

A photograph of a woman with long blonde hair and a young boy with glasses, both wearing red polka-dot shirts, leaning on a metal railing and looking towards the right. The woman is smiling, and the boy has a curious expression. The background is a blurred indoor setting with a staircase and some pink flowers in the lower left corner.

**LivaNova**

Health innovation that matters

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**2021  
Annual Report**

## Dear Shareholder:

**We are pleased to report that in 2021, LivaNova delivered on its guidance metrics and was able to improve cash flow generation against a continued backdrop of COVID-19-related headwinds. We focused on what we could control—managing costs, strengthening the balance sheet and adapting our operations to continue delivering life-saving products and therapies. During the year, the management team undertook additional actions to shape our portfolio and realign the organization to ensure the Company remains well positioned to serve our patients and drive shareholder value.**

In 2021, we had three areas of focus:

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

Execution in these three areas will ensure that we are well positioned to maximize the value of our diverse portfolio and strengthen top- and bottom-line results in the years to come.

## Core Growth

Our core businesses include Epilepsy, which is currently the primary driver of the Neuromodulation segment, as well as our Cardiopulmonary and ACS segments. The foundation of these core businesses supports investments into our three Strategic Portfolio Initiatives (SPIs): Difficult to Treat Depression (DTD), Heart Failure and Obstructive Sleep Apnea (OSA).

**Epilepsy.** Our progress in U.S. Epilepsy is being led by our go-to-market initiative, which currently encompasses 12 dedicated Comprehensive Epilepsy Center (CEC) teams that are supporting our VNS Therapy™ System as the standard of care. These multi-disciplinary teams 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. Our dedicated go-to-market teams cover 25% of CECs in the U.S. and we plan on adding additional teams this year. In 2022, we forecast a continued rebound in new implants in the U.S. as patients and their caregivers return to in-person physician visits and hospital capacity improves. We also expect another solid year of replacement implants related to the backlog created due to COVID-19.

**Cardiopulmonary.** Our Cardiopulmonary portfolio is expected to deliver lower, but durable organic growth with its long-standing legacy of cardiac surgery equipment and much-anticipated next-generation heart-lung machine (HLM), Essenz™, launching this year. COVID-19's impact on non-emergent cardiac procedures challenged the Cardiopulmonary business in both 2020 and 2021. We expect this business to improve throughout the year as cardiac surgery procedures return to pre-pandemic levels and Essenz is released.

**ACS.** ACS represents a subset of mechanical circulatory support options that go beyond the current standards of care. The foundation of this business is the LifeSPARC™ platform, which includes our next-generation pump and controller system that launched in 2020. LifeSPARC represents a significant technological upgrade with improved ease of use, more power, better flow rate and more versatility. All these features are intended to treat more patients in more places. During 2021, the ACS business delivered double-digit growth for the fourth consecutive year, growing

**25+**  
years of  
experience with  
VNS Therapy

**17%**  
organic sales  
growth<sup>1</sup>

**45+**  
years of proven  
Cardiopulmonary  
innovation

<sup>1</sup>Worldwide net sales growth excludes the Heart Valves business, which was divested effective June 1, 2021. Percent change performance is shown on a year-over-year constant-currency basis, which is a non-GAAP measure. Constant-currency eliminates the effects of foreign currency fluctuations. Additionally, other non-GAAP measures referenced in this document include adjusted free cash flow, adjusted operating margin and adjusted R&D as a percentage of net sales. For reconciliations of certain non-GAAP measures, see the tables at the back of this document.

more than 30%. This growth was driven by continued adoption and utilization of LifeSPARC and higher usage rates to treat COVID-19 patients. ACS faces tougher comparisons as COVID-19 cases decline, which should be offset by higher overall utilization as non-COVID procedures and sales force expansion occurs.

