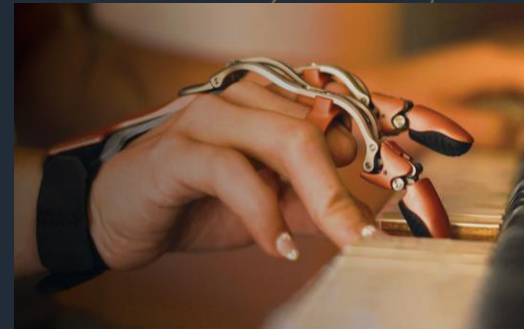
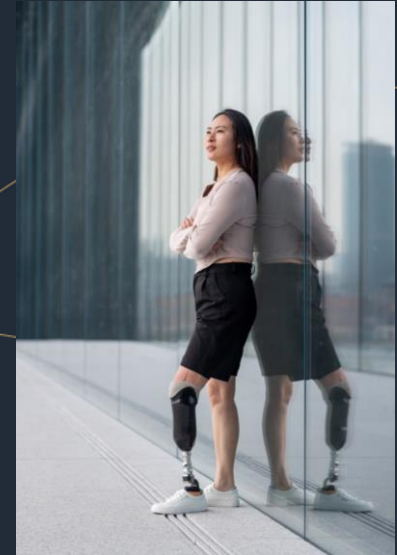




A leading global provider of innovative mobility solutions

# Q3 2024 Investor Road Show Presentation

October 22, 2024



# Q3 2024 Business update and financial performance



# Key highlights for the third quarter 2024

Strong momentum continues; Full year guidance remains unchanged

## Q3 Performance

Organic sales growth

+7%

Local currency growth

+11%

Incl. +3pp from M&A

EBITDA margin increasing 3pp YoY

22%

## Operations

R&D progress in Q3

- ✓ NAVii® and Icon® in limited launch progressing as planned
- ✓ Naked Prosthetics next generation technology launched

Fior & Gentz integration

- ✓ Distribution transition underway
- ✓ Neuro Orthotics being rolled out in new markets including UK and Australia during Q3

ForMotion™

- Unifying Patient Care under new ForMotion brand
- Netherlands rebranded in Q3
- US and Denmark set for Q4

## External

US Medicare Expands Access to Bionics

- As of September 1st 2024 less-mobile K2 patients have access to Microprocessor controlled knee (MPKs) solutions
- In some cases, patients will be eligible for an advanced feet solution



7 11 4 5 PARALYMPIC RECORDS

### The Choice of Champions

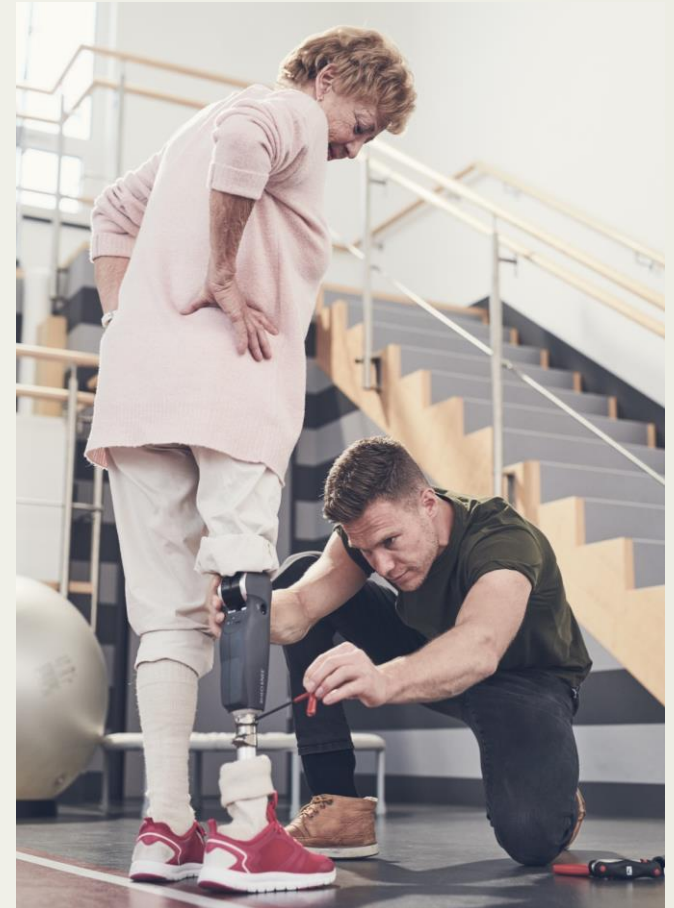
Congratulations to all Team Össur athletes and Össur Ambassadors on their amazing performances in Paris!



# US Medicare Expands Access to Advanced Bionics for K2 patients as of September 1, 2024

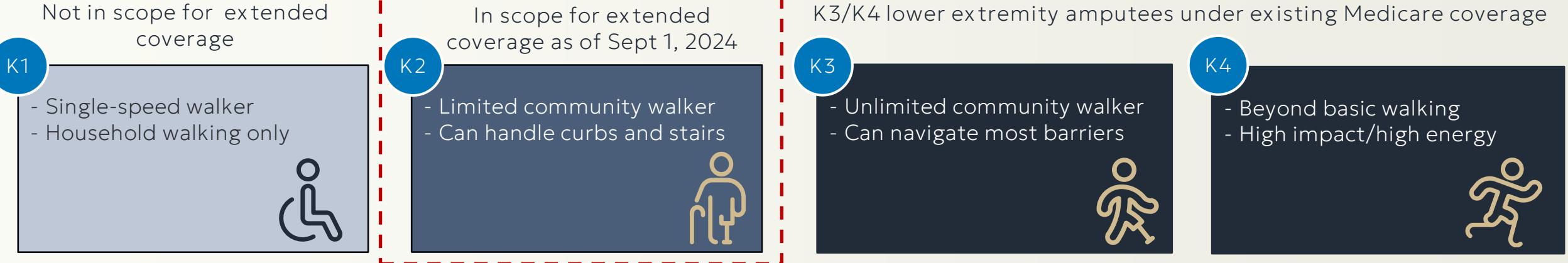
## Coverage Expansion Key Facts

- The Big Takeaway: Less-mobile patients get access to microprocessor-controlled knees (MPKs)
- Why? Clinical research shows MPKs provide significant benefits to less-mobile amputees
- Secondary Benefit: Less-mobile amputees now getting an MPK are also eligible to receive more advanced feet
- Unexpected Win: Updated requirements also create opportunities for *all* lower-extremity amputees to get more advanced devices

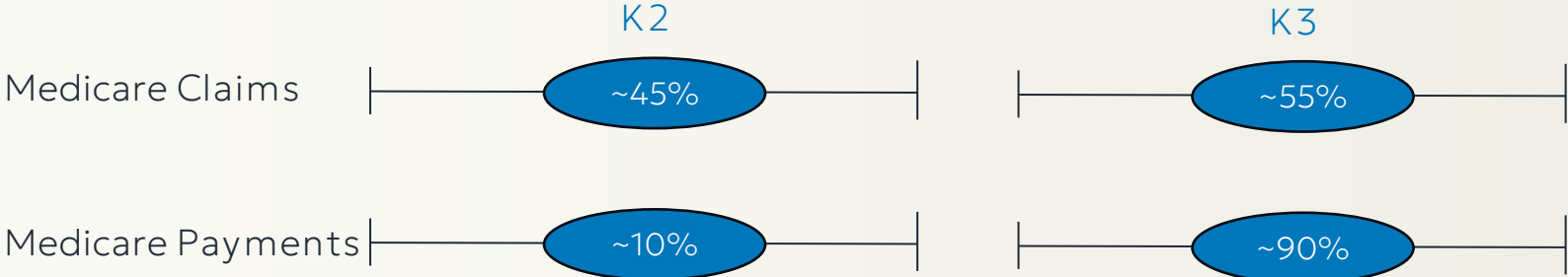


# Expanding US Medicare coverage to K2 patients represents a Mid-to-Long-Term Growth Opportunity for Embla Medical

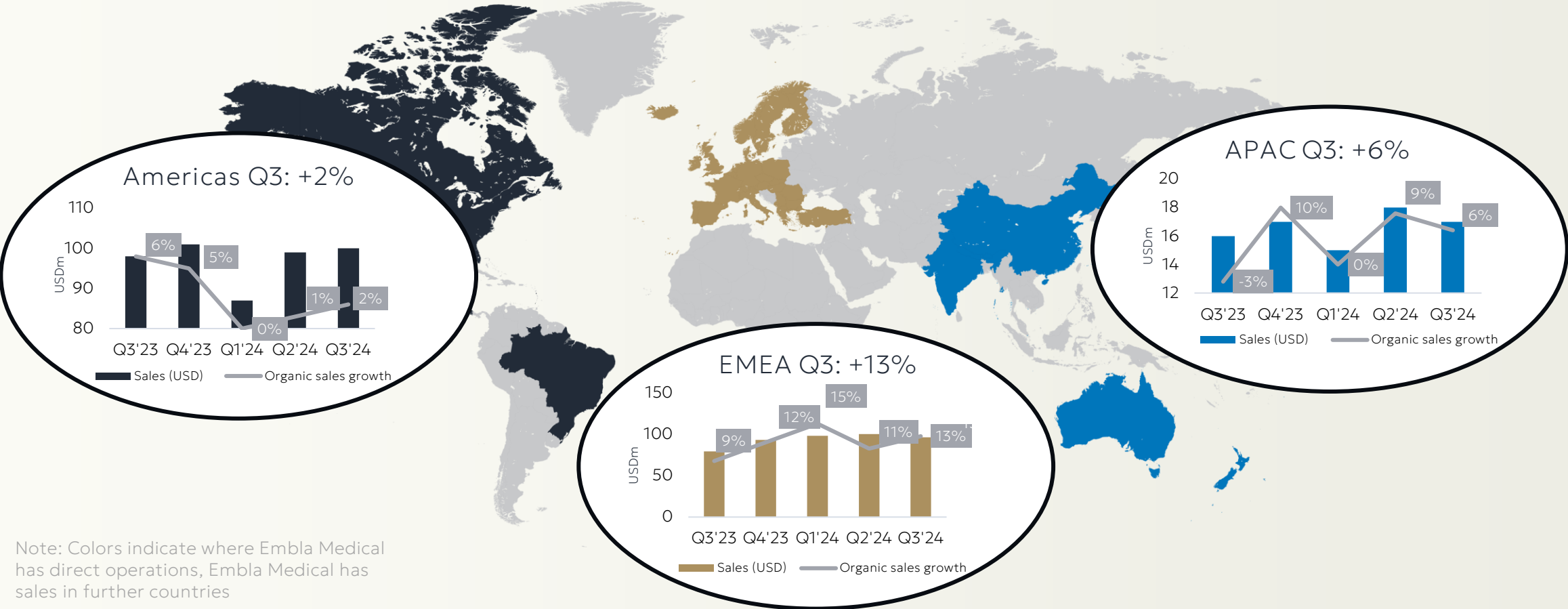
## Classification of functional levels for prosthetic users



