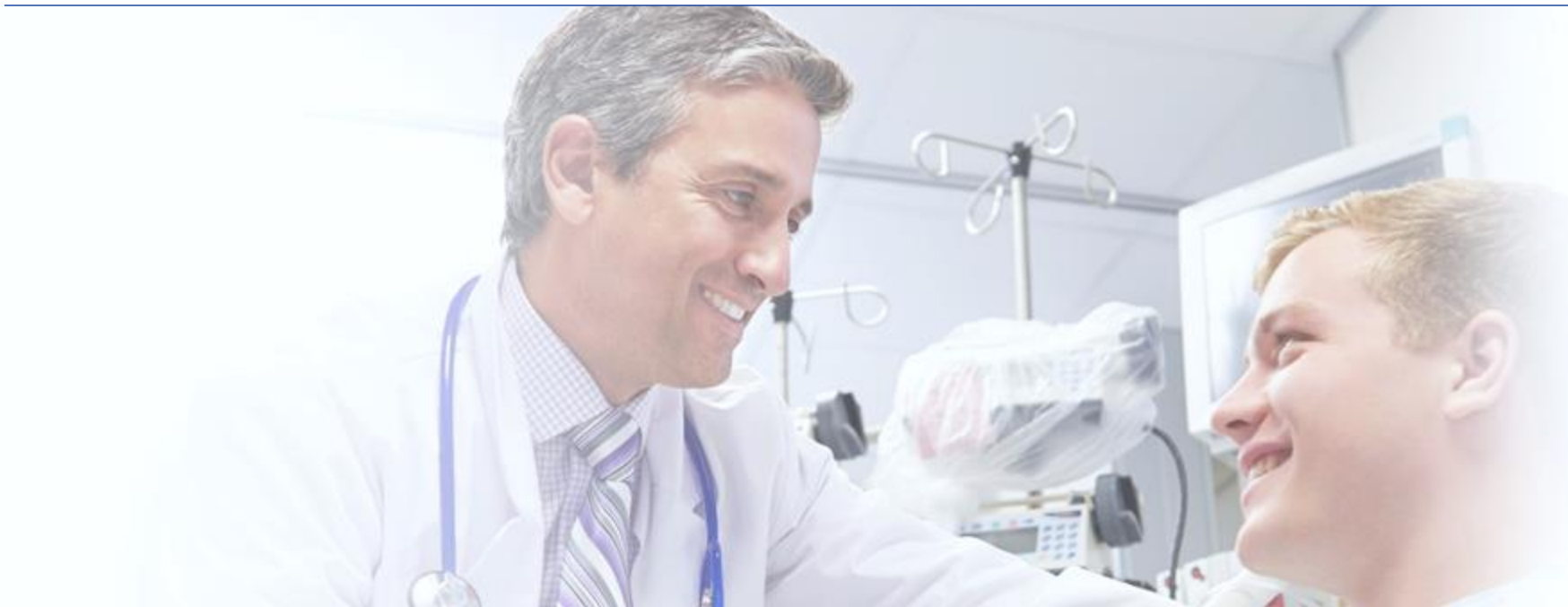


# PAION Earnings Call

Financial Results H1 2021



Dr. Jim Phillips, CEO | Abdelghani Omari, CFO

Conference Call | 23 August 2021

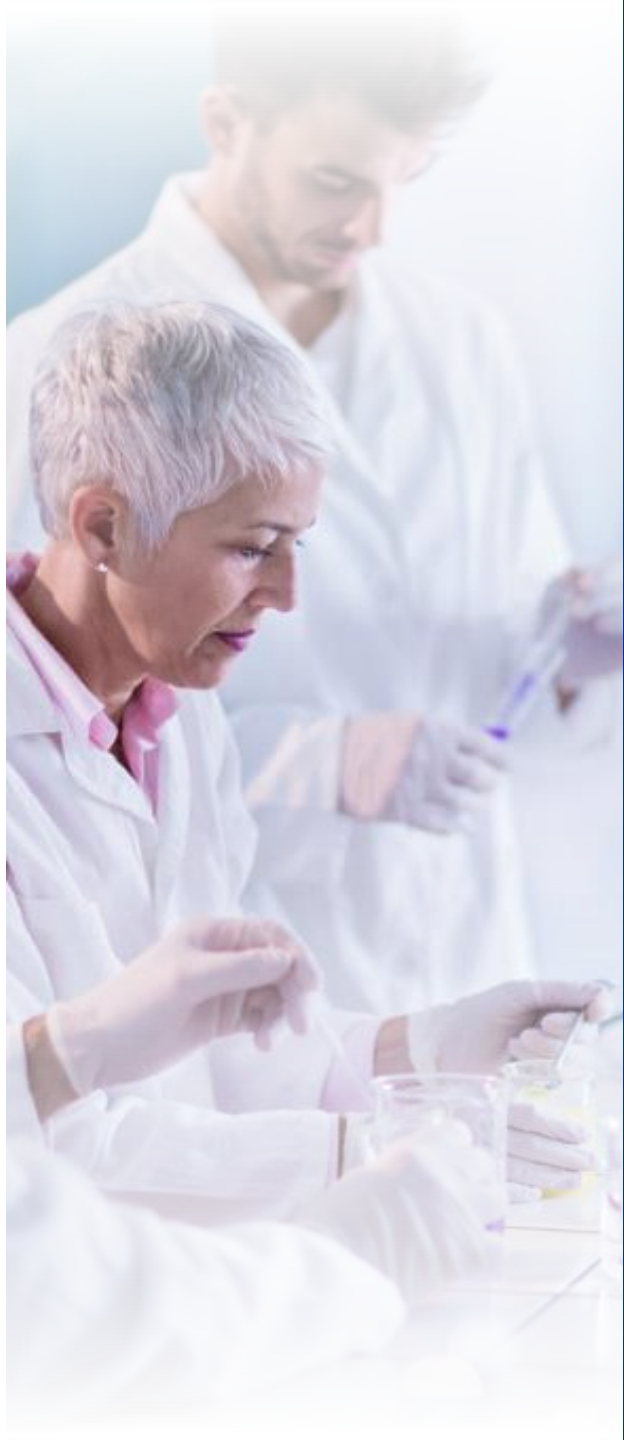
# Disclaimer

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It is important to note that this information contains forward-looking statements which are based on the currently held beliefs and assumptions of the management of PAION AG, which are expressed in good faith and, in its opinion, reasonable. Forward-looking statements involve known and unknown risks, uncertainties and other factors, which may cause the actual results, financial condition, performance, or achievements of PAION AG, or industry results, to differ materially from the results, financial condition, performance or achievements expressed or implied by such forward-looking statements. Given these risks, uncertainties and other factors, recipients of this information are cautioned not to place undue reliance on these forward-looking statements. PAION AG disclaims any obligation to update these forward-looking statements to reflect future events or developments.

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# AGENDA

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

---

## PAION Mission Statement

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

# PAION Strategy

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- Become a recognized innovative leader in Anesthesia & Critical Care within 3 years
- Create leading commercial capabilities in Europe in 2021-22
- Launch Byfavo<sup>®</sup>, GIAPREZA<sup>®</sup> and XERAVA<sup>®</sup> in key EU markets over 2021-22
- Drive rapid revenue growth & reach profitability end of 2023/beginning of 2024 as a leading specialty pharma company in our field
- Continue to explore synergistic opportunities and in-licensing to drive longer term growth

# Corporate overview

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PAION AG is a **specialty pharma company** with a focus on anesthesia and critical care products



PAION has commercial partners for Byfavo® in the U.S., China, South Korea, Southeast Asia, Canada, Russia + CIS, Turkey, Taiwan, Japan and the MENA region



Byfavo® (remimazolam), GIAPREZA® & XERAVA® are highly complementary fits for commercial optimization & buildout



EUR 21.2 million cash and cash equivalents (30 June 2021)



## Management Board



### Dr. James (Jim) Phillips, CEO

Dr. Jim Phillips was appointed Chief Executive Officer in 2019. He is a physician who also holds an MBA from the Cass Business School in London. Dr. Phillips holds a supervisory board directorship at Herantis Pharma. Career: Managing Director Imexvax, CEO Midatech Pharma, President of EUSA Pharma Europe in its key growth phase prior to its sales to Jazz Pharma in 2012, CEO and founder of Talisker Pharma, Chairman of Prosonix, senior executive for Johnson & Johnson and Novartis



### Abdelghani Omari, CFO

Mr. Abdelghani Omari holds a degree in Business Administration from the University Aachen and was appointed Chief Financial Officer in 2014. He joined PAION in 2008 as VP Finance and has more than 20 years experience in Finance.

