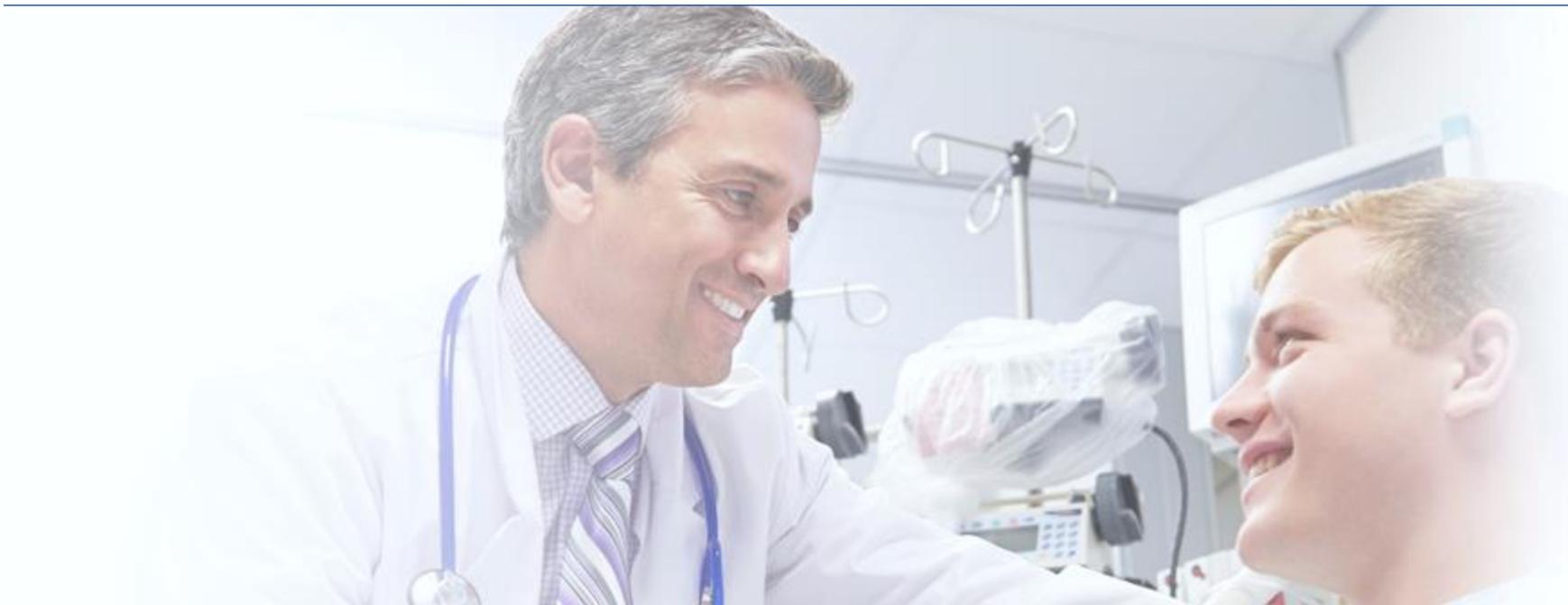


PAION

Baader Investment Conference



Dr. Jim Phillips, CEO | Abdelghani Omari, CFO

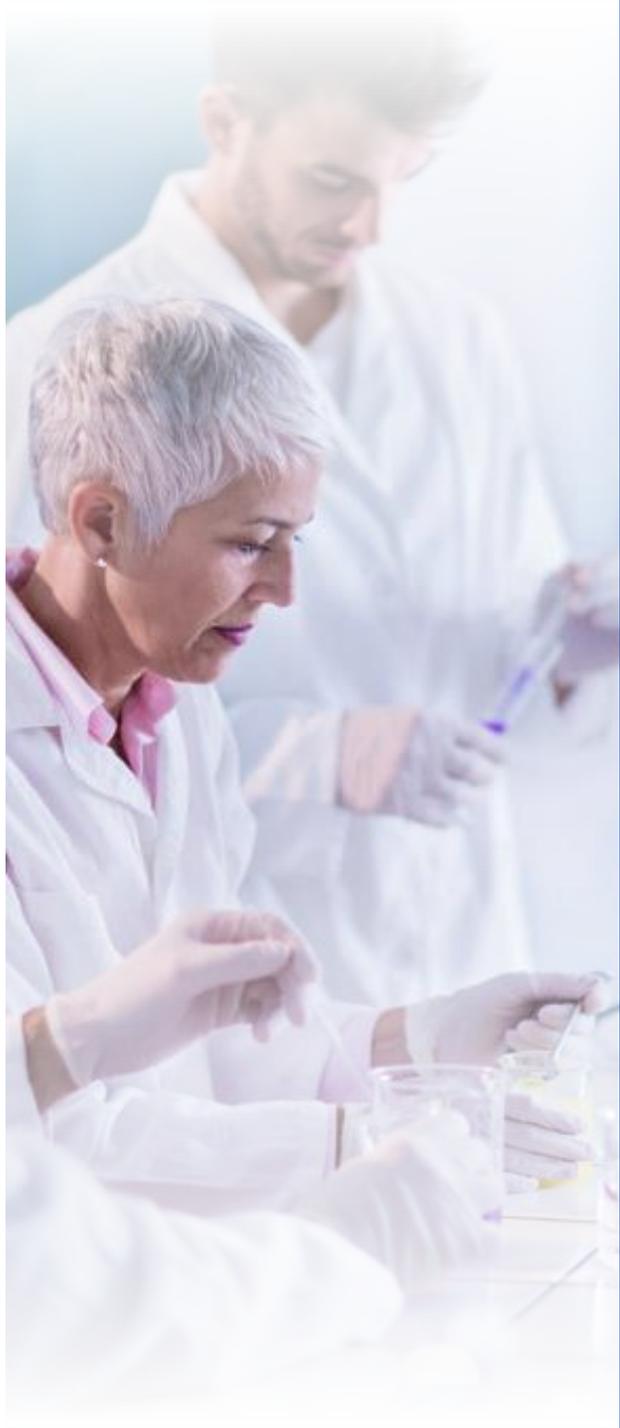
25 September 2020

Disclaimer

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AGENDA

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

Corporate overview



PAION AG is an emerging specialty pharma company with a focus on anesthesia critical care products



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



Remimazolam, PAION's lead drug candidate, has multiple approvals in U.S. & Asia



EUR 12.4 million cash and cash equivalents (30 June 2020)



Supervisory Board

Dr. Jörg Spiekerkötter (Chairman)

Background: Former CFO, Schering AG, Organon

Dr. Karin Dorrepaal

Background: Former Schering AG Board Member

Dr. Dr. Irina Antonijevic

Background: Senior VP Development Triplet Therapeutics

Dr. Chris Tanner

Background: Non-Executive Director Cosmo Pharmaceuticals

Dr. Markus Leyck Dieken

Background: Managing Director Gematik

PAION Strategy

- Bring remimazolam to market over 2020-2022
- Build a commercial capability in attractive geographies in Anesthesia & Critical Care
- Launch remimazolam & in-licence complimentary medications to grow revenue
- Reach profitability within the next 5 years as a leader in our field with fast revenue growth

PAION Commercialization plans

- PAION continues to conduct pre-commercial activities
- The build-up of its own distribution structure in Europe is dependent on PAION's ability to add more products to its commercial portfolio
- Thus, PAION is also considering outlicensing remimazolam for commercialization in Europe