Today Medicare accounts for ~30% of the revenue of an avg O&P facility in the US  
 K2 and K3 patients account for the majority of Medicare's prosthetics claims today



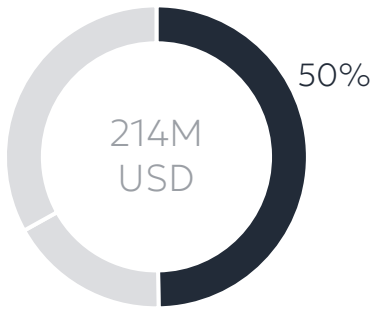
# Continued strong momentum in EMEA driven by Prosthetics & Neuro Orthotics and Patient Care; Sales in Americas remained soft



Note: Colors indicate where Embla Medical has direct operations, Embla Medical has sales in further countries

# Prosthetics & Neuro Orthotics sales grew +9% organic in Q3 driven by strong volume growth and increased fitting of high-end solutions

% of total sales Q3



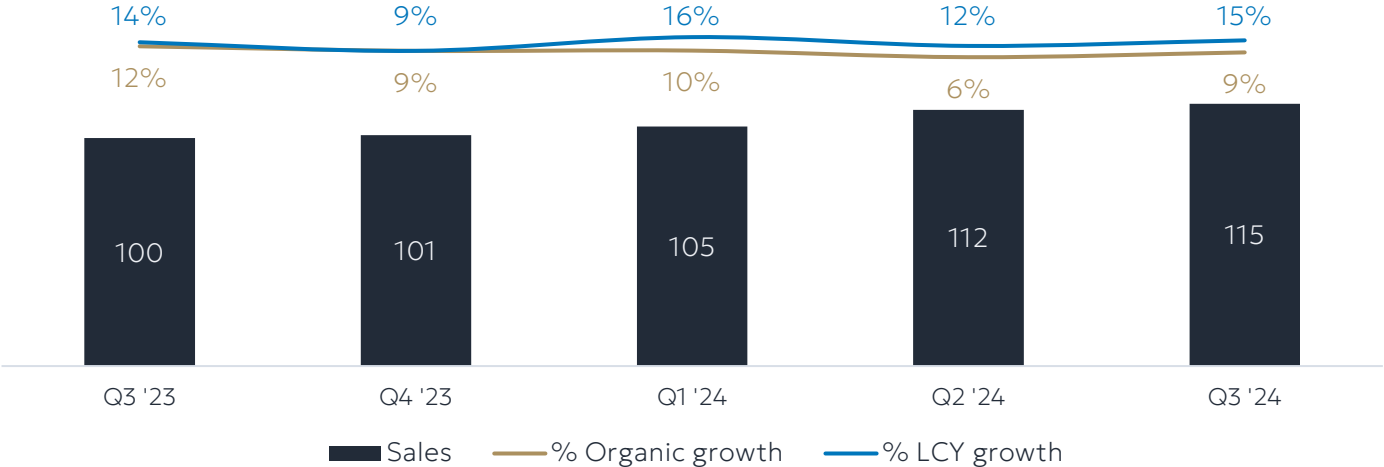
Year-to-date sales

332  
USD million

Year-to-date growth

8%  
organic growth

Sales  
USD million

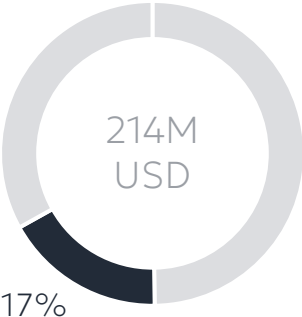


### Q3 Highlights

- EMEA: Continued strong momentum in EMEA driven by volume growth across most European markets; especially in Bionics
- Americas: Sales remained soft with good performance in some locations and product categories, offset by softness in others
- APAC: Strong sales in Australia as the backlog from reimbursement has gradually improved, performance was however offset by weaker performance in selected markets in APAC
- Neuro Orthotics (Fior & Gentz): Continued solid performance; during the quarter we expanded our Neuro Orthotic offerings into new markets such as UK and Australia
- High-end solutions: Bionics continued to contribute strongly for the quarter

# Bracing & Supports grew moderately for the quarter; strong performance in APAC but softer in other markets

% of total sales Q3



Year-to-date sales

112  
USD million

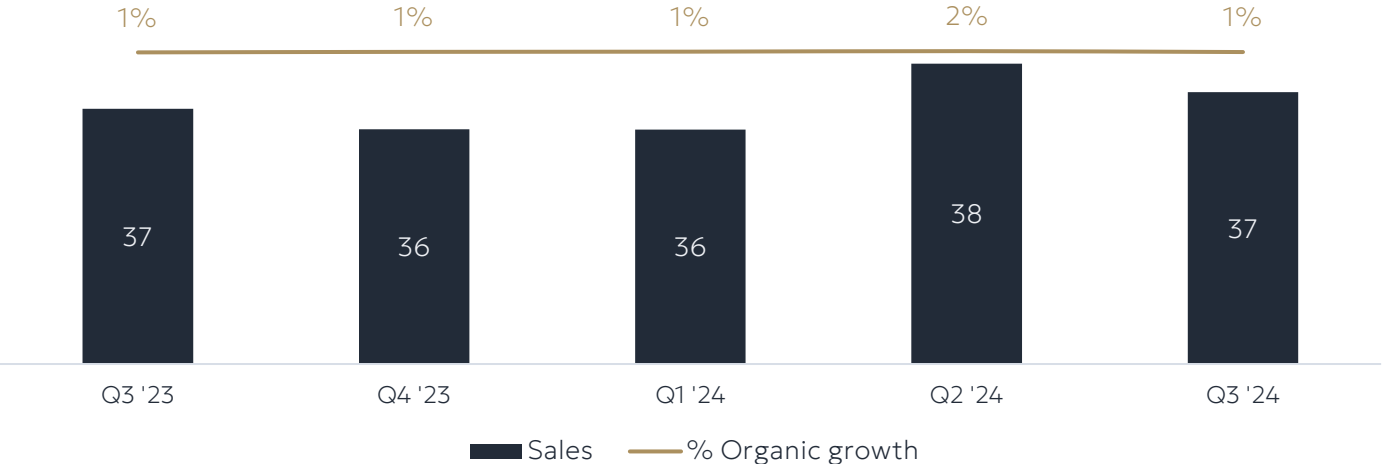
Year-to-date growth

1%  
organic growth

Q3 Highlights

- EMEA/Americas: Soft performance in both EMEA and Americas due to challenging market dynamics in selected product categories and markets
- APAC: Strong performance in the region mainly driven by China as well as Australia and New Zealand delivered good growth

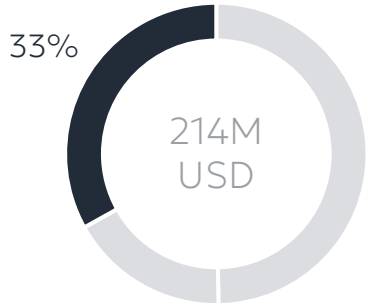
Sales  
USD million





# Patient Care business delivered +9% organically in Q3 driven by strong volume growth and positive mix effect, especially in EMEA and Australia

% of total sales Q3



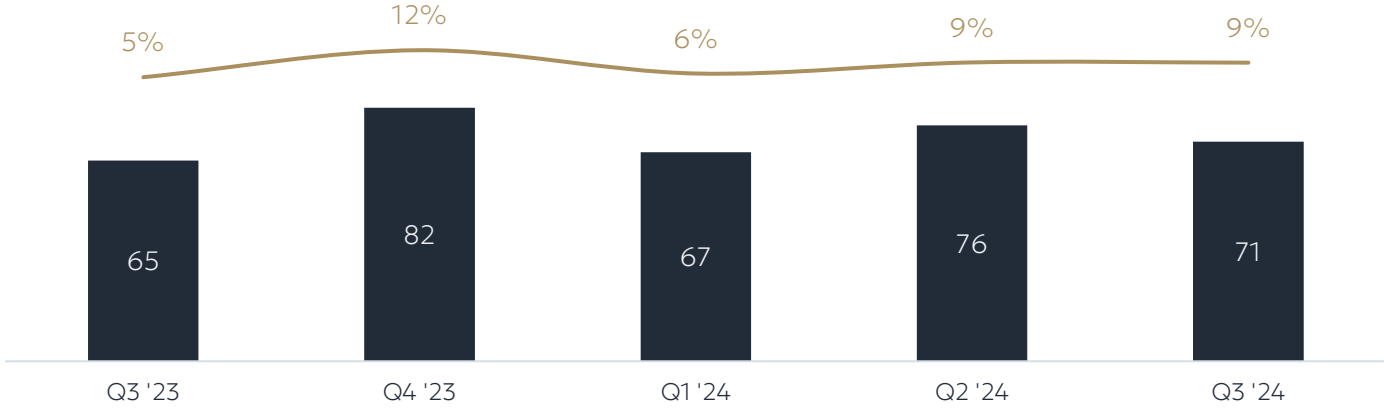
Year-to-date sales

214  
USD million

Year-to-date growth

8%  
organic growth

Sales  
USD million



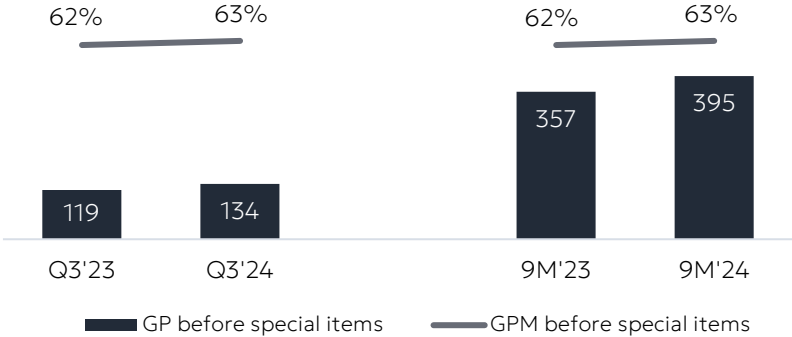
■ Sales — % Organic growth

### Q3 Highlights

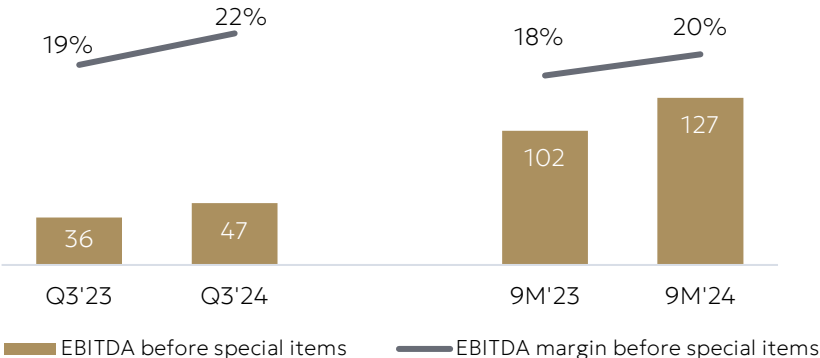
- EMEA: Strong performance in EMEA driven by strong contribution across key market and increased efficiency at the clinics
- Americas: Modest performance in Americas with solid contribution from most locations offset by weaker performance in other areas
- APAC: Sales in Australia delivered strongly as the impact from the reimbursement delay earlier this year is seeing a gradual recovery