Career: Before joining PAION he worked in different roles at KPMG where he advised international clients on accounting, post-merger integration and financial reporting. He started his career in the audit department of KPMG where he worked several years with a focus on the chemical industry.

# PAION AG is listed on Frankfurt Stock Exchange



Listed on Frankfurt Stock Exchange, Prime Standard (FSE: PA8)



Market capitalization: cEUR130 m

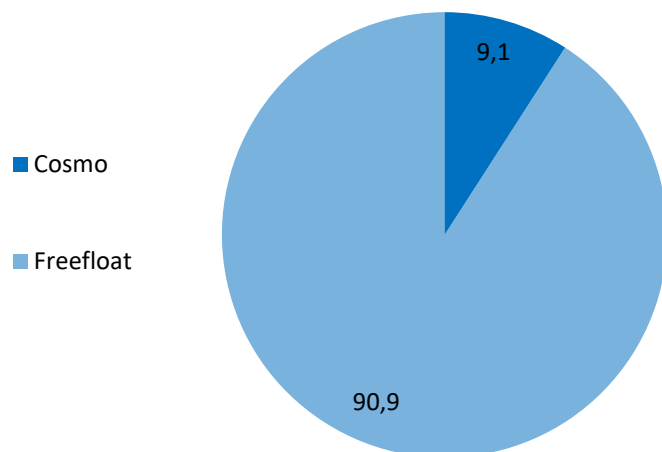


Liquidity (last six months) (Xetra, Tradegate & FRA stock markets): **c 30 million shares traded** (c 45% of Free Float)



## Shareholder structure

(According to the latest notifications)



## Market Data

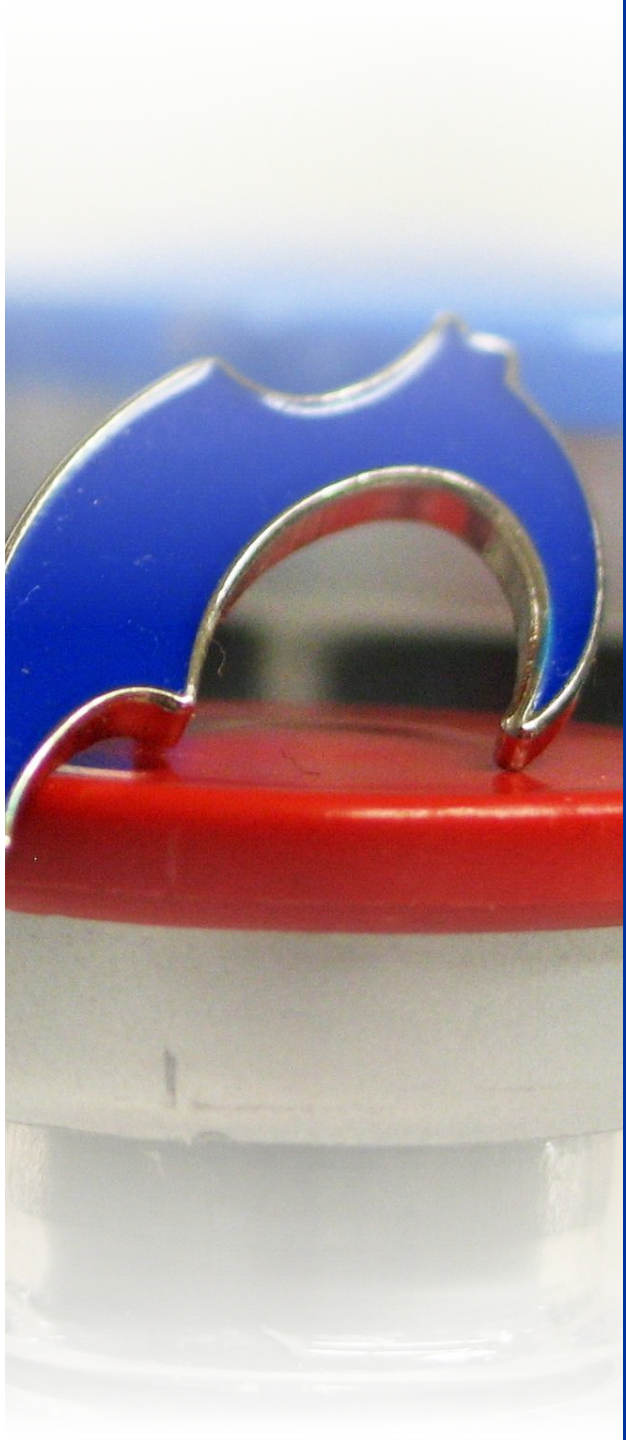
### Capitalization (as of 23 August 2021)

Current Share Price	€ 1.90
FD Shares Outstanding	71.3 million
Market Cap	c€ 130m
Mean target price of analyst reports (First Berlin, FMR, Oddo BHF, Stifel)	€ 4.01

# Key targets and news flow for PAION in 2021

- 
- ▲ Licensing of Byfavo<sup>®</sup>, GIAPREZA<sup>®</sup> & XERAVA<sup>®</sup> in non-core EU markets
  - ▲ Filing Byfavo<sup>®</sup> in GA until the end of 2021
  - ▲ Ongoing Byfavo<sup>®</sup> partners sales growth & launch activities
  - ▲ Commercial launch of Byfavo<sup>®</sup> ✓, GIAPREZA<sup>®</sup> ✓ & XERAVA<sup>®</sup> in Europe
  - ▲ Market approval Byfavo<sup>®</sup> EU and UK Procedural Sedation ✓
  - ▲ Byfavo<sup>®</sup> CHMP meeting EU Procedural Sedation ✓
  - ▲ BYFAVO<sup>™</sup> commercial launch in U.S. ✓





# AGENDA

- 1 Corporate Overview
- 2 Products**
- 3 Financials
- 4 Conclusion

# Pipeline overview

## Status of Development

Compound	Indication	Status of Development					
		PC	Ph I	Ph II	Ph III	NDA/ MA*	Launch
<b>Byfavo<sup>®</sup></b> Remimazolam Besylate	General Anesthesia	[Progress bar from PC to Launch]					
	Procedural Sedation	[Progress bar from PC to Launch]					
	ICU Sedation	[Progress bar from PC to Ph II]					
<b>GIAPREZA<sup>®</sup></b> Angiotensin II	Blood pressure management to treat septic shock	[Progress bar from PC to Launch, labeled EU / EEA / CH / UK]					
<b>XERAVA<sup>®</sup></b> Eravacycline	Complicated Intra-abdominal Infections	[Progress bar from PC to Launch, labeled EU / EEA / CH / UK]					





\* NDA = New Drug Application; MA = Market Approval

# Byfavo<sup>®</sup> / Remimazolam

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# 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>

 **Remimazolam offers the opportunity to substitute both midazolam and propofol in an attractive market setting**

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

# Broad Label for Byfavo<sup>®</sup> provides ample opportunity

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***BYFAVO<sup>®</sup> (remimazolam besylate) is indicated in adults for procedural sedation***



# Remimazolam (Byfavo<sup>®</sup> / Anerem<sup>®</sup> / Ruima<sup>®</sup>) – IP Status

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- Besylate salt – Protection until at least 2031 in the U.S.
- Formulation patent – Protection until at least 2033 in the EU
- Dosing patent – Protection until at least 2033 in Japan
- Growing IP portfolio to secure attractive period of market exclusivity in major markets
- Paion now investing in lifecycle management

# Commercialization strategy

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Regions	Western Europe	Ex-EU + Southeast EU
Strategy	Own commercialization	Partnering
Rationale	<ul style="list-style-type: none"><li>• Own commercialization as the basis to develop the company to a specialty pharma company</li><li>• Highest margin</li></ul>	<ul style="list-style-type: none"><li>• Search for local champions</li><li>• “String of pearls”</li></ul>



## Our Partnering strategy EX-EU

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# PAION's partners – product revenues in the amount of EUR 2.7 million in H1 2021

