UNITED STATES
SECURITIES AND EXCHANGE COMMISSION
Washington, D.C. 20549

FORM 8-K

Current Report Pursuant to Section 13 or 15(d) of the Securities Exchange Act of 1934

Date of Report (Date of earliest event reported): **September 9, 2021**

Nuwellis, Inc.

(Exact Name of Registrant as Specified in its Charter)

Delaware	**001-35312**	**No. 68-0533453**
(State or Other Jurisdiction of Incorporation or Organization)	**(Commission File Number)**	**(I.R.S. Employer Identification No.)**

12988 Valley View Road, Eden Prairie, MN 55344
(Address of Principal Executive Offices) (Zip Code)

(952) 345-4200
(Registrant's Telephone Number, Including Area Code)

Securities registered pursuant to Section 12(b) of the Act:

Title of each class	Trading Symbol(s)	Name of each exchange on which registered
Common Stock, par value $0.0001 per share	NUWE	Nasdaq Capital Market

Check the appropriate box below if the Form 8-K filing is intended to simultaneously satisfy the filing obligation of the registrant under any of the following provisions:

☐ Written communications pursuant to Rule 425 under the Securities Act (17 CFR 230.425)

☐ Soliciting material pursuant to Rule 14a-12 under the Exchange Act (17 CFR 240.14a-12)

☐ Pre-commencement communications pursuant to Rule 14d-2(b) under the Exchange Act (17 CFR 240.14d-2(b))

☐ Pre-commencement communications pursuant to Rule 13e-4(c) under the Exchange Act (17 CFR 240.13e-4(c))

Indicate by check mark whether the registrant is an emerging growth company as defined in Rule 405 of the Securities Act of 1933 (§230.405 of this chapter) or Rule 12b-2 of the Securities Exchange Act of 1934 (§240.12b-2 of this chapter).

Emerging growth company ☐

If an emerging growth company, indicate by check mark if the registrant has elected not to use the extended transition period for complying with any new or revised financial accounting standards provided pursuant to Section 13(a) of the Exchange Act. ☐

Item 7.01 Regulation FD Disclosure.

On September 9, 2021, Nuwellis Inc. (the "Company") posted on its website an updated slide presentation, which is attached as Exhibit 99.1 to this Current Report on Form 8-K and is incorporated herein by reference. Representatives of the Company will use the presentation in various meetings with investors, analysts and other parties from time to time. Within the presentation, the Company provided the following update regarding the COVID-19 Delta variant: "COVID Delta variant is limiting access and procedural volumes in some locations; this could adversely impact the Company's sequential growth."

The Company also provided an update on the implementation of its strategy, including market development for the pediatric segment and heart failure patients in an outpatient setting.

In accordance with General Instruction B.2 of Form 8-K, the information included in this Current Report on Form 8-K (including Exhibit 99.1) is furnished pursuant to Item 7.01 and shall not be deemed to be "filed" for the purpose of Section 18 of the Securities Exchange Act of 1934, as amended, or otherwise subject to the liabilities of that section.

Item 9.01 Financial Statements and Exhibits.

(d) Exhibits

Exhibit No.	**Description**
99.1	Nuwellis, Inc. Investor Presentation September 2021
104	Cover Page Interactive Data File (embedded within the XBRL document)

SIGNATURES

Pursuant to the requirements of the Securities Exchange Act of 1934, the registrant has duly caused this report to be signed on its behalf by the undersigned hereunto duly authorized.

Date: September 9, 2021

NUWELLIS, INC.

By: /s/ Nestor Jaramillo
Name: Nestor Jaramillo
Title: President and Chief Executive Officer

Exhibit 99.1

nuwellis™

Restoring Fluid Balance. Transforming Care.

Corporate Presentation

(Nasdaq: NUWE)

September 2021

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, 2020 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.

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.

nuwellis™
Restoring Fluid Balance. Transforming Care.

