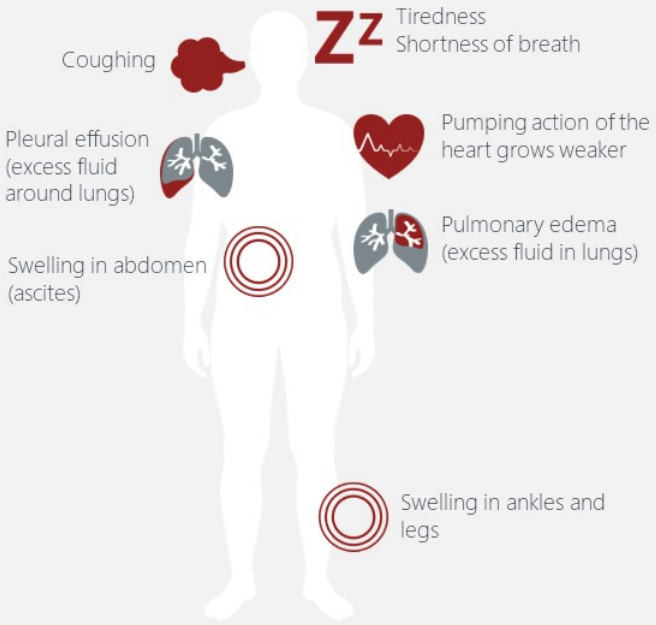
What is Hypervolemia (Fluid Overload)?

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



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

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

PATIENT	HOSPITAL

• Over 1 million HF hospitalizations occur annually in the US[1]
• Efficacy of diuretic use in HF & CV surgery patients
  • 10-40%[5] are refractory
  • 68%[5] show sub-optimal response
	• Decompensated HF admission drives economic loss per admission
	• High readmission rates lead to Medicare penalties[4]

The Healthcare Burden of Heart Failure/Fluid Overload

90% of Heart Failure (HF) hospitalizations are due to signs and symptoms of Fluid Overload[1]

Unresolved congestion → **Poor clinical outcomes**[1]

Long Lengths of Stay & High Costs of Care

8 Days
Average HF Length of Stay[2]

$24,027
Total True Inpatient Cost per Encounter[3]

Low Reimbursement High Loss per HF Hospitalization

High Readmission Rates

24%
30-Day Readmission rate[1]

50%
90-Day Readmission rate[1]

Related Costs/Penalties

$24,027
Non-reimbursable cost estimate for readmission encounter[3]

Opportunity Cost of occupied bed

Up to 3%
of ALL Medicare reimbursements[4]

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

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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[2]

Heart Failure

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

Critical Care

For critically ill patients in the ICU, Fluid Overload **was associated with a markedly increased risk** for 90-day mortality[3]

Pediatric

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

1. Costanzo MR, et al. JACC. 2017 May 16;69(19):2428-2445. 2. Iribarne A, et al. Ann Thorac Surg. 2014; 98(4):1274-80. 3. Vaara ST et al. Crit Care.2012;16:1-11. 4. Sutherland SM, et al. Am J Kidney Disease. 2010; 5(2): 316-25. 5. Gillespie RS, et al. Ped Nephro. 2004;19(12):1394-99.

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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[1]

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

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

"Extracorporeal Ultrafiltration for Acute Heart Failure"
Cardiorenal Medicine Journal

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

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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.

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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[1]
~30% of current Nuwellis sales