## U.S. – Acacia Pharma



- **Lead indication: Procedural Sedation**
- Acacia launched BYFAVO™ in Jan 2021
- Royalty rate: 20-25%

## Japan – Mundipharma



- **Lead indication: General Anesthesia**
- Mundipharma launched Anerem® in mid-2020
- Current royalty rate: 15.5%

## Taiwan – TTY BIOPHARM



- License agreement signed in March 2021
- Supply of drug product at a percentage of net selling price

## China – Yichang Humanwell



- **Indications General Anesthesia + Procedural Sedation**
- Yichang Humanwell launched Ruima® in July 2020
- Royalty rate: 5%

## South Korea + Southeast Asia – Hana Pharm



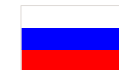
- **Lead indication: General Anesthesia**
- Launched end of March 2021 in SK – positive feedback
- Extended license territory by adding Southeast Asia in January 2020
- Royalty rate: Low double-digit

## Canada – Pharmascience



- **Lead indication: Procedural Sedation**
- Canada can use U.S. filing dossier for own filing
- Structured royalties

## R-Pharm (Russia, Turkey, MENA Region)



- **Lead indication: General Anesthesia**
- R-Pharm successfully completed a Phase III trial in General Anesthesia in November 2018
- Royalty rate: Low double-digit

# Japan (Anerem®) & China (Ruima®)

## JAPAN



- NHI national reimbursed price of ¥2,218 per 50 mg vial (~ €17)
- 400 hospitals had product listed by year-end 2020
- Strong market but previous batch recall and therefore limited supply hindered the sales in market



## CHINA



## Yichang Humanwell

- Pricing at launch RMB139 / Vial (~ €17)
- Currently the strongest market globally
- Chinese KOLs supportive
  - “[...] four major advantages: low impact on blood pressure, heart rate and respiratory depression, and low injection pain.” [Professor Qulian Guo, Xiangya Hospital, Central South University](#)
  - “Remimazolam besylate has the clinical advantages of "short", "flat" and "fast" [...].” [Professor Wang Dongxin, Peking University First Hospital](#)
- Filed NDA in General Anesthesia in July 2021
- Yichang Humanwell won the annual drug innovation achievement award (Securities Times journal’s "Drug Innovation Award“) and remimazolam was selected for the "Annual Pharmaceutical Innovation Achievement Award"



# BYFAVO™ U.S. launch

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- 47 accounts open (30 June 2021) including Mayor Clinics, against an FY 2021 expectation of 150; this represents an increase of 40 accounts since March 2021
- A critical success factor was to avoid the necessity for administration by anesthesiologists or nurse anesthetists only, to provide the required economic differentiation from propofol
- However, access to clinics and prescribers has been severely limited in the first half of 2021 by Covid-19 effects on the healthcare system, and PAION is hoping to see growth accelerating in the second half of 2021

## Report of early use in the USA – CRNA letter

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Our practice has used BYFAVO (remimazolam) in more than 20 patients during the month of February, 2021, primarily focusing on geriatric patients who have had the concomitant need for short-duration amnesia/anxiolysis and rapid recovery. We care for more than 800 surgical patients per month in an area of the country where there's a large proportion of active men and women over the age of 65. Preventing delirium and other peri-operative neurological derangements in the elderly is a challenge for clinicians striving to provide a safe surgical experience while optimizing outcome. Of primary importance is ensuring brain health,<sup>2</sup> avoiding morbidity, mortality, excessive length of stay, and cost of care.

We've targeted remimazolam use in select, older patients where we felt propofol, ketamine, midazolam, or dexmedetomidine might have inferior clinical profiles. The procedures included cataract surgery, rigid laryngoscopy, bronchoscopy, intramedullary nailing, and hemiarthroplasty/hip fracture. The drug appears to be easily titrated and remimazolam is metabolized by tissue esterases to essentially inactive metabolites with little clinical significance, although there may be concerns in those with severe hepatic disease.<sup>3</sup>

In assessing the return of responsiveness (MOAA/S scores<sup>4</sup>) following administration of 5 mg to 20 mg over varying time intervals, we have appreciated a remarkably clear distinction compared to our historical pharmaceutical benchmarks. It has been our experience that BYFAVO (remimazolam) appears to cause less "insult" to our patients' neuropsychiatric function following their surgical procedures.

## Paion commercial build up in Europe

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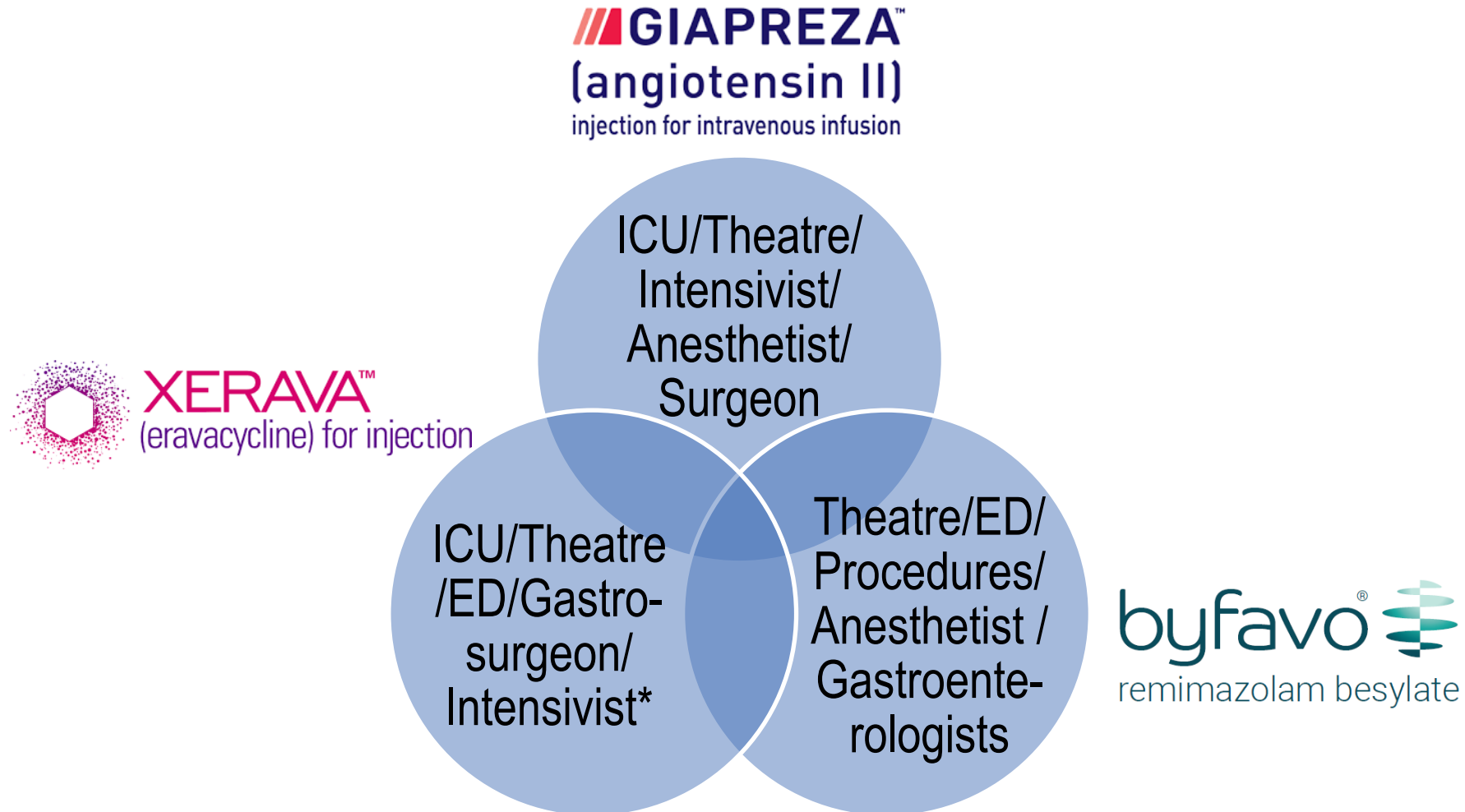


# Early Partner launches provide education for EU launches

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- Successful partner launches confirmed high market potential
- Targeted sales team approach has the highest risk/benefit ratio
- The launch comes at a time when COVID-19 has caused significant backlogs for elective surgeries and routine procedures
- With ongoing shortages for existing drugs in these therapeutic areas, puts PAION in a strong position as the Company enters these markets

