

LivaNova

Health innovation that matters

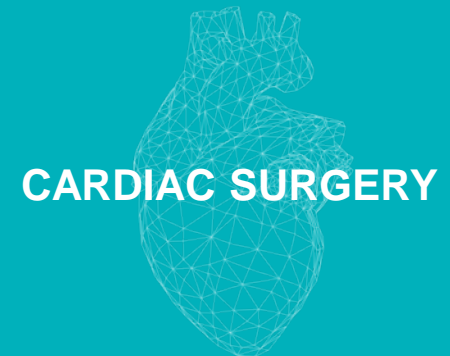
LivaNova Investor Day

Strategy

Damien McDonald

Chief Executive Officer

September 14, 2017



Safe Harbor Statement

Certain statements in this presentation, other than purely historical information, are “forward-looking statements” within the meaning of the Private Securities Litigation Reform Act of 1995, Section 27A of the Securities Act and Section 21E of the Securities Exchange Act of 1934, as amended (the “Exchange Act”). These statements include, but are not limited to, LivaNova’s plans, objectives, strategies, financial performance and outlook, trends, the amount and timing of future cash distributions, prospects or future events and involve known and unknown risks that are difficult to predict. As a result, our actual financial results, performance, achievements or prospects may differ materially from those expressed or implied by these forward-looking statements. In some cases, you can identify forward-looking statements by the use of words such as “may,” “could,” “seek,” “guidance,” “predict,” “potential,” “likely,” “believe,” “will,” “should,” “expect,” “anticipate,” “estimate,” “plan,” “intend,” “forecast,” “foresee” or variations of these terms and similar expressions, or the negative of these terms or similar expressions. Such forward-looking statements are necessarily based on estimates and assumptions that, while considered reasonable by LivaNova and its management based on their knowledge and understanding of the business and industry, are inherently uncertain. These statements are not guarantees of future performance, and stockholders should not place undue reliance on forward-looking statements. There are a number of risks, uncertainties and other important factors, many of which are beyond our control, that could cause our actual results to differ materially from the forward-looking statements contained in this press release, including those described in the “Risk Factors” section of Annual Reports on Form 10-K, Quarterly Reports on Form 10-Q, Current Reports on Form 8-K, the Registration Statement on Form S-4 and other documents filed from time to time with the United States Securities and Exchange Commission by LivaNova.

The Company does not undertake or assume any obligation to update publicly any of the forward-looking statements in this presentation to reflect actual results, new information or future events, changes in assumptions or changes in other factors affecting forward-looking statements, except to the extent required by applicable law. If we update one or more forward-looking statements, no inference should be drawn that we will make additional updates with respect to those or other forward-looking statements. We caution you not to place undue reliance on any forward-looking statements, which are made only as of the date of this presentation.

We are a \$1.2B focused medical innovator

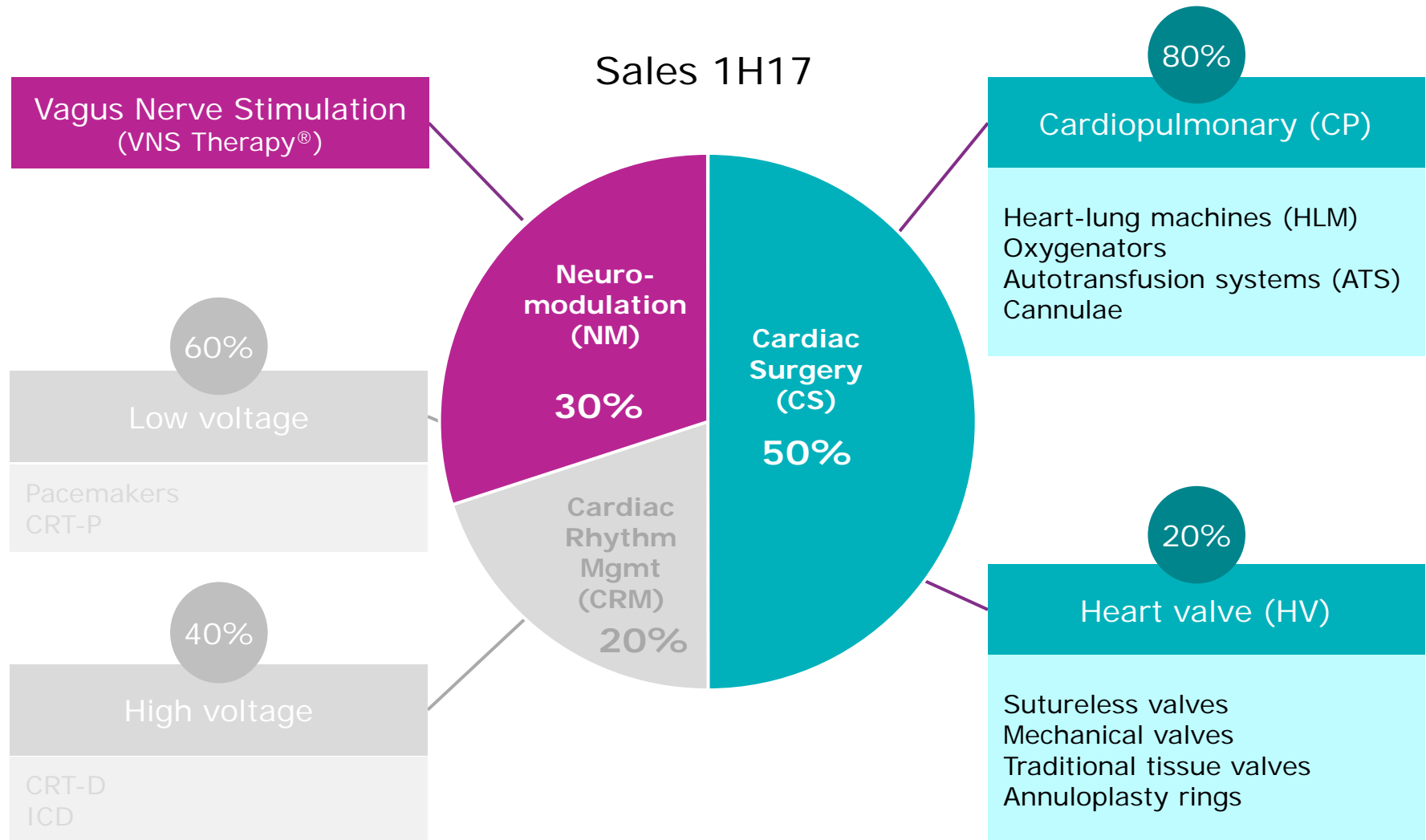
Improving quality of
patients' lives

Strong leadership
position in
Neuromodulation and
Cardiac Surgery

Targeting underserved
and high-growth
market segments



Leading positions in critical areas of treatment



Exploring strategic options for Cardiac Rhythm Management

Sharpening our focus on areas of strength and market leadership

Committed to ensuring portfolio is optimally positioned to deliver long-term value

CRM is no longer a fit within LivaNova's portfolio, but is a global business with attractive assets, a robust pipeline and growth potential

No timeline for completion of the process has been set

Do not intend to disclose further developments until a definitive decision has been reached



Committed to ensuring portfolio is optimally positioned to deliver long-term value

Leading positions in Neuromodulation and Cardiac Surgery

Innovative technology focusing on high-margin products

Targeting high-growth and underserved markets

Executing disciplined portfolio management to strengthen and enhance category leadership

New management team has strategy to deliver enhanced shareholder value

LivaNova:
An attractive
long-term
investment

Focusing portfolio on “Head & Heart”

	NEUROMODULATION	CARDIAC SURGERY	
		CARDIOPULMONARY	HEART VALVES
	Creator, leader of VNS Therapy	Market-leading positions	Only sutureless valve on the market
Global Market (2016)*	\$4.1B	\$2.0B	\$1.7B
Market Growth	Low-double-digit	Low-single-digit	Low-single-digit
Sales (2016)*	\$350M	\$475M	\$140M
Disease State	Drug-resistant epilepsy Treatment-resistant depression (TRD)	Heart valve disease Coronary disease Congenital heart defect Heart failure	
Customers	Neurologists Epileptologists Psychiatrists Neurosurgeons Patients	Perfusionists Cardiac Surgeons Cardiologists	

Our portfolio has multiple near-term growth drivers

NEUROMODULATION

AspireSR® advances the science of VNS Therapy®



100,000
patients treated with
VNS Therapy

CARDIAC SURGERY

S5® HLM reduces transfusions and improves recovery



40
years as market
leader in
heart-lung machines

Inspire® oxygenator provides personalized perfusion



750,000+
patients treated
with Inspire

Perceval® optimizes the surgical approach to sutureless aortic valve replacement



10
years of clinical use

Our portfolio has multiple mid- to long-term growth drivers: strategic portfolio initiatives

TREATMENT-RESISTANT DEPRESSION

VNS Therapy may provide better outcomes and symptom improvement



Depression is the leading cause of disability worldwide

TRANSCATHETER MITRAL VALVE REPLACEMENT

Unique transseptal investigational device



2-3 times the size of aortic market opportunity

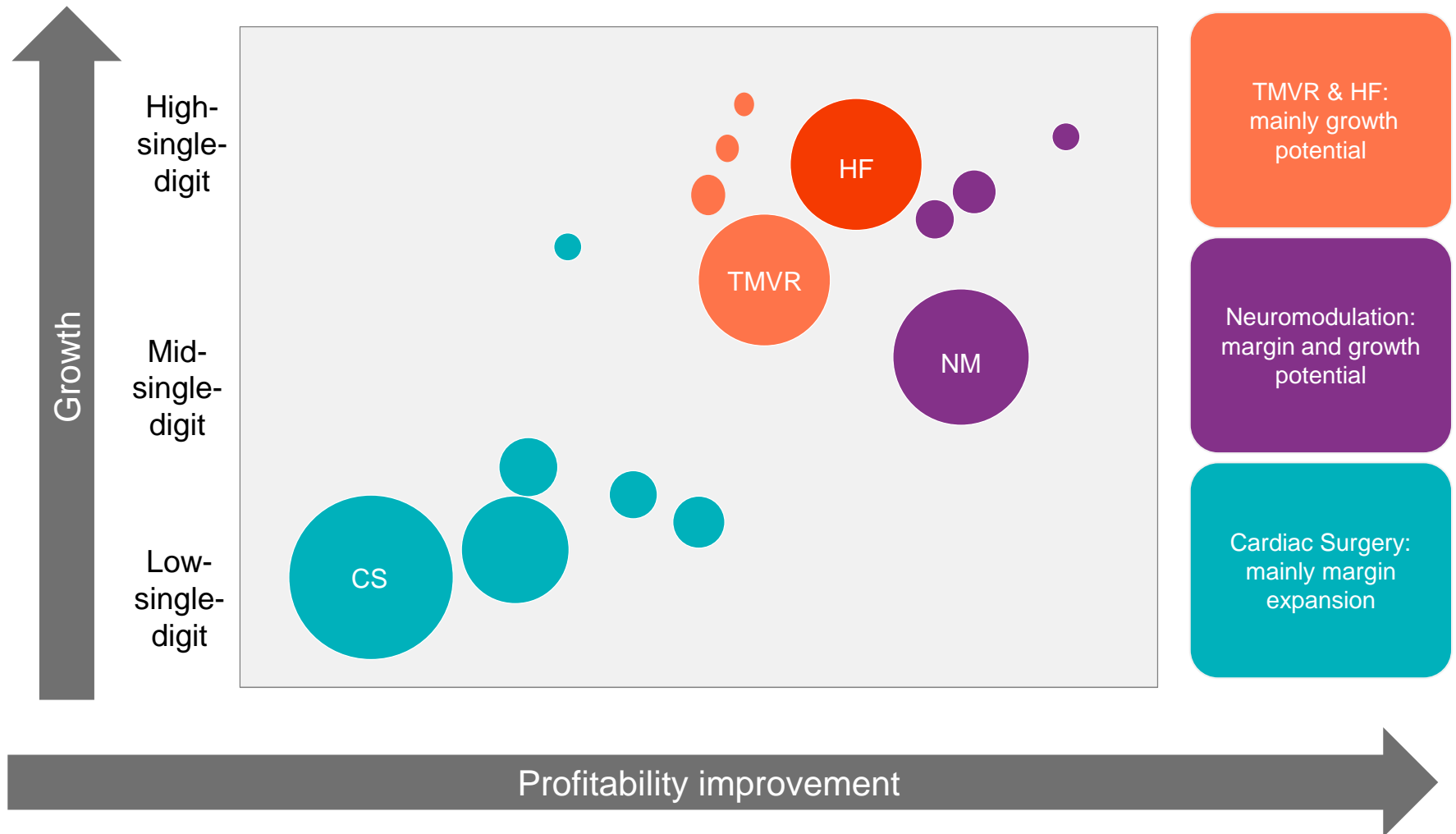
CHRONIC HEART FAILURE

Novel delivery of Autonomic Regulation Therapy (ART) may improve regulation of cardiovascular function

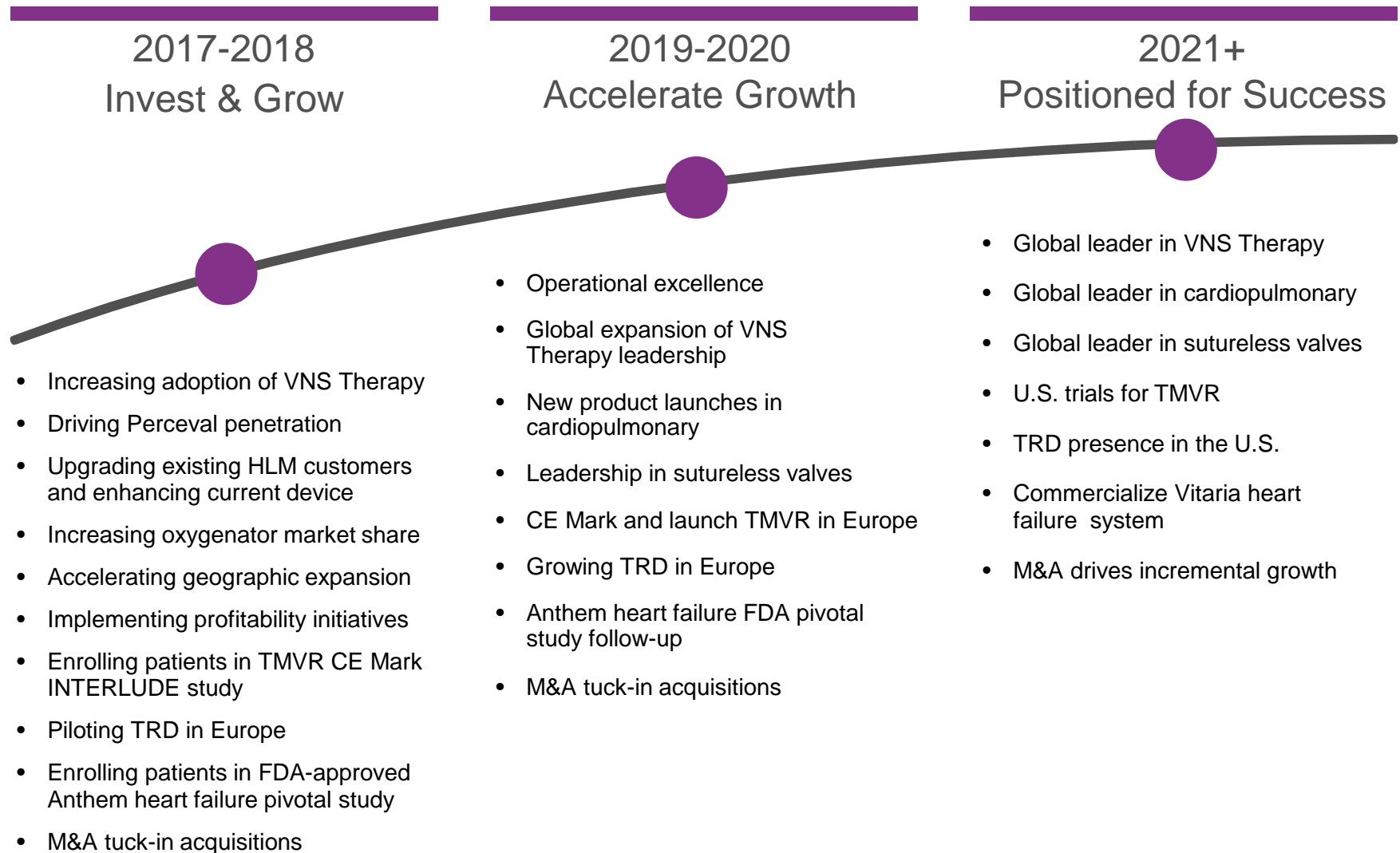


Leading cause of morbidity and mortality

M&A strategy targets growth and margin expansion



Clear roadmap for value creation



Four pillars to transform the organization



Strategy to accelerate growth

Drive demand

Build pipeline

Expand portfolio

LivaNova
Sales Force Effectiveness
KPIs

Target to Improve
Set targets in order of priority according to top level PD matrix

