



# Investor Presentation

S e p t e m b e r 2 0 2 3



# 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 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<sup>®</sup>

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



# 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



**Rob Scott**  
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 &  
QA/RA



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

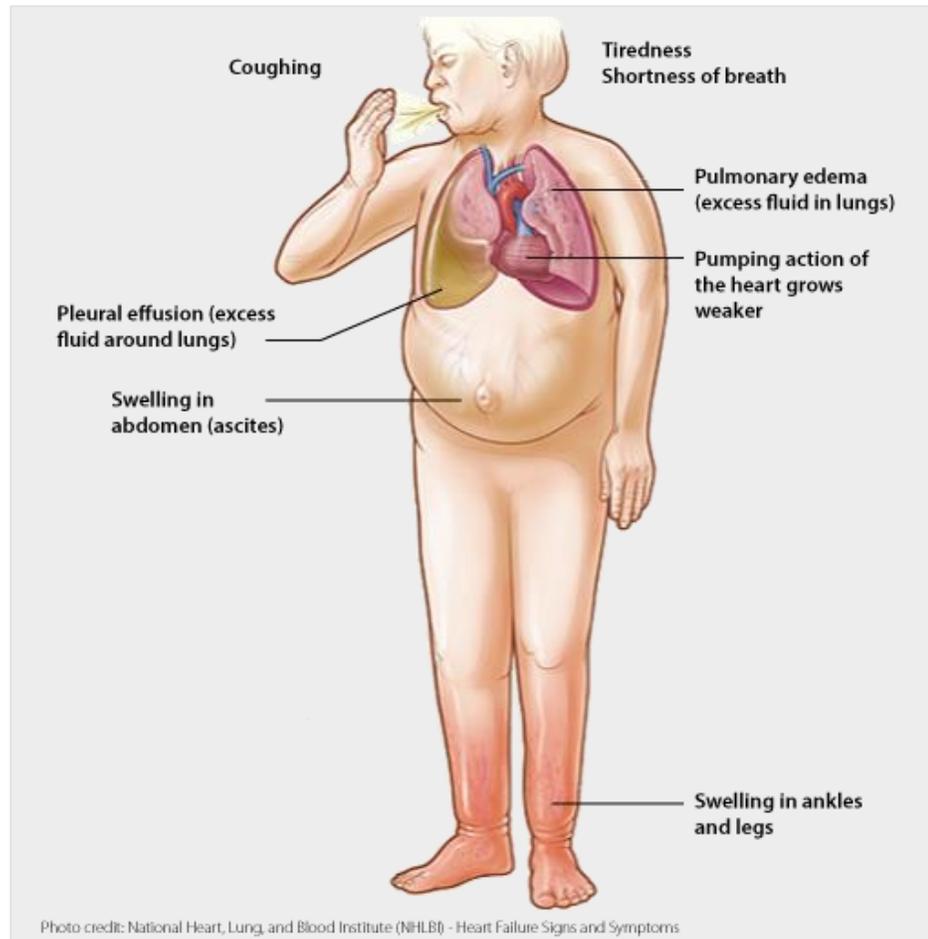


**Laurent Duhoux**  
Vice President of International  
Business Development

- 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 a condition

Where there is too much fluid in the bloodstream, vital organs and interstitial space



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



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



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



**In pediatric patients,** fluid overload is associated with significant increases in mortality<sup>4-5</sup>

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



# Nuwellis Provides a Solution to Millions of Heart Failure Patients

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

## 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



1

**90%**

of Heart Failure (HF) Hospitalizations are Due to Signs and Symptoms of Fluid Overload<sup>1</sup>

UNRESOLVED CONGESTION = POOR CLINICAL OUTCOMES<sup>1</sup>

2

**8.3 Days**<sup>2</sup>



Average HF Length of Stay

**\$24,027**

Total True Inpatient Cost Per Encounter<sup>2</sup>

3

LOW REIMBURSEMENT = HIGH LOSS PER HF HOSPITALIZATION

DRG 291

\$8,283<sup>3</sup>

**\$15,744**

Loss per Visit

DRG 292

\$5,708<sup>3</sup>

**\$18,319**

Loss per Visit

DRG 293

\$3,901<sup>3</sup>

**\$20,126**

Loss per Visit

4

HIGH READMISSION RATES

**24%** 30-Day Readmission Rate<sup>1</sup>

**50%** 90-Day Readmission Rate<sup>1</sup>

RELATED COSTS/PENALTIES

**\$24,027**



Non-Reimbursable Cost Estimate for Readmission Encounter<sup>2</sup>

Opportunity Cost of Occupied Bed

Up to **3%** of ALL Medicare Reimbursements<sup>4</sup>

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.