# Strong overlap in accounts and target groups

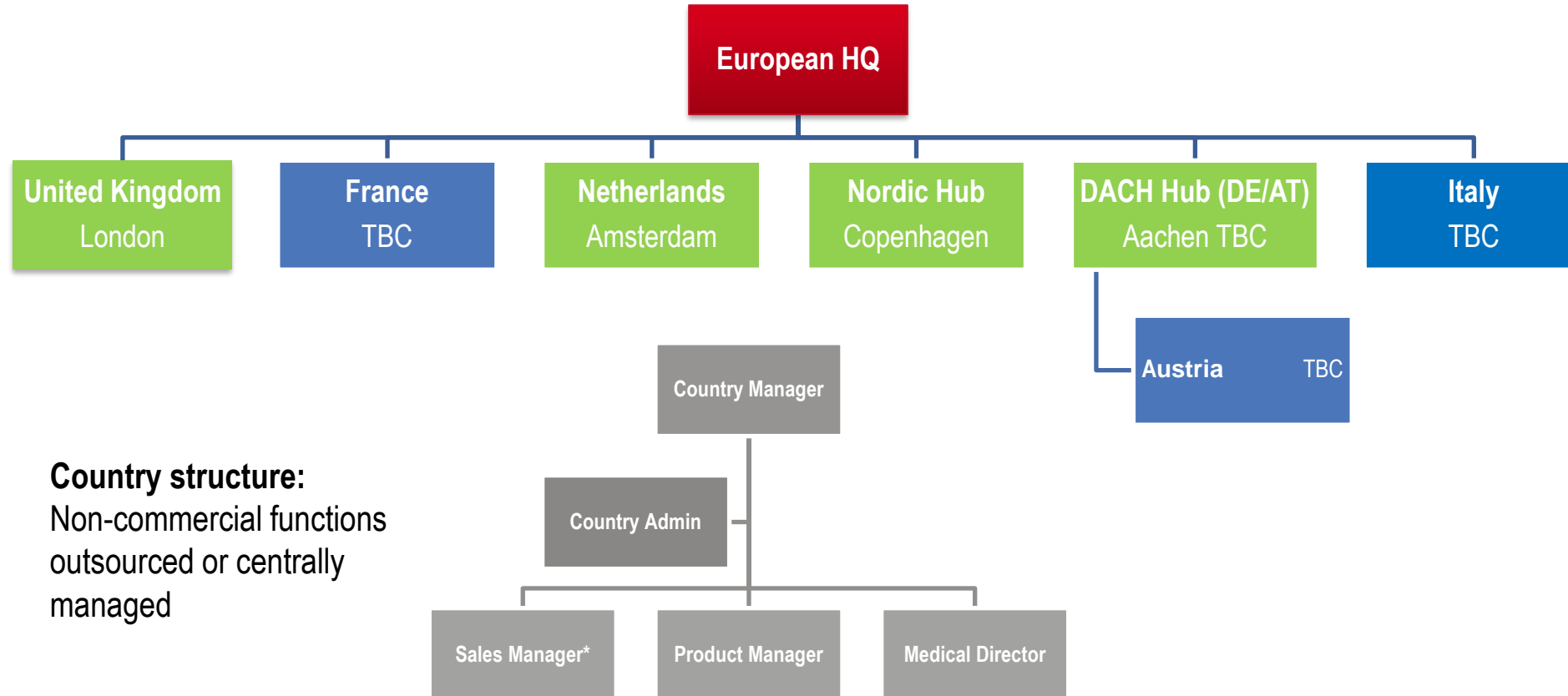


\* Other specialties key for formulary listing, eg Infectious disease, Hospital antimicrobial stewardship

# Commercial Organisation in Europe – investing for growth

## EU Head Office structure:

1. Corporate Management & Finance
2. EU Marketing, Commercial & Market Access Support
3. Medical, Regulatory Affairs & PhV
4. Supply Chain
5. Quality Assurance
6. Ongoing R&D



## Country structure:

Non-commercial functions outsourced or centrally managed



# Dedicated field-based commercial team structure (green - in place)

## Targeted approach from Key Account Manager (KAM) and Medical Science Liaison (MSL)

Country	KAMs	MSLs	Total
Netherlands	4	1	5
Denmark	2	1	3
Germany*	8	2	10
France*	8	2	10
UK	8	2	10
Italy*	8	2	10
Sweden	2	1	3
Norway	1	1	2
Finland	1	1	2
Austria*	2	1	3
<b>Total</b>	<b>44</b>	<b>14</b>	<b>58</b>



\*Intention to launch to be confirmed towards end of 2021

# Staggered launches of complete portfolio in 2021-22

## *Aligned with sales/profit expectations over time*

- In July 2021, GIAPREZA® was launched in Germany
- In August 2021, Byfavo® was launched in UK

		
<b>Aug 21 - Q2/22*</b>	<b>July 21 - Q3/22*</b>	<b>Q4/21-Q4/22*</b>

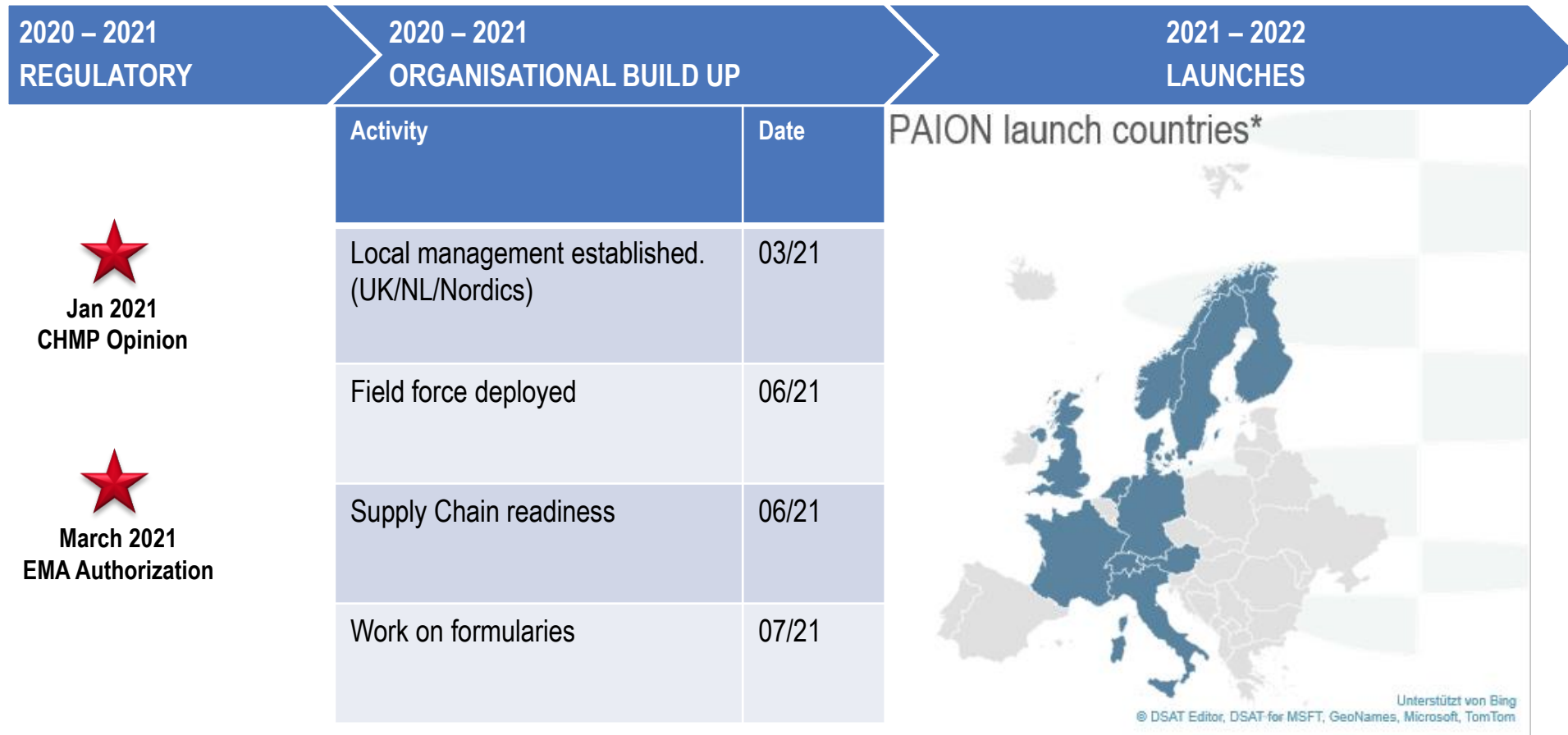


**PAION will target nearly all mid- to large-sized accounts\*\***

\*Timelines subject to successful Pricing & Reimbursement processes

\*\*Covering 100% of universe in Netherlands & Denmark, Covering majority of top-to-midsize accounts in EU Top4 and other EU territories