# EBITDA margin expanding by 3%-points to 22% for the quarter vs. Q3'23; Expansion driven by higher Gross Profit margin and modest OPEX growth

Gross Profit and Gross Profit margin  
USD million



EBITDA and EBITDA margin  
USD million

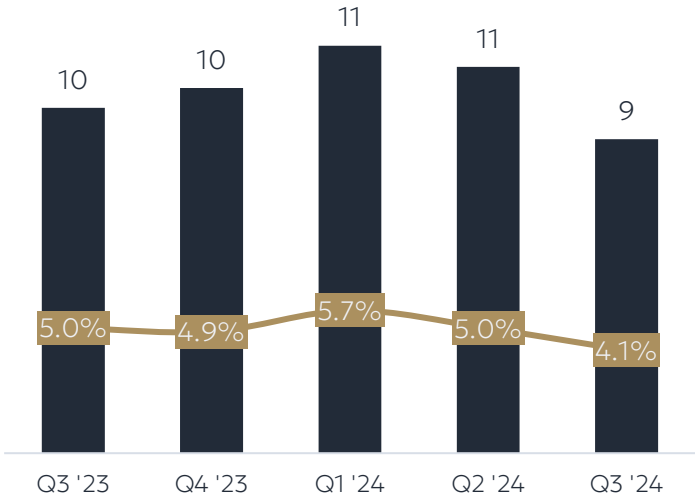


### Highlights

- Gross Profit: Gross profit margin was 63% in the quarter compared to 62% in Q3 2023, partly resulting from cost reduction initiatives executed during Q1 2024 as well as positive product mix and manufacturing efficiency had a positive impact
  - OPEX: Growing +4% (organic) vs organic sales growth of +7%, the lower OPEX growth is attributed to effective cost control
  - EBITDA: EBITDA margin before special items expanded to 22% compared to 19% in Q3 2023; effects from currencies was positive by 40 basis points in Q3 but neutral in 9M
- Net Profit: Net profit was USD 22m for the quarter or 10% of sales vs. 7% of sales in Q3 2023
- Effective Tax: The Q3 tax rate was 22%

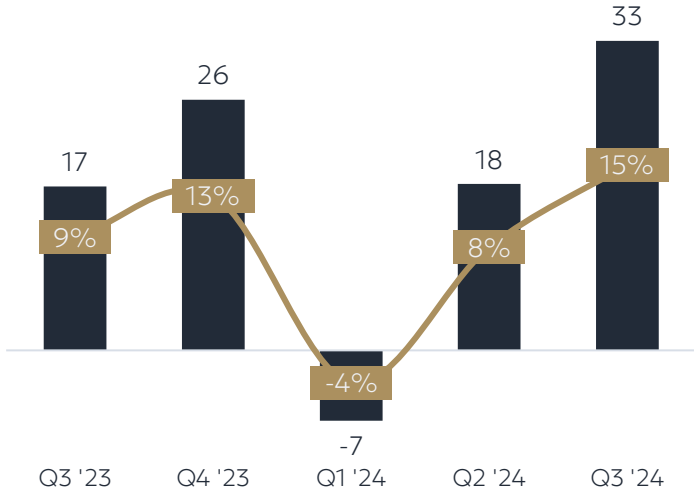
# Strong free cash flow during the quarter; Mainly benefitting from increased cash from operations

Capital expenditures and % of sales  
USD million on actual rate



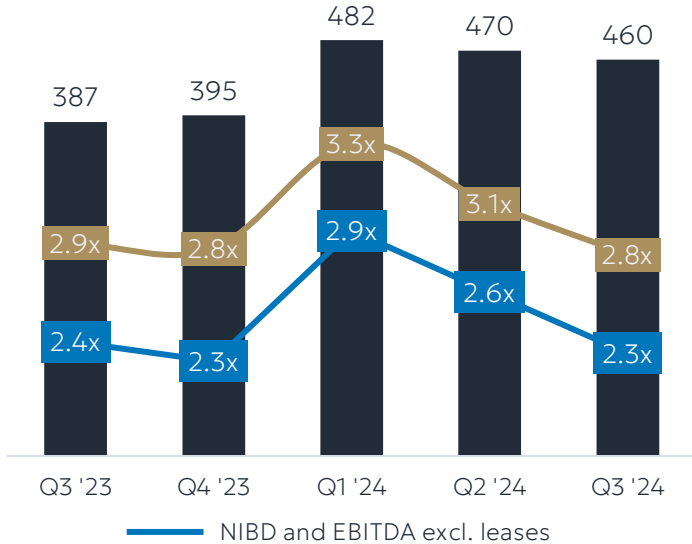
- CAPEX have come down to 4% of sales for the quarter as facility expansion programs have been concluded
- CAPEX is expected to return to normalized levels of 3-4% in the periods to come, all things equal

Free cash flow and % of sales  
USD million on actual rate



- Strong free cash flow during the quarter; mainly benefitting from increased cash from operations, positive effect from working capital, and less CAPEX
- Inventories remain elevated following the build-up of new Bionics solutions in preparation for launch

Net Interest-Bearing Debt and Leverage  
USD million on actual rate



- Leverage was 2.8x end of Q3 2024 (2.3x excl. leases)
- Share buybacks continue to be paused

# Outlook for 2024 unchanged

	Guidance as of Sept 2024	9M 2024	Guidance as of July 2024
Sales growth Organic	6-8%	+7%	6-8%
EBITDA margin Before special items	~20%	20.1%	~20%
For modeling purposes:			
Special items In USD million	4	4	4
CAPEX % of sales	4-5%	5%	~4%
Tax Effective tax rate	~24%	23%	~24%



A woman with a prosthetic leg and a dog in a field at sunset. The woman is standing on the right, holding a blue leash attached to a light-colored dog. Another person is kneeling on the left, petting the dog. The background shows a vast field of tall grass under a golden sunset sky with mountains in the distance.

# About Embla Medical

A leading global provider of innovative mobility solutions



# Embla Medical at a glance

## Global medical device company



- A global leader in innovative mobility solutions
- Operations worldwide in 36 countries
- Over 4,000 employees across the globe
- Listed on Nasdaq Copenhagen (Ticker: EMBLA)

## Innovation driven



- ~5% of sales invested in R&D
- Over 2,100 patents
- New product launches every year
- World-renowned brands

## Profitable growth



- Organic and acquisitive sales growth
- 17% sales growth CAGR since listing in 1999
- 18% EBITDA margin in 2023
- ~85% of EBIT converted into free cash flow past decade

## Sustainability

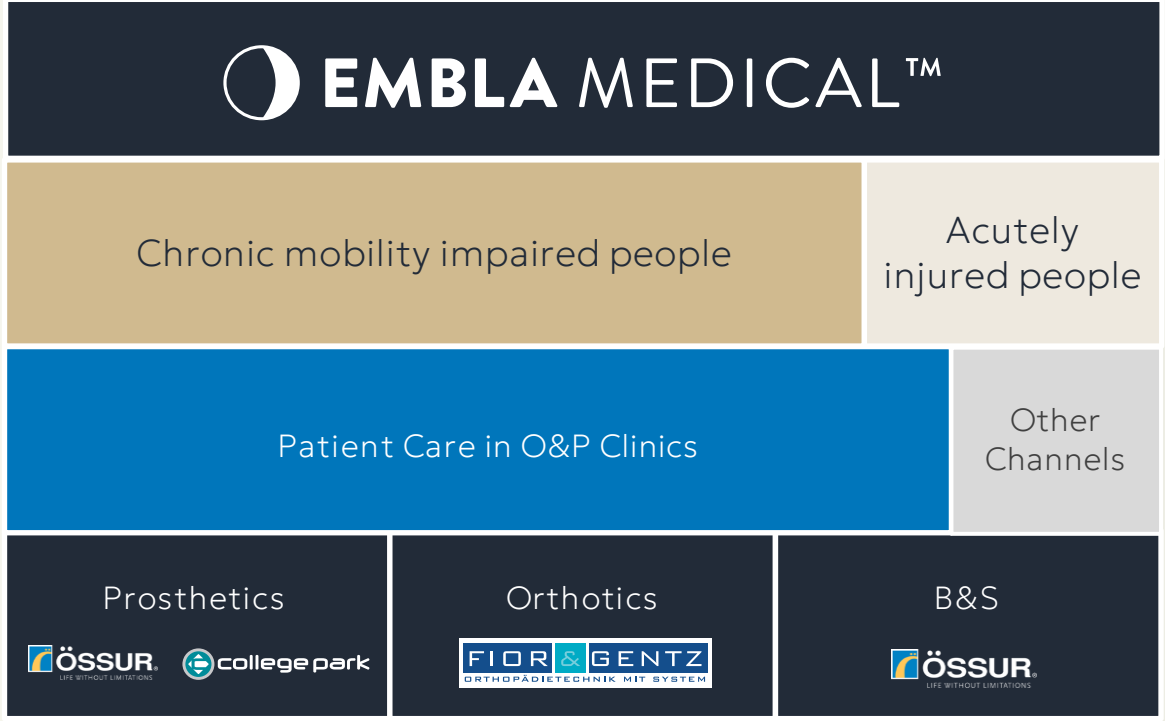


- Sustainability commitment Responsible For Tomorrow
- Contribute to six UN Sustainable Development Goals
- ≥95% electricity purchased from renewable energy sources
- 50% male vs. 50% female gender ratio in 2023

