

**LivaNova**

Health innovation that matters

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2020  
Annual Report

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## Dear Shareholder:

**During 2020, the COVID-19 pandemic presented unique operating challenges for LivaNova. Many markets around the globe functioned unevenly or shut down for varying periods of time—a dynamic that has continued thus far into 2021. In response, the management team, with the support of the LivaNova Board of Directors, has taken a number of actions to shape our portfolio and structure the organization to ensure the Company remains well-positioned to serve our patients and drive shareholder value.**

LivaNova has two compelling platforms in Neuromodulation and Cardiovascular, both of which we believe have growth opportunities beyond what has been achieved to date. We recognize there is more work to be done and remain focused on delivering the underlying value embedded in these businesses. For this reason, we are targeting three key areas:

- Executing on our core growth drivers;
- Delivering on our strategic pipeline initiatives; and
- Improving profitability and cash generation.

## Core Growth Drivers

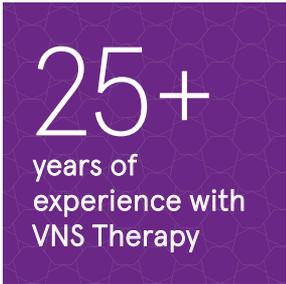
With respect to growth drivers, we are focused on achieving consistent, profitable revenue growth. We continue to implement our go-to-market strategy targeting drug-resistant-epilepsy (DRE) patients and focus on clinical research supporting our VNS Therapy® System

as the standard of care. Advanced Circulatory Support (ACS), which achieved greater than 30% growth in 2020, should continue to benefit from last year's U.S. launch of the LifeSPARC™ platform and salesforce expansion. A component to our organic growth is also our Cardiopulmonary portfolio with its long-standing legacy of cardiac surgery equipment and planned innovations on the horizon.

**Epilepsy.** COVID-19's impact on non-emergent procedures negatively impacted our epilepsy sales results. The most severe impact was experienced in the second quarter of 2020, and results improved in each of the subsequent quarters during the year. Despite the difficult market backdrop, we advanced our commercial strategy to positively impact the underserved DRE population in Comprehensive Epilepsy Centers (CECs) through the continued roll-out of our enhanced go-to-market approach in the U.S. Physicians prescribe and implant VNS Therapy in nearly 90% of these advanced epilepsy centers in the U.S. as they treat the highest concentration of DRE patients. As a result, CECs account for 50% of our revenue. Our new approach includes multi-disciplinary dedicated teams that are focused on partnering with CECs to deliver improved outcomes by bringing expertise in the areas of clinical research, education and training, and community outreach. These teams are additive to our existing sales structure and complement their work in the field. Today, our dedicated go-to-market teams cover nearly 20% of CECs in the U.S. and we plan on expanding this model further in 2021.

**ACS.** The ACS business has continued to maintain strong double-digit growth for the third consecutive year, growing in excess of 30% last year. In 2020, we achieved full commercial release of LifeSPARC™, our next-generation pump and controller system. The system represents a significant technological

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25+  
years of  
experience with  
VNS Therapy

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>30%  
organic growth  
in Advanced  
Circulatory  
Support in 2020

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45+  
years of proven  
Cardiopulmonary  
Innovation

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upgrade with improved ease of use, more power, better flow rate and more versatility. All these features should allow us to treat more patients in more places, and we have seen strong demand for the LifeSPARC system in both new and existing customers. The launch of LifeSPARC, coupled with the strong commercial execution of our expanded salesforce, is expected to drive growth greater than 20% for our ACS business in 2021 and beyond.

**Cardiopulmonary.** COVID-19's impact on non-emergent cardiac procedures also challenged the Cardiopulmonary business in 2020. In addition, we are now in the late stages of a product replacement cycle for heart-lung machines (HLMs). As cardiac surgery procedures recover globally, we expect this business to improve as we move through the year.

### Strategic Pipeline Initiatives

We are making significant near-term advancements in depression, heart failure and obstructive sleep apnea (OSA). For depression, we anticipate transitioning the RECOVER study to a registry phase by late 2022 or early 2023. For heart failure, we recently achieved our first clinical milestone of 300 patients enrolled. For OSA, we submitted for U.S. Food and Drug Administration (FDA) investigational device exemption (IDE) approval in late 2020. Finally, for HLMs, we believe that the development of our next-generation product is a key initiative to support our market leadership position, and we continue to make progress toward regulatory approval and commercialization, which are both expected in 2022.