# Overview of Byfavo<sup>®</sup> launch and market preparation – Launched in UK in August

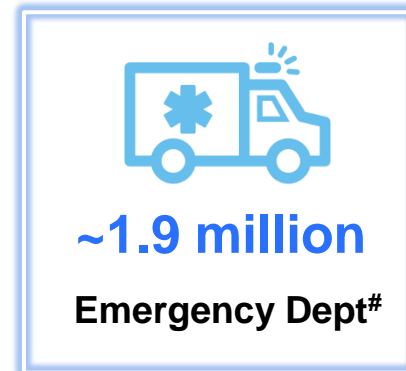
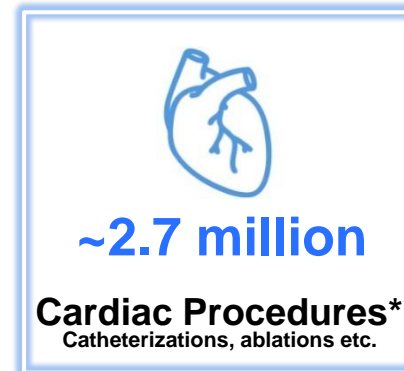
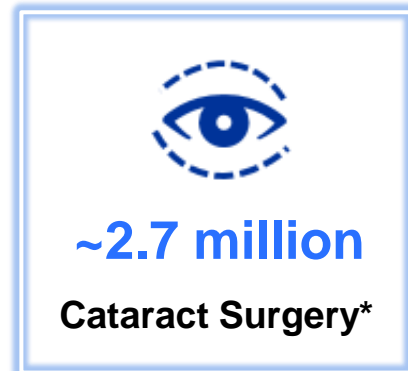
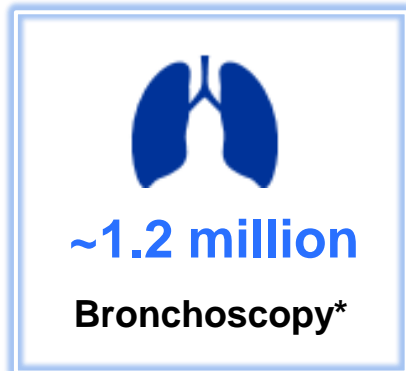
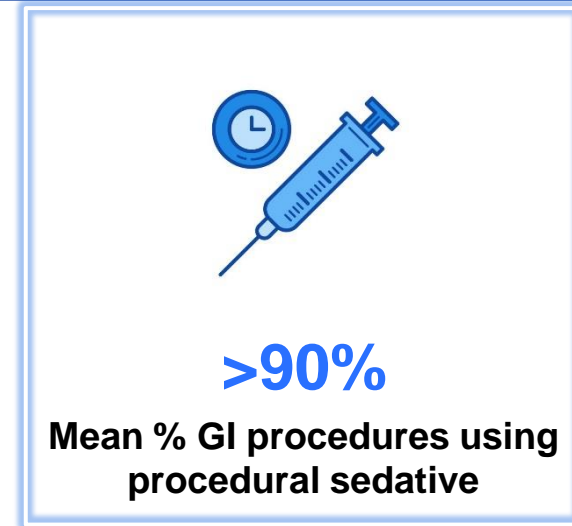


★  
Jan 2021  
CHMP Opinion

★  
March 2021  
EMA Authorization

\*Other EU territories subject to licensing; Regulatory filing in CH planned; launch intentions in DE/FR/IT/AT to be further confirmed

# Procedural Sedation: EU Market Opportunity



\* Figures based on annual total number of procedures in EUROPE TOP5 (UK, FR, GE, IT, SP)

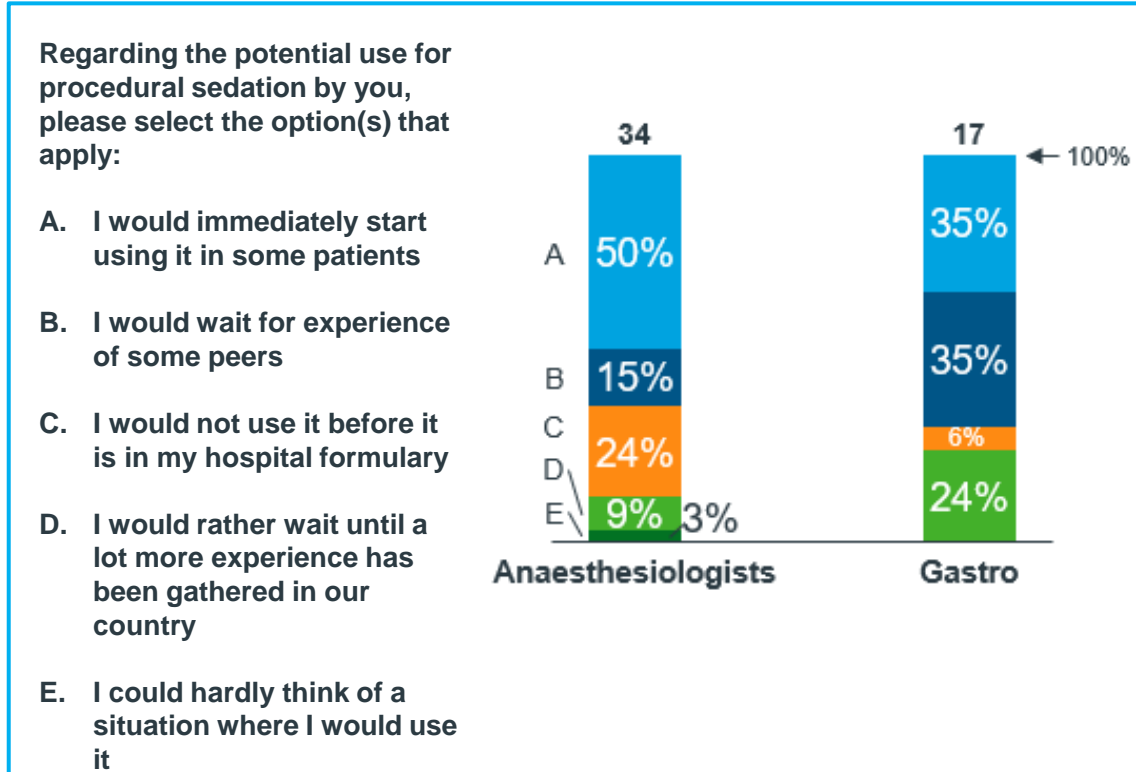
# Figures based on annual total number of procedures, with PS. Procedures included are repair of lacerations, bone fracture reduction, wound care, extraction of foreign body and bladder catheterization

Reference: Remimazolam Global Value Dossier, 2021

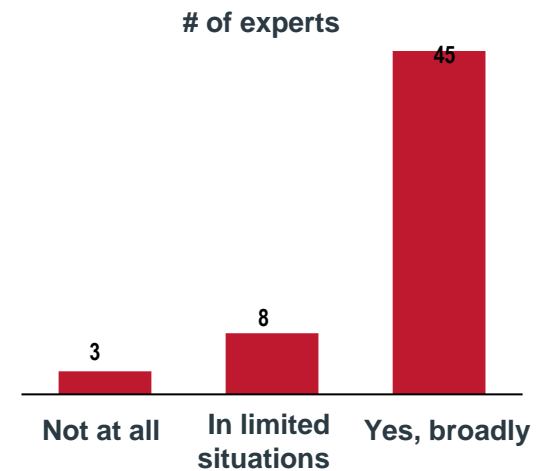
Sources: Data on file [8]; QuintilesIMS 2009 model, HES online, ISD Scotland, NISRA, Welsh Assembly government, Insee France, DeStatis - Statistisches Bundesamt, Ministero della Salute, Rapporto SDO 2015, Walnut Medical data, Eurostat.