Critical Care

$900M Market[1]
~40% of current Nuwellis sales

Pediatric

$130M Market[1]
~30% of current Nuwellis sales

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

Differentiated Solutions

Nuwellis is a different company today

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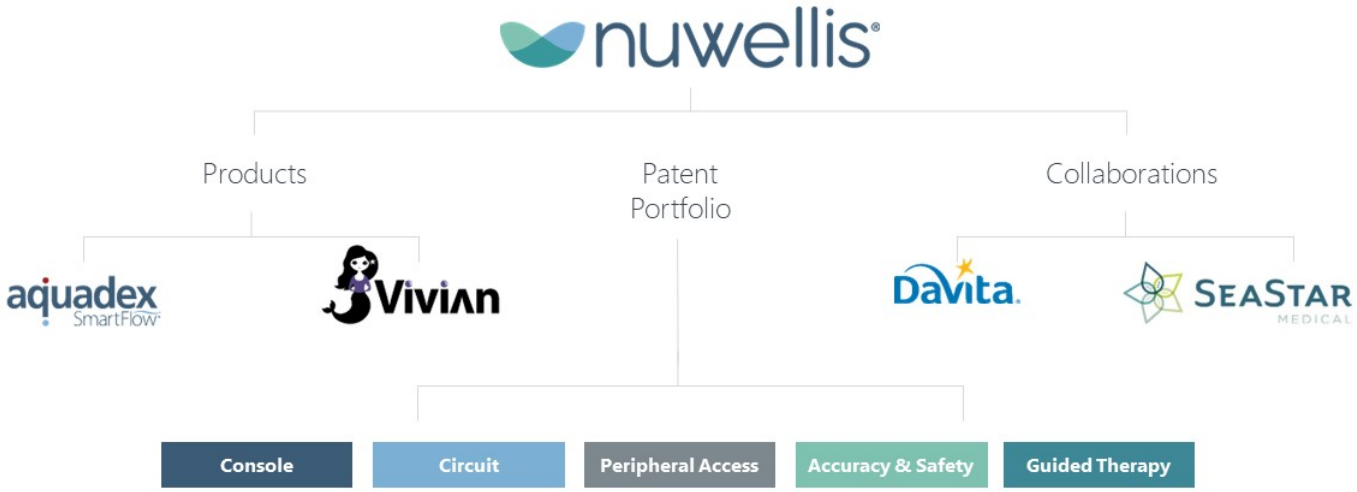
Aquadex represent our foundation, positioning the company to effectively address significant market opportunities

Robust clinical foundation reinforces strategic technology expansion and collaboration



Our hero therapy:

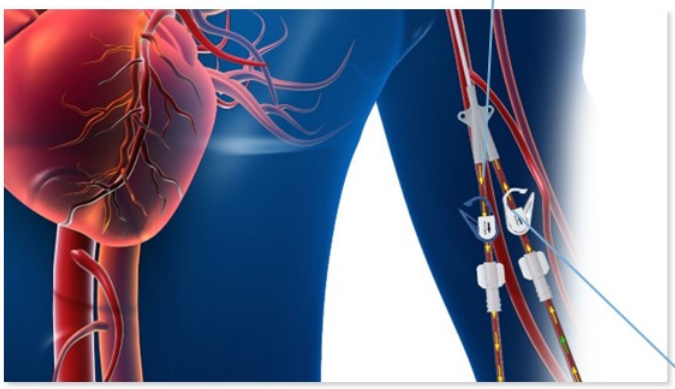
Aquadex®

A clinically superior solution for Fluid Overload

The *only* device of its kind in the market

How the Aquadex system works

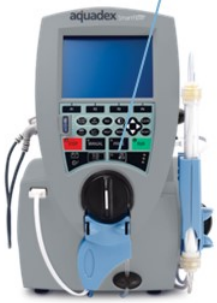
Predictable and precise fluid removal



1. Blood is taken from the patient via the withdrawal line using proprietary catheters technology

2. The blood is pushed through the filter by the blood pump

   (0-40 ml per minute)



