



# Conference Call | First Quarter 2023

Gregor Siebert, CEO | Sebastian Werner, CFO

17 May 2023



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# AGENDA

- ▶ **1 Corporate Overview**
- 2 Products
- 3 Financials

# PAION Mission Statement

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**“** *PAION’s mission is to be a leading specialty pharmaceutical company in the fields of anaesthesia & critical care by bringing novel products to market to benefit patients, doctors & other stakeholders in healthcare.* **”**

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# PAION strategy

## Establishment of professional commercial hospital sales organizations in Europe

- for Anesthesia and Critical Care Products

## Accelerate the launch of the lead drug remimazolam

- in Procedural Sedation
- In General Anesthesia (from end Q2 onwards)

## Piggybacking the launch of

- Angiotensin II
- Eravacycline in the EU and UK

**Objective:**  
Innovative Leader in  
Anesthesia &  
Critical Care

**Explore additional outlicense and distribution opportunities** outside Europe for the lead drug remimazolam

**Evaluate synergistic opportunities** (lifecycle management) and in-licensing to drive long term growth

**Build up a solid and robust financing concept** for the development of the commercial infrastructure and business

# PAION AG at a glance



PAION AG is a specialty pharmaceutical company focusing on anesthesia and critical care products



Approval for remimazolam in all major pharmaceutical markets, Market launch in Europe, Japan, South Korea, Taiwan and the USA, plus licensing in Latin America and Southeast Asia.



3 innovative products for acute care in Europe: remimazolam, angiotensin II and eravacycline



Listed on the Frankfurt Stock Exchange, Prime Standard (FSE: PA8K)



Market capitalization: ~ € 35m



Shareholder structure (according to the latest notifications)  
Over 3%: Cosmo Pharmaceuticals

# PAION's product portfolio and market access



Attractive **Sales Target Group** addressed by speciality portfolio in anesthesia and intensive care



**Market access** and technical sales readiness achieved in main markets



Long-term patent validity of +10 years, **just at the beginning**



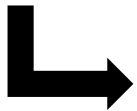
**Gross margin potential**, peak sales at €200m



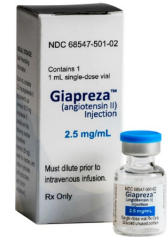
Saturation for product portfolio; **green field chance for the product portfolio** with huge potential due to low market penetration



Strong **partner network** (e.g. Viatris, Medis)



**Solid foundation for the rapid execution of strategy**



# Gregor Siebert appointed as CEO with more than 35 years of pharma & medical device industry experience

**Global Sales & Marketing Executive with proven track record of restructuring, building and driving sales organizations**

**Key Expertise:** Europe and Emerging Markets, Sales & Marketing Strategy and Execution, Business Development and creation of new businesses, Gx/Rx Hospital & Retail pharmaceuticals in **anesthesia and intensive Care** with focus on **injectables**

Since 12/2022	Chief Executive Officer at <b>PAION</b>
2022 – 11/2022	Supervisory Board member at <b>PAION</b>
2015 – 2021	Head of Sales and Marketing at <b>Curasan</b>
2014 – 2015	Head of International Sales and Marketing at <b>GL-Pharma</b>
2010 – 2013	Vice President Hospital at <b>Pfizer</b>
2004 – 2010	Commercial Lead Europe at <b>Hikma</b>
1985 – 2004	Division Director at <b>Abbott</b>



# Sebastian Werner appointed as CFO with more than 20 years of pharma experience

## Finance Executive with proven track record in the pharma industry

**Key Expertise:** Extensive experience in finance. Senior positions in the pharmaceutical and life science industry for over 20 years. He started this international career at Hoffmann La Roche where, among other things, he worked for 6 years as Chief Financial Officer for the Corporate Operations Division. Most recently he worked for Zimmer Biomet Deutschland GmbH, where he was Chief Financial Officer and Managing Director for Central Europe for 9 years.