Owner	YTD	JAN	FEB	MAR	APR	MAY	JUN	JUL	AUG	SEP	OCT	NOV	DEC
Level 1 KPIs													
CP - levels (low - 1 / rep / quarter)	0.0	Plan							9.0	9.0	9.0	9.0	9.0
	0.0	Act											
	0.0	Var											
	0.0	PV											
AV - % of Target accounts implanting (have implanted regularly in last 2 months)	0%	Plan	0%	0%	0%	0%	0%	0%	0%	0%	0%	0%	0%
	0%	Act	0%	0%	0%	0%	0%	0%	0%	0%	0%	0%	0%
	0%	Var	0%	0%	0%	0%	0%	0%	0%	0%	0%	0%	0%
	0%	PV	0%	0%	0%	0%	0%	0%	0%	0%	0%	0%	0%
AV - Personal Average Daily Sales Units (ADU)	0.0	Plan	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0
	0.0	Act	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0
	0.0	Var	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0
	0.0	PV	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0
NMI - # new implants / rep / week	0.0	Plan	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0
	0.0	Act	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0
	0.0	Var	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0
	0.0	PV	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0
CRM - Active Implants / rep / mo	0.0	Plan	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0
	0.0	Act	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0
	0.0	Var	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0
	0.0	PV	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0
CRM - Maintain tachy revenue mix @ 70%	0%	Plan	0%	0%	0%	0%	0%	0%	70%	0%	0%	0%	0%
	0%	Act	0%	0%	0%	0%	0%	0%	0%	0%	0%	0%	0%
	0%	Var	0%	0%	0%	0%	0%	0%	0%	0%	0%	0%	0%
	0%	PV	0%	0%	0%	0%	0%	0%	0%	0%	0%	0%	0%
Level 2 KPIs													
Open territories	0.0	Plan	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0
	0.0	Act	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0
	0.0	Var	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0	0.0

Level 3 KPIs

of positions that...

of regions (SC)

Organizational Chart

Flowchart: Change Approval Process

1. User proposed change
Change Approval Process

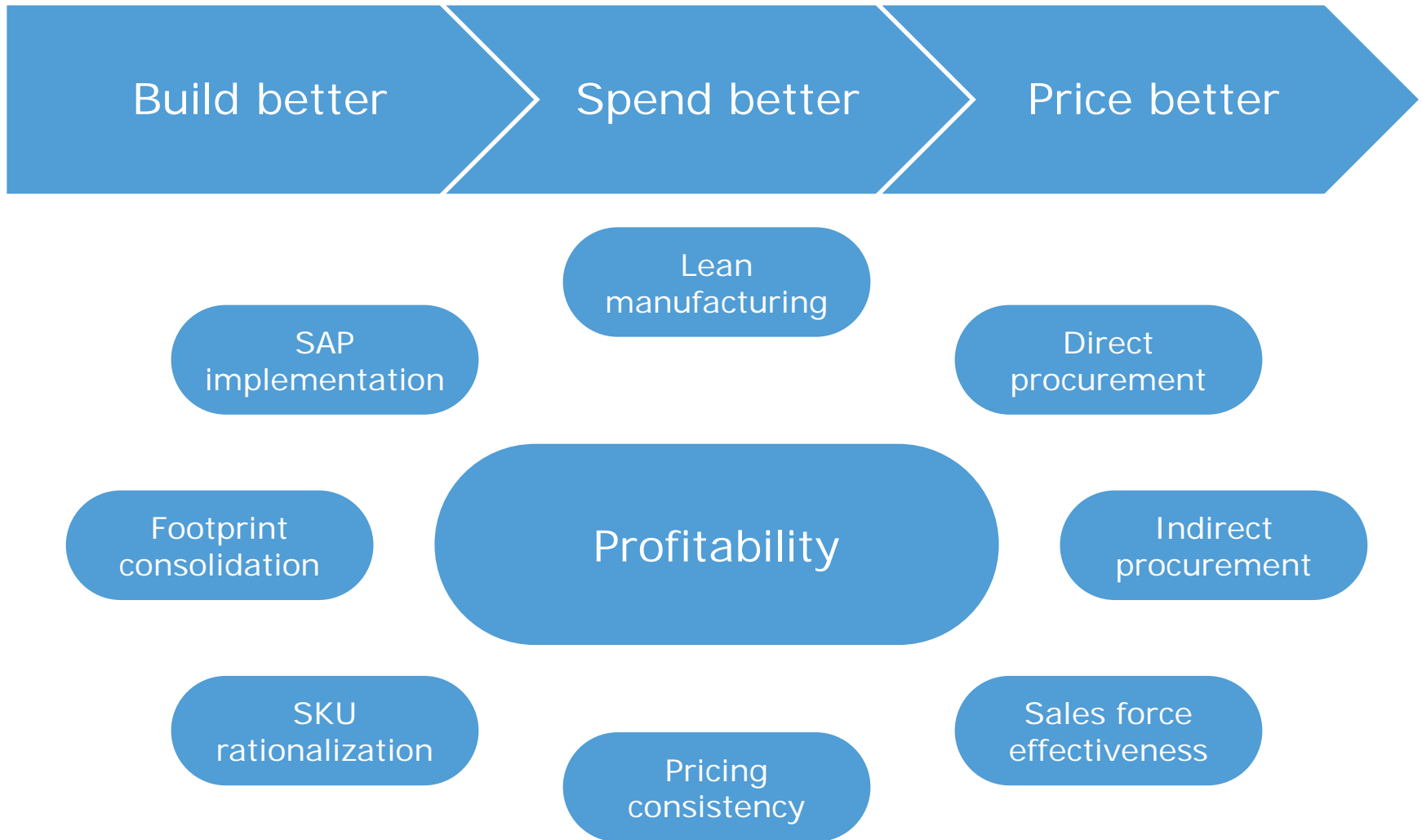
Project Manager/ME Contractor Integrated Digital Tools (PTE) Executive Oversight Board (EOR)

Decision points: Is the change a major change? Is the change a minor change? Is the change a critical change?

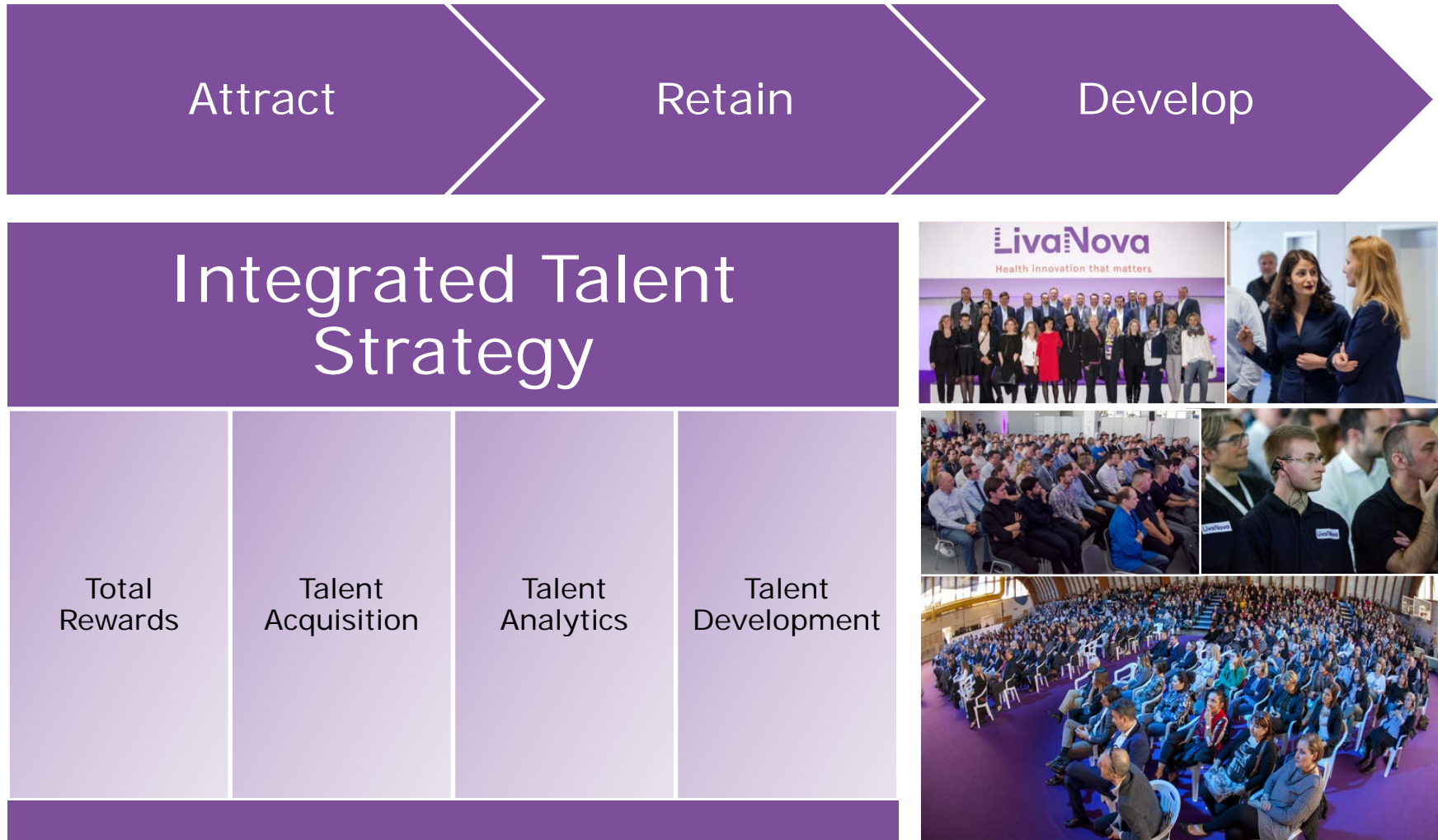
Flow: Proposed Change → Review → Approval/Rejection → Implementation/Reporting



Significant opportunities to improve profitability



Attracting new talent and developing existing talent

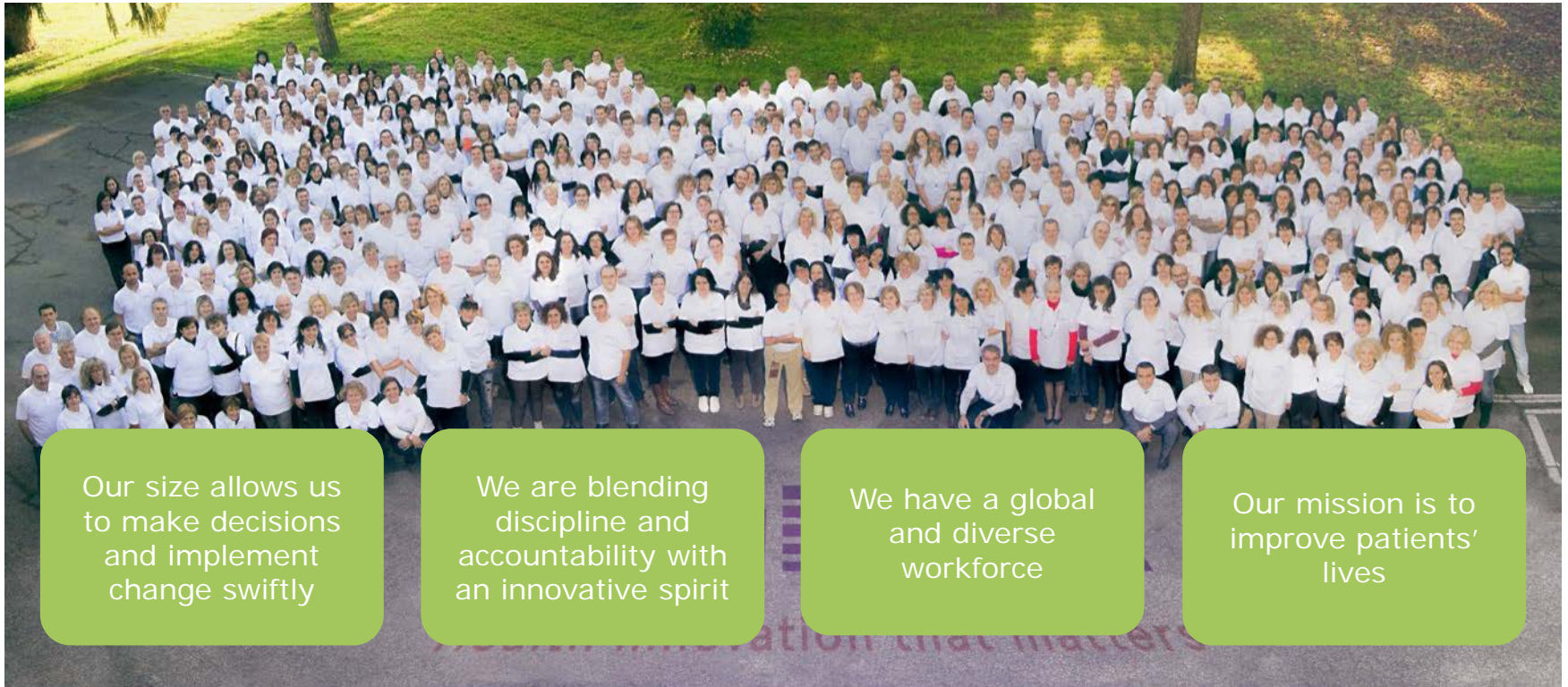


Creating a culture of continuous improvement

Discipline

Accountability

Teamwork



Our size allows us to make decisions and implement change swiftly

We are blending discipline and accountability with an innovative spirit

We have a global and diverse workforce

Our mission is to improve patients' lives

We are a compelling investment

Leadership positions in most of our served markets

Innovative products with patient/physician benefits

Significant barriers to entry

Opportunities for geographical expansion

Multiple drivers to accelerate growth

Executing on initiatives for margin expansion

We are poised for success

Growing	Top and bottom line	<ul style="list-style-type: none">• Large, globally expanding markets• Broad geographic presence• Growing positions in head and heart• Customer-centric innovation• Realizing capital and operational efficiencies
Transforming	Organization	<ul style="list-style-type: none">• Four pillars transforming organization• Growth, profitability, talent, culture
Creating	Value	<ul style="list-style-type: none">• Clear roadmap for value creation• Invest and grow• Accelerate growth• Positioned for success

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LivaNova Investor Day

Financial Outlook

Thad Huston

Chief Financial Officer

September 14, 2017

NEUROMODULATION



CARDIAC SURGERY

First-half 2017: measurable growth across the company

Strong earnings
performance based on
expanding margins,
disciplined spending and
focused R&D

