



Nuwellis Expands Pediatric Access to Ultrafiltration Therapy at Hospitals in Florida and Arkansas

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Pediatric Segment Growth Continues at 36% CAGR

MINNEAPOLIS, June 14, 2022 (GLOBE NEWSWIRE) -- Improving access to life-saving fluid management therapies is a commitment by which [Nuwellis, Inc.](#) (Nasdaq: NUWE) stands. The company today announced its Aquadex SmartFlow® system is now available at two new pediatric hospitals in Florida and Arkansas.

“By expanding access to Aquadex, we are another step closer to fulfilling our purpose-driven mission of positively transforming the lives of people suffering from fluid overload,” said Nestor Jaramillo, Jr., President and CEO of Nuwellis. “Fluid overload can quickly lead to severe complications, and children have limited treatment options. Our current technology gives providers a tool they can rely on to remove excess fluid effectively and efficiently.¹ This commitment to pediatric patients has resulted in significant growth for this segment of our business.”

Acute kidney injury (AKI) and volume overload are common and are associated with morbidity and mortality in critically ill pediatric patients.^{2,3,4} These patients require gentle treatment approaches, which makes Aquadex uniquely beneficial for children. The Aquadex device is designed to remove small amounts of fluid over time and only requires 35 mL (around 2.5 tablespoons) of blood outside of the body. This is a key differentiator compared to other larger and more complex fluid management devices that can be taxing on the small bodies of children. Aquadex is cleared by the FDA for use in children weighing 20 kg or more.

Nuwellis’ therapy meets an unmet need in pediatric patients, and the benefit of the clinically-proven⁵ technology can be demonstrated through its recent expansion to health centers in Florida and Arkansas.

In addition to bringing its existing technology to new pediatric health centers, Nuwellis is currently developing a new, fully integrated pediatric continuous renal replacement therapy (CRRT) device designed to provide care for small babies and children. This device will be funded in part by a \$1.7 million grant from the National Institutes of Health (NIH). Nuwellis has partnered with Minneapolis-based research and development firm Koronis Biomedical Technologies Corporation (KBT), the grant recipient, to design and develop a custom pediatric product that will enable clinicians to better care for babies with limited kidney function.

“The simple, gentle, and smart design of Aquadex SmartFlow makes it uniquely beneficial for pediatric patients,” said Mr. Jaramillo. “But when it comes to patient care, especially the care of children and babies, we can’t settle for good enough. Physicians have expressed a real need for neonatal fluid management therapies designed specifically to support the small body size of children and we are fully committed to getting safe innovation to market as fast as possible to help these pediatric patients. We’re immensely grateful to the NIH, KBT, and our pediatric nephrologist medical advisors in supporting the development of our pediatric CRRT device. I want to personally thank the medical staff at all pediatric institutions that dedicate their lives to treating so many children needing the right medical attention.”

About Nuwellis

Nuwellis, Inc. (Nasdaq: NUWE) is a medical device company dedicated to transforming the lives of patients suffering from fluid overload through science, collaboration, and innovation. The Company is focused on developing, manufacturing and commercializing the Aquadex SmartFlow® system for ultrafiltration therapy. Nuwellis is headquartered in Minneapolis, with a wholly-owned subsidiary in Ireland.

About the Aquadex SmartFlow® System

The Aquadex SmartFlow system delivers clinically proven therapy using a simple, flexible and predictable method of removing excess fluid from patients suffering from hypervolemia (fluid overload). The Aquadex SmartFlow system is indicated for temporary (up to 8 hours) or extended (longer than 8 hours in patients who require hospitalization) use in adult and pediatric patients weighing 20 kg or more whose fluid overload is unresponsive to medical management, including diuretics. All treatments must be administered by a health care provider, within an outpatient or inpatient clinical setting, under physician prescription, both having received training in extracorporeal therapies.

Forward-Looking Statements

Certain statements in this release may be considered forward-looking statements within the meaning of the Private Securities Litigation Reform Act of 1995, including without limitation, statements regarding the new market opportunities and anticipated growth in 2022 and beyond. Forward-looking statements are predictions, projections and other statements about future events that are based on current expectations and assumptions and, as a result, are subject to risks and uncertainties. Many factors could cause actual future events to differ materially from the forward-looking statements in this release, including, without limitation, those risks associated with our ability to execute on our commercialization strategy, the impact of the COVID-19 pandemic, 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 ability to integrate acquired businesses, our expectations regarding anticipated synergies with and benefits from acquired businesses, and other risks and uncertainties described in our filings with the SEC. Forward-looking statements speak only as of the date when made. Nuwellis does not assume any obligation to publicly update or revise any forward-looking statements, whether as a result of new information, future events or otherwise.

¹ Watson R, et al. (2020). Journal of Cardiac Failure, 26(10).

² Kaddourah A, et al. N Engl J Med 376: 11–20, 2017

³ Jetton JG, et al. Lancet Child Adolesc Health 1: 184–194, 2017

⁴ Menon S, et al. Nephrol Dial Transplant 31: 586–594, 2016

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