- Supply chain activities
 - PAION is building up the supply chain in order to be able to regularly provide remimazolam product to the licensees as well for PAION's potential own commercialization
 - Activities include establishing structures and processes and obtaining all necessary pharmaceutical permits and will be implemented in the second half of 2020

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 has more than 19 years experience in Finance.

Career: At KPMG he advised international clients on accounting, post-merger integration and financial reporting and also worked several years in the audit department with a focus on the chemical industry



Dr. Jürgen Beck, CDO

Dr. Jürgen Beck was appointed Chief Development Officer in 2017. He is a physician and holds a diploma in business administration. Dr. Beck has over 25 years of experience in the European pharma business.

Career: Senior management positions at Synthélabo, Managing Director of Monitoring Force GmbH, Senior Vice President at Epigenomics and Vice President at InterMune International AG

PAION AG is listed on Frankfurt Stock Exchange



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



Market capitalization: cEUR170 m



Liquidity (last six months) (Xetra, Tradegate & FRA stock markets): **30 million shares traded**



Stock Performance (2020) (price and volume in EUR)



Market Data

Capitalization (as of 23 September 2020)

Current Share Price	€ 2.40
FD Shares Outstanding	66.2 million
Market Cap	c€ 170m
Mean target price of analyst reports (Edison, First Berlin, FMR)	€ 4.72