## Pipeline Execution

Our SPIs include three, major neurological indications that target medical conditions with significant unmet needs, specifically DTD, Heart Failure and OSA. These SPIs represent a significant part of the Company's future with each one of these opportunities offering the potential to be transformative to our business. The SPIs for DTD and Heart Failure leverage our VNS Therapy platform. This is meaningful since the safety and efficacy for VNS Therapy is well understood with over 125,000 patients implanted to date.

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

Depression continues to be an important health concern globally and an area in need of more effective treatments. Major Depressive Disorder (MDD) is the leading cause of disability, morbidity and mortality worldwide. Of patients with MDD, approximately 15-20% have DTD, meaning they have not been responsive to multiple antidepressant treatments. For DTD, the U.S. Centers for Medicare & Medicaid reimbursement study, RECOVER, continues to advance. This study is designed to evaluate VNS Therapy, which is U.S. Food and Drug Administration (FDA) approved, for unipolar and bipolar DTD patients. We recently announced that the 250th unipolar depression patient was implanted in the study, which allows for the initial interim analyses to be conducted for that cohort. We believe a series of interim analyses is likely needed as we collect follow-up data from these patients over time during which we will

continue to recruit into the randomized controlled trial. We anticipate transitioning to the prospective longitudinal study, or registry, for the unipolar cohort in late 2022 or early 2023.

**Heart Failure.** We are also applying our VNS Therapy technology to treat heart failure, a condition that affects more than 25 million people worldwide. We combined our learnings 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. Since the inception of our ANTHEM-HFrEF pivotal trial, patient enrollment has exceeded trial goals and most recently achieved two key milestones: enrolling the 400th patient and completing the nine-month follow-up visit for the 300th patient. These milestone achievements allow for the first interim analysis to be conducted by independent statisticians. As part of the interim analyses, independent statisticians will review five pre-specified conditions, including safety, a trend toward the primary endpoint and the three pre-specified functional endpoints. Once all pre-specified conditions have been met, we may submit the functional dataset to the FDA. If we do not meet all criteria, the independent statisticians will take another look at the data after the 500th patient is enrolled.

### Obstructive Sleep Apnea (OSA).

Since acquiring ImThera and its hypoglossal nerve stimulation (HGNS) device for the treatment of OSA, we have fully remediated and enhanced the aura6000™ System. We also have analyzed the results of the THN3 pivotal study and applied these learnings to the design of our OSPREY confirmatory study. In 2021, we obtained FDA approval for the OSPREY trial with the first patient implanted in February 2022. The OSPREY study will be the first randomized controlled trial to confirm efficacy of HGNS for OSA.

## Strategic Priorities



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



**Pipeline Execution**  
Depression, Heart Failure,  
Obstructive Sleep Apnea  
and Next-Generation HLM



**Operational Excellence**  
Margin Expansion  
Cash Generation

While the world has entered 2022 with continued uncertainty, we remain committed to delivering on our three areas of focus, or our “Strategic Triangle,” and the full value of our diverse portfolio. In particular, 2022 is shaping up to be a pivotal year for some of our major clinical and product development initiatives with the commercialization of Essenz, and data readouts for RECOVER and ANTHEM-HFrEF all expected to occur before year end.

## Operational Excellence- Improving Profitability and Cash Generation

Our commitment to operational excellence is captured in our LivaNova Business System (LBS), our guide to excellence in how we operate and the framework by which we continuously improve our business. This includes expanding LBS across the Company to enhance operational excellence.

In 2021, we employed our LBS framework to drive continued focus on increasing cash generation and operating profitability, rightsizing our cost structure, improving margins and investing in our core growth drivers and SPIs. In 2021, we generated \$84 million in adjusted free cash flow as compared to \$24 million in the prior year, improved adjusted operating margin by 500 basis points and maintained adjusted R&D of approximately 16% of sales.

During 2021, we also strengthened our balance sheet and financial position by completing an equity offering, raising \$323 million of net proceeds, allowing the early retirement of a \$450 million term loan, as well as by executing a \$125 million secured revolving credit facility that is available for general corporate purposes. Additionally, during 2021, we completed the sale of our heart valve business, enabling us to sharpen our focus on our primary Cardiopulmonary, Neuromodulation and ACS segments.