Solid cadence of
customer-centric new
product innovation

Executing on integration
of Caisson acquisition

On track to meet \$80M
synergy targets by end
of 2018

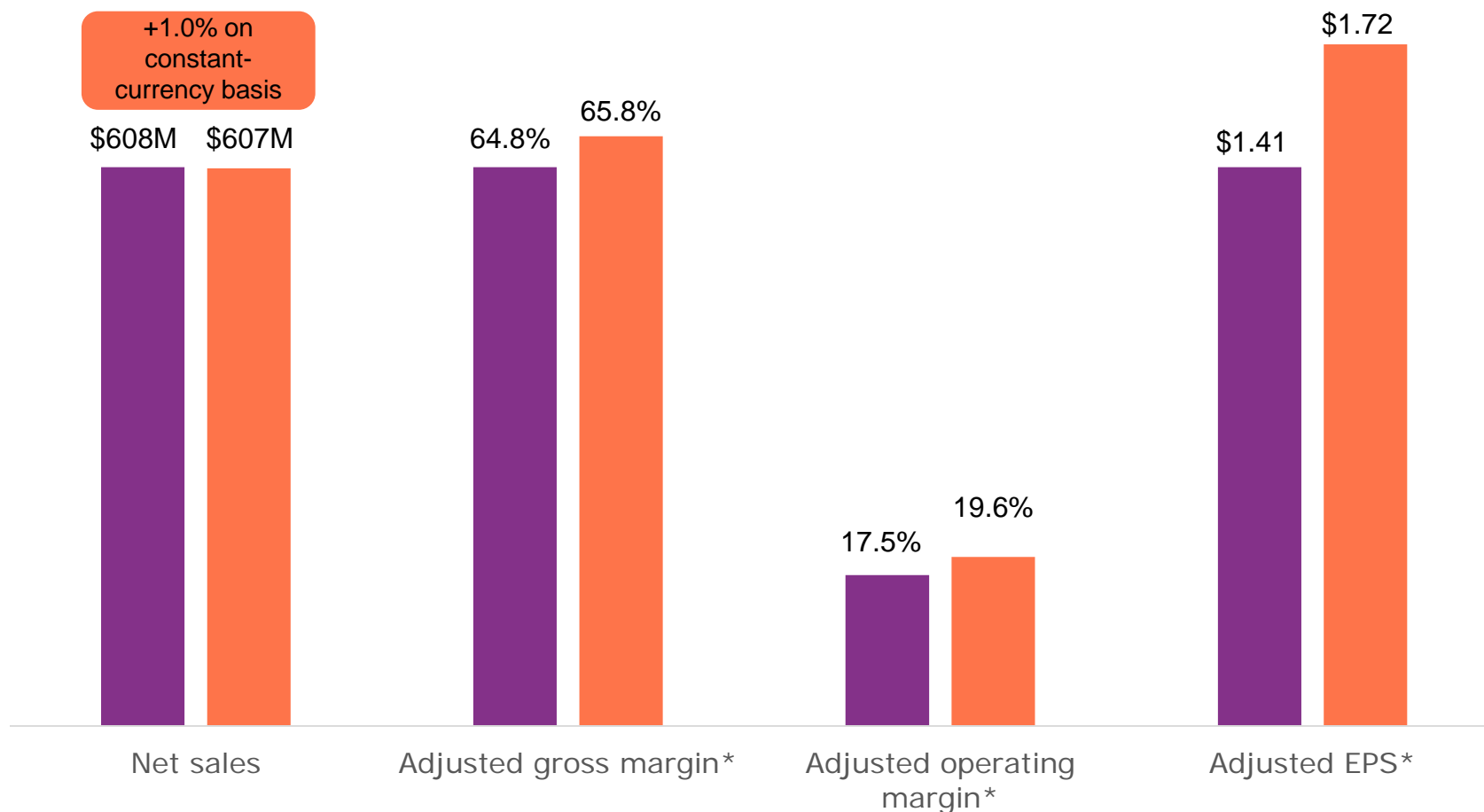
Improved in-channel
inventory levels and
enhanced distributor
relationships

Strong balance sheet,
low net debt

Improving margins and delivering on our commitments

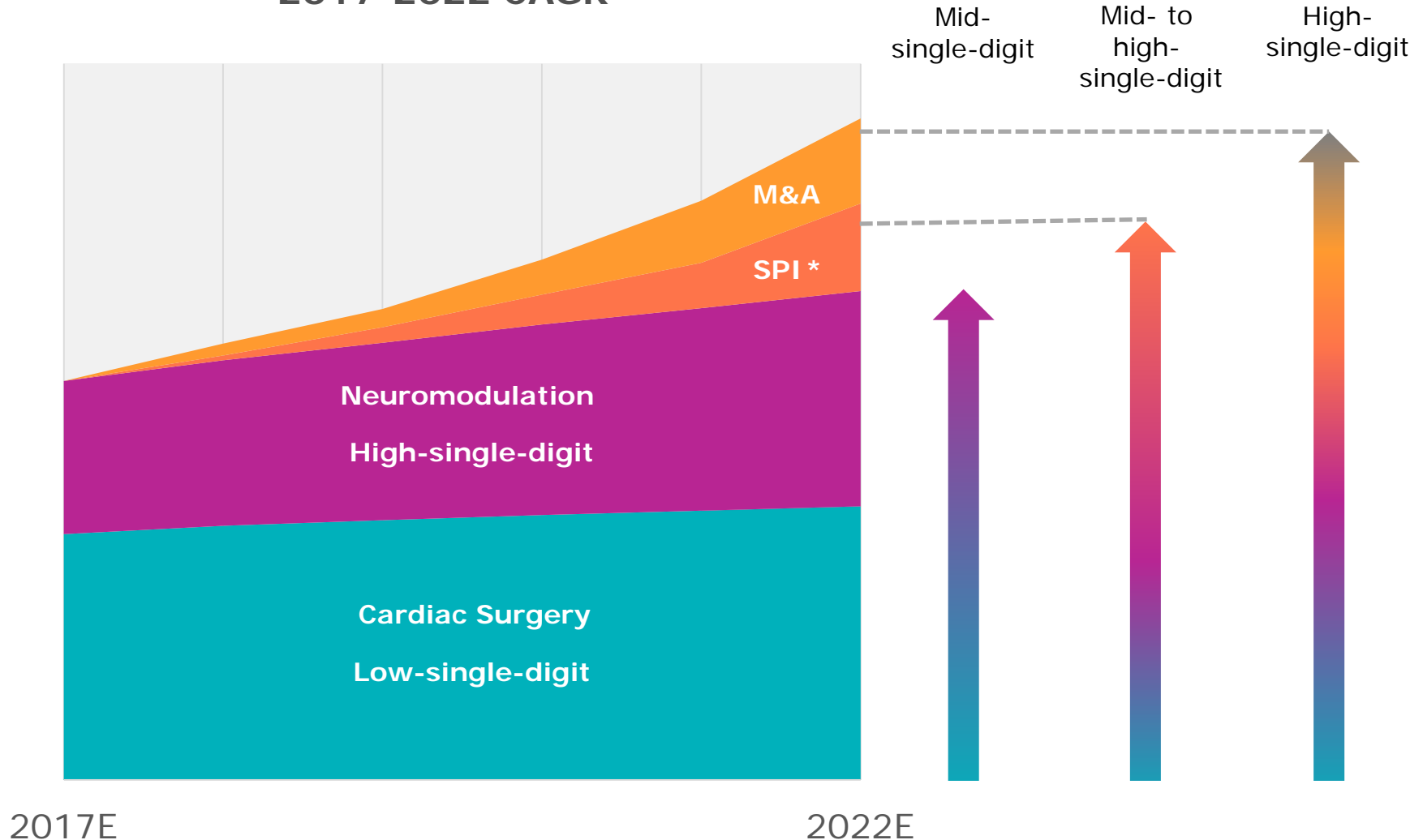
1H16

1H17



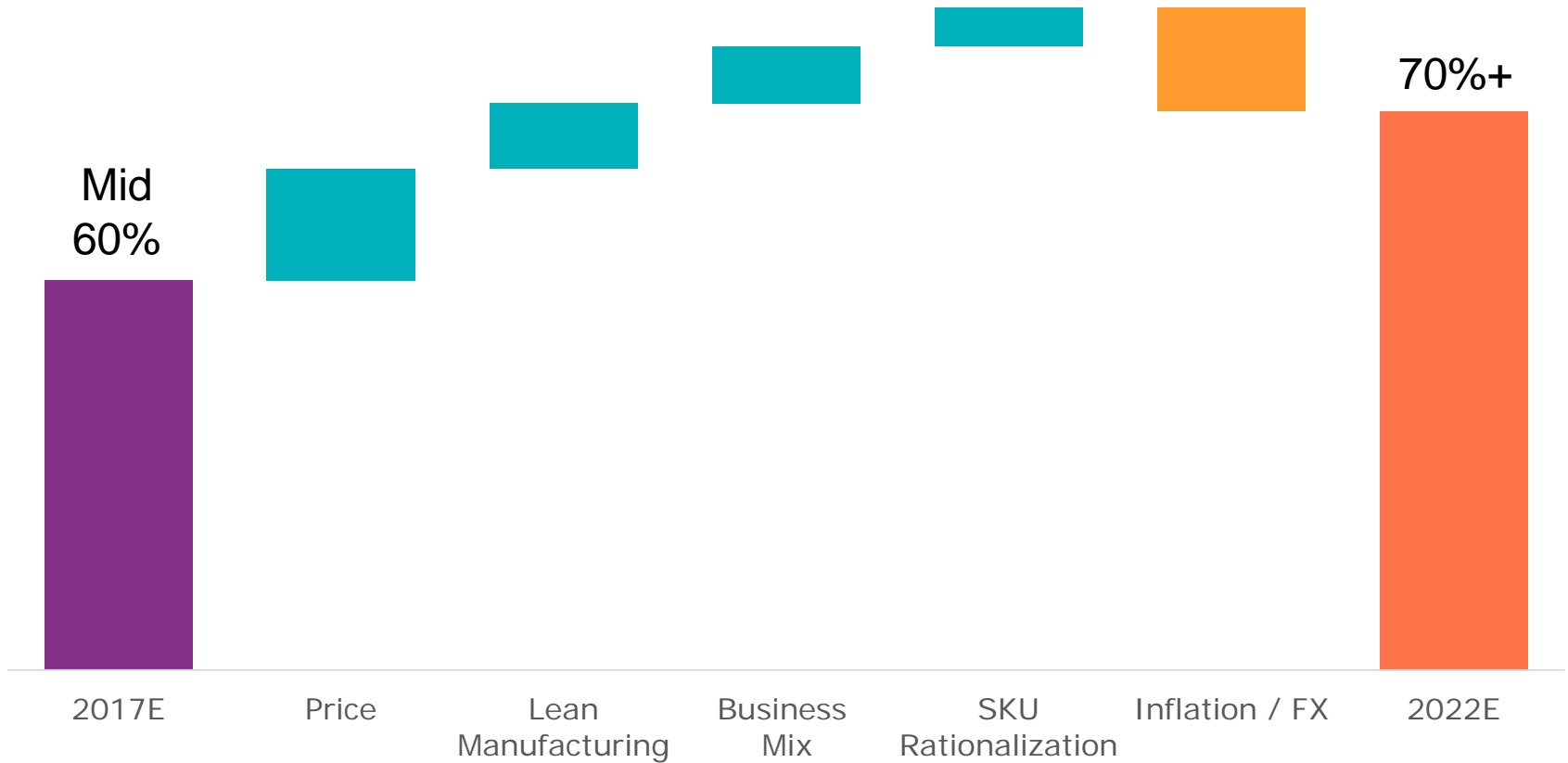
Building a strong future through top line growth

2017-2022 CAGR



Expanding our gross margins

Gross margin* as a percentage of revenues

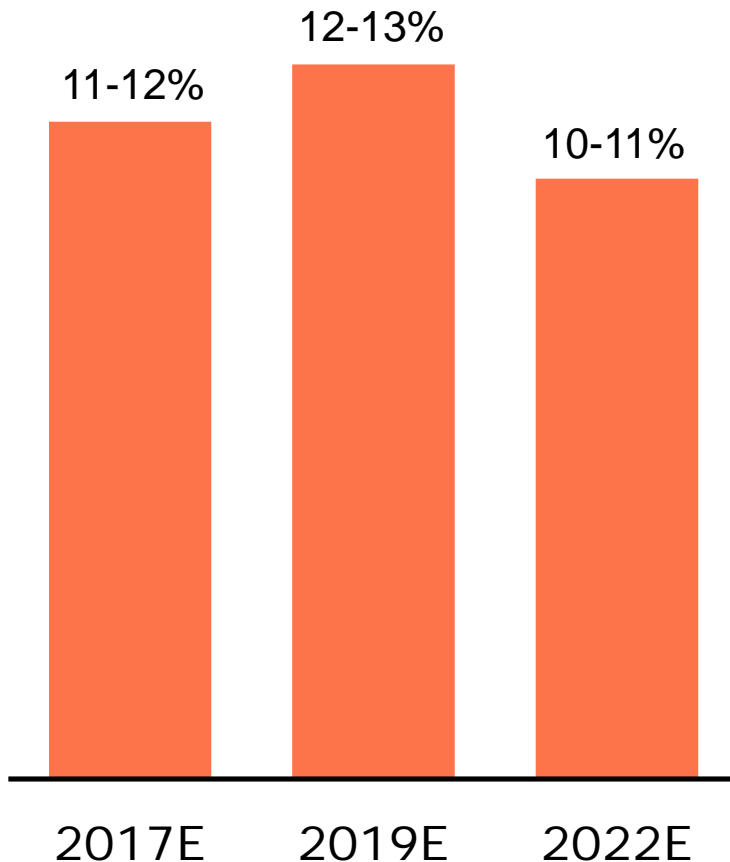


Executing on initiatives to drive profitability

1	COGS	Direct procurement	Central purchasing aligned by common strategy across functions
2		Lean manufacturing	Identify and replicate best practices, apply strict performance management
3		SKU rationalization	Streamlining product portfolio and focusing on high gross margin products
4		Footprint consolidation	Global real estate review, including facilities and offices
5	SG&A	Indirect procurement	Comprehensive focus on vendor negotiations and management
6		SG&A post-merger integration	A global integrated shared services model for finance, HR, IT and marketing

Invest in R&D today to drive growth tomorrow

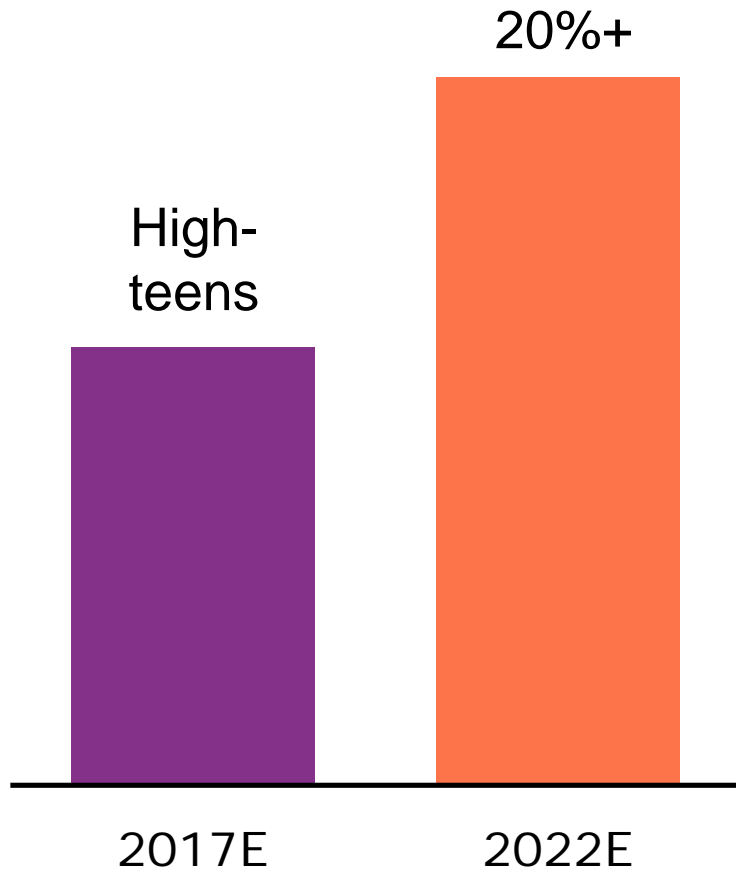
R&D* as a percentage of revenues



- In 2016/2017, prior to Caisson acquisition, R&D* expense was 9-11% of net sales
- R&D profile will increase mid-term to support investment in portfolio expansion
- Expanding margins enable longer-term R&D investments