Risk Factors

Investing in our securities includes a high degree of risk. You should consider carefully the specific factors discussed below, together with all of the other information contained in our SEC filings. If any of the following risks actually occurs, our business, financial condition, results of operations and future prospects would likely be materially and adversely affected. This could cause the market price of our securities to decline and could cause you to lose all or part of your investment. Risks include but are not limited to:

- We have a limited history of operations and limited experience in sales and marketing, and we might be unsuccessful in increasing our sales and cannot assure you that we will ever generate substantial revenue or be profitable. We have incurred operating losses since our inception and anticipate that we will continue to incur operating losses in the near-term.
- Our near-term prospects are highly dependent on revenues from a single product, the Aquadex system. We face significant challenges in expanding market acceptance of the Aquadex system, which could adversely affect our potential revenues.
- We have limited commercial manufacturing experience and could experience difficulties in producing commercial volumes of the Aquadex system and related components or may need to depend on third parties for manufacturing.
- We believe that we will need to raise additional capital to fund our operations. If additional capital is not available, we will have to delay, reduce or cease operations.
- We depend upon third-party suppliers, including single-source suppliers, making us vulnerable to supply problems and price fluctuations.
- If we cannot develop adequate distribution, customer service and technical support networks, then we may not be able to market and distribute the Aquadex system effectively and our sales will suffer.
- We may face significant risks associated with international operations, which could have a material adverse effect on business, financial conditions and results of operations.
- The COVID-19 pandemic and other public health threats or outbreaks of communicable diseases could have a material adverse effect on our operations and overall financial performance
- We are a "smaller reporting company" under federal securities laws and the company cannot be certain whether the reduced reporting requirements applicable to such companies will make the common stock less attractive to investors.

nuwellis™
Restoring Fluid Balance. Transforming Care.

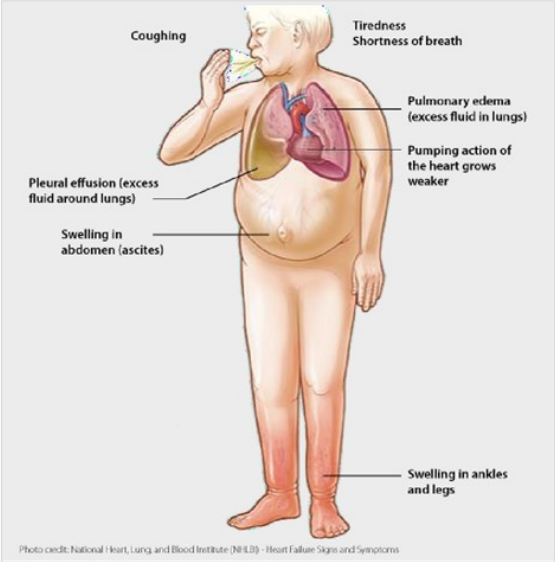
Our Vision

nuwellis™

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

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 [1]

Fluid overload is the leading cause of hospital readmission post 30 days following cardiac surgery[2]

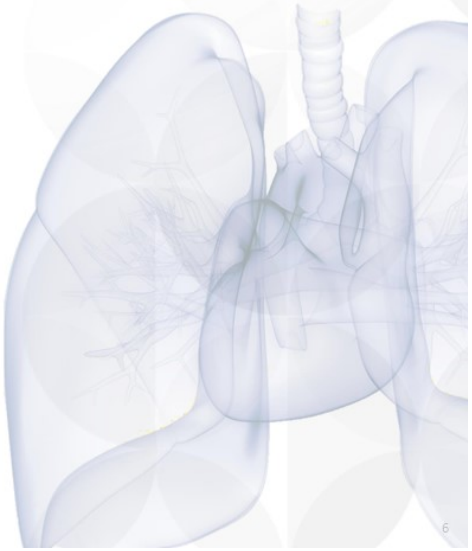
Fluid overload is the leading cause of death for critically ill patients in the ICU within 90 days[3]

In pediatric patients, fluid overload is associated with significant increases in mortality[4-5]

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.