## Environmental, Social and Governance (ESG)

We recognize the growing importance of ESG. As a global medical technology company, we are committed to fostering a

sustainable business that supports the well-being of our patients, employees and communities. To help achieve this, we integrate ESG objectives into our decision making to deliver long-term value to our stakeholders. We continued to evolve our ESG initiative by establishing a cross-functional ESG Task Force and including a dedicated item on our Board Nominating and Corporate Governance Committee agenda for ESG matters.

During 2021, the ESG Task Force organized a framework around various LivaNova ESG efforts, culminating in the creation of a Sustainability section on the Company website. The Task Force continues to implement actionable strategies while ensuring alignment with our 2022 strategic priorities.

## Outlook

While the world has entered 2022 with continued uncertainty, we remain committed to delivering on our three areas of focus, or our “Strategic Triangle,” and the full value of our diverse portfolio. In particular, 2022 is shaping up to be a pivotal year for some of our major clinical and product development initiatives with the commercialization of Essenz, and data readouts for RECOVER and ANTHEM-HFrEF all expected to occur before year end.

We believe that we are well positioned to execute on our 2022 goals and look forward to providing updates on our progress throughout the year. On behalf of LivaNova, our Board of Directors and approximately 3,000 colleagues around the world who are all united by our mission, we would like to express our sincere appreciation for your investment, continued trust and support in our journey of life-saving and life-changing innovation.



**William Kozy**  
Chair of the Board of Directors



**Damien McDonald**  
Chief Executive Officer

Note: The shareholder letter contains forward-looking statements, including statements about LivaNova's plans, strategies, financial performance and outlook. Factors that could cause actual results to differ materially from management's expectations are disclosed in LivaNova's most recent filings with the U.S. Securities and Exchange Commission, including its Annual Report on Form 10-K for the year ended December 31, 2021 (included herewith) and its Quarterly Reports on Form 10-Q. The shareholder letter also contains non-GAAP financial measures. See the tables below for a reconciliation of these measures to the most directly comparable GAAP measures.

## RECONCILIATION OF GAAP TO NON-GAAP FINANCIAL MEASURES – UNAUDITED

Twelve Months Ended December 31, 2021

	GAAP Financial Measures	Depreciation and Amortization Expenses (A)	Heart Valves (B)	Product Remediation Expenses (C)	Certain Legal, Contingent Consideration and Other (E)	Stock-based Compensation Costs (F)	Merger and Integration Expenses (G)	Restructuring Expenses (H)	Adjusted Financial Measures
Research & Development %	17.7%	--	--	--	(1.1)%	(0.8)%	--	--	15.8%
Operating Margin %	(0.1)%	2.7%	0.2%	0.1%	7.2%	3.9%	0.1%	0.9%	15.0%

Twelve Months Ended December 31, 2020

	GAAP Financial Measures	Depreciation and Amortization Expenses (A)	Heart Valves (B)	Product Remediation Expenses (C)	Financing Transactions (D)	Certain Legal, Contingent Consideration and Other (E)	Stock-based Compensation Costs (F)	Merger and Integration Expenses (G)	Restructuring Expenses (H)	Adjusted Financial Measures
Research & Development %	16.4%	--	--	--	--	0.2%	(0.4)%	--	--	16.2%
Operating Margin %	(29.3)%	4.4%	22.3%	0.8%	0.3%	6.2%	3.8%	0.8%	0.8%	10.0%

GAAP results include:

- (A) Includes depreciation and amortization associated with purchase price accounting.
  - (B) Loss associated with the sale of Heart Valves in the twelve-month period ending December 31, 2021, and impairment primarily associated with the classification of Heart Valves as held for sale in the twelve-month period ending December 31, 2020.
  - (C) Costs related to the 3T Heater-Cooler remediation plan.
  - (D) Costs associated with the June 2020 financing transactions, including the mark-to-market adjustment for the exchangeable option feature and capped call derivatives.
  - (E) 3T Heater-Cooler litigation provision, legal expenses primarily related to 3T Heater-Cooler defense, settlements and other matters, remeasurement of contingent consideration related to acquisitions, and for the twelve-month period ending December 31, 2021, includes, gain from remeasurement of an investment and dividend income, and for the twelve month-period ending December 31, 2020, provision for decommissioning at our Saluggia site.
  - (F) Non-cash expenses associated with stock-based compensation costs.
  - (G) Merger and integration expenses related to our legacy companies and recent acquisitions.
  - (H) Restructuring expenses related to organizational changes.
- \* Numbers may not add precisely due to rounding.

## ADJUSTED FREE CASH FLOW RECONCILIATION – UNAUDITED

(U.S. dollars in millions)

	Twelve Months Ended December 31,	
	2021	2020
Net cash provided by (used in) operating activities	\$102.5	\$(79.2)
Less: Purchases of plant, property and equipment	(25.5)	(35.0)
Less: Cash received from tax stimulus	(24.5)	--
Less: Dividends received from investment	(3.4)	--
Add: 3T litigation payments	34.8	138.2
Adjusted free cash flow	<b>\$84.0</b>	<b>\$24.0</b>

## NET SALES: COMPARISON OF ACTUAL RESULTS TO CONSTANT CURRENCY – UNAUDITED <sup>(1)</sup>

(U.S. dollars in millions)

	Twelve Months Ended December 31,		% Change at Actual Currency Rates	% Change at Constant-Currency Rates
	2021	2020		
Total Net Sales	\$1,035.4	\$934.2	10.8%	9.7%
Less: Heart Valves net sales <sup>(2)</sup>	36.2	88.0	**	**
Total Net Sales, Excluding Heart Valves	<b>\$999.2</b>	<b>\$846.2</b>	<b>18.1%</b>	<b>17.1%</b>

(1) Constant-currency growth, a non-GAAP financial measure, measures the change in sales between current and prior-year periods using average exchange rates in effect during the applicable prior-year period.

(2) Includes results for the Heart Valves business, which was divested effective June 1, 2021.

\* Numbers may not add or recalculate precisely due to rounding.

\*\* Indicates that variance as a percentage is not meaningful.

## Board of Directors

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### **William Kozy**

Chair of the Board, LivaNova.  
Former Executive Vice President and Chief Operating Officer at Becton, Dickinson and Company.

### **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**

Chair 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.

### **Daniel Moore**

Former Chief Executive Officer and member of the board of directors of Cyberonics.

### **Alfred J. Novak**

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

### **Dr. Sharon O’Kane**

Non-executive director of Health Products Regulatory Authority Board in Ireland.  
Co-Founder and former Chief Scientific Officer and Executive Director of Renovo Group.

### **Dr. Arthur L. Rosenthal**

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

### **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**

Chief Financial Officer

### **Keyna Skeffington**

Senior Vice President,  
General Counsel  
and Company Secretary

### **Stephanie Bolton**

President, International Region

### **Paul Buckman**

President, Advanced Circulatory Support

### **Matthew Dodds**

Senior Vice President,  
Corporate Development and IT

### **Marco Dolci**

President, Cardiopulmonary

### **Trui Hebbelink**

Chief Human Resources Officer

### **Ryan Miller**

Senior Vice President, Strategy

### **Bryan Olin, PhD**

Senior Vice President and  
Head of Product Development,  
Neuromodulation

## Key Worldwide Locations

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### **Europe**

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

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

### **North America**

Houston, Texas  
Arvada, Colorado  
Pittsburgh, Pennsylvania

### **South America**

Sao Paulo, Brazil

### **Asia-Pacific**

Melbourne, Australia  
Shanghai, China  
Singapore  
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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