# 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

- 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



**SIMPLE**



**FLEXIBLE**



**SMART**

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

1. Watson R et al. *J Cardiac Fail.* 2020; 26(10): s56. 2. Kiziltepe, U, et al. *Ann Thorac Surg.* 2001;71(2): 684-93. 3. Sahoo, TK, et al. *Indian J Thorac Cardiovas Surg.* 2007;23(2): 116-24. 4. Boga et al. *Perfusion.* 2000;15:143-50. 5. Onoe et al. *Perfusion.* 2001;16:37-42.65. 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.



# 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>

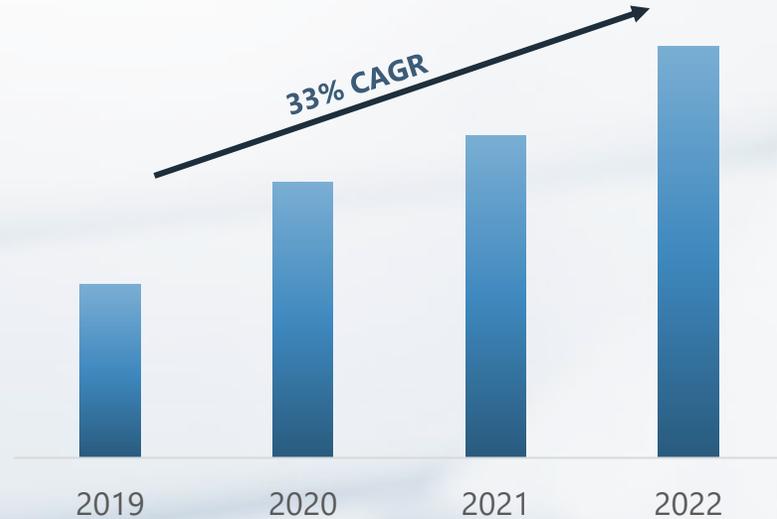
1. Derived from: <https://www.grandviewresearch.com/industry-analysis/coronary-artery-bypass-graft-cabg-market> and growth rate from: <https://www.hcup-us.ahrq.gov/reports/statbriefs/sb171-Operating-Room-Procedure-Trends.pdf>. 2. Derived from: <https://www.healthline.com/health/liver-transplant-survival> and this for growth rate: <https://www.marketwatch.com/press-release/organ-transplantation-market-size-to-grow-at-934-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/PMC6557150/>. 5. Derived from: <https://www.ncbi.nlm.nih.gov/pubmed/25291348>. 6. Derived from: <https://www.uclahealth.org/medical-services/heart/ecmo/research/statistics> and growth rate from same source.



## Growing Pediatric Business

Pediatric revenue has outpaced total growth over past two years

### Pediatric Revenue



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."*

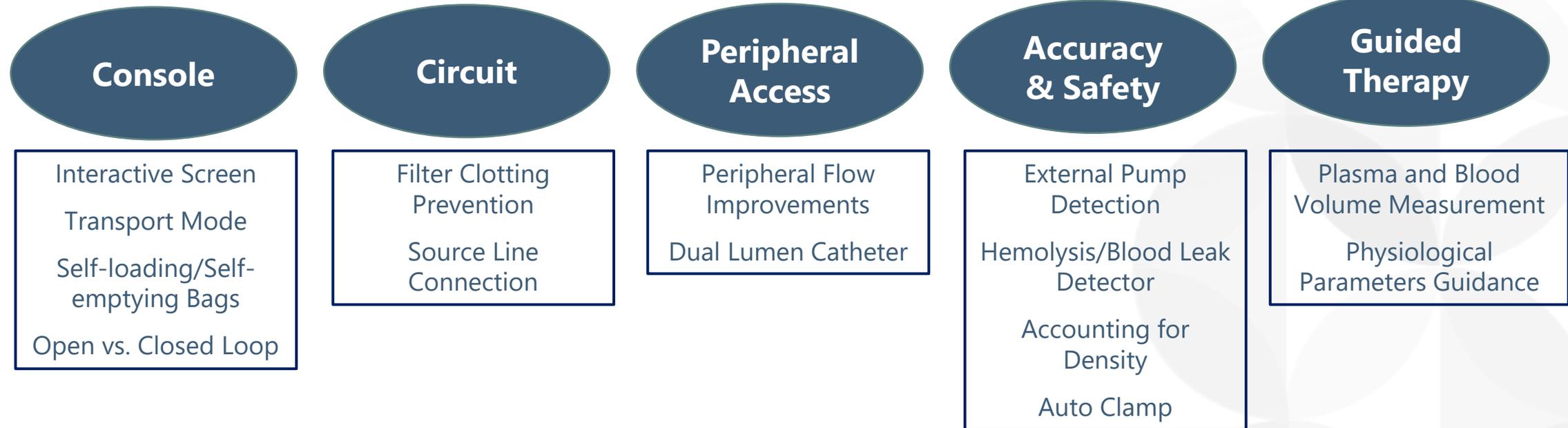
Kara Short, MSN, CRNP, NICU nurse practitioner at Alabama Children's Hospital

Aquadex is currently cleared for use in pediatric patients weighing 20 kg or more.