Since 06/2022

Chief Financial Officer at **PAION**

2013 – 2022

Managing Director & CFO for Central Europe **Zimmer Biomet**

1996 – 2013

CFO Corporate Operational Divisional Group at **Hoffmann La Roche**



# Important events 2023

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- ✔ **EU approval** of remimazolam in general anesthesia in the EU
- ✔ Extraordinary General Meeting approves **capital reductions** and creates scope for further corporate financing
- ✔ The CMS (Centers for Medicare & Medicaid Services) has established a „**J-code**“ for remimazolam in the U.S. that will be effective on July 1, 2023
  - A unique J-code for remimazolam is an important step in facilitating reimbursement and broadening access
- ✔ TTY Biopharm **submitted marketing authorization application** in general anesthesia in March 2023 in Taiwan

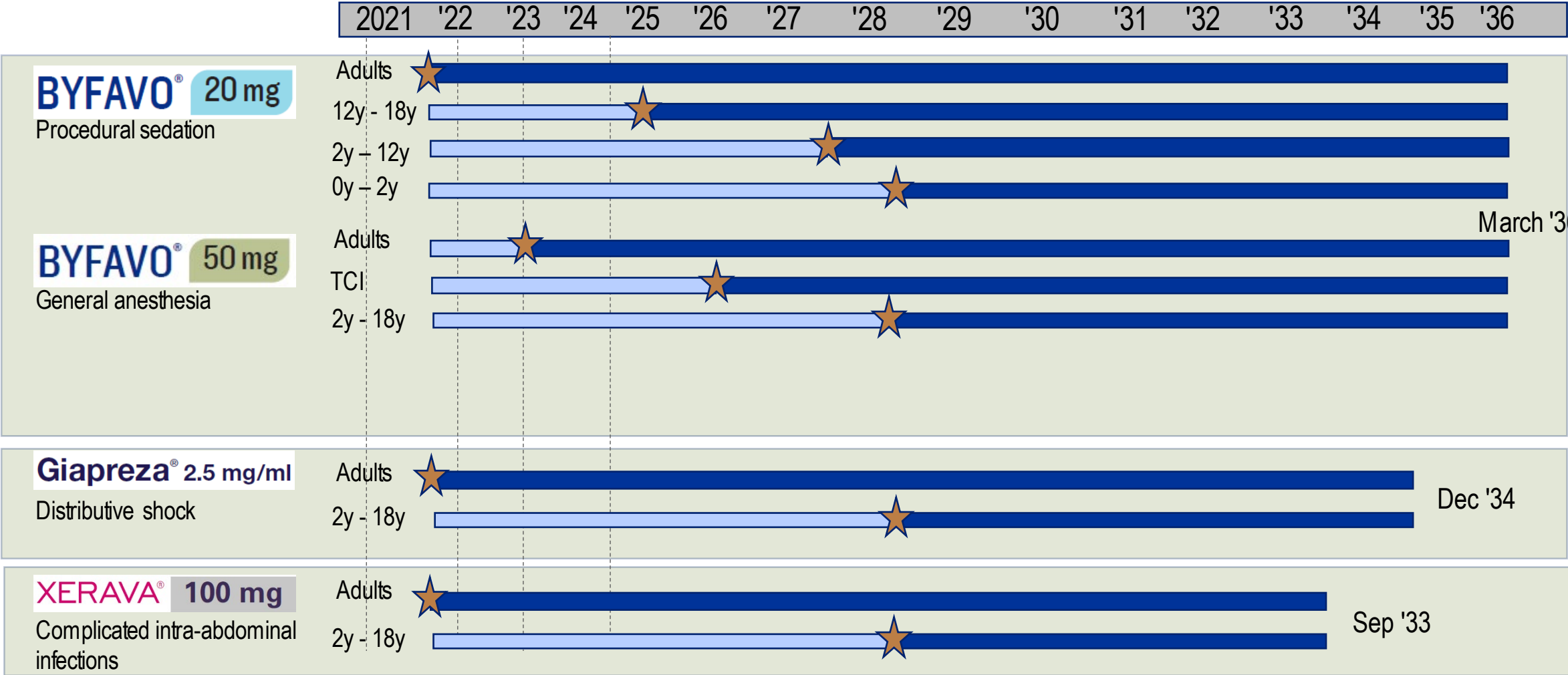
# Targets for PAION 2023

	Remimazolam launch in General Anesthesia in the EU	
	Market access and launch implementations of Angiotensin II and Eravacycline in EU	
	Growth in remimazolam sales in the key markets in Europe	
	Market approval remimazolam EU General Anesthesia	
	Remimazolam CHMP meeting EU General Anesthesia	

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# Lifecycle Management



★ Year of first launch in Europe; development phase; commercial phase; arrow ends at expiry of latest granted patent; EMA market protection ends as follows: Xerava 2028, Giapreza 2029, Byfavo 2031 | TCI – computer in pump controls rate of infusion

# Three innovative products for acute care in Hospitals for Europe

## Angiotensin II

Indication: septic or other distributive shock\*.