3. The ultrafiltration pump withdraws fluid across filter membrane using negative pressure

   Hematocrit sensor monitors preset hematocrit limits

4. Ultrafiltration pump can pull 0-500 ml of fluid per hour

5. Filtered blood returns to the patient via the infusion line

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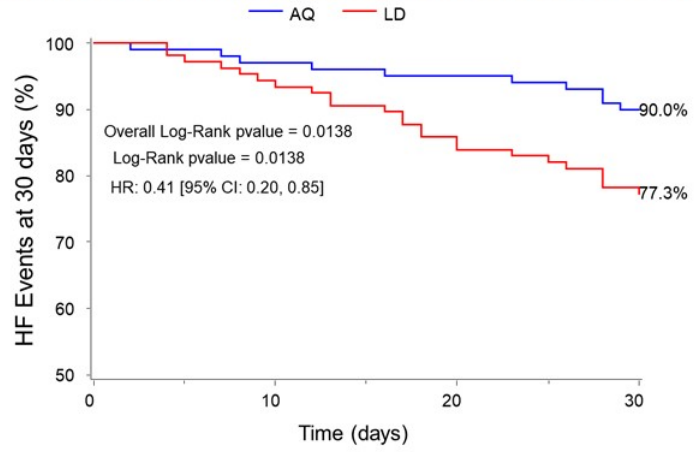
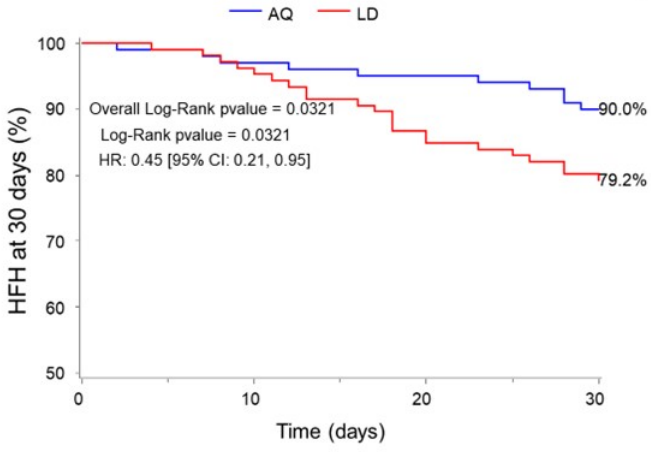
At a Recent Late Breaking Clinical Trials, Significant Reduction in HF Events and HF Hospitalization at 30 Days

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.



Number at risk:

AQ	105	98	94	88
LD	108	100	91	81



Number at risk:

AQ	105	98	94	88
LD	108	102	92	83

THT Boston 2024 – Featured Late-Breaking Clinical Science Abstract III – Aquapheresis for Management of Decompensated Heart Failure: A Re-appraisal of AVOID-HF

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Aquadex

A proven and predictable solution for Fluid Overload.

1.74 fewer hospitalizations[1]
At one year after Aquadex therapy treatment, compared to 2.14 before treatment

12.4% readmission rate
Compared to the 24% national average at 30 days[1]

$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[9]
- 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[2-5]
- Easier to set-up than CRRT; built-in Hematocrit sensor allows real-time measurement of blood volume changes
- Designed for multiple settings: ICU, Stepdown Unit, Telemetry Unit, HF Floor, and Outpatient – versus ICU only for CRRT
- Predictably removes excess isotonic fluid (water and sodium)[8]
- No significant changes to kidney function[1]

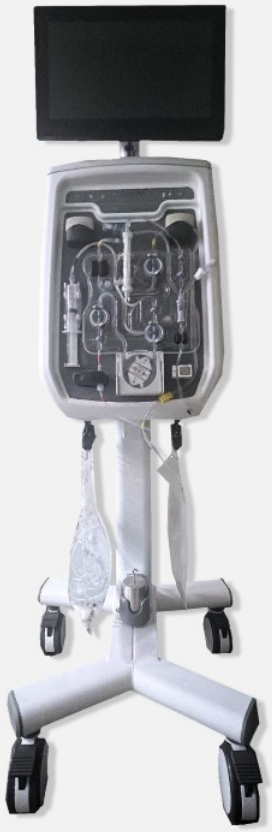
1. Watson R. et al. *J Cardiac Fail.* 2020; 26(10): s56. 2. Kazlitepe, U, et al. *Ann Thorac. Surg.* 2001;71(2): 684-93. 3. Sahoo, TK, et al. Indian J Thorac Cardiovas Surg. 2007;23(2): 116-24. 4. Boga et al. *Perfusion.* 2000;15:143-50. 5. Onoe et al. *Perfusion.* 2001;16:37-42.65. 6. Costanzo MR et al. *JACC.* 2005; 46(11); 2457-51. 7. Costanzo, et al., ISPOR 23rd Annual Int'l Mtg., May 19-23, 2018, Baltimore, MD, USA. 8. Kazory A, Sgarabotto L, Ronco C. Extracorporeal Ultrafiltration for Acute Heart Failure. Cardiorenal Med 2023;13:1-8. doi: 10.1159/000527204. 9. Utilization figures are based upon Company estimates, including certain good faith assumptions of the number of blood circuits used per adult and per pediatric procedures, such that patients served equals total number of units sold divided by a per procedure estimate of circuit used per adult and pediatric patients.