# Market Research

## Suggests there is a high willingness to use Byfavo



### Willingness to use Byfavo for procedural sedation:



*Please note: Respondents were not informed about price of Byfavo*

# GIAPREZA® & XERAIVA®

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# GIAPREZA<sup>®</sup> approved for septic shock in EU & U.S.

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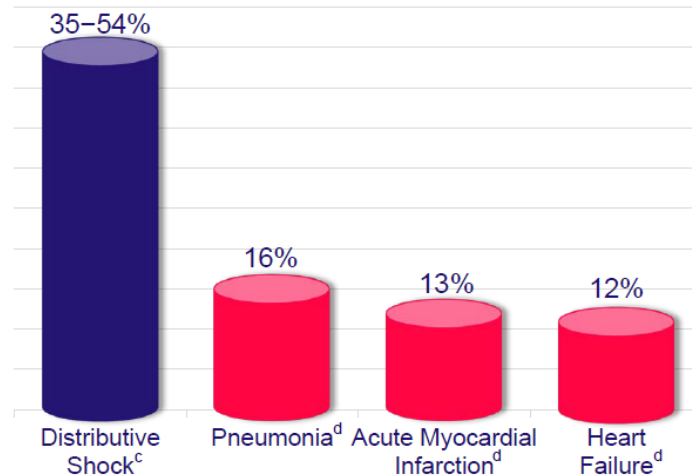
- GIAPREZA<sup>®</sup> is approved by the EMA as a vasoconstrictor indicated for the treatment of refractory hypotension in adults with septic or other distributive shock who remain hypotensive despite adequate volume restitution and application of catecholamines and other available vasopressor therapies
- Used in ICU
- Currently 3rd line therapy (life-saving)
- Pricing & Reimbursement work looks very supportive for premium pricing
- In July 2021, GIAPREZA<sup>®</sup> was launched in Germany and can be ordered and delivered to customers through direct sales



# Distributive shock as a result of sepsis remains one of healthcare's major unmet medical needs

Septic shock accounts for >90% of distributive shock<sup>a</sup>

Mortality Rate



- Mortality rate exceeds that of most acute conditions requiring hospitalization
- Shock affects one-third of patients in the intensive care unit (ICU)<sup>b</sup>

<sup>a</sup> Vincent et al. *New England Journal of Medicine* 2013; 369(18):1726-1734

<sup>b</sup> Sakr et al. *Critical Care Medicine* 2006; 34:589-597

<sup>c</sup> Based on the 28-day mortality rates of: (i) 35% from Russell et al. *New England Journal of Medicine* 2008; 358:877-87; (ii) 49% from De Backer et al. *New England Journal of Medicine* 2010; 362:779-82; and (iii) 54% from Khanna et al. *New England Journal of Medicine* 2017; 377:419-430

<sup>d</sup> 30-day mortality rate from [Medicare.gov](http://www.Medicare.gov)

stop sepsis save lives

## WORLD SEPSIS DAY INFOGRAPHICS

### A GLOBAL HEALTH CRISIS

47 000 000 - 50 000 000 cases per year

At least 11 000 000 die - 1 death every 2.8 seconds

Survivors may face lifelong consequences

1 in every 5 deaths worldwide is associated with sepsis

Infographic 2/21

Global Sepsis Alliance [www.worldsepsisday.org](http://www.worldsepsisday.org) [www.global-sepsis-alliance.org](http://www.global-sepsis-alliance.org)

September 13, 2020 | World Sepsis Day



# Market Environment in septic shock



## 1<sup>st</sup> Line Therapy

- Catecholamine (dopamine, adrenaline, norepinephrine)
- ~770k patients in EU



## 2<sup>nd</sup> line Therapy

- Vasopressors (Argipressin [Brandname: Empressin], Vasopressin\*)
- ~ 300k patients in EU



## Patients who do not adequately respond to 1<sup>st</sup>/2<sup>nd</sup> line

- GIAPREZA®
- ~ 100k – 150k patients in EU

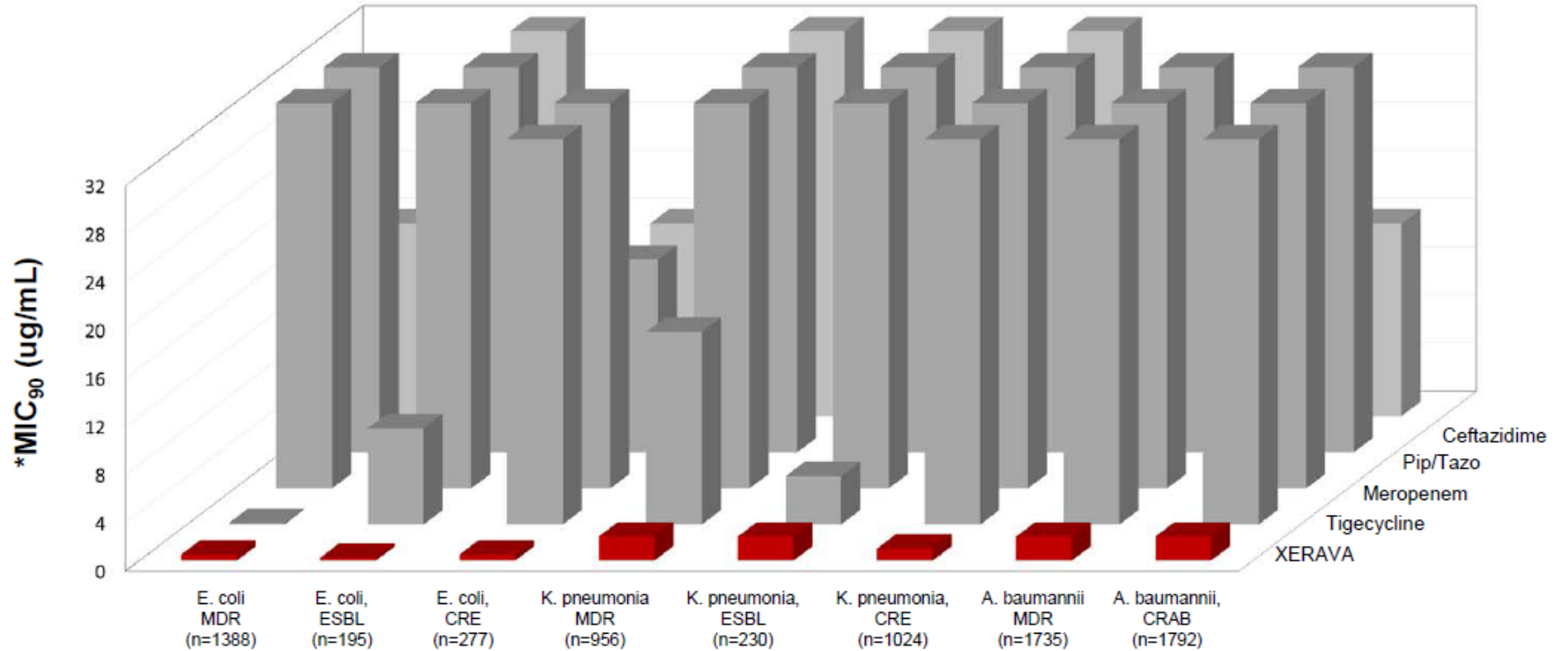
\*Other vasopressins than argipressin not indicated for septic shock

## About XERAVA®

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- XERAVA® (eravacycline) is approved by the European Commission for the treatment of complicated intra-abdominal infections in adults
- Novel broad-spectrum tetracycline initially developed by U.S.-based company Tetrphase
- Potential to become a first line therapy prior to bacterial identification
- Will be competitively priced compared to other novel antibiotics

# XERAVA<sup>®</sup> effective against a wider range of AMR bacteria



## Multidrug-Resistant Pathogens

\*MIC<sub>90</sub>: Minimum Inhibitory Concentration: Lowest concentration of the antibiotic at which 90% of the isolates were inhibited  
 Sources: CANWARD 2014, IHMA 2013-2014, IHMA 2015 and IHMA 2016