- Leverages a system (RAAS) that is currently not targeted by other therapies for hypotension in distributive shock
- Median response time for angiotensin II responders was approximately 5 minutes
- The plasma half-life of angiotensin II is less than 1 minute, which allows for individualised dose adjustment

**Estimated peak sales p.a.: € 50m**

## Remimazolam

Indication: procedural sedation for adults.

- Delivers an efficient process from start to finish, procedure after procedure
- Suitable for a broad and complex range of patients
- Helps to optimise the overall patient journey

**Estimated peak sales p.a.:**

**€ 40 to 50m (procedural sedation)**

**€ 50 to 60m (general anesthesia)**

## Eravacycline

Indication: treatment of complicated intra-abdominal infections (cIAI) in adults\*\*.

- Provides greater confidence as an alternative (empiric) antibiotic choice
- Establishing vital, broad-spectrum coverage as monotherapy
- Has potent in vitro activity and proven clinical efficacy against Gram-negative, Gram-positive and anaerobic pathogens

**Estimated peak sales p.a.: € 25 to 35m**





\* Angiotensin II is indicated for the treatment of refractory hypotension in adults with septic or other distributive shock who remain hypotensive despite adequate volume restitution and application of catecholamines and other available vasopressor therapies

\*\* Consideration should be given to official guidance on the appropriate use of antibacterial agents