Coming soon:

Vivian™

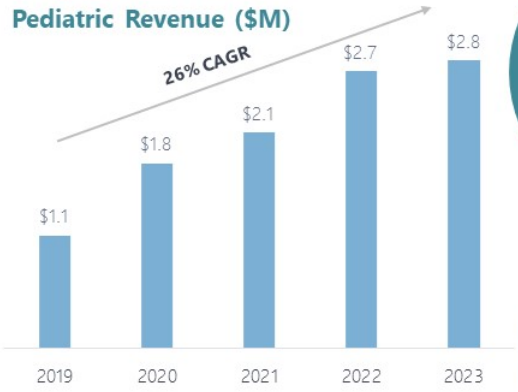
Our pediatric solution

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

Pediatrics represents a $130M TAM



4-10 circuits/pts

3-6 consoles per hospital

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

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 29% cardiac	54% kidney 31% other	38% kidney 28% cardiac
Survival at end of treatment (Aquadex)	43 **(60%)**	13 **(100%)**	33 **(97%)**

Group 1 patients traditionally do not receive any kind of therapy

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

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

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Introducing Vivian™

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

Ultrafiltration
Hemofiltration
Hemodialysis

8.5x mortality

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

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

60% survival to end therapy

Providing renal support and hemodynamic stability can be life-saving

In patients <20 kg who primarily received Slow Continuous Ultrafiltration (SCUF)[3]

$130m addressable pediatric market

Launch best-in-class pediatric CRRT system, H1 2027

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

Product Strategy & Differentiation

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

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

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

Strategic Collaborations

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

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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[1]

2,500+ clinic[1]

65,000+ employees[1]

11.6B in revenue in 2022[1]

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[1]
At day 60

NO dialysis dependency[2]
At day 60

2x length of stay in ICU for patients with AKI
(8 days vs. 4 days) as ICU patients without AKI[3]

1) 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 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 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.

Financial Snapshot
Key Milestones
Executive Team
Investment Highlights

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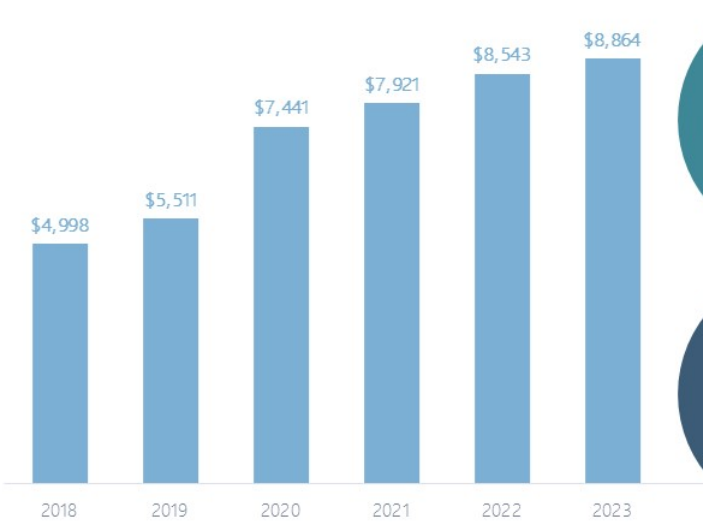
With a track record of revenue growth, we believe our strategy will lead to continued revenue growth