Diuretics:
Standard of care with significant limitations

- **>40% of heart failure patients** have poor diuretic response[1]
- **High risk** of rehospitalization[2]
- **Long-term use of diuretics** has been associated with kidney damage[2-5]
- **Diuretics provide insufficient symptom relief** and are associated with worsening heart failure; increased mortality after discharge[2]



1. Testani JM, et al. *Circ Heart Fail.* 2016;9(1):e002370. 2. Costanzo MR, et al. *JACC.* 2017;69(19)2428-2445. 3.Felker MG & Mentz RJ. *JACC.* 2012;59(24):2145-53. 4. Al-Naher et al. *Br J Clin Pharmacol.* 2018 Jan; 84(1): 5–17. 5. Butler J et al. *Am Heart J.* 2004 Feb;147(2):331-8.

aquadex SmartFlow®

SIMPLE FLEXIBLE SMART

nuwellis™

A superior solution for fluid overload

- Safe and easy to use and flexible in application
- Predictably removes excess fluid
- No significant changes to kidney function[1]
- Stabilizes or improves cardiac hemodynamics[2-5]
- Compared to diuretics, reduces hospitalization per patient per year by 81%[1]
- Rehospitalizations for patients after receiving ultrafiltration with Aquadex were 48% fewer than the national average at 30 days[1]
- Reduces length of hospital stay when initiated early, resulting in average savings of $3,975 (14%)[6-7]

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

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

Key Milestones – *Solid Progress*

KEY MILESTONES		EXPECTED TIMING
FDA 510(k) clearance of:	Expanded use in pediatric population (≥ 20kg) Next generation Aquadex SmartFlow® console	Complete
Nationwide Access to Ultrafiltration Therapy Possible with Nuwellis and Premier, Inc. Collaboration		Complete
Clinical Data Release at Heart Failure Society of America (HFSA) and American College of Cardiology (ACC)		Complete
Receive CPT Category III code for therapeutic ultrafiltration		Complete
Single-Center Experience With Ultrafiltration Immediately Following Cardiac Surgery manuscript at Baylor Scott & White - Potentially advances Aquadex therapy in the medical guidelines to earlier in treatment pathway		Q4 2021
Commence enrollment in the Heart Failure Control randomized multicenter clinical trial - To make Aquadex therapy the first line of treatment and standard of care for re-hospitalized heart failure patients		Q4 2021
10-Year Experience With Ultrafiltration for the Management of ADHF: Real World Experience at Abington Hospital - Continue building clinical evidence to support adoption by healthcare providers		Q1 2022
Evaluate synergistic product opportunities - Accelerate growth and cost efficiencies through disciplined, opportunistic corporate development		2022

Aquadex SmartFlow:

A novel treatment targeting growing underserved addressable market segments

$2B

$150M Market

$950M Market

$900M Market

TREATING THE MOST VULNERABLE

From children[1] to the elderly, our therapy is critical to improving care and outcomes

1. Approved for use in pediatric patients weighing 20 kg or more.

Providing Pediatric Patients with High Mortality Risk an Opportunity at Life [1]

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
Survival at end of treatment (Aquadex)	43 **(60%)**	13 **(100%)**	33 **(97%)**

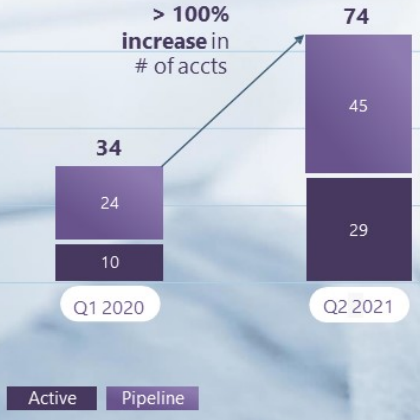
Group 1 patients traditionally do not receive any kind of therapy

1. Source: Menon S, et al. CJSN, 2019; 14: 1432-40. Aquadex is currently approved for use in pediatric patients weighing 20 kg or more.

Growing Pediatric Business

In five quarters, we have more than doubled the number of active and pipeline pediatric accounts

Received 510(k) in February 2020 and launched commercially in March 2020.