# Market environment in complicated Intra-Abdominal Infections (cIAI)

## 1<sup>st</sup> line (empiric) therapy

- Carbapenems:
  - Imipenem
  - Ertapenem
  - Meropenem – indicated in cIAI
- Tigecycline - indicated in cIAI
- Amoxicillin
- Cefotaxime
- Cefuroxime
- Ciprofloxacin
- Gentamicin
- Piperacillin/tazobactam
- Others.....

generic molecules

## 2<sup>nd</sup> line (empiric) therapy

- Combination therapy of generic 1st line antibiotics
- Non-generic brands indicated in cIAI
  - ZAVICEFTA (AVIBACTAM/CEFTAZIDIME)  
Originator: Pfizer  
Marketing Authorization in EU: 06/2016
  - ZERBAXA (CEFTOLOZANE/TAZOBACTAM)  
Originator: Merck (MSD)  
Marketing Authorization in EU: 04/2016
  - VABOREM (MEROPENEM/VABORBACTAM)  
Originator: Menarini  
Marketing Authorization in EU: 11/2018





# AGENDA

1 Corporate Overview

2 Pipeline

**3 Financials**

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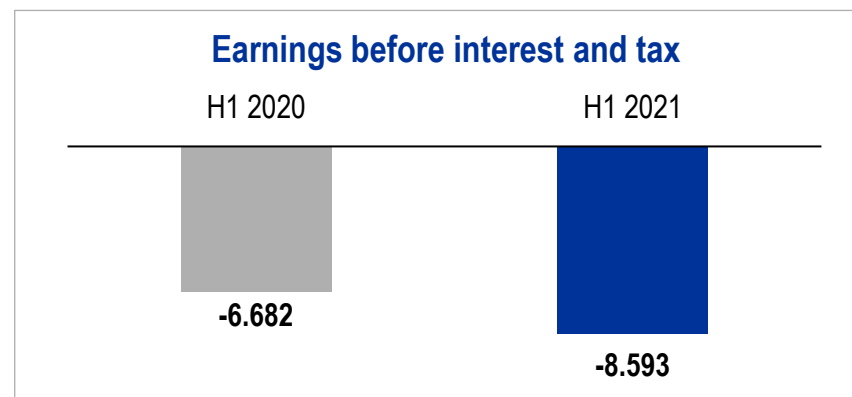
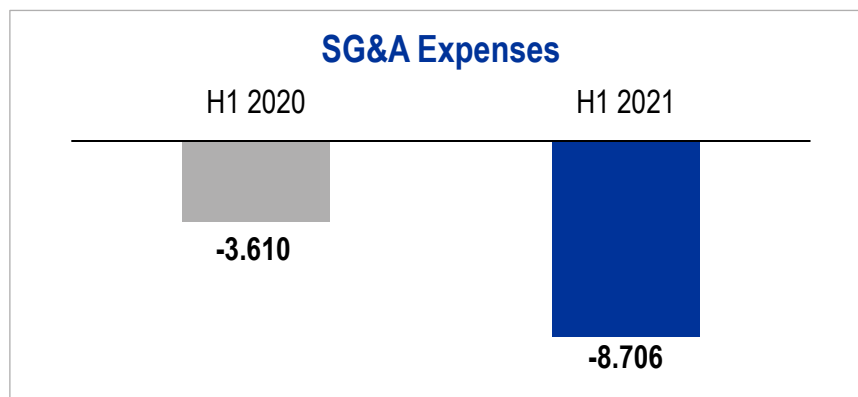
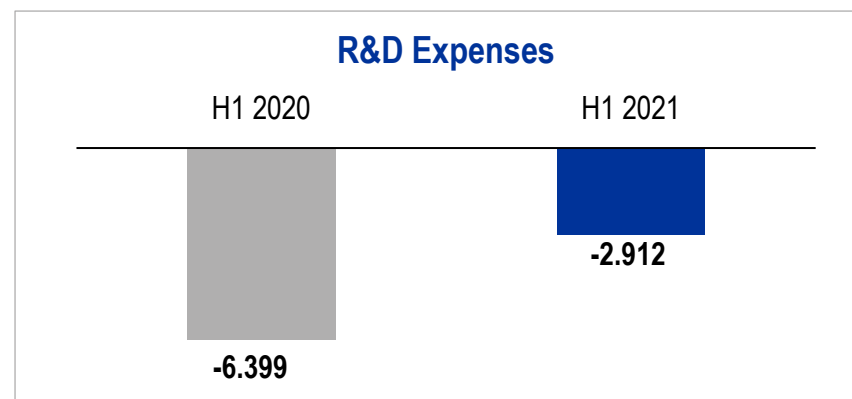
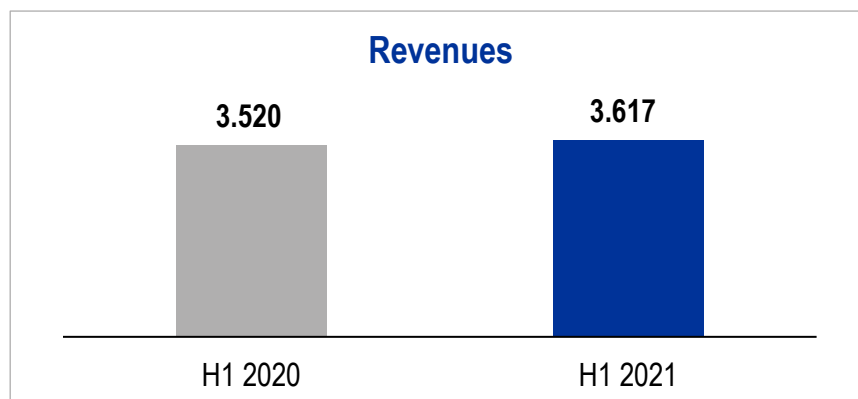
# Cash position and financing

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- Cash of EUR 21.2 million (as of 30 June 2021)
- EIB loan of EUR 20 million
  - The first two tranches totalling EUR 12.5 million drawn in February 2021
  - Third tranche of EUR 7.5 million drawn in June 2021
- Capital increase with subscription rights with gross proceeds of EUR 7.8 million completed in April 2021
  - 5,095,499 new shares issued
  - Subscription rate above 90%
  - Backstopped by a U.S.-based institutional investor
- Additional funds are required
  - Liquidity runway into H1/2022
  - PAION expects increasing revenues in the coming years, both from license agreements and from its own commercialization in parts of Europe
  - PAION has a financing requirement in the mid double-digit million range in the coming years until break-even (end of 2023 or beginning of 2024)
    - Could be raised through different financing measures and further partnerships

