



Nuwellis Inc. Announces Pilot Agreement With DaVita Inc.

June 20, 2023

Supply Agreement to Pilot Ultrafiltration Therapy Services Offering in Select Markets

MINNEAPOLIS, June 20, 2023 (GLOBE NEWSWIRE) -- Nuwellis, Inc. (Nasdaq: NUWE), a medical technology company focused on transforming the lives of people with fluid overload, today announced it has entered into a Supply and Collaboration Agreement with DaVita Inc. (NYSE: DVA) to pilot Aquadex ultrafiltration therapy to treat adult patients with congestive heart failure and related conditions within select U.S. markets. Today, DaVita provides extracorporeal therapies such as continuous renal replacement therapy and apheresis to patients across a network of hospitals and outpatient clinics.

Pairing the Aquadex system with DaVita's care team could expand access to ultrafiltration therapy to millions of heart failure patients in the U.S. suffering from fluid overload and reduce related healthcare costs for providers and payers.

"We are honored that DaVita is collaborating with Nuwellis to pilot a services model alongside Aquadex," said Nestor Jaramillo, Jr., President and CEO of Nuwellis. "We believe DaVita's clinical infrastructure could potentially help accelerate the clinical adoption of ultrafiltration when first-line medical treatments are ineffective. Our clinical and commercial teams are excited and ready to begin working together on the pilot program to introduce ultrafiltration to a broader patient population."

"Ultrafiltration therapy using Aquadex is a novel solution for patients suffering from fluid overload – a key driver of negative outcomes in heart failure patients. It offers clinicians the opportunity to restore fluid balance and alleviate heart failure symptoms precisely and gently," said John Jefferies, MD, Chief Medical Officer of Nuwellis. "We believe the pilot with DaVita can support the role ultrafiltration can play in heart failure patient management and could enable accelerated commercial expansion of this therapy. Near-term, there's value in providing these services in acute settings for hospital patients. Nuwellis also sees a future path to treating heart failure patients earlier, in outpatient settings."

The pilot program is expected to launch by the end of the third quarter 2023 and extend through May 31, 2024. Via the pilot, ultrafiltration therapy using Aquadex would be available at a combination of DaVita's hospital customers and outpatient center locations, with both companies collaborating on the roll-out of the therapy, clinician training, and patient support. At the conclusion of the pilot, DaVita has the option to extend the supply agreement with Nuwellis for continued provision of both inpatient and outpatient ultrafiltration services for up to 10 years.

In conjunction with the agreement, Nuwellis issued DaVita a warrant for approximately 1.3 million shares of Nuwellis Inc. common stock. The warrant is subject to certain vesting milestones and a blocker that prevents the warrant from being exercised for a number of shares that would represent greater than 19.9% ownership in Nuwellis. Nuwellis has also granted DaVita registration rights and rights to participate in future equity financings of Nuwellis, in each case conditioned on DaVita electing to extend the Supply and Collaboration Agreement after completion of the pilot. Details of the Supply and Collaboration Agreement may be found in Nuwellis' Current Report on Form 8-K, to be filed with the Securities and Exchange Commission later today.

About Nuwellis

Nuwellis, Inc. (Nasdaq: NUWE) is a medical technology company dedicated to transforming the lives of patients suffering from fluid overload through science, collaboration, and innovation. The company is focused on commercializing the Aquadex SmartFlow® system for ultrafiltration therapy. Nuwellis is headquartered in Minneapolis, Minnesota, with a wholly owned subsidiary in Ireland. For more information visit www.nuwellis.com or visit us on [LinkedIn](#) and [Twitter](#).

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 2023 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.

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