# Unlocking a larger playing field as an increasingly patient driven organization

Increasingly Patient Focused

Product Company



OUR VISION

To enable Life  
Without Limitations

OUR MISSION

We Improve People's Mobility



# Our business segments are highly synergistic

## Prosthetics & Neuro Orthotics



Full portfolio of Prosthetic product solutions

46%  
of total sales  
in 2023



Lower limb product offering in Neuro Orthotics

FIOR & GENTZ  
acquired in 2024

## Bracing & Supports



Broad product offering in Bracing & Supports

18%  
of total sales  
in 2023

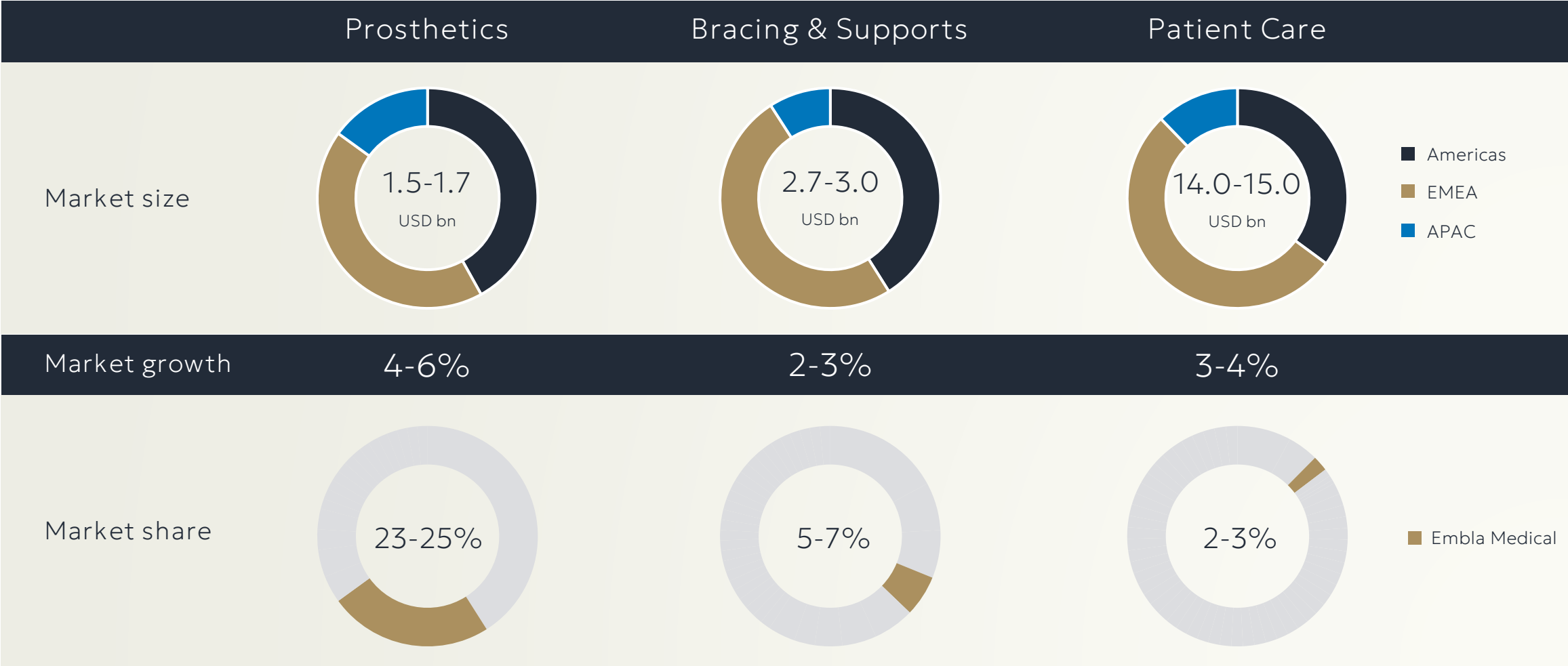
## Patient Care



Orthotic & Prosthetic services

36%  
of total sales  
in 2023

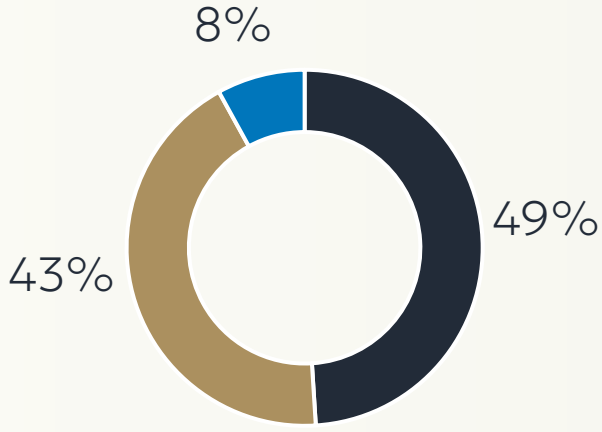
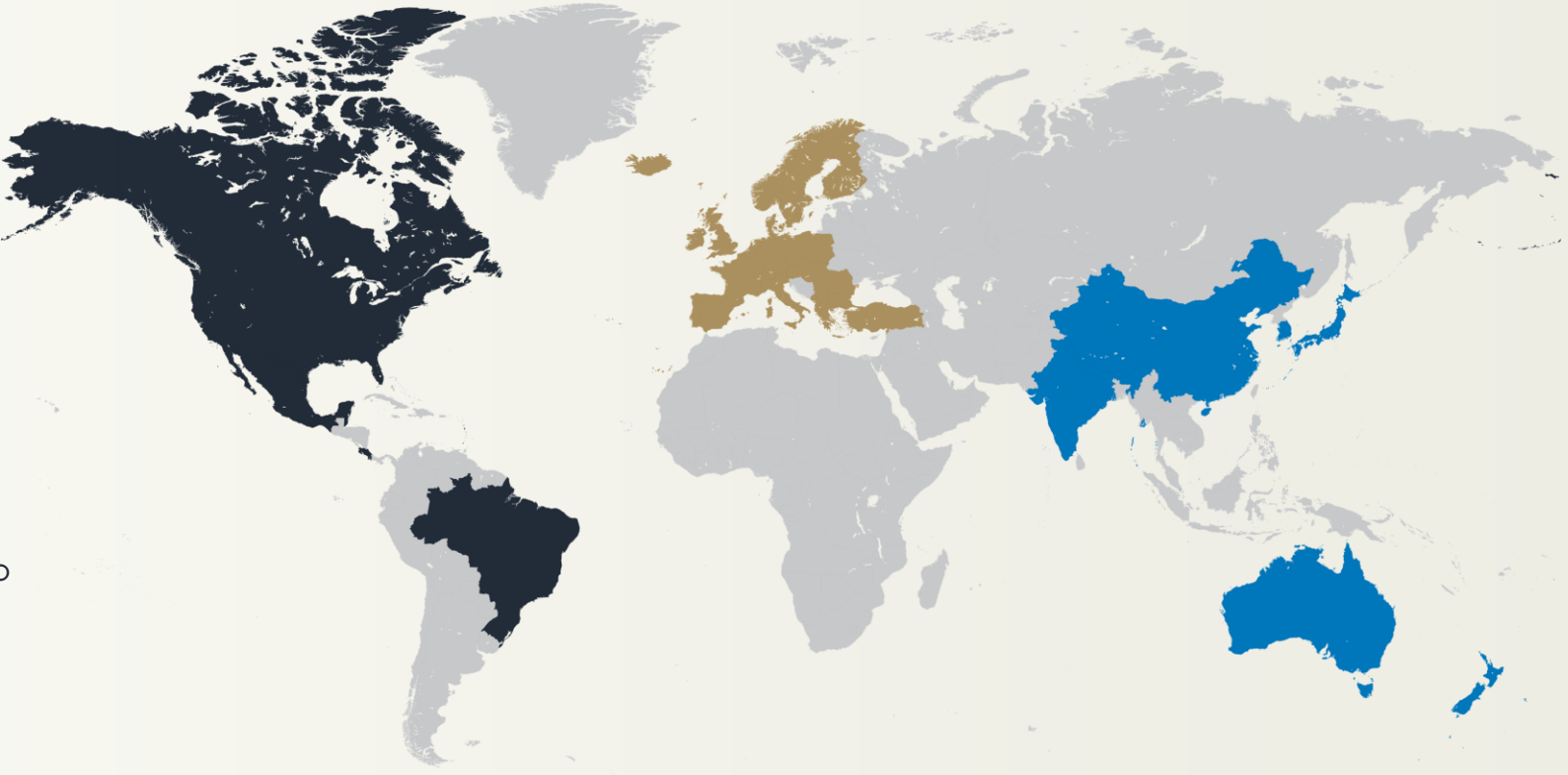
# Embla Medical has opportunities for further growth in key markets



# Embla Medical regional sales split 2023

Operations in 36 countries

Sales 2023  
**USD 786**  
million



■ Americas ■ EMEA ■ APAC

# Embla Medical manufacturing locations

- Manufacturing of advanced prosthetic solutions, including Bionics, takes place in Iceland and Scotland
- Manufacturing of most other prosthetics solutions, components and premium bracing solutions takes place in the U.S. and Mexico
- Manufacturing of soft goods is outsourced to China
- In addition, we have a few smaller specialized manufacturing facilities in selected countries



Since 2009, the global manufacturing platform has consolidated its operations, presently functioning in 13 fewer locations compared to in 2009

# We will continue to build on a solid foundation



2013+ Vertically integrated provider of mobility solutions

1995+ Building market access and a broad portfolio

1971-1995 Developing a product

Our leading prosthetic brands serve an amputee population that needs maintenance, renewals, and upgrades of their prosthesis



Above 70-80% of prosthetic component sales are recurring sales to existing patients

# Only 30-40% of all new leg amputees are fitted with prosthetic solutions

>850,000  
New major lower limb amputees per year

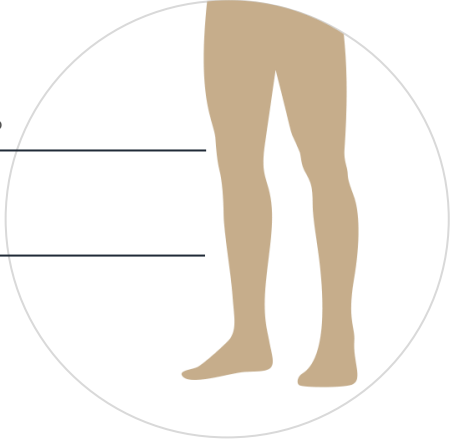
Western World	~200,000
Emerging Markets	~650,000

30-40%  
of new leg amputees are fitted with prosthetic solutions

Western World	40-60%
Emerging Markets	10-30%

Level of amputation

Above knee ~50%  
Below knee ~50%



65-70  
is the average age of the amputee population

Western World	Above 70
Emerging Markets	Below 70

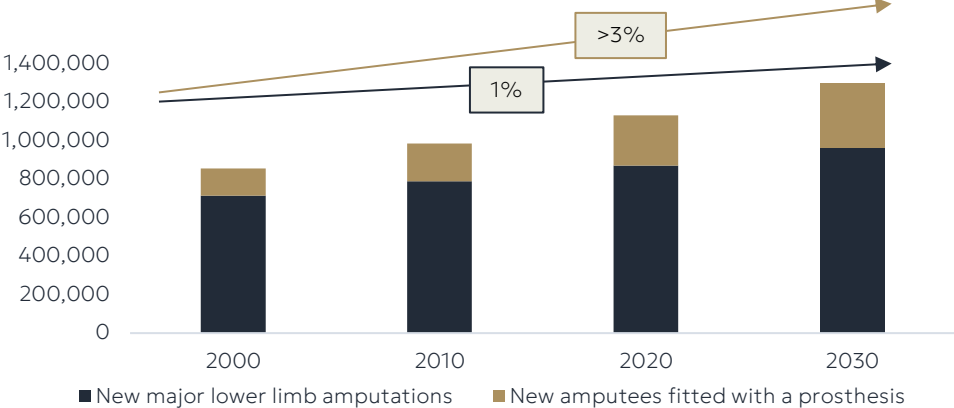
New lower limb amputations\*



■ Vascular related diseases ■ Trauma ■ Other

Western World	Vascular 70-90%
Emerging Markets	Trauma up to 40%

Growing number of amputees receiving prosthetics



Source: Embla Medical management estimates  
\* The average life expectancy of people with lower limb loss due to trauma and other causes is generally higher than of those with limb absence due to vascular related diseases, and therefore the population of amputees is likely more tilted towards trauma patients.