Expanding operating margins

Operating income* as percentage of revenues



Gross margin expansion

SG&A reduction

R&D investment

Projecting strong growth in earnings per share

2017 - 2022
CAGR

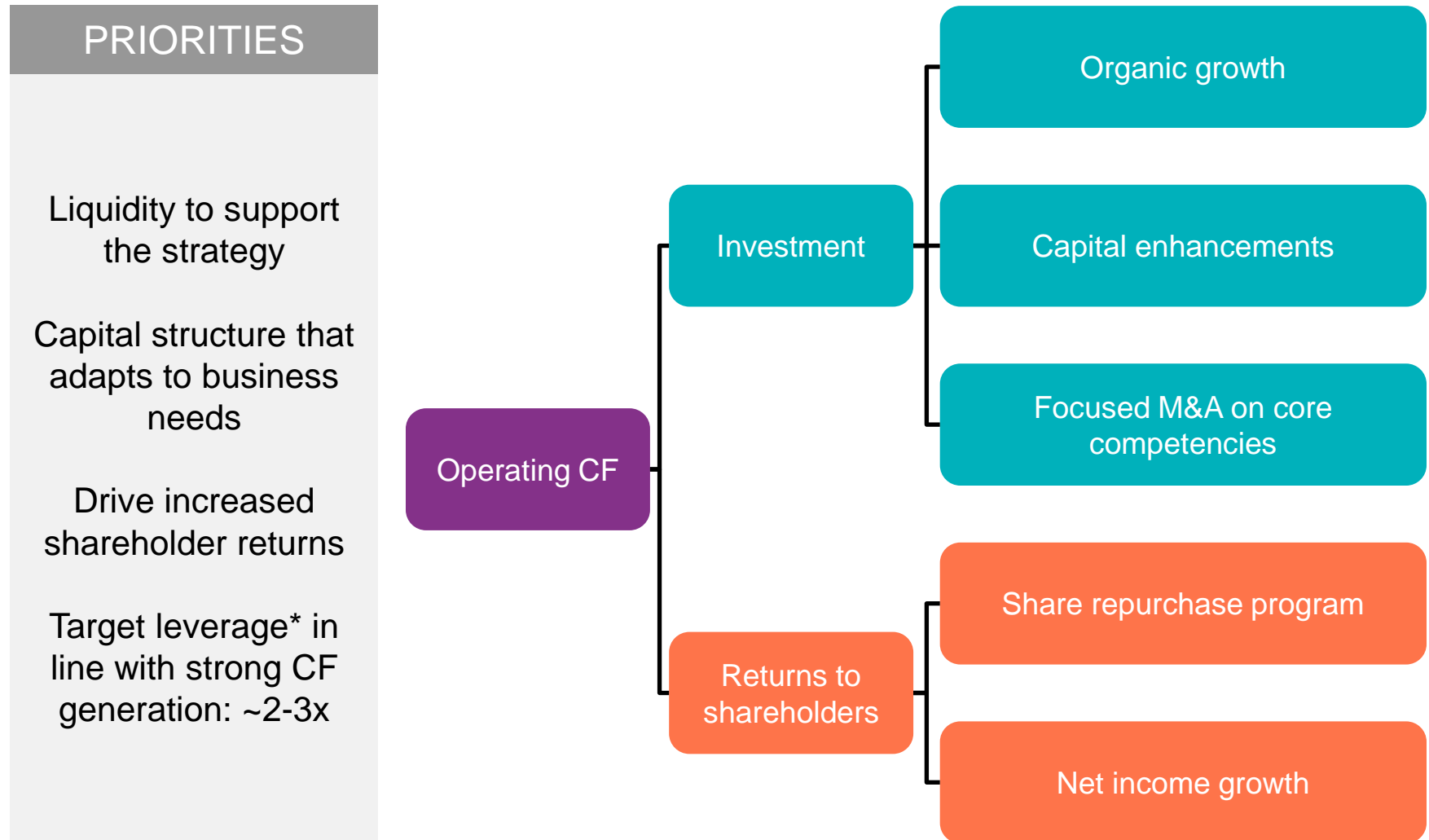


EPS*

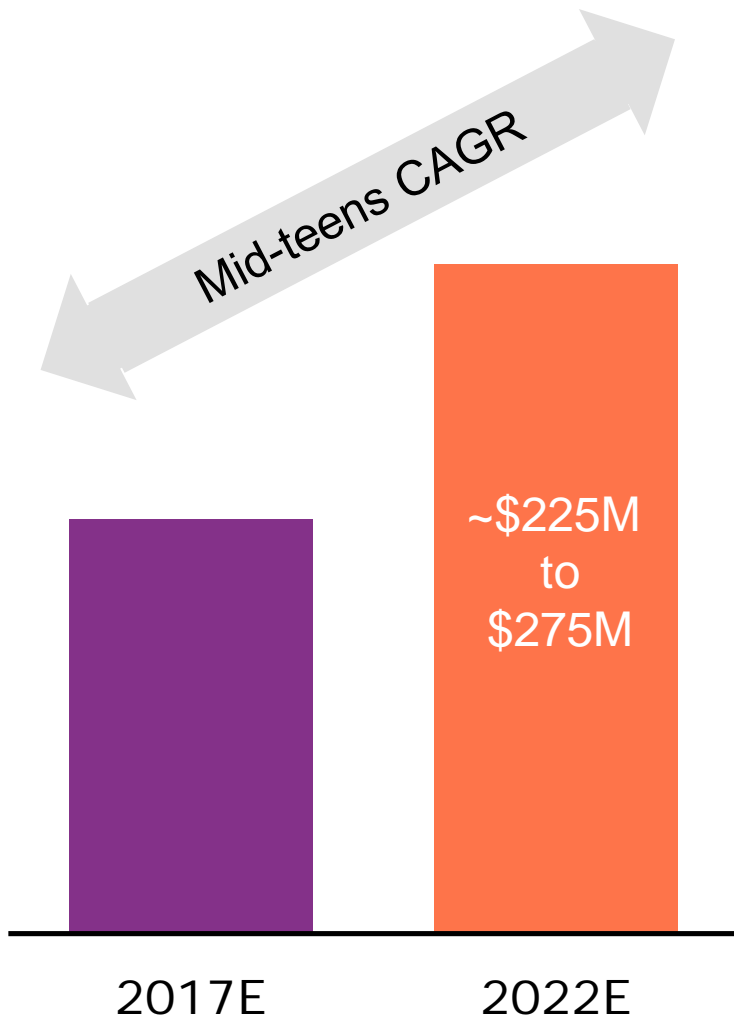


Low- to
mid-teens

Focused capital allocation strategy



Delivering strong free cash flow* growth



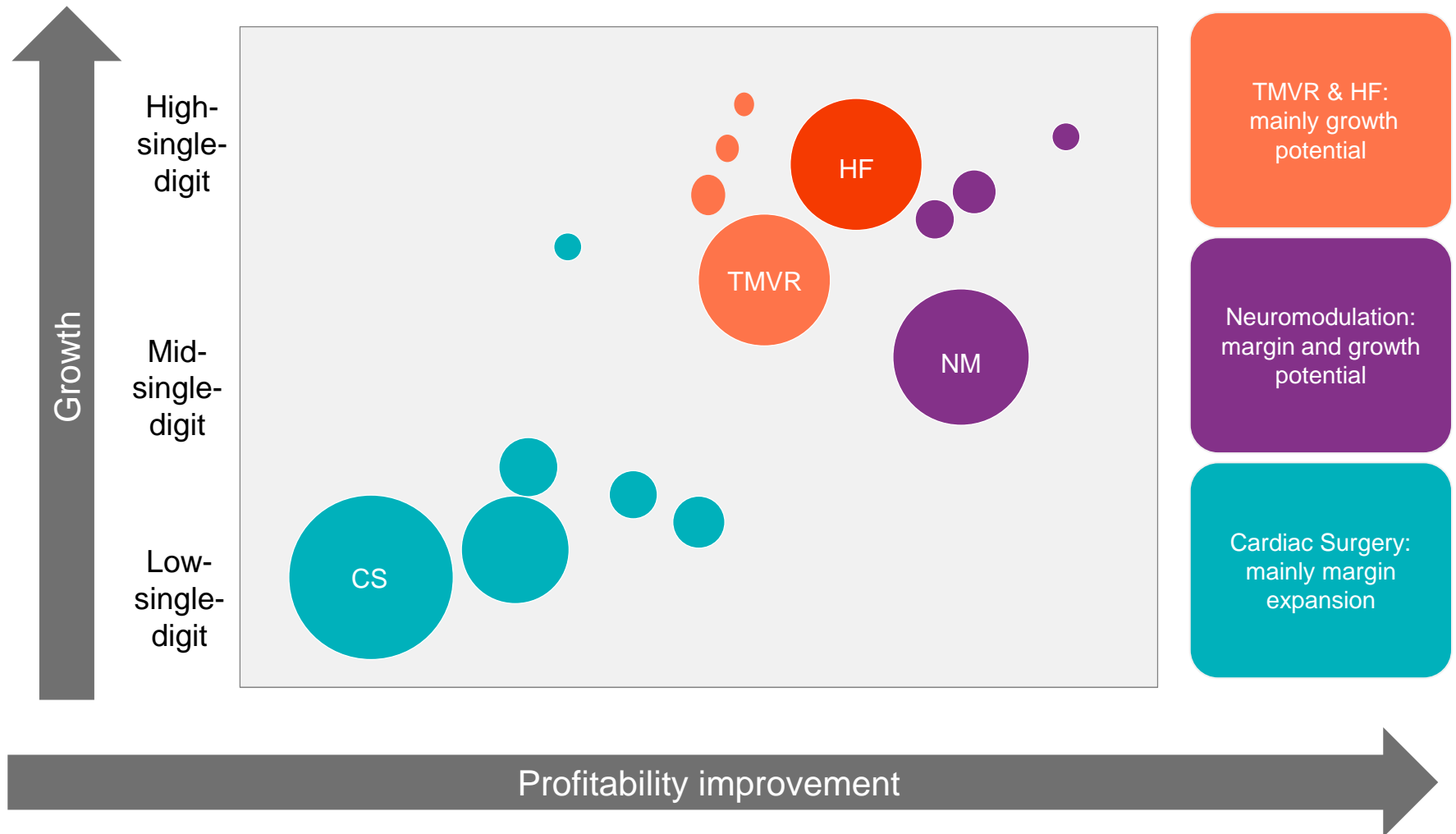
Net income is a key driver of growth

Improving cash conversion

Working capital improvements contribute to FCF through 2022

Future growth will support M&A

M&A strategy targets growth and margin expansion



Driving shareholder value creation

REVENUE GROWTH	Mid- to high- single-digit CAGR	<ul style="list-style-type: none">• Large, globally expanding markets• Broad geographic presence• Accelerating growth through execution, innovation and M&A
EPS GROWTH	Low- to mid- teens CAGR	<ul style="list-style-type: none">• Executing initiatives to improve profitability• R&D investments drive future growth• Driving toward peer margin benchmark levels longer term
CAPITAL ALLOCATION	Disciplined, focused deployment	<ul style="list-style-type: none">• Plan to improve working capital• Leveraging strong balance sheet• Disciplined, focused M&A strategy

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Appendix

RECONCILIATION OF GAAP TO NON-GAAP FINANCIAL MEASURES (UNAUDITED)

Six Months Ended June 30, 2017	Sales	Gross Profit	Income from Operations	Net Income	Diluted EPS
GAAP Financial Measures	\$606.5	\$395.2	\$49.7	\$58.8	\$1.22
Specified Items					
Merger and integration expenses (A)			4.8	3.6	0.07
Restructuring expenses (B)			11.3	9.1	0.19
Depreciations and amortization (C)		2.6	26.4	19.8	0.41
Product remediation (D)		0.9	0.9	0.7	0.01
Caisson acquisition (E)		0.2	12.1	(30.1)	(0.62)
Highlife impairment (F)				13.0	0.27
Other income / (expenses) & litigations (G)			5.5	0.5	0.01
Equity compensation (H)		0.1	8.6	7.1	0.15
Certain tax adjustments (I)				0.4	0.01
Adjusted financial measures	\$606.5	\$399.0	\$119.1	\$82.9	\$1.72

GAAP results for the six months ended June 30, 2017 include:

- (A) Merger and integration expenses related to our legacy companies
- (B) Restructuring expenses related to recent organizational changes and the shutdown of our CP plant in China
- (C) Includes depreciation and amortization associated with final purchase price accounting
- (D) Costs related to the 3T Heater-Cooler remediation plan
- (E) Impact of Caisson related acquisition costs, including \$10.9m related to R&D and \$1.0m related to merger and integration costs
- (F) Impairment of investments and net receivables
- (G) Legal expense related to 3T Heater-Cooler defense and other matters
- (H) Includes \$8.1m related to SG&A, \$0.4m related to R&D, and \$0.1m related to COGS
- (I) Primarily relates to discrete tax items and the tax impact of intercompany transactions

Appendix

RECONCILIATION OF GAAP TO NON-GAAP FINANCIAL MEASURES (UNAUDITED)

Six Months Ended June 30, 2016	Sales	Gross Profit	Income from Operations	Net Income	Diluted EPS
GAAP Financial Measures	\$608.0	\$352.2	(\$14.2)	(\$31.4)	(\$0.64)
Specified Items					
Merger and integration expenses (A)			13.0	11.1	0.23
Restructuring expenses (B)			32.8	30.5	0.62
Depreciation and amortization (C)		4.6	26.8	19.6	0.4
Product remediation (D)		1.6	1.6	1.0	0.02
Other income / (expenses) & litigations (E)			1.0	(0.4)	(0.01)
Impact of inventory step-up (F)		35.0	35.0	24.0	0.49
Equity compensation (G)		0.7	10.3	8.9	0.18
Certain tax adjustments (H)				6.2	0.13
Adjusted financial measures	\$608.0	\$394.1	\$106.3	\$69.5	\$1.41

GAAP results for the six months ended June 30, 2016 include:

- (A) Merger and integration expenses related to our legacy companies
- (B) Restructuring expenses related to our legacy companies
- (C) Includes depreciation and amortization associated with final purchase price accounting
- (D) Costs related to the 3T Heater-Cooler remediation plan
- (E) Includes a \$4.7m reimbursement of damages related to 2012 earthquake in Mirandola (Italy), a \$5.0 million write-off of receivables from Greek distributors and other minor litigations
- (F) Includes amortization of inventory step-up associated with final purchase price accounting
- (G) Includes \$9.0m related to SG&A, \$0.6m related to R&D, and less than \$0.7m related to COGS
- (H) Primarily relates to discrete tax items and the tax impact of intercompany transactions