Aquadex SmartFlow® simply & predictably removes excess fluid post cardiac surgery

Additional fluid added to compensate for blood flowing through heart lung machine[1]

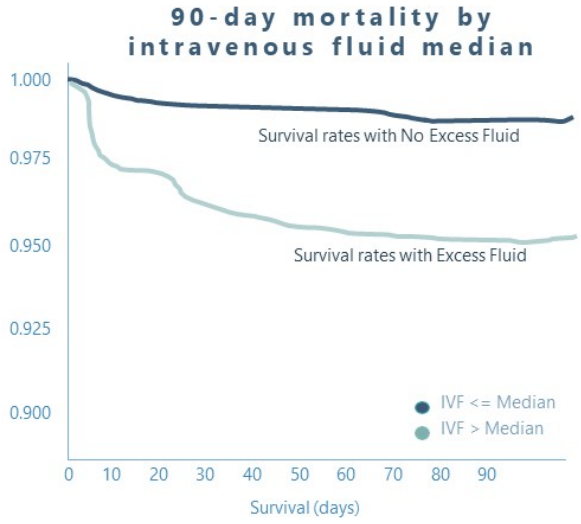
520K
Patients/Year

Immediately removing fluid post-surgery

- **Reduces** time to be extubated [2,3]
- **Shortens** time in post op care and ICU length of stay[3,4]
- **Improves** outcomes[2-5]

1. DeVore A et al. *Curr Treat Opts Cardiovasc Med.* 2014; 16(2): 283
2. Bundgaard-Nielsen M, et al. *Acta Anaesthesiol Scand* 2009; 53:843-851.
3. Wiedemann HP, et al. *N Engl J Med.* 2006, 354:2564-75.
4. Stein, A. et al. *Critical Care.* 2012;16(R99): 1-9.
5. Miller TE et al. *Can J Anesthes.* 2015; 62: 158-68.

Fluid Overload is associated with greater mortality[1]



- Excess fluid post-cardiac surgery leads to **three-fold increase** in mortality at 90 days
- BSW manuscript may indicate clinically relevant improvement in outcomes

1. Pradeep, A. et al. HSR Proc IC and Car An. 2010 Mar; 2(4): 287-296

Source: Pradeep, A. et al. HSR Proc IC and Car An. 2010 Mar; 2(4): 287-296

10-Year Real-World Experience
with Ultrafiltration[1]

nuwellis™

ABINGTON HOSPITAL
JEFFERSON HEALTH

- Retrospective, single center analysis
- **335 consecutive** acutely decompensated heart failure patients
- Treated with adjustable-rate UF using Aquadex
- Fluid removed weight loss
- Unchanged kidney function

HF HOSPITALIZATIONS

Average **2.14 hospitalizations** Year **before Aquadex Ultrafiltration** ▶ 1 Year After Aquadex ultrafiltration **Average 0.4 hospitalizations**

HOSPITAL READMISSIONS

NATIONAL AVERAGE

24% at 30 days[2]

50% at 6 months

▶

12.4% at 30 days
14.9% at 90 days
27.3% at 1 year

Significant quality of life improvement for the patients and savings to the healthcare system and to the individual hospitals

1.Watson R et al. *J Cardiac Fail.* 2020; 26(10): s56. 2. Costanzo MR, et al. *JACC.* 2017 May 16;69(19):2428-2445

Why Outpatient setting is attractive market?

Nuwellis

- Greater cumulative impact on outcomes through earlier intervention on healthier patients
- Increased revenue by treating more patients
- Uniquely positioned to deliver outpatient therapy with peripheral venous access

Patients

- Improved patient QoL:
  - Earlier resolution when diuretic therapy cannot relieve congestion → patient feels better faster[1,2]
  - Reduce hospitalizations through proactive fluid management (rate per patient per year decreased by 81%)[3]
  - Readmission avoidance[1-3]
- Reduced financial burden to patient and family[4]