# Example of megatrends that provide opportunity for positive development in volume, pricing and product mix for Embla Medical

## An aging and more active population



- The global population of 65 and older is increasing and so is the amputee population
- A growing number of people afflicted by vascular diseases, the leading cause of amputation
- An increased number of fractures, joint instability and joint afflictions

## Access to healthcare improving in emerging markets



- Global economic growth will be powered by emerging markets
- Disposable income increasing in emerging markets and willingness to pay out-of-pocket
- Increasing healthcare coverage in emerging markets

## Healthcare consolidation and budget management



- Healthcare systems efforts to manage cost, increasing need for innovation and health economic benefits
- Consolidation in the Patient Care service market
- Demand for cost effective solutions without compromising quality

## Improved treatment options and penetration of high-end solutions



- New innovative technologies being accepted for reimbursement
- Increasing healthcare coverage and better access to patients with increasing fitting rates
- Increased acknowledgment of total health economic benefits of high-end solutions

## Healthcare consumerism empowering patients



- Individuals are taking greater control of their healthcare decisions, pushing for solutions that fit their needs
- Patients leave their healthcare provider if not satisfied and search for a new one online
- Increased push for transparency that helps people make informed decisions about their care

## Digitalization increasing ease of doing business



- How people communicate is transformed through digitalization, patients to health care providers and businesses to businesses
- Increased automation through digital processes in order flow and manufacturing
- Data can enable improved and timely service delivery to patients




# Strategic priorities



# Our Growth'27 strategy


## O&P Growth Drivers

## Continuity



1

Patient Reach




2

Innovative Solutions



3

O&P Value Creation



4

Bracing Simplified



5

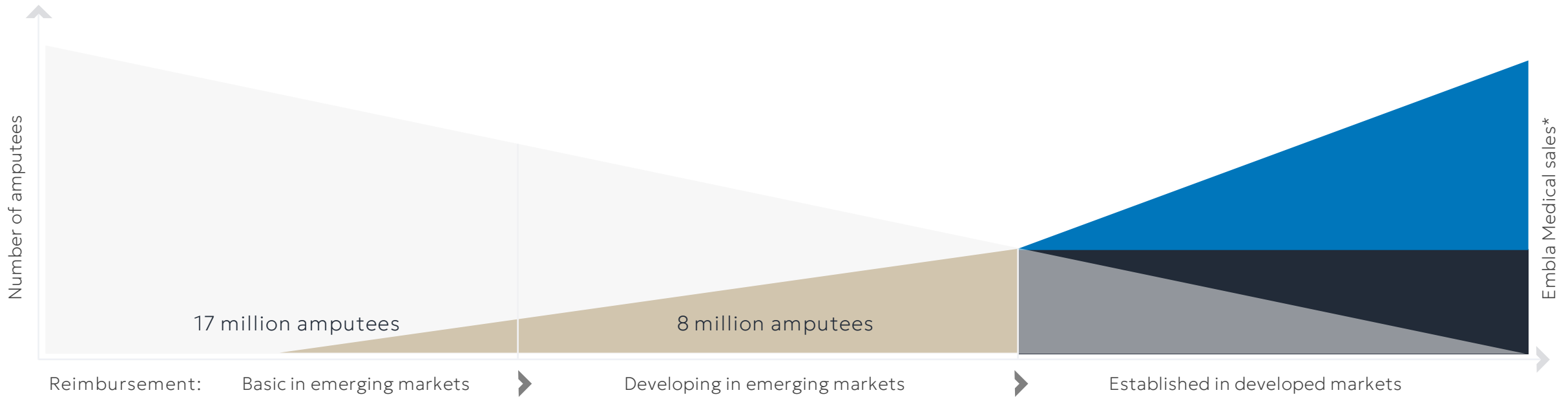
Enabled by People, Sustainability & Scalability  
OUR M&A STRATEGY SUPPORTS GROWTH'27



# 1 | Significant opportunity to grow sales in emerging markets

~10%  
of Embla Medical sales generated in emerging markets with basic and developing reimbursement systems

~90%  
of Embla Medical sales generated in developed markets with established reimbursement systems



# 1 | Reaching more patients through better understanding of the patient journey



Referrals\*



Payment considerations



Patient care



Patient reach

Developed Markets



Lower limb:  
40 - 60%  
Upper limb:  
10 - 15%



Reimbursement  
>90%  
Private pay  
<10%



Established  
patient care in  
O&P clinics



Functional trade-up  
(low active solutions)  
Access to prescriber & payer  
Strengthen O&P presence



Support both markets with  
maintenance & renewals of  
mobility solutions (70-80% of  
O&P is recurring sales)



Emerging Markets



Lower limb:  
10 - 30%  
Upper limb:  
5 - 10%



Reimbursement  
<30%  
Private pay  
>70%

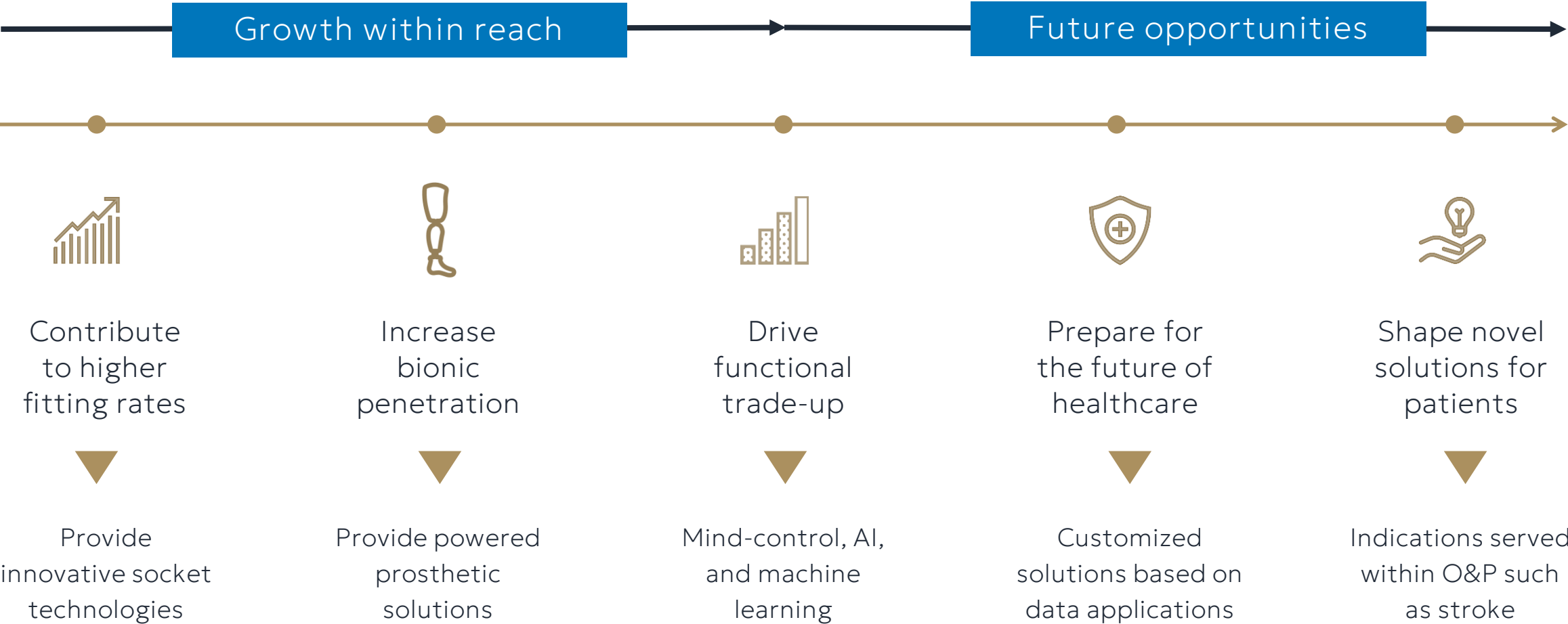


Limited access  
to established  
patient care



Functional trade-up  
(affordable solutions)  
Access to private pay  
New O&P Patient Care

# 2 | Innovation to drive near-term and future growth

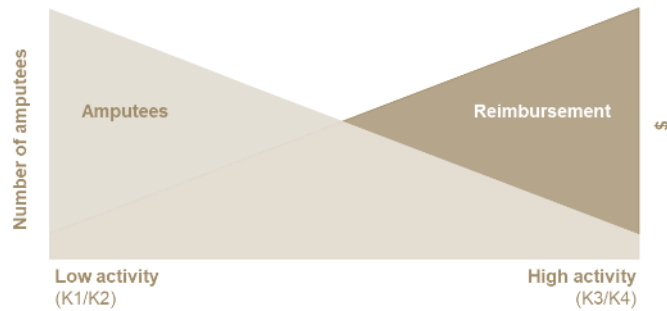


# 2 | From simple to powered, intelligent and energy efficient Bionic solutions



## 2 | Solutions that match the needs of low active amputees

Elderly don't get solutions they need



The benefits of high-end solutions

- Reduce risk of falls
- Reduce dependency on others
- Reduce cost in elderly care
- Increase mobility
- Increase daily prosthetic use