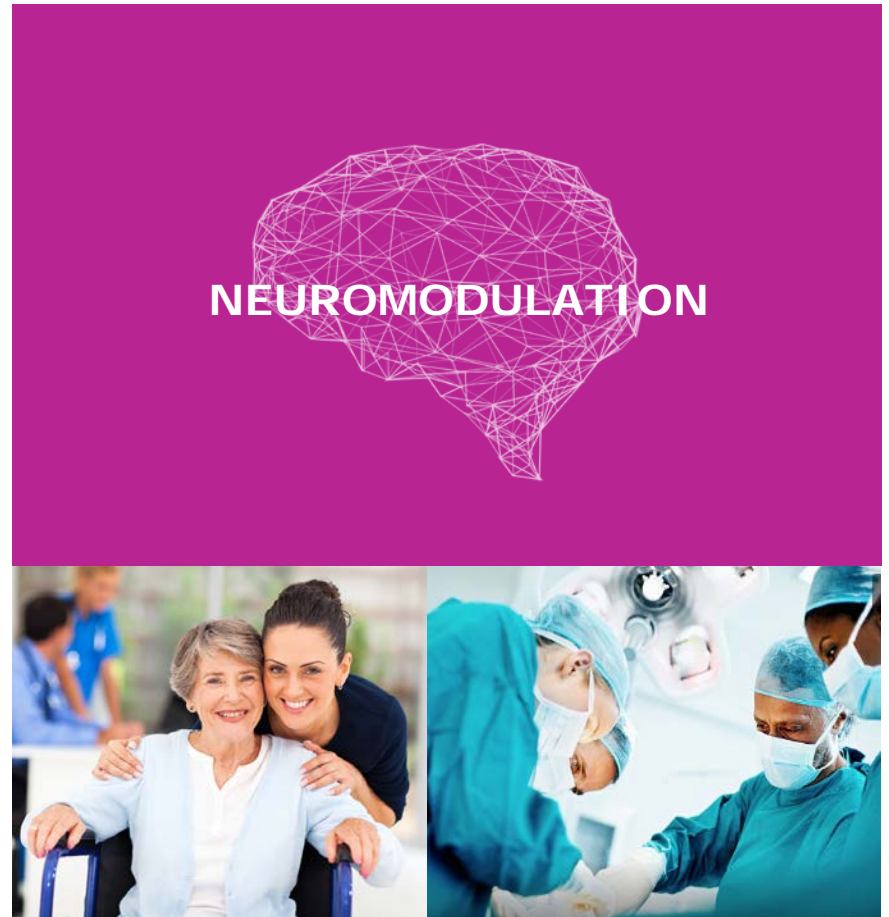
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LivaNova Investor Day

Jason Richey

General Manager,
Neuromodulation &
President, North America

September 14, 2017



We are the market leader in Vagus Nerve Stimulation (VNS) Therapy[®]

EPILEPSY



Significant growth opportunity

DEPRESSION



Unmet global need

CUSTOMERS

Neurologists
Epileptologists
Psychiatrists
Neurosurgeons
Patients

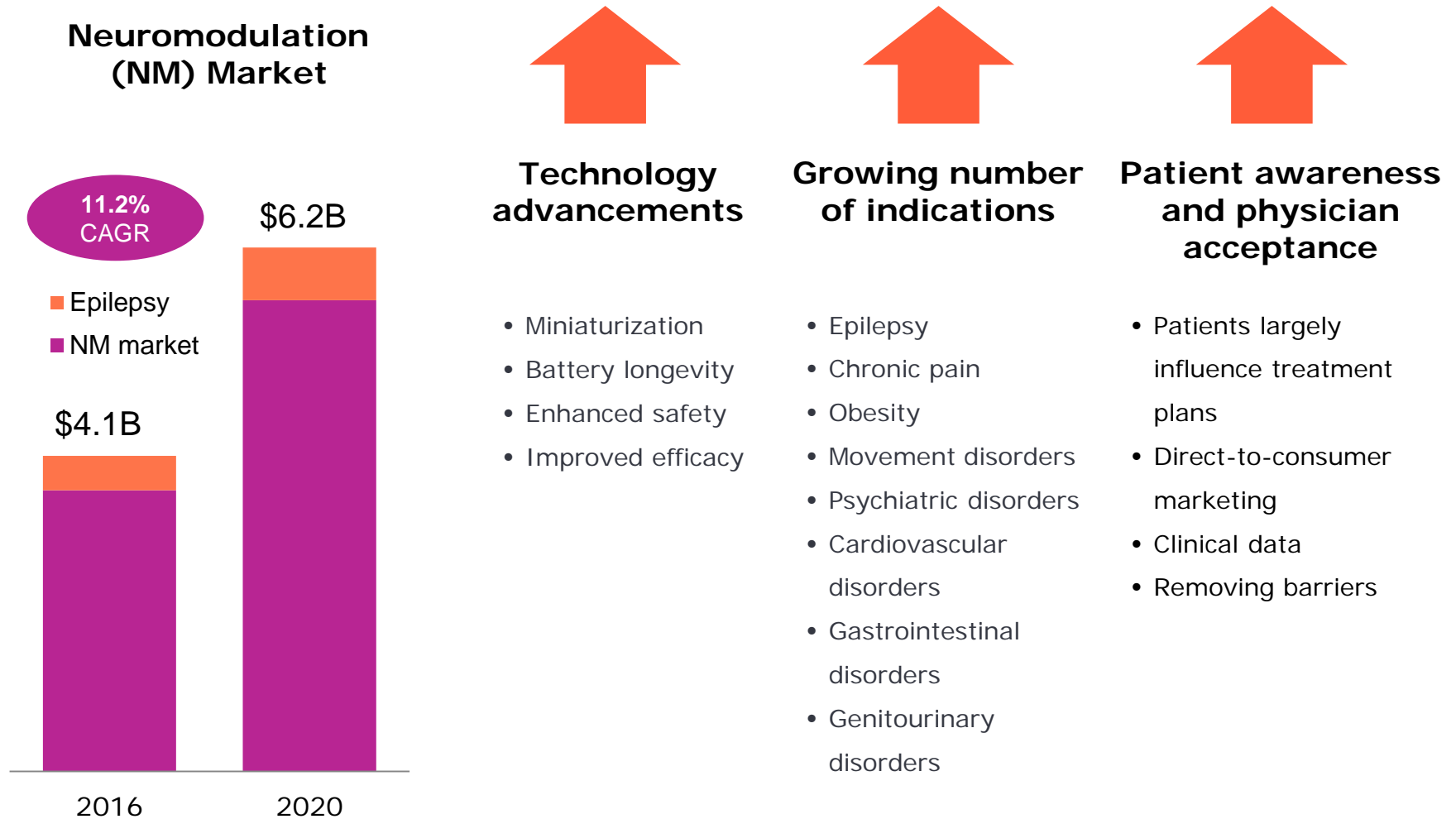
DISEASE STATE

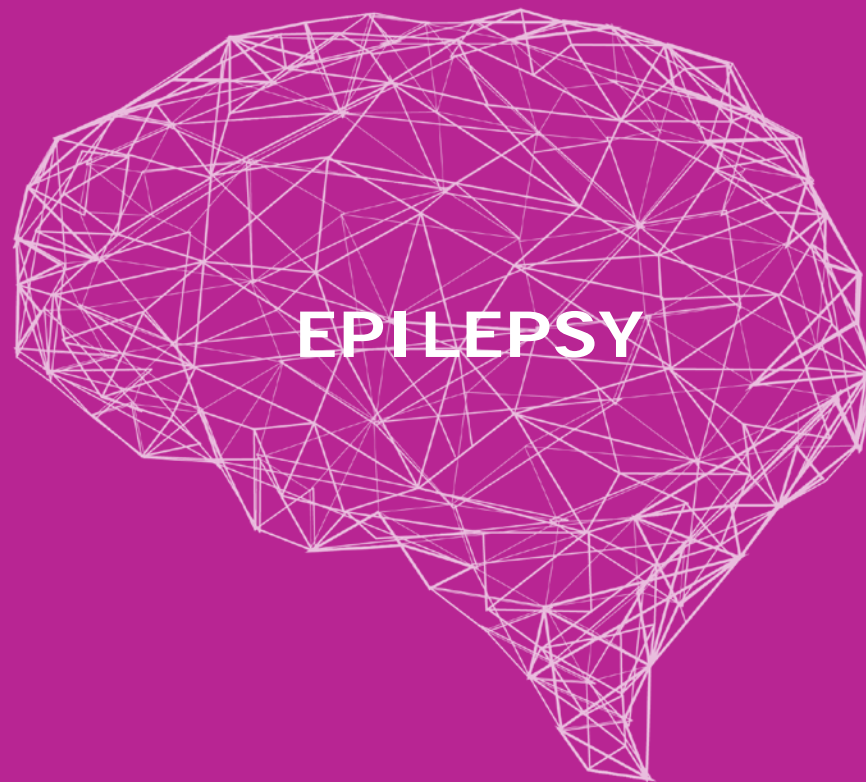
Drug-resistant epilepsy
(DRE)
Treatment-resistant
depression
(TRD)

MARKET

Large underpenetrated
markets with opportunity
for organic and inorganic
growth

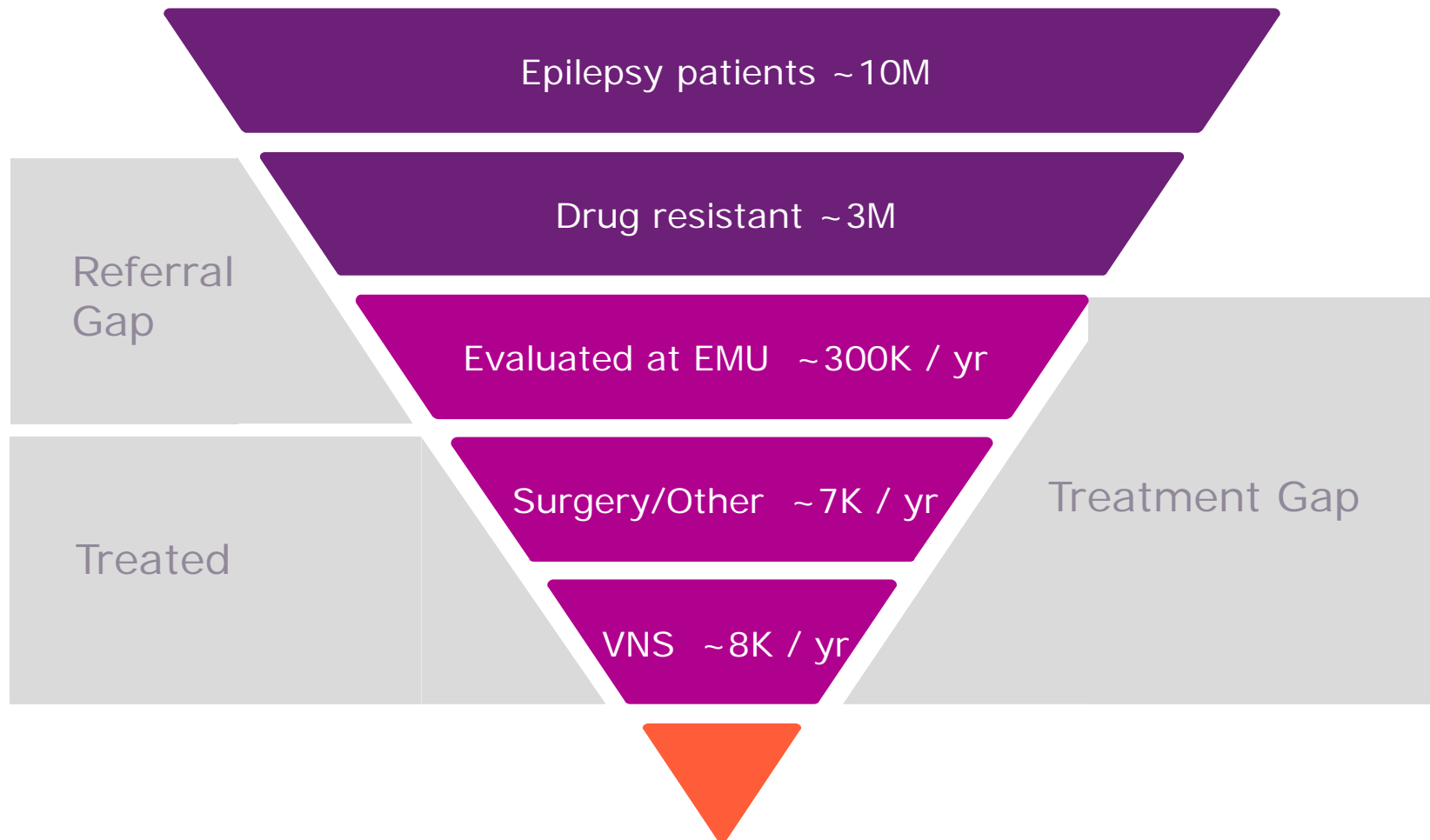
Neuromodulation is a large and growing market





~35% of patients need treatment beyond medication

Significant growth opportunity remains



Growing through innovation and patient awareness

Remove barriers

MRI (U.S. and OUS) and
pediatric labeling expansions (U.S.)

Innovation

Maintain new product cadence
every 12-24 months

International growth
opportunities

Strategic targeting of key markets

Patient awareness

Direct-to-consumer marketing
and clinical studies

Universal
platform

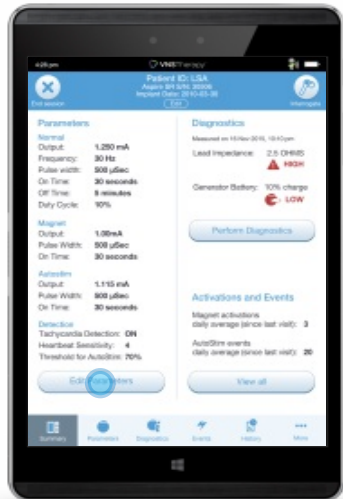
Supports cost reduction and
inorganic growth through M&A

Unlocking potential via labeling expansions

Pediatric	FDA expanded VNS Therapy access to patients as young as age 4 (2017)
	OUS CE Mark approval with no age restrictions (1994)
	Clinical data proves early adjunctive use yields better results
	Patients having seizures for <10 years respond better to VNS Therapy
	VNS Therapy has shown to help children reach important developmental milestones
MRI	FDA approval and CE Mark for expanded MRI labeling (2017)
	VNS Therapy continues to be the only implantable epilepsy device approved by FDA for MRI scans
	Patients now have access to 90% of MRI scans routinely performed on people with epilepsy
	Reduces average distance to MRI centers significantly

Developing customer-centric innovation

Providing ease of use, better patient care, cost effectiveness



SenTiva™ innovations

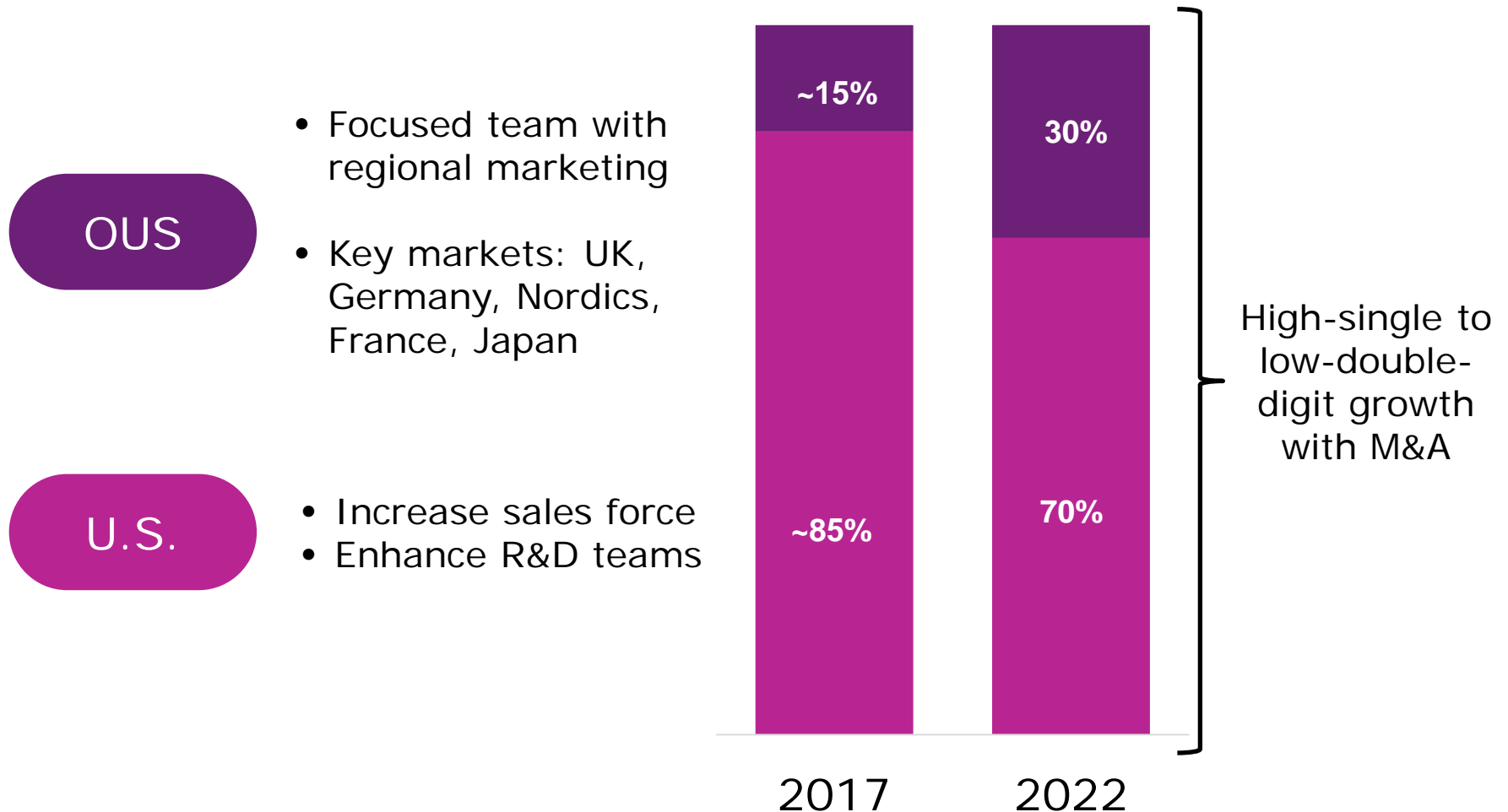
- Senses bradycardia and tachycardia
- Monitors patient sleeping position
- Provides scheduled dosing
- Next-generation programmer
- New user interface on tablet
- Wireless wand