### Difficult-to-Treat Depression (DTD).

In September 2019, the U.S. Centers for Medicare and Medicaid (CMS) accepted our protocol for the RECOVER clinical study to evaluate VNS Therapy for DTD patients. In the RECOVER study, CMS provides reimbursement for patients with the possibility of extending it into

a larger registry, which could cover up to 5,800 patients. 2020 turned out to be a challenging year to recruit patients into a new clinical trial due to the lack of physical access to clinical trial sites, psychiatrists, patients and surgical centers. These factors, coupled with our decision to briefly halt recruitment in the study in the second quarter of 2020, impacted our ability to accelerate enrollment in RECOVER throughout the year. Despite these unprecedented barriers, we were able to work remotely, open new sites and assist sites with patient recruitment activities. In the second half of 2020, we activated nearly 70% of our target number of sites and focused on patient consents, which is an important precursor to implantation. In anticipation of easing COVID-19 restrictions and a return to normality, we have significantly increased our investment in RECOVER for 2021 to maintain our target of a transition to registry by late 2022 or early 2023.

**Heart Failure.** We remain committed to advancing VNS Therapy to treat heart failure, a condition that affects more than 25 million people worldwide. We combined our learning from pre-clinical research, initial pilot clinical research and efforts of others in this space to create a clinical evaluation plan for the VITARIA® System. We used an updated and contemporary understanding of key therapy fundamentals in combination with a commitment to partner with the FDA, to obtain a "Breakthrough Technology" designation while designing the pivotal study. Since the inception of our ANTHEM-HFrEF pivotal trial, patient enrollment has exceeded trial goals and enrollment surpassed 300 patients in April 2021. Once we follow up on these 300 patients for nine months and randomize a total of 400 patients, we will review the data in anticipation of filing with the FDA based on predetermined functional endpoints. We continue to expect a decision on a PMA filing with the FDA in the first half of 2022.

## 2021 Strategy at a Glance



↑  
**Core Growth**  
 U.S. Epilepsy  
 U.S. ACS

↑  
**Pipeline Execution**  
 Depression & Heart Failure  
 Next-Generation HLM

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**Operational Excellence**  
 Margin Expansion  
 Cash Generation

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We are focused on enhanced execution to drive consistent profitable revenue growth, deliver on our pipeline and improve operational excellence.

Execution in these areas will ensure we are well positioned to realize the full value of our pipeline and strengthen top- and bottom-line results for years to come.

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**Obstructive Sleep Apnea.** Since acquiring ImThera and its hypoglossal nerve stimulation (HGNS) device for the treatment of OSA, we have been focusing on remediating the aura6000® system and analyzing the results of the THN3 pivotal study. We continue to make progress with a fully remediated system and a confirmatory study was submitted for FDA IDE approval during the fourth quarter of 2020. We expect to start the study in mid-2021.

### Operational Excellence

While driving growth and innovation are fundamental to any world-class medical technology company, we are also laser focused on increasing cash generation and operating profitability. With that in mind, we have taken a number of steps to right-size our cost structure, improve margins and focus investments on our core growth drivers. We believe these initiatives will result in expanding operating margins closer to benchmark levels.

Additionally, in the fourth quarter of 2020, we entered into an agreement with Gyrus Capital for the sale of our heart valve business. This divestiture will enable us to sharpen our focus on our primary Cardiovascular and Neuromodulation platforms. We continue to expect the initial closing, consisting of the heart valve operations, to occur in the second quarter of 2021 followed by closings of the sales infrastructure in the second half of the year.

Finally, in December, we announced a series of Board leadership changes, including appointing Todd Schermerhorn to the Board of Directors and rotating the Board Chair and two Committee Chairs following the 2021 Annual General Meeting. We believe these changes underscore a commitment to leading corporate governance and help to further enhance the Board's independent oversight.

### Impact on 2021

While 2020 did not go as expected, we have become stronger, more agile and remain cautiously optimistic that our focus on execution combined with expectations of declining COVID-19 infection rates will lead to improving results as we move through 2021.