# Consolidated statement of comprehensive income

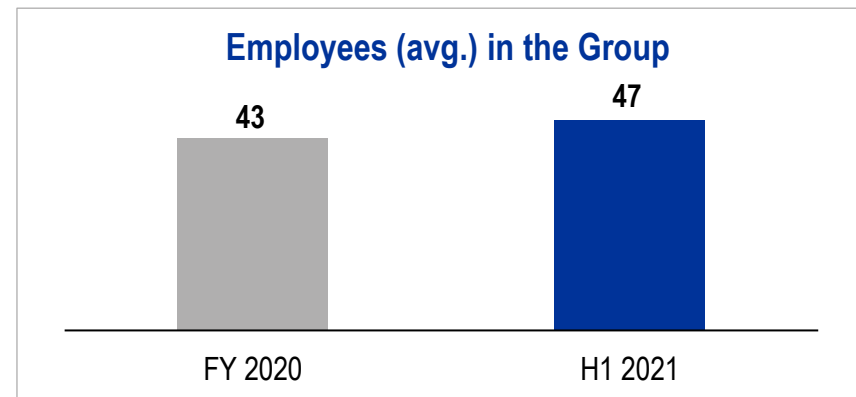
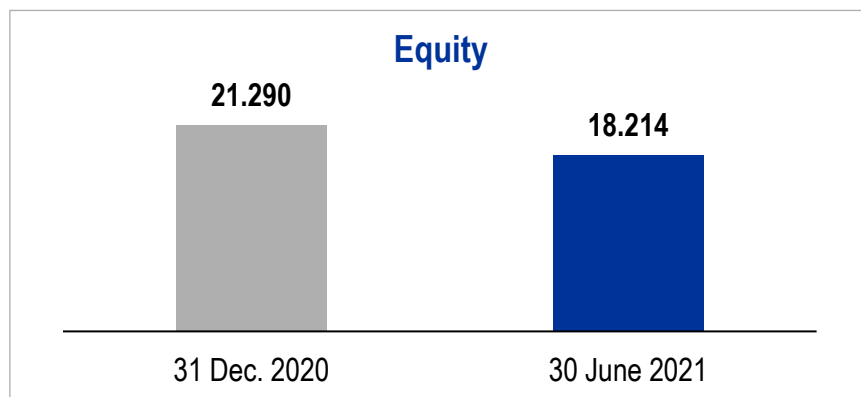
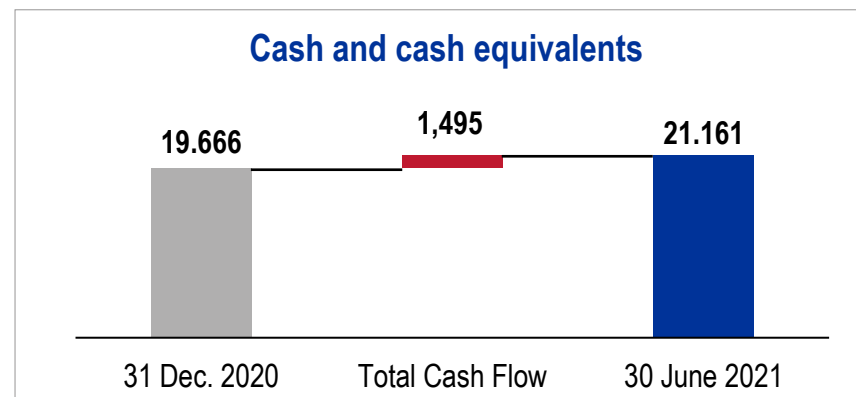
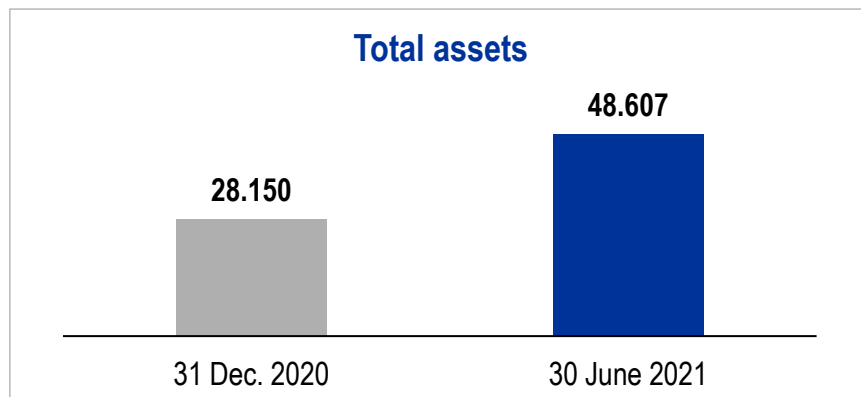
In accordance with IFRS (all figures in EUR k)



- R&D expenses decreased as planned, particularly due to completion of EU Ph III study in GA in 2020
- SG&A expenses: Selling expenses increased as planned mainly due to commercialization and supply chain activities in Europe; general and administrative expenses increased mainly due to financing activities and the expansion of IT systems and infrastructure

# Consolidated balance sheet and employees

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

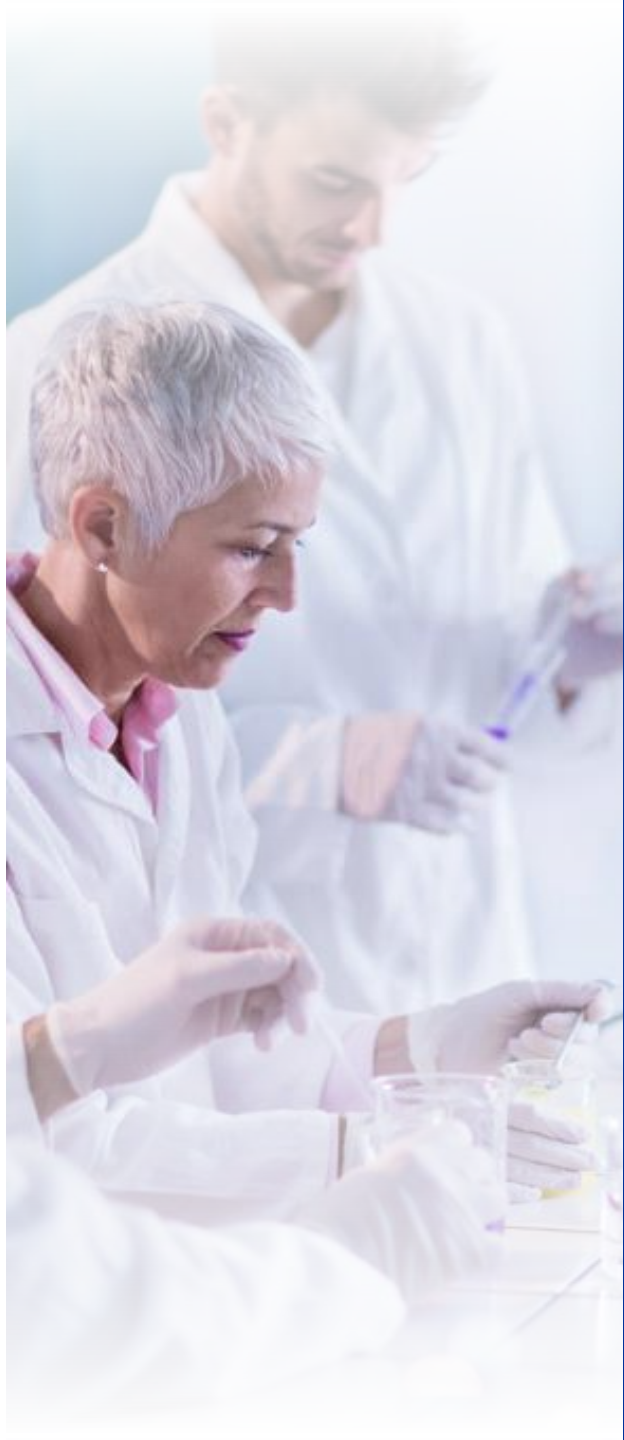


→ Equity ratio as of 30 June 2021 was 37.5%



# Financial Outlook 2021

	Actual FY 2020 EUR million	Plan FY 2021 EUR million	Comments	
Revenues	€ 19.7m	€ 8m – € 9.5m	<p>€ 8m to € 9.5m from licensees (<i>previous guidance: € 7.5m to € 9m</i>)</p> <ul style="list-style-type: none"> <li>- € 4m to € 4.5m from royalties and sale of remimazolam API (<i>previous guidance: € 5m to € 6m</i>)</li> <li>- € 4m to € 5m from milestones and upfront payments (<i>previous guidance: € 2.5m to € 3m</i>)</li> </ul> <p>No revenues from own commercialization of Byfavo<sup>®</sup>, GIAPREZA<sup>®</sup> and XERAVA<sup>®</sup> in parts of Europe included in guidance (expected in an amount of up to € 0.2m) (<i>previous guidance: € 0.5m</i>)</p>	
Cost of revenues	-	€ 3m	( <i>previous guidance: € 3.5m to € 4m</i> )	
Expenses	R&D	€ 10.3m	€ 4.5m – € 5.5m	Ongoing R&D expenses mainly in connection with market approval applications in the EU
	SG&A	€ 7.5m	€ 18m – € 20m	<ul style="list-style-type: none"> <li>- SG&amp;A expenses increase due to commercial build-up &amp; launches</li> <li>- c10% non-cash (amortisation)</li> </ul>
EBIT	€ 1.6m	€ -16m – € -20.5m	Negative EBIT expected ( <i>previous guidance: € -16.5m to € -21.5m</i> )	



# AGENDA

- 1 Corporate Overview
- 2 Products
- 3 Financials
- 4 Conclusion**

# Conclusion

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- PAION is now a commercial stage specialty pharma company
- 3 strong products exhibiting market need & use all over the world
- First commercial & profitable year was 2020
- Now investing for revenue growth in commercialization capabilities & launches
- We can become a high margin profitable business in the near to mid term



## Q&A

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