Future generations

- Auto gain control – minimal device positioning by physician
- Microburst – new vagus nerve stimulation method for different area of brain
- Wearable technology
- Patient apps and portals
- Cloud-based capabilities
- Data and analytics tools
- Comprehensive disease management

Targeting international markets

More than 100K global patients treated

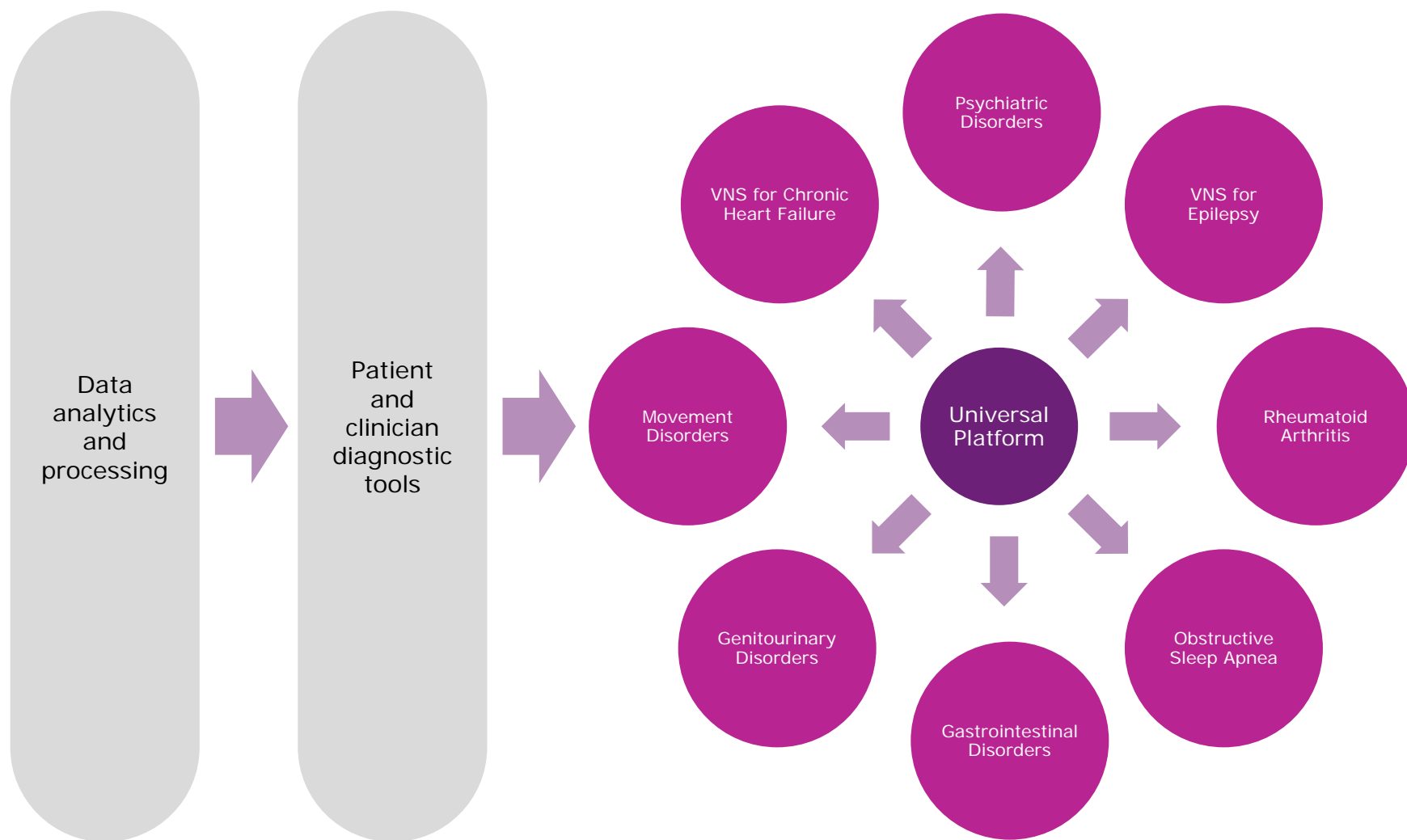


Clinical studies to further support adoption

Our customers rely on data

PATIENT REGISTRY	EARLY ADJUNCTIVE USE STUDY
<ul style="list-style-type: none">• Goes live in parallel with SenTiva launch• Tracks seizure activity and overall patient quality of life• Periodic data reviews• Health economics data	<ul style="list-style-type: none">• Prospective multi-center study• Patients 4+ years• VNS as adjunctive therapy• Early use of VNS:<ul style="list-style-type: none">• Reduces seizures• Reduces recovery time• Improves cognitive results• Enhances performance development
Multi-year Registry	Multi-year Study
Launches 2017	Launches 2018

Universal platform: foundation for additional indications





Depression affects patients in the prime of their life and burdens families and society

Depression

- 300M+ patients globally
- Median age of onset: 25 years
- Fewer than half of patients receive treatment
- Leading cause of disability and major burden

Treatment-Resistant Depression (TRD)

- ~10-30% of patients with depression
- Median age 40+ after 2+ unsuccessful treatments (medications, psychotherapy, electroconvulsive therapy)
- More relapse, less remission, more side effects

VNS Therapy as an adjunctive treatment

- 800 TRD patients with 4+ unsuccessful prior treatments for 5 years
- 40.9% responded with treatment as usual
- 67.9% responded with VNS Therapy

“We are **very encouraged** by the results of this unprecedented study, and hope that VNS becomes more readily available as a viable option for patients who have been through countless interventions for severe, chronic depression.”

- Dr. Scott Aaronson, lead investigator, Sheppard Pratt Health System

Sources: Aaronson et al. American Journal of Psychiatry. 2017; 174(7): 640-48.; WHO Depression Fact sheet: <http://www.who.int/mediacentre/factsheets/fs369/en/>; RC Kessler and EJ Bromet. Annu Rev Public Health. 2013; 34:119–138.; Rush et al. Am J Psychiatry 2006; 163:1905–1917.; Rush et al. Psychiatric Annals. 2008; 38(3):188-193.; Gaynes et al. AHRQ Publication No. 11-EHC056-EF. September 2011.

Exploring options for LivaNova's TRD treatment

Received CE Mark in 2001

Received FDA approval in 2005

Currently have 4,000 devices implanted over ~18-month period

Started pilot trial in Germany in 1Q17

Planning scaled launch in other European countries where we have approval and reimbursement

Ongoing discussions with CMS to gain U.S. reimbursement approval

Summary: a pioneer in Neuromodulation with robust growth opportunities

Epilepsy

- Strong core growth driven by consistent product innovation
- Label expansion increases patient pool
- International expansion opportunities
- Inorganic opportunities drive high-single- to low-double-digit growth trajectory

Depression

- Massive market opportunity with unmet need
- 800+ TRD patients show positive results with VNS Therapy
- Piloting in selected European countries
- In discussions with CMS on reconsideration and coverage with evidence development in the U.S.

Future Technology Enhancements

- Universal platform
- Enhanced diagnostic capabilities
- Wireless
- Wearables
- Patient/physician apps
- Improved data and analytics