As we transition out of the pandemic, we believe customers will continue to reward our innovation and actions as valued partners with increased trust and market share. Further, we believe our work to improve margins will become clearer as procedures return to normal levels.

We are focused on enhanced execution to drive consistent profitable revenue growth, deliver on our pipeline and improve operational excellence. Execution in these areas will ensure we are well positioned to realize the full value of our pipeline and strengthen top- and bottom-line results for years to come.

On behalf of LivaNova, our Board of Directors and our nearly 4,000 colleagues around the world who are all united by our mission, I would like to express my sincere appreciation for your investment, continued trust and support in our journey of life-saving and life-changing innovation. I look forward to the upcoming year and all that we can achieve together.

**Damien McDonald**  
Chief Executive Officer  
LivaNova PLC



## Board of Directors

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### **Daniel Moore**

Chairman of the Board, LivaNova.  
Former Chief Executive Officer and member of the board of directors of Cyberonics.

### **Damien McDonald**

Chief Executive Officer, LivaNova.  
Previously served as Chief Operating Officer at LivaNova. Former Group Executive and Corporate Vice President at Danaher Corporation.

### **Francesco Bianchi**

Chairman of Seven Capital Partners.  
Former member of the board of directors of Sorin. Former General Manager and Head of M&A and Corporate Finance at Bankers Trust.

### **Stacy Enxing Seng**

Former President of Covidien Vascular Therapies and former President of Covidien Peripheral Vascular.

### **William Kozy**

Former Executive Vice President and Chief Operating Officer at Becton, Dickinson and Company.

### **Hugh Morrison**

Former Chairman of the board of directors for Cyberonics. Former Managing Director at Callahan Advisors.

### **Alfred J. Novak**

Former member of the board of directors of Cyberonics. Former Chairman and Chief Executive Officer of OrbusNeich Medical Technology Company.

### **Sharon O’Kane**

Entrepreneur in Residence at University College Dublin.  
Co-Founder and former Chief Scientific Officer and Executive Director of Renovo Group.

### **Arthur L. Rosenthal**

Former member of the board of directors of Cyberonics.  
Co-Founder and former Chief Executive Officer of gEyeCue.

### **Andrea L. Saia**

Former executive at Novartis, including roles as President and Chief Executive Officer of the CIBAVision subsidiary and Global Head of the Vision Care Division.

### **Todd C. Schermerhorn**

Former Senior Vice President and Chief Financial Officer of C.R. Bard, Inc.

## Executive Management

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### **Damien McDonald**

Chief Executive Officer

### **Alex Shvartsburg**

Interim Chief Financial Officer

### **Keyna Skeffington**

Senior Vice President,  
General Counsel

### **Stephanie Bolton**

President, Europe

### **Paul Buckman**

President, North America

### **Matthew Dodds**

Senior Vice President,  
Corporate Development

### **Marco Dolci**

Senior Vice President,  
Global Operations and R&D

### **Trui Hebbelinck**

Chief Human Resources Officer

### **Ryan Miller**

Senior Vice President, Strategy

### **Bryan Olin, PhD**

Senior Vice President,  
Clinical, Quality Assurance  
and Regulatory Affairs

## Key Worldwide Locations

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### **Europe**

LivaNova PLC (Headquarters)  
20 Eastbourne Terrace  
London, W2 6LG  
United Kingdom

Paris, France  
Milan, Italy  
Mirandola, Italy  
Saluggia, Italy  
Munich, Germany

### **North America**

Houston, Texas  
Arvada, Colorado  
Pittsburgh, Pennsylvania  
Vancouver, Canada

### **Latin and South America**

San Paolo, Brazil  
Dominican Republic

### **Asia**

Shanghai, China  
Tokyo, Japan

## Additional Information

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Additional information about LivaNova, including news and financial data, is available by visiting the company’s website: [www.livanova.com](http://www.livanova.com)

Any forward-looking statements are subject to risks and uncertainties such as those described in our periodic reports on file with the U.S. Securities and Exchange Commission. Actual results may differ materially from anticipated results. These statements are not guarantees of future performance, and stockholders should not place undue reliance on forward-looking statements.



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**LivaNova PLC**  
20 Eastbourne Terrace  
London, W2 6LG  
United Kingdom  
+44 20 3325 0660  
[www.livanova.com](http://www.livanova.com)