From socket molding to user-friendly technology



From a mechanical knee to a powered knee



From passive feet to energy efficient feet



# 3 | The Patient Care journey



11  
Countries

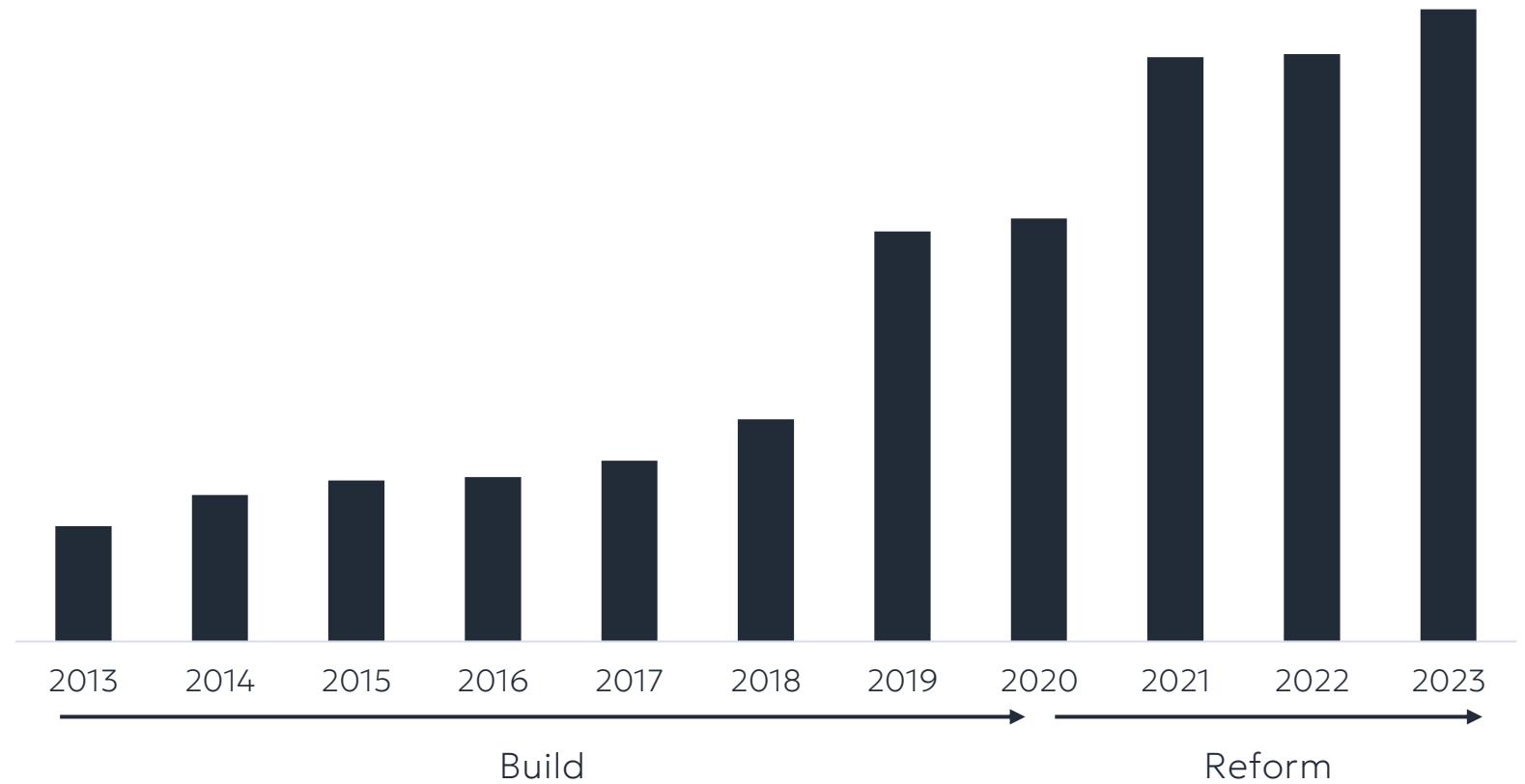


~200  
Locations



1,500+  
Employees

Patient Care represents a growing part of sales





# 3 | Creating value for O&P Clinics

Key trends in O&P Clinics calling for new ways of working		O&P Clinic P&L in the US**	Potential impact	Relative time to impact
CPO shortage*	<b>Increased Sales</b> Reach more patients through clinically proven innovative solutions	100%		
New generation of CPOs	<b>Lower Cost of Goods and Technical Labor</b> Centralize sourcing, use of own products, complete solutions, and central manufacturing	36%		
Regulatory burden	<b>Clinical Efficiency and Clinical Labor</b> Standardization and full treatment pathway	15%		
Reimbursement dynamics	<b>General and Administrative Efficiency</b> Centralize back-office, process and system support, and scalability	41%		
Digitalization	<b>Operating Profit</b> Opportunities for increased sales and cost efficiencies	8%		

### 3 | O&P services is an offering that strengthens Embla Medical as a business partner

Service offering

Key benefit



Outsourced fabrication

- Central fabrication
- Össur Leg

Reduced need for manpower and floor space

Service offering

Key benefit



Patient outcomes

- PRO App
- Outcomes mgmt.

Reimbursement justification and optimal product selection



Practice management

- Business IT solution
- Claims mgmt.

Management software to increase efficiency



Business support

- Compliance audit
- Reimbursement
- Regulatory
- Partner network

Support to accelerate sales growth

## 4 | Bracing Simplified strategy



### Identity

Be the trusted partner for our customers

- 
- Sales enablement training
  - Marketing campaign



### Customer Convenience

Reduce complexity for our partners

- 
- Curated digital education
  - Digital inventory management solution



### Product Confidence

Provide our partners with a simplified and strong portfolio

- 
- Value engineering
  - Portfolio streamlining



### Responsibility

Reduce our footprint and that of our partners

- 
- Responsible packaging

# 5 | Our M&A strategy supports Growth'27

Tactical and strategic opportunities to accelerate long-term growth



Market Access



Reaching more patients



Portfolio Expansion



Serving more chronic patients



Technology



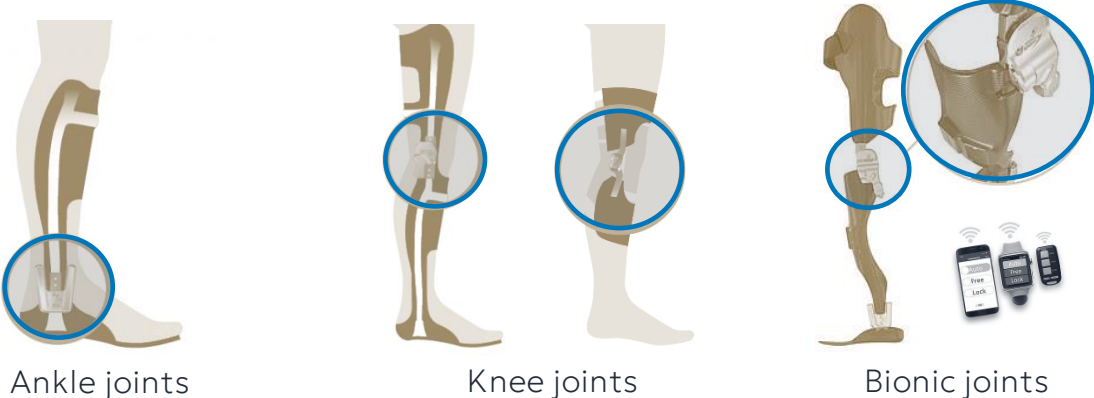
Innovative O&P solutions

# 5 | Introduction to Neuro Orthotics; Fior & Gentz acquisition in Jan 2024 provides a strong fit to address chronic mobility challenges more broadly

## Addressing patients with chronic neurological conditions

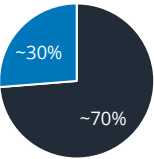
The F&G portfolio of innovative and customized orthotic joints for knees (KAFOs) and ankles (AFOs) offer a unique opportunity to address a significant number of patients suffering from chronic neurological conditions such as MS, CP, CMT, stroke and partial foot amputation

## Broad and innovative portfolio of joints for knee and ankle



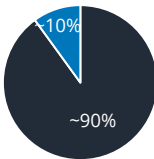
## Untapped market offering repeated business

### Regional split



Germany  
International

### Customer split<sup>1</sup>



Repeat customer  
New customer

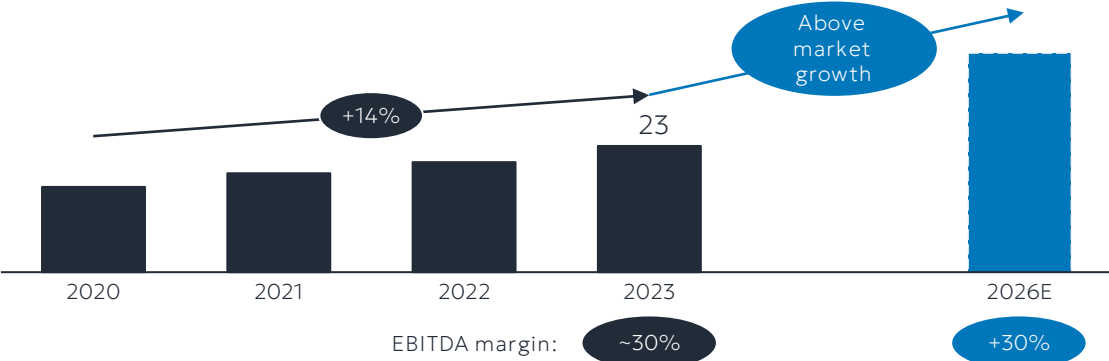
### Customer split



O&P clinics<sup>2</sup>  
Other

## Attractive profitable growth

In EUR million, for illustrative purposes



# Embla Medical and Sustainability



# Our Sustainability Commitment

- We provide products and services that contribute to good health, using responsible production methods and supporting climate action, while being a sponsor for inclusivity and transparency.
- We believe that sustainable growth is the only way to build a successful and responsible business for the benefit of future generations.

## RESPONSIBLE FOR TOMORROW®



# Our Environment

Responsible for our environmental impact

## Our Operations

We have set science-based targets and are actively working towards net-zero operations by 2050.

## Our Products

We are reducing the environmental impact of our products and services.

## Our Supply Chain

We are reducing the environmental impact in our supply chain.



scope 1 and 2, and selected scope 3 emissions

>95%

electricity purchased from renewable energy sources

60%

average reduction in cardboard weight for OA and ligament knee braces

Science Based Targets (SBT)

Committed in 2022, submitted in 2023, validated in 2024

Near-term SBT's reached

Net-Zero operations





# Our People

Responsible for enhancing the social well-being of our people & communities

## Our Customers

We develop quality products and services that improve people’s mobility.

## Our Suppliers

We partner with suppliers that are committed to quality, and ethical and sustainable practices.

## Our Employees

We nurture the well-being and development of our employees within an inclusive and safe work environment.

## Our Communities

We create a lasting positive impact on our communities, helping more people to live a Life Without Limitations.



design and market functional products for the elderly, 3 out of 4 already launched of target set for 2024



Gender Ratio  
50 / 50 %

40% female in management positions



4 of 5

global employee satisfaction as measured by Gallup



606

implemented employee suggestions on improved workplace safety in 2023



# Our Business

Responsible business leading with integrity and transparency

## Our Governance Practices

We practice sound governance in all our activities.