# 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
  - 2 granted, 15 pending
- Wide technology scope coverage



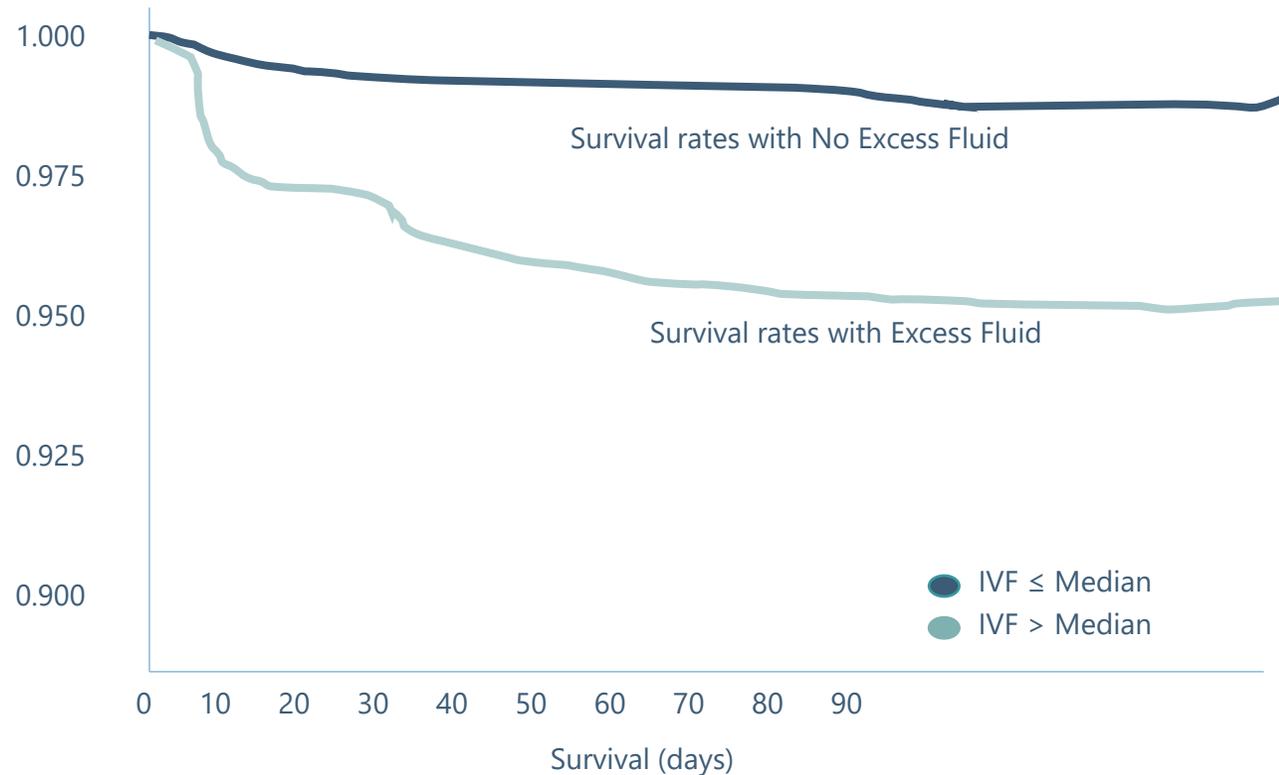


nuwellis®

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

# Fluid Overload is Associated with Greater Mortality in Post-Cardiac Surgery Patients

**90-day mortality by intravenous fluid median**



- 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. Costanzo MR, et al. *J Am Coll Cardiol*. 2017 May 16;69(19):2428-2445.



# Providing Pediatric Patients with High Mortality Risk an Opportunity at Life<sup>1</sup>

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
<b>Survival at end of treatment (Aquadex)</b>	<b>43 (60%)</b>	<b>13 (100%)</b>	<b>33 (97%)</b>

**Group 1 patients traditionally do not receive any kind of therapy**

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.