LivaNova

Health innovation that matters



Health innovation that matters

LivaNova Investor Day

Alistair Simpson
General Manager,
Cardiac Surgery

September 14, 2017



We are a market leader in Cardiac Surgery

CARDIOPULMONARY



Preferred HLM* by perfusionists,
fastest oxygenator adoption

HEART VALVES



Differentiated in a large, growing
segment: the only sutureless valve

CUSTOMERS

Perfusionists
Cardiac surgeons
Cardiologists

DISEASE STATE

Heart valve disease
Coronary disease
Congenital heart defect
Heart failure

MARKET

Large markets with
opportunity for organic
and inorganic growth

We have a strong core foundation with key growth drivers

S5®

HEART-LUNG MACHINE



Reduces transfusions and improves recovery

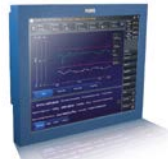
Inspire®

OXYGENATOR



Personalized perfusion

CONNECT™



Data drives better outcomes in clinical efficacy

Perceval®

SUTURELESS VALVE

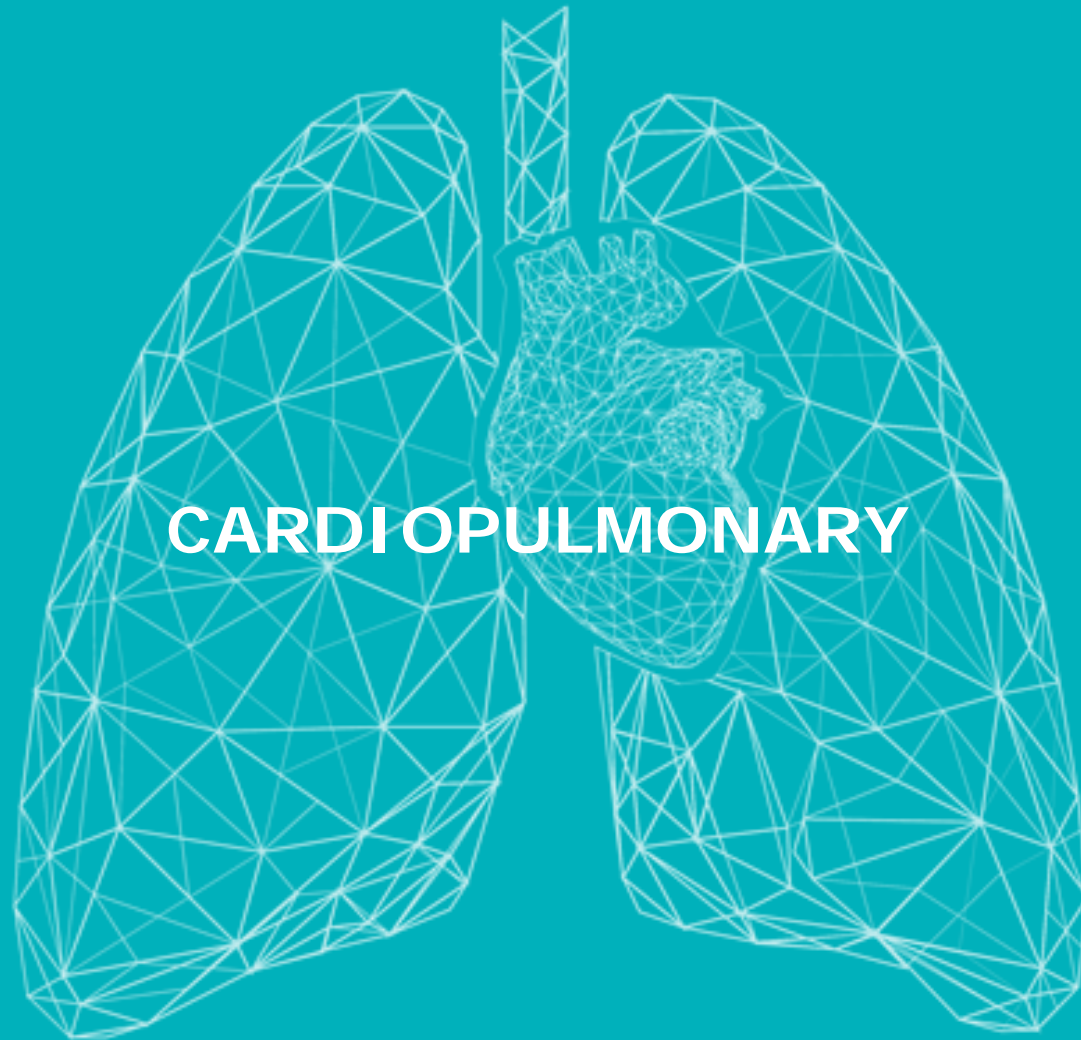


Optimizing the surgical valve replacement

Cannulae

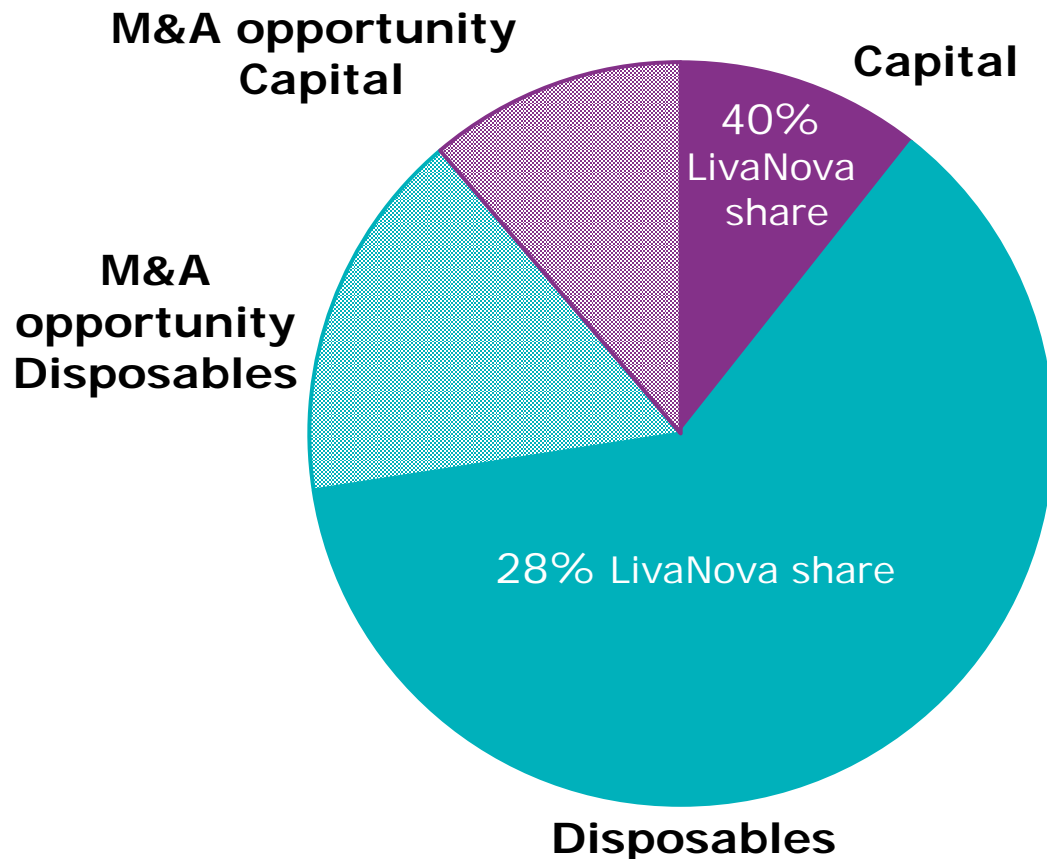


High performance with maximum flexibility



Large market with opportunity to further surround the perfusionist

\$2.3B market



Market is growing low-single digits

M&A enables faster than market / mid-single-digit growth

Our HLM is the market leader



Near-term: commercial execution and S5 enhancements

Mid- to long-term:
next-generation device

LivaNova

Reduces transfusions, better neurological protection

70% market share,
available in 30 languages

Proven safety over 40 years

Robust, proven reliability,
made in Germany

100% customizable, flexible,
easy to use

Inspire ignited the fastest adoption of oxygenators



Reduces transfusions, better neurological protection

30% market share, market leader

Broad choice from complete family of products

Fastest adoption ever, closing in on 1 million patients

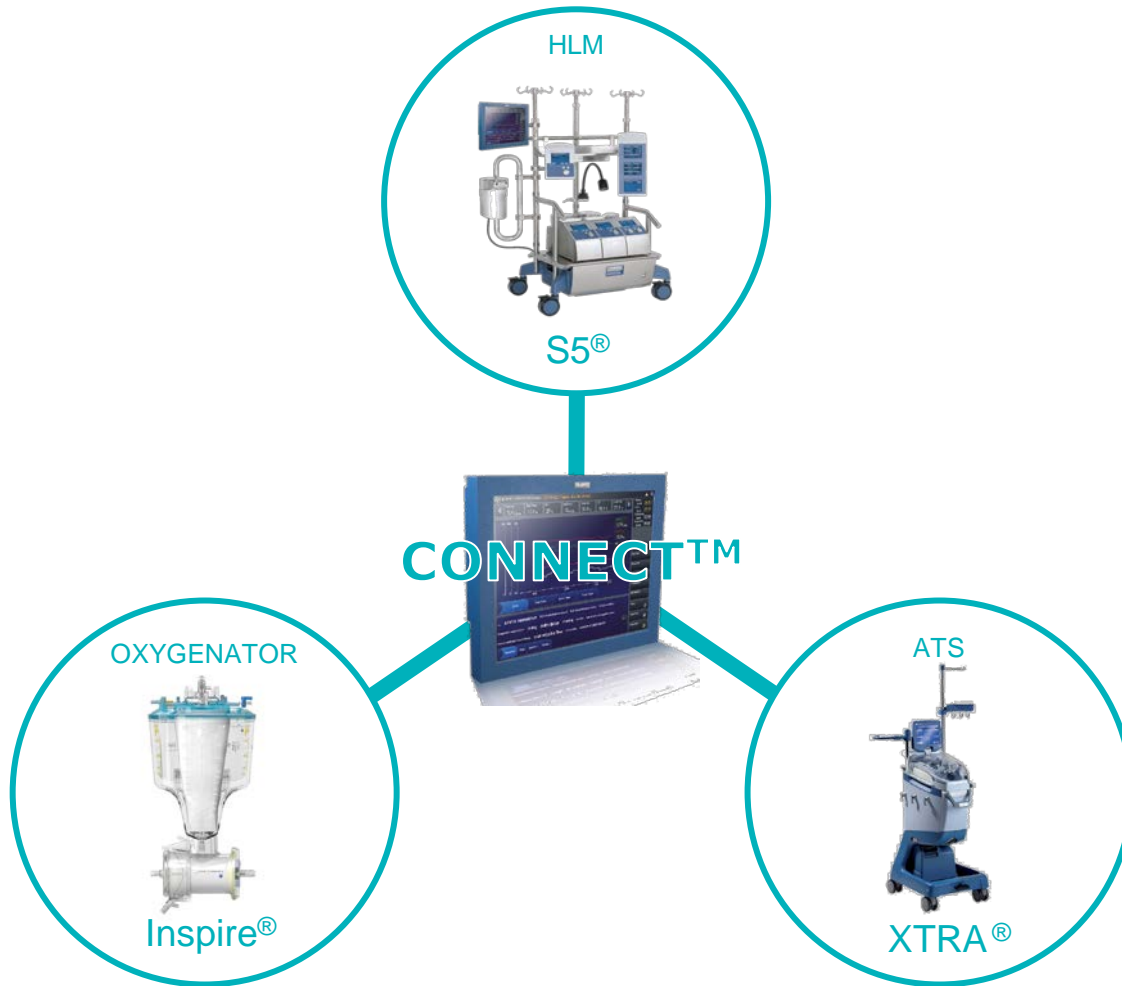
100% customizable, flexible, easy to use

Near-term: commercial execution and leverage HLM footprint

Mid- to long-term: next-generation device; pediatric line extensions

CONNECTing the cardiopulmonary workflow

Data is the driver for Goal Directed Perfusion



- One system connects data from all devices
- Automatic integration of perfusion data, patient parameters and product information
- Allows user to tailor perfusion to individual patient factors
- Improves patient outcome

Investing in the future of cardiopulmonary

Capital



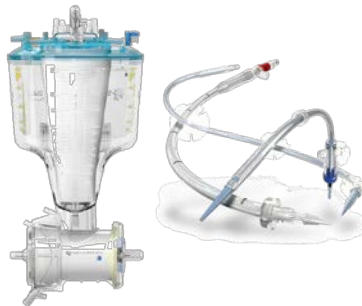
CLINICAL NEEDS

- MICS support
- Data compatibility with hospital systems
- Improved patient management

LIVANOVA SOLUTION

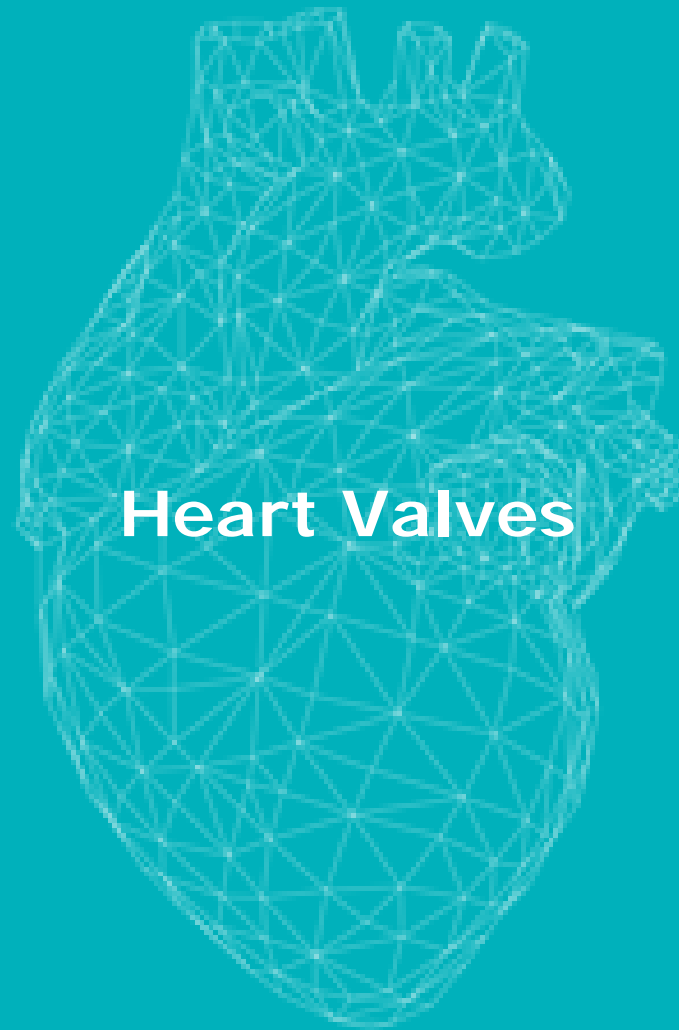
- Near-term S5 enhancements
- Mid- to long-term next-generation S5
- Next-generation Connect
- M&A capital opportunity

Disposables



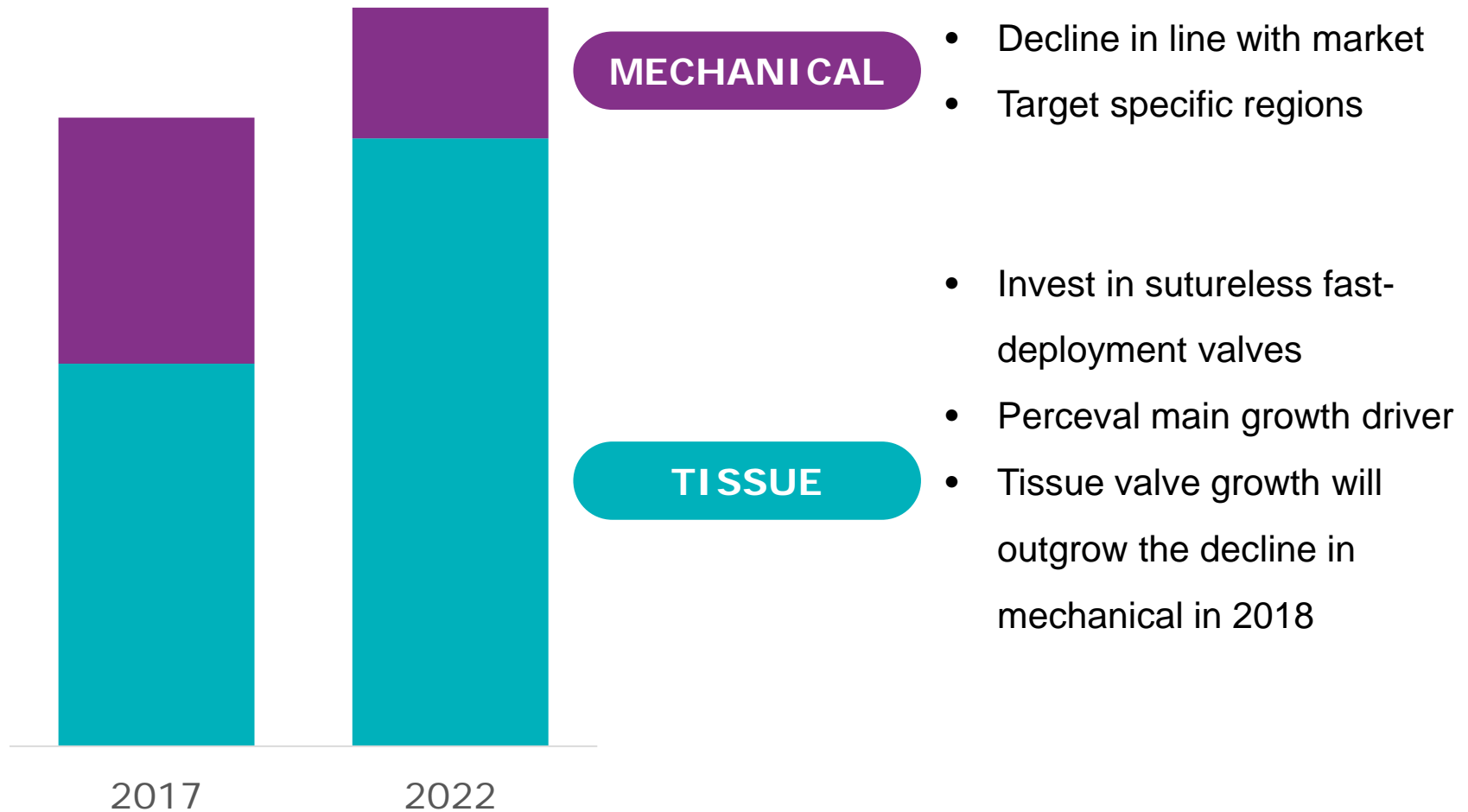
- Patient safety
- Options for different surgeries
- Neurological protection

- Next-generation Inspire
- Inspire pediatric
- MICS cannulae
- M&A disposable opportunity



Heart Valves

Tissue valves will be a larger component of the valve portfolio



Perceval: the only sutureless fast-deployment valve in the market



10+ years of clinical use/data

190+ publications

Enabler for minimally invasive procedures

Strong economic benefits

Our goal is \$80M by 2018

Recent studies continue to show clinical and economic benefits of Perceval

REVIEW ARTICLE

(Innovations 2017;12:155–173)

The Perceval Sutureless Aortic Valve

Review of Outcomes, Complications, and Future Direction

Ramsey Powell, BEng,* Marc P. Pelletier, MD,† Michael W. A. Chu, MD,‡ Denis Bouchard, MD,§
Kevin N. Melvin, MD,|| and Corey Adams, MD||

Comprehensive systematic review of 9 years of studies, reports the following main findings for Perceval:

- **Simplify surgery** by reducing ischemic time in all procedures
- **Facilitate MICS**
- Show **lower mortality** and PVL vs TAVR

Surg Today
DOI 10.1007/s00595-017-1516-8



ORIGINAL ARTICLE

Hospital cost savings and other advantages of sutureless vs stented aortic valves for intermediate-risk elderly patients

Tomoyuki Minami · Sarah Sainte^{1,2} · Herbert De Praetere^{1,2} · Filip Reys^{1,2} · Willem Flameng^{1,2} · Peter Verbrugghe^{1,2} · Bart Meuris^{1,2}

Real-life analyses imply cost compression benefits of Perceval vs Stented: **26% cost reduction** in favor of Perceval in Leuven, Belgium

Sutureless Valves Reduce Hospital Costs Compared to Traditional Valves

François Laborde¹, Thierry Folliquet², Gabriel Ghorayeb³, Konstantinos Zannis¹

¹Département de Pathologie Cardiaque, Institut Mutualiste Montsouris, Paris. ²CHU de Strasbourg, Institut Lorrain du Cœur et des Vaisseaux Louis Mathieu, Vandœuvre les Nancy, Université de Lorraine. ³Service de Chirurgie Cardio-Vasculaire, Hôpital privé de Paris II, Le Chesnay, France

The Journal of Heart Valve Disease 2017;26:1-8

Real-life analyses imply cost compression benefits of Perceval vs Stented: **15% cost reduction** in favor of Perceval in Paris, France

Validated by CMS NTAP approval

Driving expansion and penetration of Perceval



Near-term

- Focusing on \$200M MICS segment
- Sales force effectiveness
- Proctorship expansion
- Deeper penetration into existing accounts
- Product enhancements

Medium-term

- Larger sizes to increase addressable market
- Continued clinical and economic evidence to support efficacy
- Geographic expansion: Japan in 1H18

Summary: the market leader in cardiopulmonary and sutureless valves

Cardiopulmonary	<ul style="list-style-type: none">• Strong core business, significant market share• Life cycle management and new product innovation enhances base business• Inorganic opportunities drive above-market growth
Valves	<ul style="list-style-type: none">• Superior new technology sutureless valve• Global expansion opportunities• Small and growing position in large surgical market
Execution	<ul style="list-style-type: none">• Targeted new product development• Commercial execution and operational excellence

LivaNova

Health innovation that matters



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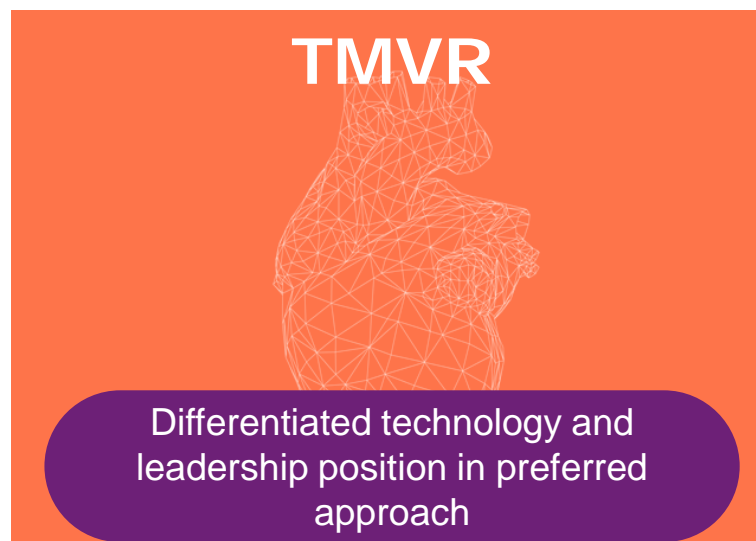
Paul Buckman
General Manager,
TMVR