# Lead drug Remimazolam (Byfavo®)



# The ideal drug would combine “the best of both worlds”\*

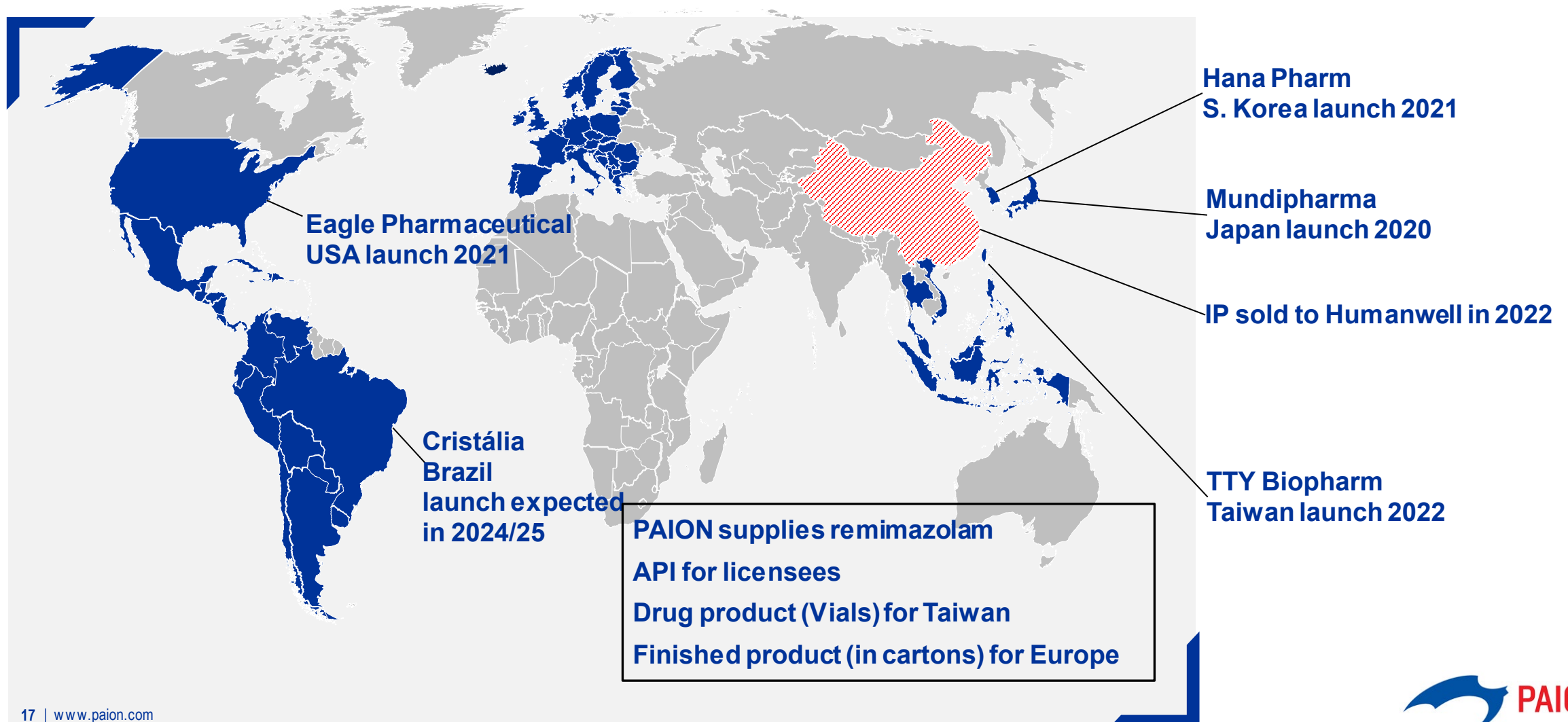
Propofol	Remimazolam		Midazolam
			
<ul style="list-style-type: none"><li>• CV/Respiratory depression</li><li>• No reversal agent</li><li>• Pain on injection</li></ul>	<ul style="list-style-type: none"><li>• Rapid onset/offset</li><li>• Predictable recovery time</li><li>• Less resources for supervision (after procedure)</li></ul>	<ul style="list-style-type: none"><li>• Lower safety issues</li><li>• Reversal agent</li><li>• Less resources for supervision (during procedure)</li></ul>	<ul style="list-style-type: none"><li>• Variable and prolonged periods of sedation</li><li>• Re-sedation risk</li><li>• Slow onset</li></ul>



**Predictable outcome for the Anesthetist / Increased safety for the patient**

\* said Physicians at the first ever Market Research performed in 2008 by the Company

# Remimazolam launched worldwide – licensing and supply of acute and specialty pharmaceuticals to regional experts



# PAION's partners

## U.S. - Eagle Pharma



- **Lead indication: procedural sedation**
- BYFAVO™ launched in 2021
- Royalties 20-25%

## Japan - Mundipharma



- **Lead indication: general anesthesia**
- Mundipharma launched Anerem® in 2020
- Current royalties: 15.5%

## Taiwan - TTY BIOPHARM



- License agreement signed in 2021
- Approval received 2022
- Supply of medicinal products at a percentage of the net selling price

## Cristália (Latin America)



- Exclusive license agreement signed with Cristália in 2022
- Market approval expected in 2024
- Royalties 20%

## South Korea + Southeast Asia - Hana Pharm



- **Lead indication: general anesthesia**
- Market launch in 2021 in SK
- Expansion of the license area to include Southeast Asia in 2020
- License fee: Low double digits

## Eastern Europe - Medis



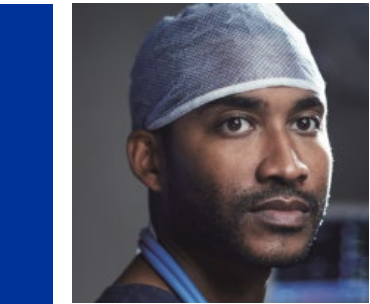
- Exclusive cooperation agreement signed with Medis in 2022
- Supply, distribution, marketing and sales of remimazolam, angiotensin II and eravacycline
- Medis pays PAION a transfer price for the finished products

## Viartis



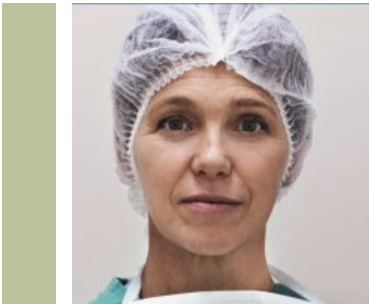
- **Exclusive cooperation agreement** with Viartis signed in 2022
- Viartis is responsible for the launch, marketing and commercial distribution of PAION's products in a total of 7 European markets, particularly in Southern Europe