Annual Revenue ($000)



CASH
$1.4 million as of Mar 31, 2024

NO DEBT

Common Shares Outstanding	**515,744**
Common Share Equivalents:	
Preferred Shares:	
Preferred F: 127 units	15,240
Preferred J: 88 units	62
Warrants:	
Historical Warrants	495
Preferred J Warrants: 67,168 units	23,762
April 2024 Warrants: 16,875,000 units	482,146
DaVita Warrants*: 1,289,081 units	36,830
Employee & Director Options:	
Options Issued & Outstanding	3,979
Total Common Share Equivalents	**562,514**
Total Common Share & Share Equivalents	**1,078,258**

*DaVita warrants are milestone based split between 4 tranches. No milestones achieved to date.

Capitalization Table as of June 30th, 2024

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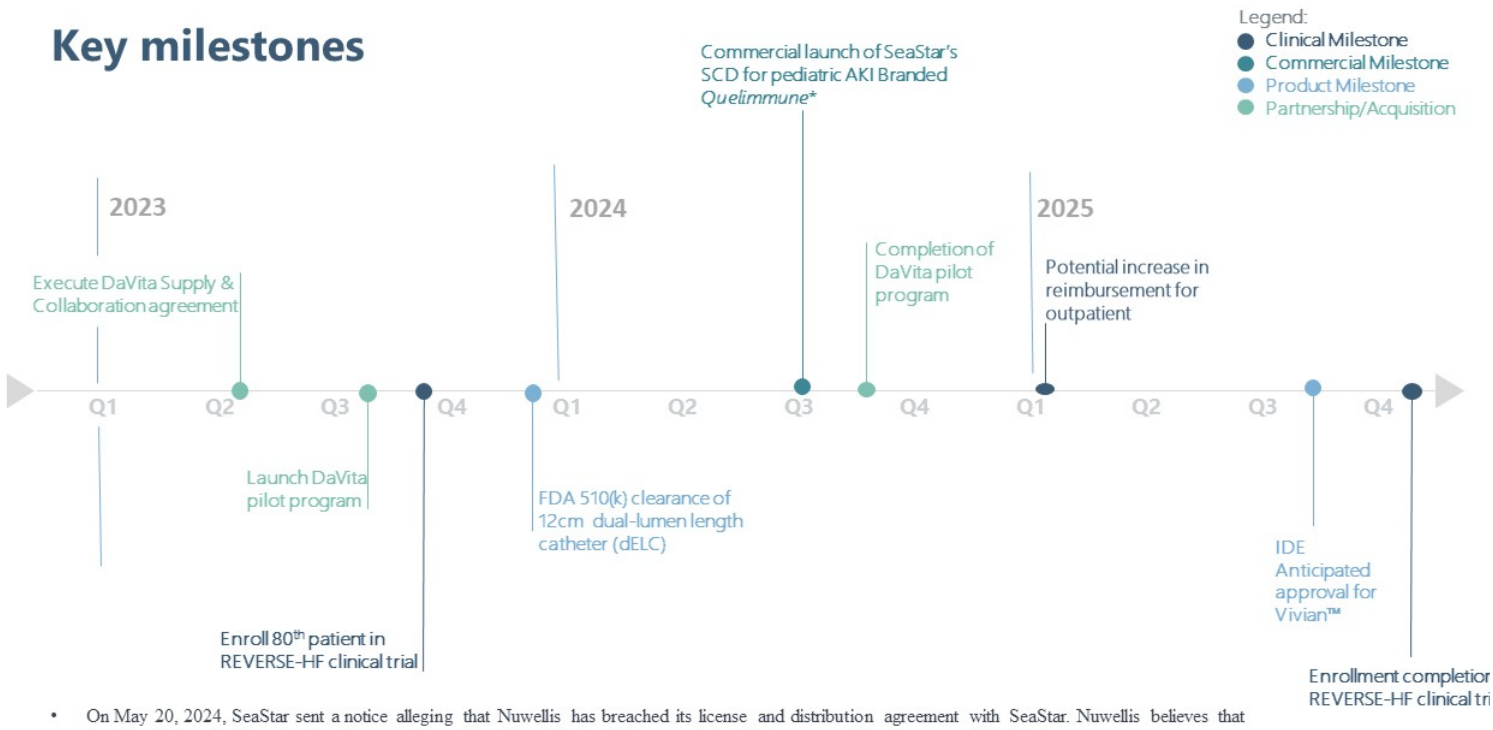
Key milestones