## Our Business Integrity

We set high ethical standards and act with honesty and integrity.

## Our Reporting Transparency

We ensure transparent reporting of our business practices.



**74%**  
of employees trained  
in our Code of  
Conduct





 **EMBLA MEDICAL™**

# CLIMATE TARGETS VALIDATED

by the Science Based  
Targets initiative

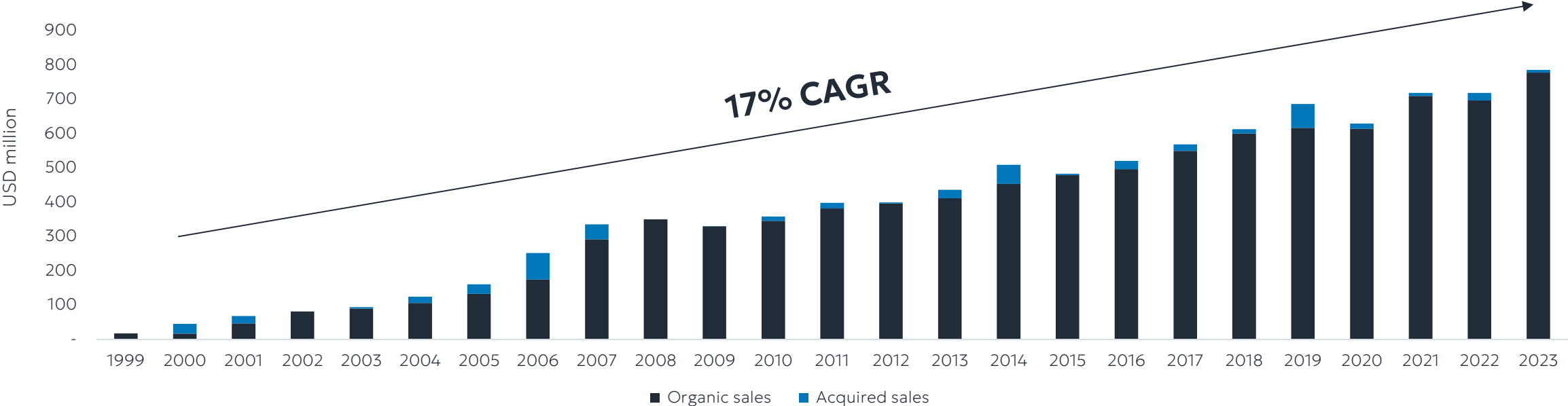


DRIVING AMBITIOUS CORPORATE CLIMATE ACTION

# Financials



# Embla Medical has grown through a healthy combination of organic growth and acquisitions

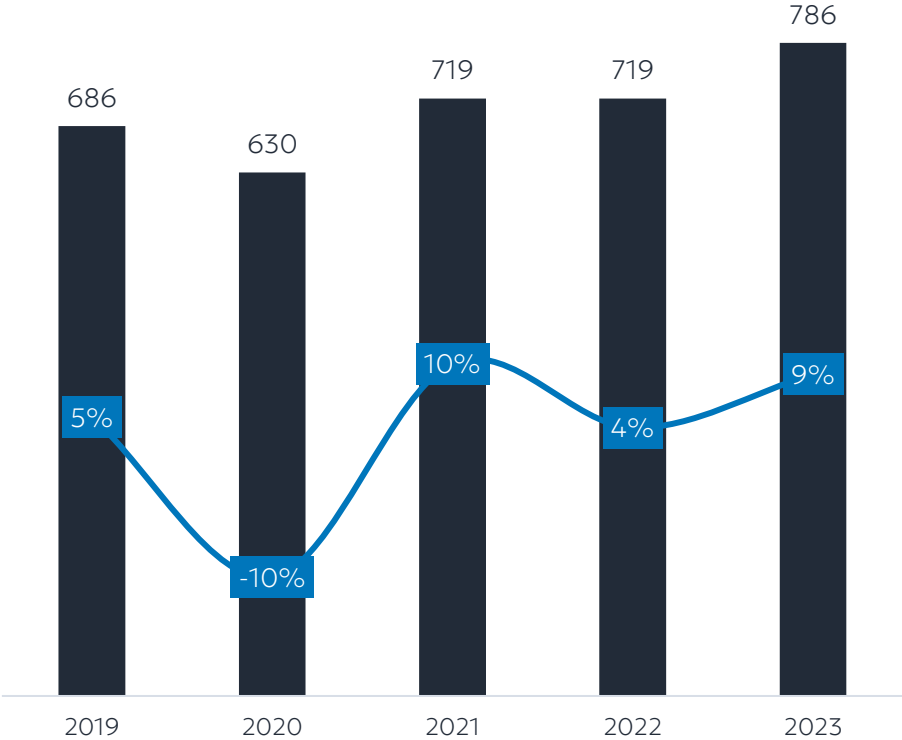


- 1999** Listed on the stock exchange
- 2000** Acquisition of Flex-Foot (Pros)
- 2004** 1<sup>st</sup> gen of RHEO KNEE, is launched
- 2005** Acquisition of Royce Medical (B&S)
- 2006** Acquisition of Gibaud (B&S)
- 2013** Acquisition of TeamOlmed and OCH, its first O&P clinics (Clinics)
- 2016** Acquisition of Touch Bionics and Medi Prosthetics (Pros)
- 2019** Acquisition of College Park (Pros) and Orthoway (Clinics) and divests Gibaud (B&S)
- 2021** 3<sup>rd</sup> gen of bionic POWER KNEE is launched
- 2022** Acquisition of Naked Prosthetics (Pros)
- 2024** Acquisition of FIOR & GENTZ
- 2024** Embla Medical parent organization established

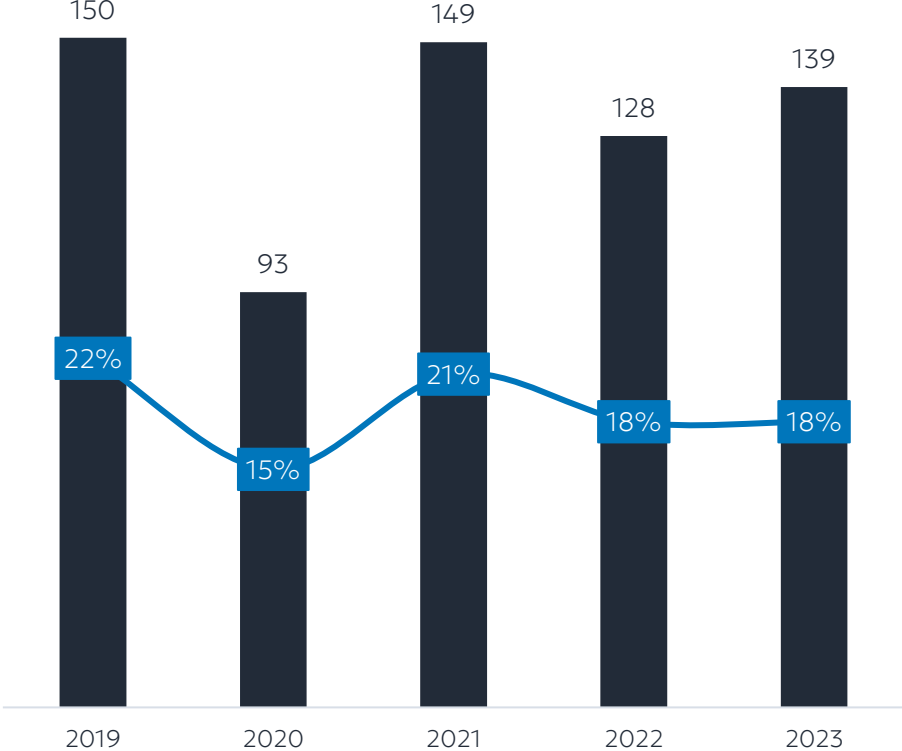
Note: The chart is an approximation for split between organic and acquired growth

# Embla Medical has a solid and focused business

Sales and organic growth  
USD million



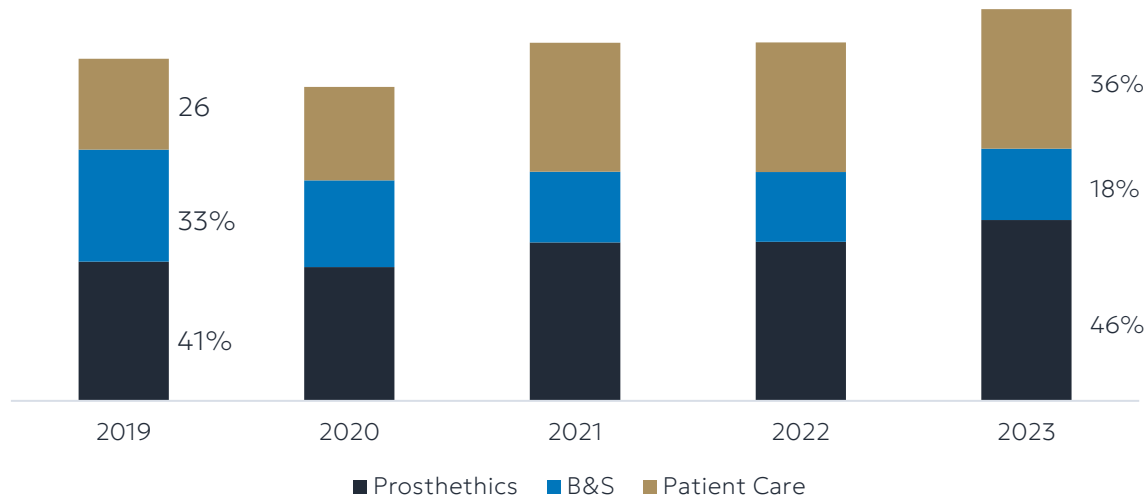
EBITDA and EBITDA margin before special items  
USD million



# Our business mix has changed significantly

Increased focus on chronic mobility challenges

- Strong organic growth and acquisitions in both Prosthetics and Patient Care
- Divestments of Gibaud and B&S sales entities



# We have an increasingly scalable infrastructure

Category	Scalability	Key drivers impacting profitability
COGS	High	<ul style="list-style-type: none"><li>▪ Scalable manufacturing platform</li><li>▪ Centralized procurement (strategic sourcing)</li><li>▪ 13 fewer locations since 2009</li></ul>
S&M	Medium	<ul style="list-style-type: none"><li>▪ Implementation of a new CRM platform</li><li>▪ Growing high-end solutions sales (e.g. Bionics)</li><li>▪ Investments in market access in emerging markets</li></ul>
G&A	High	<ul style="list-style-type: none"><li>▪ Shared service center in Poland</li><li>▪ Global IT supporting majority of Embla Medical entities</li><li>▪ Centralized back-offices in Patient Care</li></ul>
R&D	Low	<ul style="list-style-type: none"><li>▪ Investments in high-end product development</li><li>▪ New innovation</li></ul>