# Target groups: Physicians and judgements about remimazolam



## The sedation experts: Anesthetist

- Safety oriented & specialist skillset
- Key person for the introduction of a new sedation drug
- Decision-makers in favor of promoting remimazolam, very positive toward remimazolam























## The experts for interventions: gastroenterologists

- Focus on **gastroenterologists** due to the good data available
- Focused on the **successful completion** of the procedure
- **Autonomy in the selection and administration of sedation agents**

<p><i>"Anyone capable of sedating patients with midazolam, can sedate patients with remimazolam."</i></p>	<p><i>"I just love sedating with remimazolam. It's easy to use, and patients are awake and able to absorb information as soon as they wake up."</i></p>
<p><i>"Very fast recovery, and already awake before you come to rest."</i></p>	<p><i>"I can inform the patient right after the procedure which saves me time not having to go back to the recovery room to inform the patient about the procedure"</i></p>

 Complex “hospital launch” process with the alignment of multiple stakeholders

# Three different innovative drugs in one commercial organization

		<div>byfavo<sup>®</sup> remimazolam besylate</div>	<div>XERAVA<sup>™</sup> (eravacycline) for injection</div>	<div>GIAPREZA<sup>™</sup> (angiotensin II) injection for intravenous infusion</div>
Place of Usage	OR			
	ICU			
	Endoscopy			
Decision Makers				
Anesthetist				
Microbiologist				
Gastroenterologist				
ICU –Specialist				
Pharmacist				

Strong overlap in accounts (decisionmakers) and target groups

# PAION hosted a sponsored angiotensin II symposium at ISICEM in Brussels

42nd ISICEM International Symposium 2023 | 21-24 March 2023, Brussels, Belgium

## Management of refractory distributive shock: new insights and practical aspects

Wednesday 22 March, 12.30–13.30 (CET)  
400 Hall

### AGENDA

Chair: Professor Peter Pickkers

Insights into the ATHOS-3 trial and post hoc analyses

Professor Peter Pickkers  
(The Netherlands)

Refractory distributive shock in cardiac surgery patients

Professor Alexander Zarbock  
(Germany)

Practical perspectives for the management of refractory shock with vasopressors

Professor Arthur van Zanten  
(The Netherlands)

Q&A

All

Content will be available on demand after the event until March 2024. Refreshments will be provided.

RAAS ACTIVATION  
MAP ELEVATION



Job code: EU-RH-0062  
Date of preparation: February 2023

This symposium is organised and funded by PAION.  
This symposium will contain promotional content and prescribing information will be available.  
The product discussed in this symposium may not be licensed or available in all countries.

*Physician's Comment:  
"We need to position  
Angiotensin II after  
epinephrine.  
We should stop increasing  
the dose of epinephrine and  
switch more quickly to  
second-line options."*



# PAION will host a sponsored remimazolam symposium at EUROANAESTHESIA in Glasgow

PAION-SPONSORED SATELLITE SYMPOSIUM AT EUROANAESTHESIA 2023



## Remimazolam<sup>▼</sup>: a new horizon in general anaesthesia?

**Sunday 4 June, 12.15–13.15 BST**

**Room: NESS**

Scottish Event Campus, Glasgow, UK

**Chair: Prof Maurizio Cecconi (Italy)**

### AGENDA

**Welcome and introduction**

Prof Maurizio Cecconi (Italy)

**Remimazolam on the world stage**

Prof Maurizio Cecconi (Italy)

**The pharmacology of remimazolam in general anaesthesia**

Dr Remco Vellinga (The Netherlands)

**Remimazolam general anaesthesia in practice**

Dr Heena Bidd (UK)

**Q&A**

All

**Summary and close**

Prof Maurizio Cecconi (Italy)

# General anesthesia launch of remimazolam - target i.v. market and critically ill patients

## IV MARKET

- Concentration on the IV market
- Switching strategy from IV anesthetics (e.g., propofol) to remimazolam

## PATIENT FOCUS

- Concentration on the IV market
- Focus on ASAIII and IV patients.
  - Phase III studies conducted
- Integrated analysis shows hemodynamic benefit is more pronounced in sick patients