Hospitals

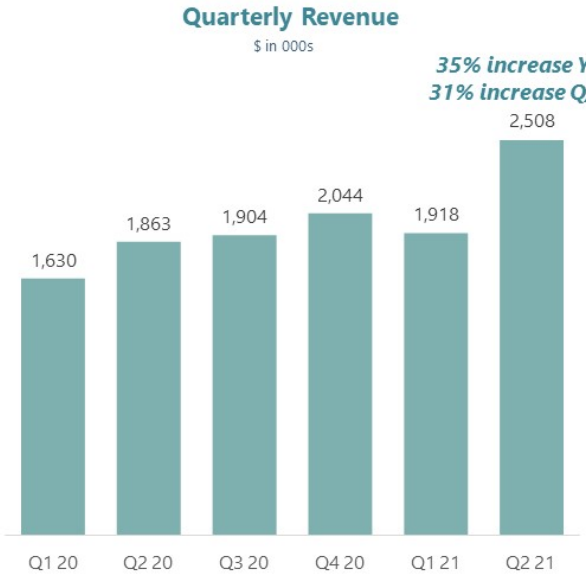
- Hospitals actively trying to reduce economic burden of heart failure (HF)
- Reduced patient readmissions within 30-days may help decrease costly CMS penalties[9]
- Early intervention may help decrease patient hospital length of stay (LOS)[5]
  - Most US hospitals lose money on HF admissions: average LOS is ~5 days [6], while DRG payments often cover ≤ 4 days[7]

US Healthcare System

- Concern throughout the US healthcare system regarding the growing economic burden of HF treatment.[6, 8]
- HF treatment is Medicare's largest expenditure[9]
- CMS controlling HF spending through the Hospital Readmission Reduction Program focused on 30-day readmissions[9]
  - Readmissions after UF treatment with Aquadex was 48% less than nat'l average at 30 days[5]

1. Costanzo MR et al. JACC. 2007; 48: 467-83. 2. Stamper J, Rawal A, & Jefferies. *JACC.* 2021; 77(18): 734. 3. Watson R & Hummell M. et al. HFSA poster session. 2020. 4. Costanzo MR, et al. *J Med Econ.* 2019; 22(6): 6, 577–583. 5. Costanzo MR et al. *JACC.* 2005; 46(11):2047-51. 6. Rizzo JA et al. 2013. Value in Health. https://www.valueinhealthjournal.com/action/showPdf?pii=S1098-3015%2813%2901533-7_7. Premier Applied Sciences Data 2021. 8. Samsky MD et al. *JAMA Cardiol.* 2019; 4(5): 444-453. 9. www.cms.gov

Financial Metrics



2021 growth considerations

- Expand into new pediatric accounts
- Increase utilization among existing pediatric accounts
- Increase utilization to treat non-COVID 19 critically ill patients in ICU
- Maturing sales organization, strategy and structure
- COVID Delta variant is limiting access and procedural volumes in some locations; this could adversely impact the Company's sequential growth

Cash

$24.0M as of June 30, 2021

Investment Highlights

1. Attractive capital equipment + consumables revenue growth model
2. $2 billion addressable market: pediatrics, critical care and heart failure
3. Leveraging commercial infrastructure to rapidly penetrate pediatric and critical care segments while maintaining presence in heart failure
4. Optimizing therapy through differentiated product development, including dedicated pediatric device and diagnostics to guide therapy
5. Demonstrating therapeutic value through increased clinical evidence
6. Advocating for medical-society guidelines and improved provider reimbursement, including payment for treating patients in the outpatient setting

Capitalization Table

Capitalization as of June 30, 2021

Common Shares Outstanding (Nasdaq: NUWE)	**6,532,018**
Series F Convertible Preferred (1)	23,114
Warrants from 2020 Financings (2)	1,479,040
Other warrants (3)	152,766
Options	812,561
Fully Diluted Shares	**8,999,499**

Notes

(1) From November 2017 offering. Convertible at $5.50 per share, anti-dilution rights to next offering price.

(2) Consists of 130,170 warrants at $5.50, price protection down to $1.65, exp. 1/25; 138,715 warrants at $11.18, exp. 9/25; 85,506 warrants at $11.15, exp. 10/25; 59,966 warrants at $12.30, exp. 11/25; 1,064,683 at $13.50, exp. 8/25.

(3) Consists of 19,196 warrants at $42.30, exp. 4/25; 40,638 warrants at $29.83, exp. 11/24; and 92,932 warrants exercisable at a weighted average exercise price of $360.96, expiring Feb 2022-Nov 2024. No anti-dilution rights.

Thank You