

April 7, 2023

Dear Nuwellis Stockholders,

2022 was a year of significant progress for Nuwellis! After emerging from the pandemic-constrained environment of the prior two years, we were again able to access hospitals and clinicians. While we experienced some turnover early in the year in our commercial team, we were fully staffed in all key positions and territories by year-end. As we entered 2023, our field sales organization is now better able than ever to promote, educate, and train healthcare providers to treat patients suffering from fluid overload using the Aquadex SmartFlow® system.

Throughout 2022, we continued to advance the three pillars of our growth strategy. With the expansion of our field organization and focused sales strategy, we achieved year-over-year revenue growth of 8% and capped off the year with fourth quarter revenue growth of 42% over fourth quarter 2021. In particular, our Pediatrics segment has grown at a 33% compound annual growth rate since 2019 and grew 92% year-over-year in the fourth quarter.

In the second half of the year, we made significant strides in our clinical evidence development, with key heart failure data presented in September at the Heart Failure Society of America conference, followed by additional clinical evidence published in various peer-reviewed publications, supporting not only the benefits of ultrafiltration therapy in treating heart failure patients but also in post-cardiac surgery, as well as data linking use of ultrafiltration with reduction in acute kidney injury. As the capstone initiative in our clinical research efforts, we have continued to activate sites and enroll patients in our prospective, randomized controlled clinical trial, REVERSE-HF (Ultrafiltration Versus IV Diuretics in Worsening Heart Failure), to evaluate the clinical outcomes and economic value of the Aquadex® ultrafiltration therapy in comparison to intravenous diuretics for the treatment of fluid overload in patients with worsening heart failure.

Toward the goal of extending our reach in the Pediatrics segment, we are on track with our key product development initiative, which is the development of a dedicated pediatric continuous renal replacement therapy (CRRT) device. We have recently “christened” this device with the product name **Vivian**. We are on track with the key development milestones for Vivian and anticipate submission of an investigational device exemption (IDE) to the FDA by the end of the year.

Lastly, we continue to explore corporate development initiatives and pursuit of strategic partnerships. We were extremely pleased to announce the signing of an exclusive license and distribution agreement with SeaStar Medical (Nasdaq: ICU) in December. Under this agreement, Nuwellis has the exclusive right to sell SeaStar’s selective cytopheretic device (SCD) within the U.S. pediatric market. Our commercial launch of the SeaStar SCD will begin upon SeaStar’s receipt of a humanitarian device exemption (HDE) from the FDA, anticipated in the first half of 2023.

Between the clinical introduction of Vivian and the SeaStar SCD, acceleration of patient enrollment in REVERSE-HF, and our recent initiation of a direct-to-consumer marketing strategy designed to increase the use of the Aquadex System across a variety of indications and settings, we have exciting work and growth opportunities ahead.

I am intensely proud of the Nuwellis organization and what we have accomplished in 2022. We remain steadfast in our goal of making ultrafiltration the standard of care for patients suffering from fluid overload who are resistant to diuretics. Every day our employees demonstrate resilience, passion, and tenacity in carrying out Nuwellis’ mission. In 2022, together with our customers, we treated and transformed the lives of approximately 4,200 people suffering from diuretic-refractory fluid overload. We have a ten-year goal to treat 100,000 people per year, and I am confident we will get there.

Thank you for your continued support as we work to expand the availability and use of this transformational medical technology. We remain optimistic about our business and the value we can bring to our customers, investors, and the patients we serve.

Very truly yours,



Nestor Jaramillo, Jr.
President and Chief Executive Officer