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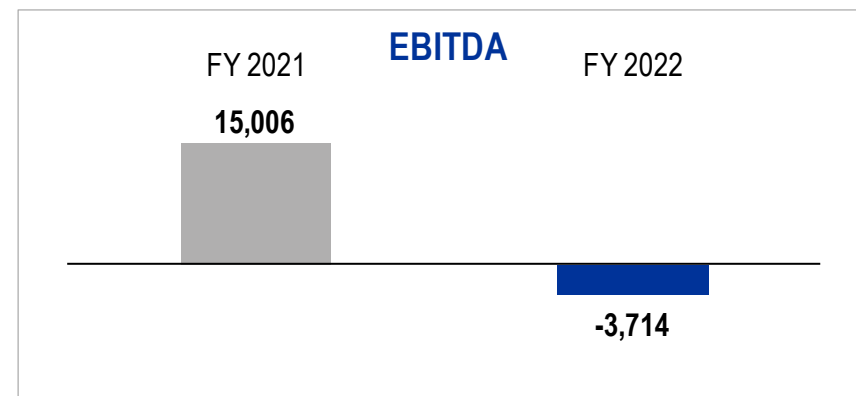
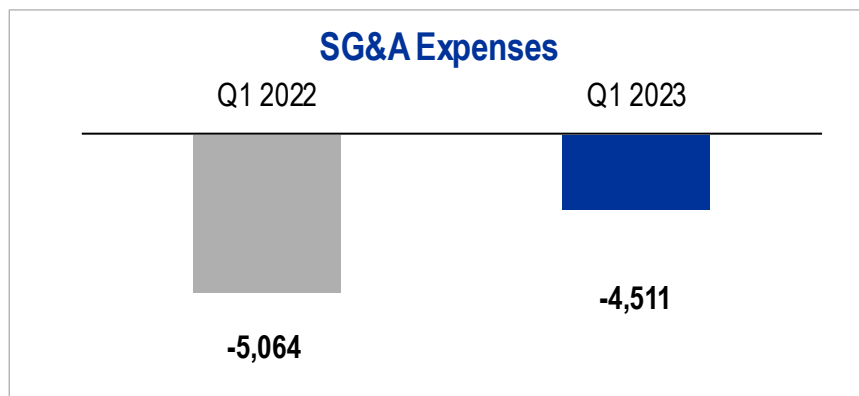
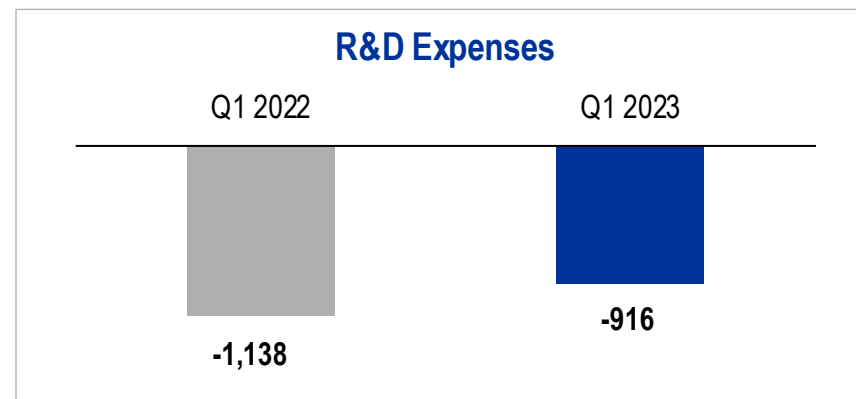
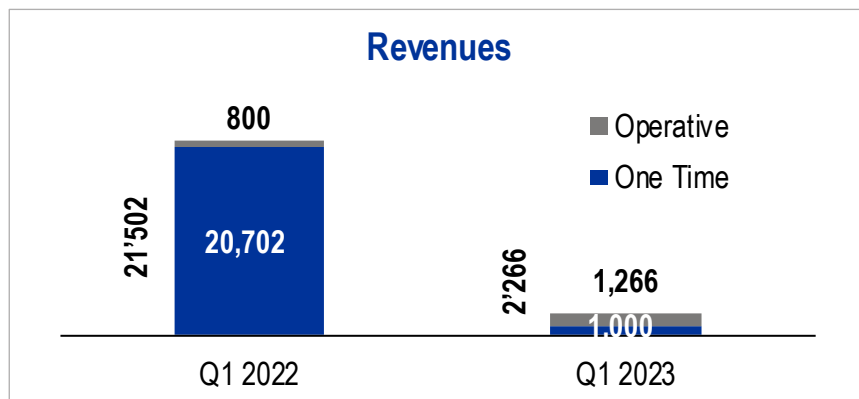
▶ 3 **Financials**