- 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.

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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

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' ofcollective 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.

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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

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Thank you!

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Appendix

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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

790+ hospital partnerships[1]

2,500+ clinic[1]

65,000+ employees[1]

11.6B in revenue in 2022[1]

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

1. Used with permission from DaVita

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[1]
At day 60

NO dialysis dependency[2]
At day 60

2x length of stay in ICU for patients with AKI
(8 days vs. 4 days) as ICU patients without AKI[3]

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 Ill Children Requiring Continuous Renal Replacement Therapy: A Probable Benefit-Risk Assessment Stuart L. Goldstein, Nicholas J. Ollerding, David J. Askenazi, Rajit K. Basu, David T. Selewski, Kelli . Krallman, 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 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.

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Ultrafiltration: Positive ROI, clinical and economic benefits

81% reduction in heart failure hospitalizations per year

10-Year, real-world experience with ultrafiltration[1]

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

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[2]

50% at 6 months

12.4% at 30 days

14.9% at 90 days

27.3% at 1 year

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

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

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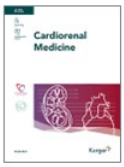
Peer-reviewed publication advocates for early clinical application of ultrafiltration in diuretic resistant patients

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.

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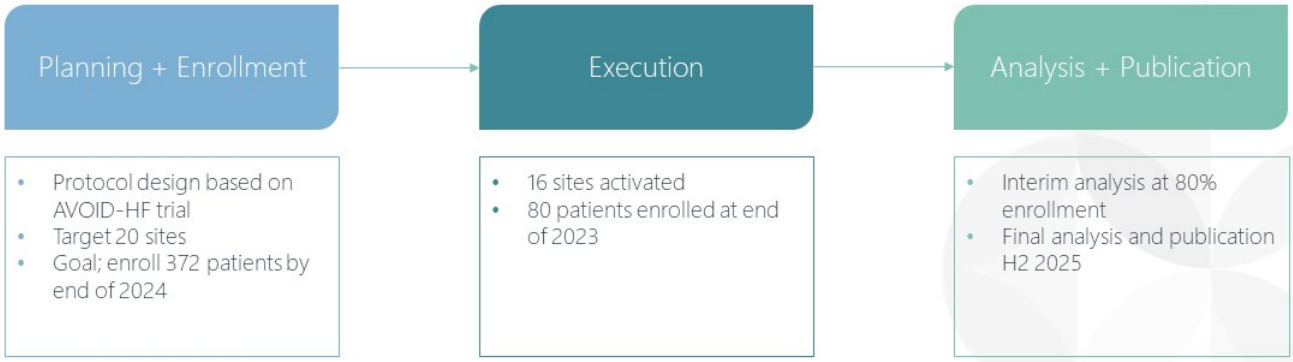
With 15 sites and 125 patients enrolled, we are in the midst of executing our REVERSE-HF Clinical Study with Aquadex

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



- Protocol design based on AVOID-HF trial
- Target 20 sites
- Goal; enroll 372 patients by end of 2024

- 16 sites activated
- 80 patients enrolled at end of 2023

- Interim analysis at 80% enrollment
- Final analysis and publication H2 2025

As of July 12, 2023

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Growth Strategy

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

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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**

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