September 14, 2017

TRANSCATHETER MITRAL VALVE REPLACEMENT (TMVR)



We are in a leadership position in TMVR



CUSTOMERS

Interventional cardiologists
Cardiac surgeons
Echocardiographers

DISEASE STATE

Mitral regurgitation
Heart failure

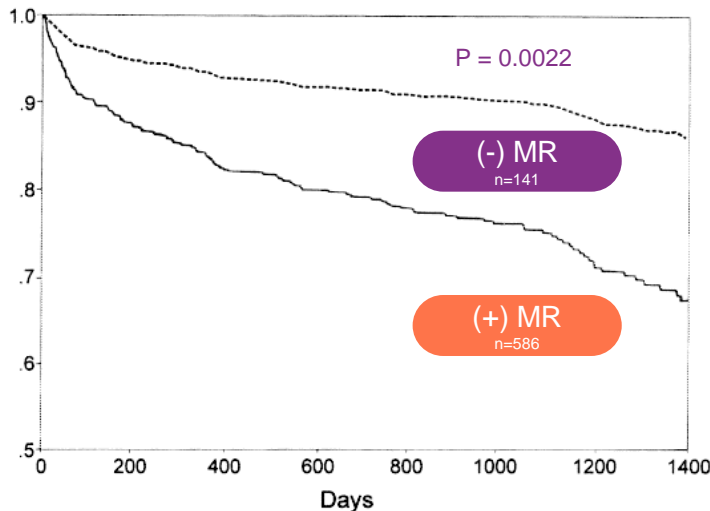
MARKET

Potential to become 2-3 times the size of Transcatheter Aortic Valve Replacement (TAVR)

Mitral Regurgitation (MR) is a reliable predictor of health outcomes, including mortality

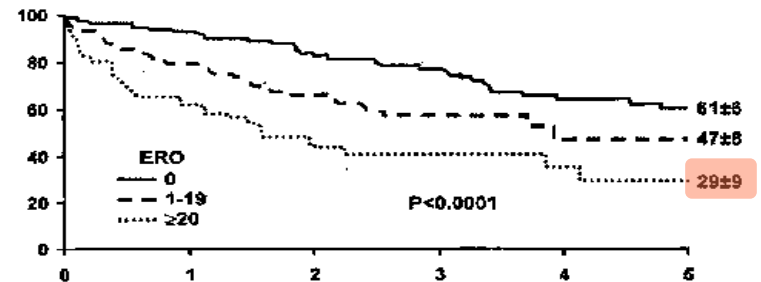
SAVE sub study, n=727

Cardiovascular survival



16 days after Q-wave MI, n=303, 194 with IMR

Survival, %






“Mild MR is an independent predictor of post-MI mortality.”

Lamas et al: Circ, 1997;96:827

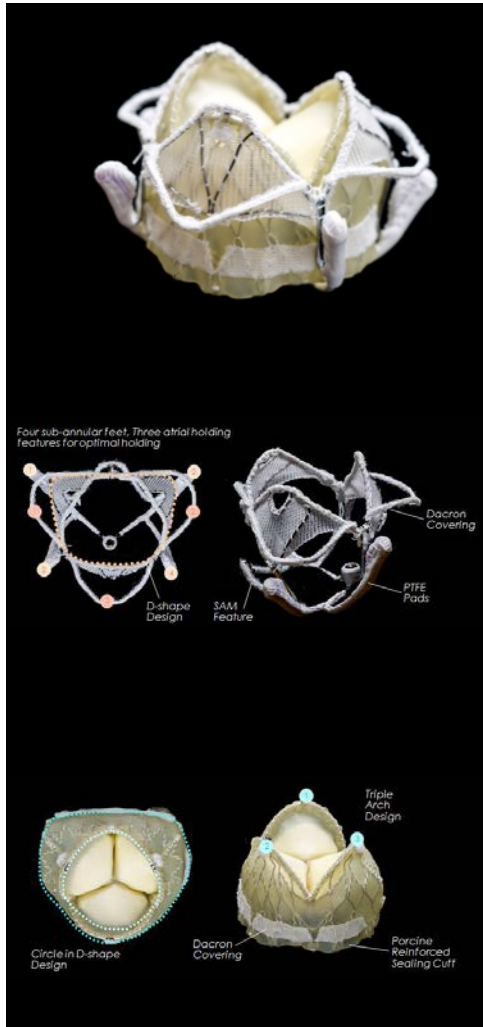
“The mortality risk is related directly to the degree of IMR.”

Grigioni et al: Circ, 2001;103:1759

Surgical treatments are imperfect, creating opportunity for new interventional approaches

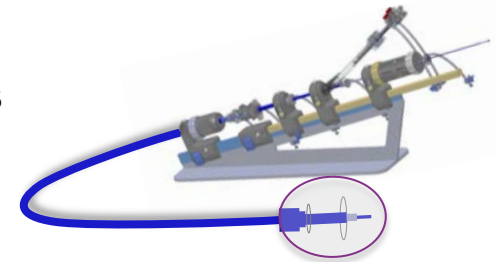
Established Surgical (open chest)	Repair	“Gold standard”	Challenging surgery, 30%+ recurrence	
	Replace	Excellent mechanical durability	Lifetime anticoagulation, poor tissue durability	
Emerging Interventional (percutaneous)	Repair	Strong safety	Modest efficacy, 30%+ recurrence after 1 year	
	Replace	Open race for TMVR leadership. Best clinical outcome and ease of use will be key.		

LivaNova TMVR Concept



- **Delivery System**

- Completely transvenous percutaneous approach
- 2-step implant
- Fully reversible

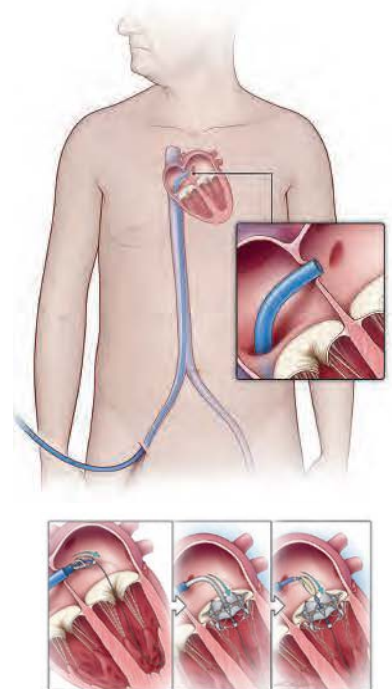


- **Anchor**

- 4 sub-annular anchoring feet
- SAM management feature
- Nitinol self-expanding frame
- Covered with polyester and ePTFE

- **Valve**

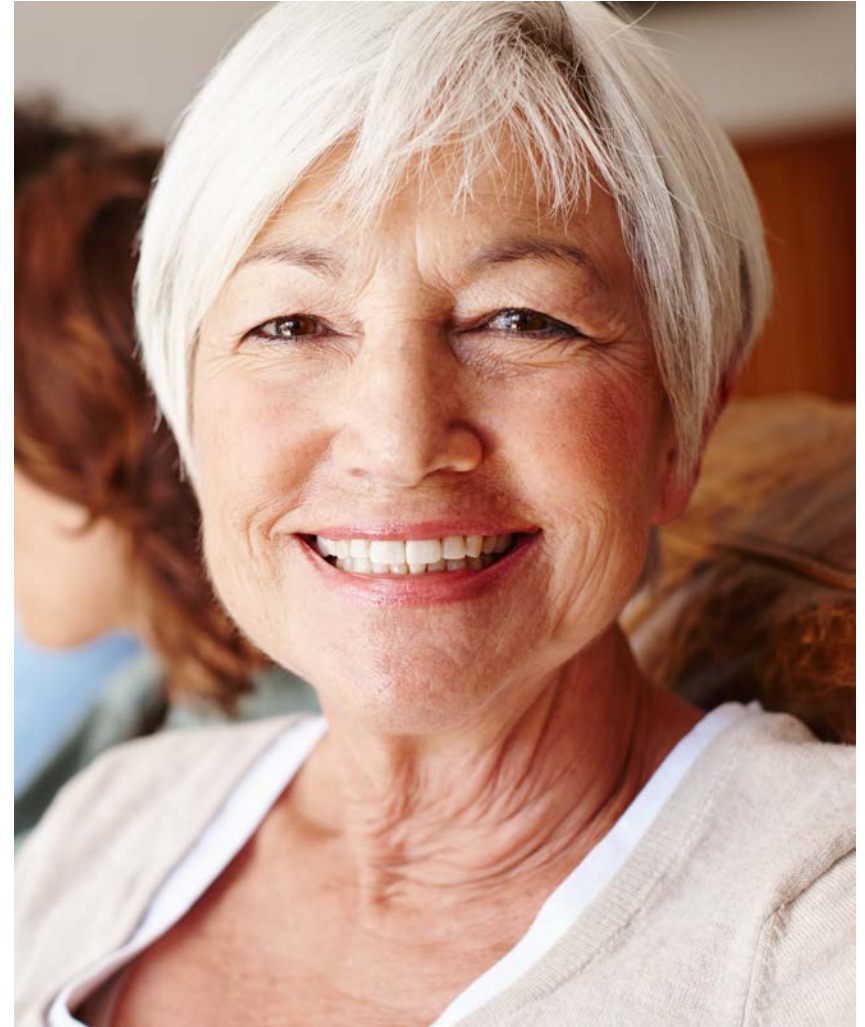
- Porcine pericardium
- 3 leaflet circular valve, EOA>3.0cm²
- D-shaped outer stent
- Nitinol self-expanding











LivaNova TMVR Animation

TMVR is giving new hope to patients with little to no other options

Typical patient		
Female (79%), ~79 years old, generally too sick for surgery		
Severe MR	Grade 3-4	100%
Heart disease	CAD	64%
	Previous procedure	55%
Heart failure	NYHA III/IV	81%
Pulmonary dysfunction	COPD	46%
Kidney disease	Renal insufficiency	46%



TMVR advantages have recently created significant interest from leading players

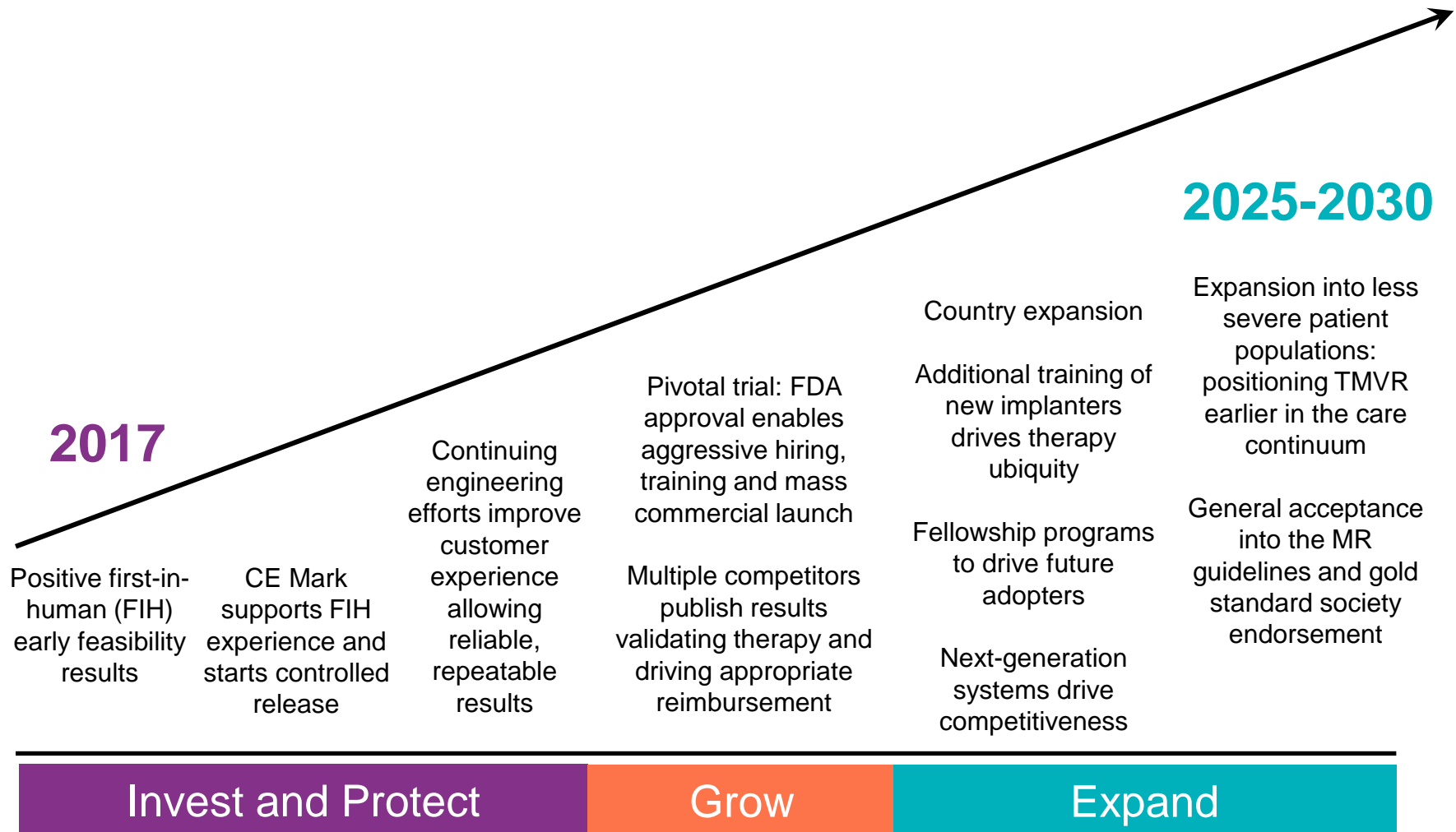
	Caisson Interventional	\$120M
 Edwards	Internal Fortis development	Not disclosed
 Edwards	CardiAQ Valve Technologies	\$400M
 Edwards	Valtech	\$690M
 Abbott	Tendyne	\$250M
 Abbott	Cephea Valve Technologies	Not disclosed
	Twelve Intrepid	\$458M
	Option to buy MValve	Reportedly \$200M

Key investments to creating a TMVR market that is 2-3 times larger than TAVR










Current  **Future**



We have the patience to build and are committed to investing in the market















Executing on a clinical data development plan designed to enable commercialization

		Patients	Centers	Objective	Status
		20	8-10	FIH study proving TMVR concept	Continuing enrollment
	  	75	15	Confirmatory study to secure CE Mark in Europe	Started to enroll
	 	400	20-30	U.S. IDE study to build on FIH and CE Mark study to secure FDA approval	Finalizing protocol with enrollment planned in 2019

A proven approach to ensuring physician competence and confidence

Patient selection	<ul style="list-style-type: none">• Therapy awareness tools to drive local education and awareness• Joint screening activities with clinical sites• Virtual implant fit to ensure proper sizing
Physician training/tools	<ul style="list-style-type: none">• On-site instruction at hospital• Full day didactic and hands-on training• Modeling of ideal approach for patient case• On-site refresher training and virtual implant simulation in actual hospital catheterization lab
Procedure support	<ul style="list-style-type: none">• Expertise for onsite training and case support• Procedure observation worksheet on every case to institutionalize learning and continuously improve

Competitive advantage in TMVR and opportunity to lead the transseptal market

TRANSSEPTAL	LivaNova	Caisson	
	Edwards	CardiAQ	
	Abbott	Cephea	
	Edwards	Valtech	
TRANSAPICAL	Edwards	CardiAQ	
	Abbott	Tendyne	
	Medtronic	Twelve	
	MValve		
	Neovasc		
	HighLife		
	Sinomed		
	Direct Flow		

Summary: positioning for leadership in TMVR

Technology	<ul style="list-style-type: none">• Transseptal delivery• Distinct competitive advantages
Clinical evidence	<ul style="list-style-type: none">• Investment in clinical trials• Post-market studies for reimbursement and/or expanded indications
Physician focus	<ul style="list-style-type: none">• Collaboration and responsiveness• World-class training• Procedural support• Podium presence• Advocacy

LivaNova

Health innovation that matters