# Cash position and financing

- ✓ Cash of € 7.1m (as of 31 March 2023)
- ✓ Additional funds required
  - Sufficient cash until end of 3rd Quarter 2023
  - Expected payments from revenues, potential financing and/or out-licensing
- ✓ PAION expects increasing revenues from licensing agreements and commercialization in the coming years
- ✓ Mid-term financing need of approx. € 30m
  - Will be raised through various financing measures and further partnerships
- ✓ Rigorous cost control

# Consolidated statement of comprehensive income

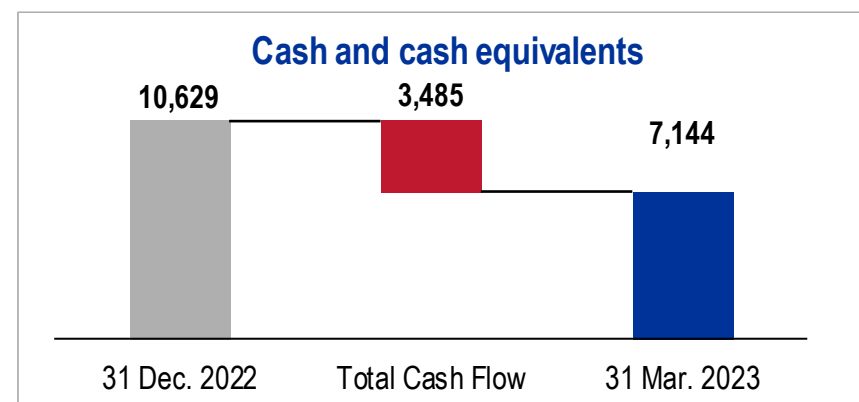
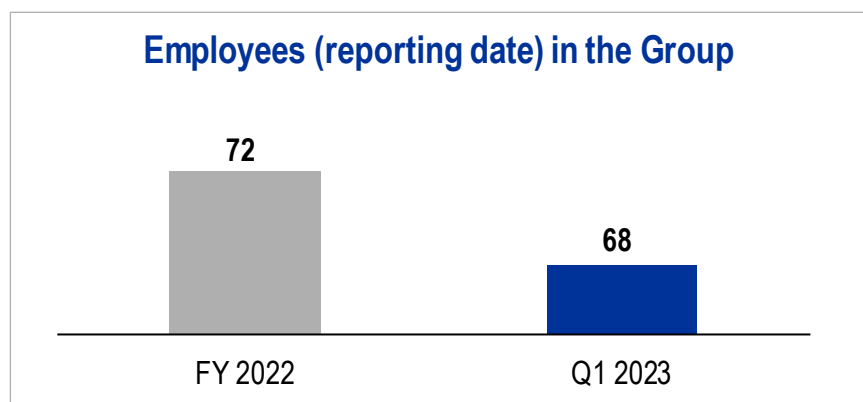
In accordance with IFRS (unaudited figures in EUR k)



- Q1 2022 revenues were driven by patent sell to Humanwell (€ 20.5m)
- SG&A expenses decreased by rigorous cost management

# Cash and employees

In accordance with IFRS (unaudited figures in EUR k, if not otherwise noted)



# Financial Outlook 2023

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## Revenues

Low: 13 Mio. €; High: 19 Mio. €

## EBITDA

Low: -15 Mio. €; High: -13 Mio. €

# Suitable Financing Concept progressing

- ✔ Extraordinary General Meeting 2023 in January approved the proposed capital reductions by redemption and consolidation of shares
- ✔ EGM Resolutions were entered into the commercial register at the local court of Aachen on 14 March 2023
- ✔ With regard to the option of financing through equity, the resolutions passed provide the necessary leeway for a possible capital increase in the future
- ❑ Various financing options are considered up to break-even



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