



Nuwellis to Advance Treatment of Critically-Ill Children and Babies Under \$1.7 Million NIH Grant

August 5, 2021

Funds will Support Creation of Life-Saving Pediatric Fluid Management Product

EDEN PRAIRIE, Minn., Aug. 05, 2021 (GLOBE NEWSWIRE) -- Critically-ill children and babies with kidney failure or who are dependent on artificial kidney support currently do not have enough therapeutic options. Nuwellis (Nasdaq: NUWE) plans to fill this unmet need with the development of a fully integrated pediatric continuous renal replacement therapy (CRRT) device designed to provide care for small babies and children. Nuwellis is a medical device company dedicated to transforming care for patients suffering from fluid imbalance.

The new device will build on the existing technology of the company's Aquadex SmartFlow® system, and 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.

"Historically, providers who treat children face tremendous challenges as we try to adapt therapies designed for adults to small children," said David Askenazi, MD, MSPH and director of the Pediatric and Infant Center for Acute Nephrology (PICAN) at Children's of Alabama and University of Alabama at Birmingham. "Using Aquadex at Children's of Alabama has enhanced the way we care for children as the small circuit improves how we treat our young patients. Now, with this grant, Nuwellis has the opportunity to create a machine that is a game-changer by addressing the additional unmet needs that we still face on a day-to-day basis."

CRRT machines are fluid management devices designed to aid or replace kidney function by removing excess fluid and toxins when the patient's kidneys are unable to support the demands of the body. The new device will be designed to lower the potential complications, enhance the functionality of traditional CRRT machines, and incorporate technologies that are needed to address issues relevant to small children.

Newborns who are born without sufficient kidney function need life-sustaining therapies until they are big enough for chronic dialysis machines. In addition, those who develop sudden temporary kidney failure will ultimately benefit from the innovation by enabling the clinician to support them while their kidneys are not working. Nuwellis and KBT plan to design a pediatric-specific CRRT device to address limitations of the current therapy options on the market. Sahar Fathallah, MD, professor of pediatrics and director of pediatric dialysis at Children's of Alabama and University of Alabama at Birmingham will serve as the site principal investigator of the future study analyzing the technology, and Dr. Askenazi will serve as the sub investigator. Both physicians contributed to the grant application by determining the most-needed features in the device.

"The gentle, predictable and effective fluid management design of Aquadex SmartFlow makes it uniquely beneficial for pediatric patients," said Nestor Jaramillo, Jr., President and CEO of Nuwellis. "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're committed to getting safe innovation to market as fast as possible. We're immensely grateful to the NIH, KBT, and our pediatric nephrology medical advisors, such as Dr. Askenazi and Dr. Fathallah, for making the development of our pediatric CRRT device possible."

Aquadex SmartFlow® ultrafiltration is currently approved for adults and pediatric patients weighing 20 kg (44 lbs) or more, and works to remove excess fluid to alleviate kidney burden.

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, Minn., with a wholly-owned subsidiary in Ireland. The Company has been listed on the Nasdaq Capital Market since February 2012, previously branded as CHF Solutions (Nasdaq:CHFS).

About the Aquadex SmartFlow System

The Aquadex SmartFlow® system delivers clinically proven therapy using a simple, flexible and smart 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 2021 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.

CONTACTS

INVESTORS:

George Montague
Chief Financial Officer, Nuwellis, Inc.
ir@nuwellis.com

Matt Bacso, CFA
Gilmartin Group LLC
Matt.bacso@gilmartinir.com

MEDIA:

Jessica Stebing
Health+Commerce
jstebing@healthandcommerce.com



Source: Nuwellis, Inc.