# Financial ambitions for Growth'27

- Sales growth

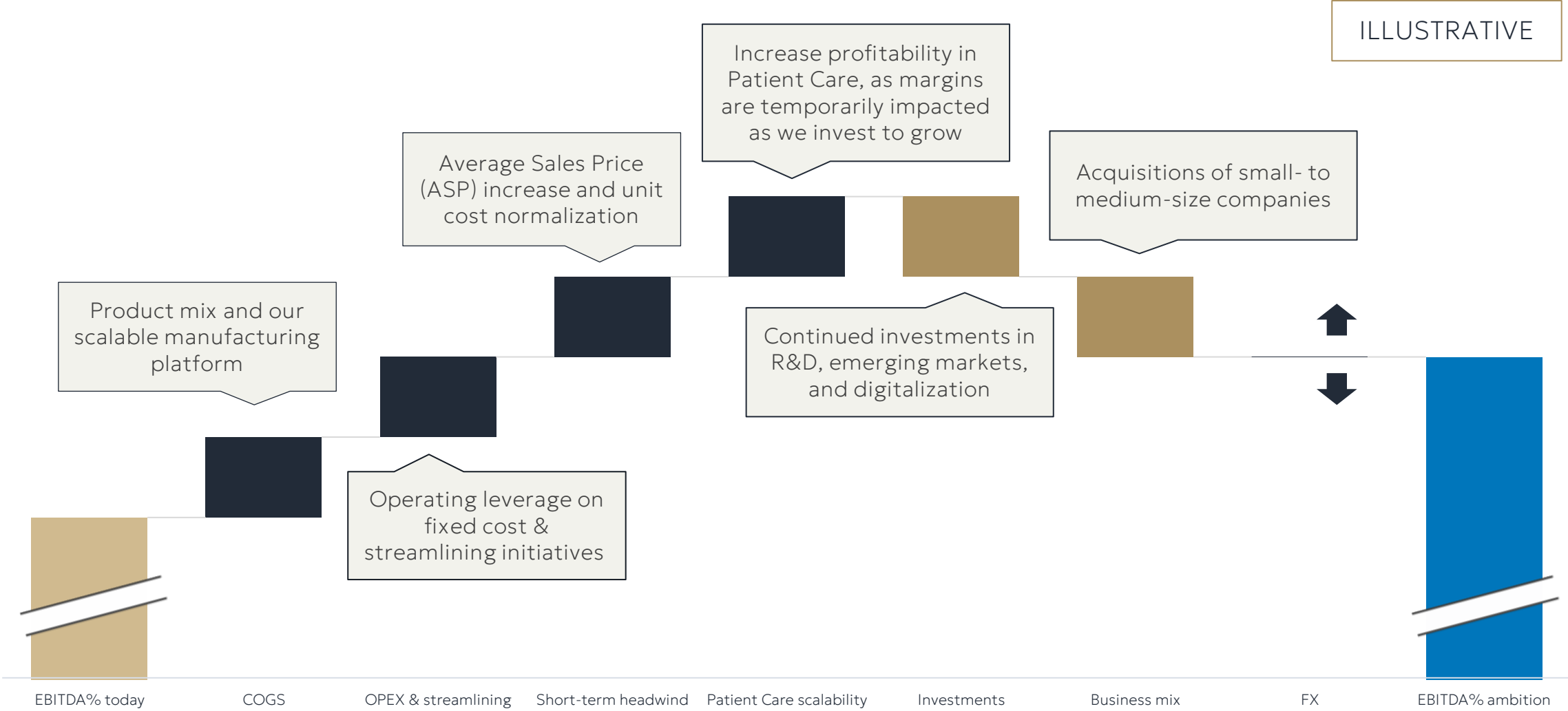
$$\begin{array}{ccc} 7-10\% & = & 5-7\% + 2-3\% \\ \text{LCY* growth} & & \text{organic growth} + \text{acquisitive growth} \\ \text{p.a. on average} & & \text{p.a. on average} \end{array}$$

- EBITDA margin before special items
  - The ambition is to gradually increase the EBITDA margin before special items
  - EBITDA margin before special items expansion is subject to acquisitions and currency movements, in addition to changes in the business mix
- Capital allocation
  - We will prioritize growth opportunities, value-adding investments and acquisitions, while maintaining a healthy balance sheet with a target range of 2.0-3.0x NIBD/EBITDA before special items
  - Excess capital will be returned to shareholders via purchase of own shares

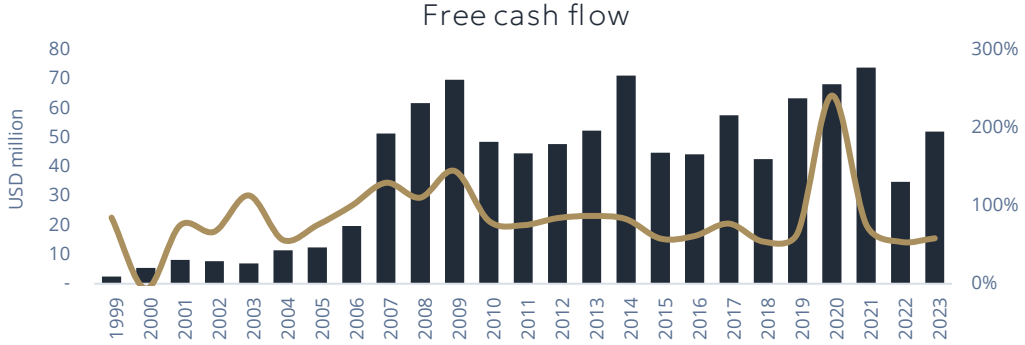


# We have numerous opportunities to increase the EBITDA margin

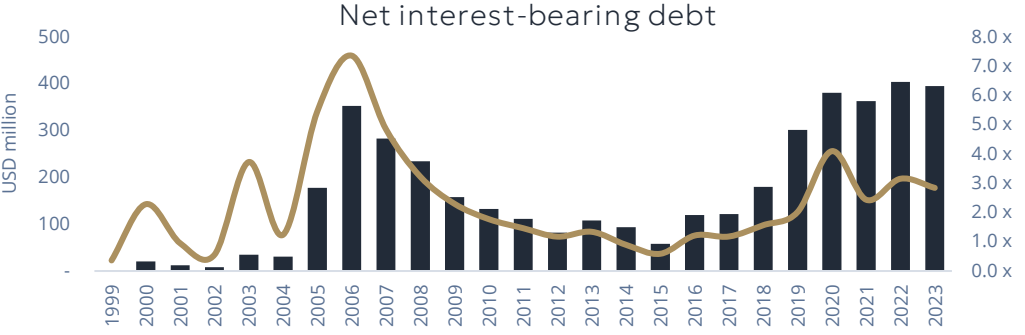
ILLUSTRATIVE



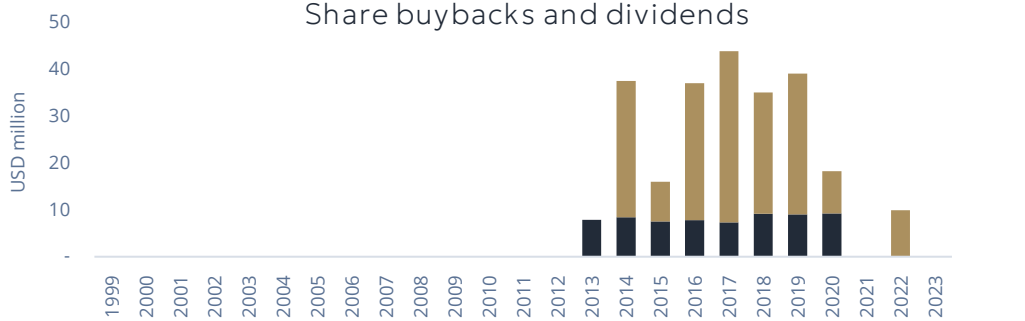
# Embla Medical has a history of strong cash flow generation



FCF  
~85% of EBIT  
on average



Target  
2.0-3.0x  
NIBD/EBITDA



Total of USD  
245 million  
since 2013



50 Note: Free cash flow to firm is calculated as cash generated by operations less capital expenditures and taxes and excluding special items  
The share buyback program was put on hold on 17 March 2020 due to the impact of the COVID-19 pandemic, as the net interest-bearing debt to EBITDA (NIBD/ EBITDA) ratio was temporarily above the target level. The share buyback program commenced again in 2022 but as the NIBD/EBITDA ratio was at the upper end of the target range at the end of Q3 2022, share buybacks have temporarily been paused.

# Contact our Investor Relations



## Investor Relations

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## Embla Medical press releases by e-mail

If you wish to receive Embla Medical press releases by e-mail, please register on our website: [www.emblamedical.com/investors](http://www.emblamedical.com/investors)

## Financial calendar and events

October 22 2024	Interim report Q3 2024
October 23 2024	Q3 Road Show Copenhagen (Nordea)
October 23 2024	Q3 presentation and Q&A virtual (HCA Capital)
October 24 2024	Q3 Road Show Paris (SEB)
October 25 2024	Q3 Road Show Frankfurt (SEB)
October 28+30 2024	Q3 Road Show UK/US virtual (Carnegie)
November 19-20 2024	Jefferies Global Healthcare Conference, London
November 26 2024	DNB Nordic Healthcare Conference, Oslo
November 27 2024	Danske Bank Winter Seminar, Copenhagen
December 3 2024	Nordea Expert Call: Neuro Orthotics (Fior & Gentz)
December 3 2024	Redeye Life Science Conference, Stockholm
December 4 2024	ABG Investor Days, Stockholm
February 5 2025	Interim report Q4 2024 and Annual Report 2024
February 6 2025	Q4/FY Road Show Copenhagen (ABG)
February 7 2025	Q4/FY Road Show Stockholm (ABG)
March 12 2025	Annual General Meeting 2025
March 26-27 2025	DNB Nordic-American Healthcare Conference, New York City



#### Forward-looking statement

This presentation contains forward-looking statements, which reflect the Management's current views with respect to certain future events and financial performance. Although the statements are based upon estimates the Management believes to be reasonable, there is no assurance that these statements will be achieved.

Statements containing the financial outlook for 2024 and the following years naturally involve risks and uncertainties, and consequently actual results will differ, and may differ materially, from those projected or implied in the forward-looking statements.

The risks and uncertainties may include unexpected developments in the international currency exchange and securities markets, financing, market driven price decreases for Embla Medical's products, delay or failure of development products, production problems and unexpected cost increases, development of new technologies by competitors, the introduction of competing products within Embla Medical's core areas, exposure to product liability and other lawsuits, changes in reimbursement rules and governmental laws.