Short-term value drivers



PAION has strong reserves in the current economic crisis

- Cash of approx. €12m (as of 30 June 2020)
- FDA Approval milestone of €15m from Cosmo (received in July 2020)
- R&D cash tax credits (for 2019 and 2020) of €3 to €4m
- EIB Loan facility of €20m

TOTAL AVAILABLE CASH & RESERVE FACILITIES APPROX. €50m

This represents 2.5 years Cash at current spend

We could extend to 3 years plus

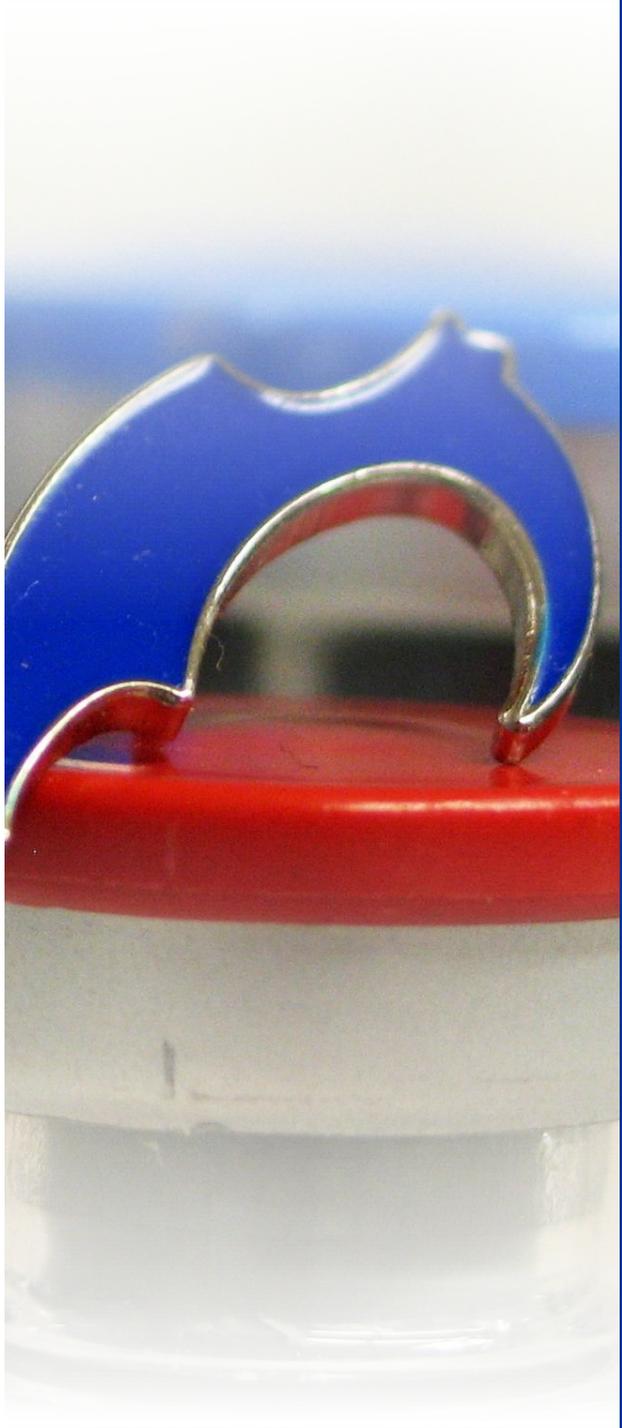
Covid-19 at PAION

- The pandemic has only led to minor direct effects on the PAION group to date
- On an operational level, the pandemic led to an earlier completion of patient recruitment of the EU Phase III study
 - Since a large part of the originally planned number of patients of the study had already been recruited at that time, PAION does not expect an impact on the activities planned subsequently.
- Likely Budget Impact 2020
 - No revised outlook due to the coronavirus pandemic
- Since the supply chain is only being established, there have been no direct effects of the pandemic to date

Compassionate Use in Italy & Belgium

- The local Ethics Committee of the **Hospital San Raffaele in Milan/Italy** granted approval for the compassionate use of remimazolam for the use of sedation of five intensive care unit (ICU) patients with COVID-19 in **June 2020**
- PAION had been contacted by the San Raffaele Hospital as to whether remimazolam could be delivered due to a shortage of propofol and midazolam caused by the coronavirus pandemic → PAION fulfilled the request and supplied the material free of charge.
- Due to the currently much more relaxed situation in the hospital with regard to COVID-19 patients on the ICU, an extension to other patients is not planned for now

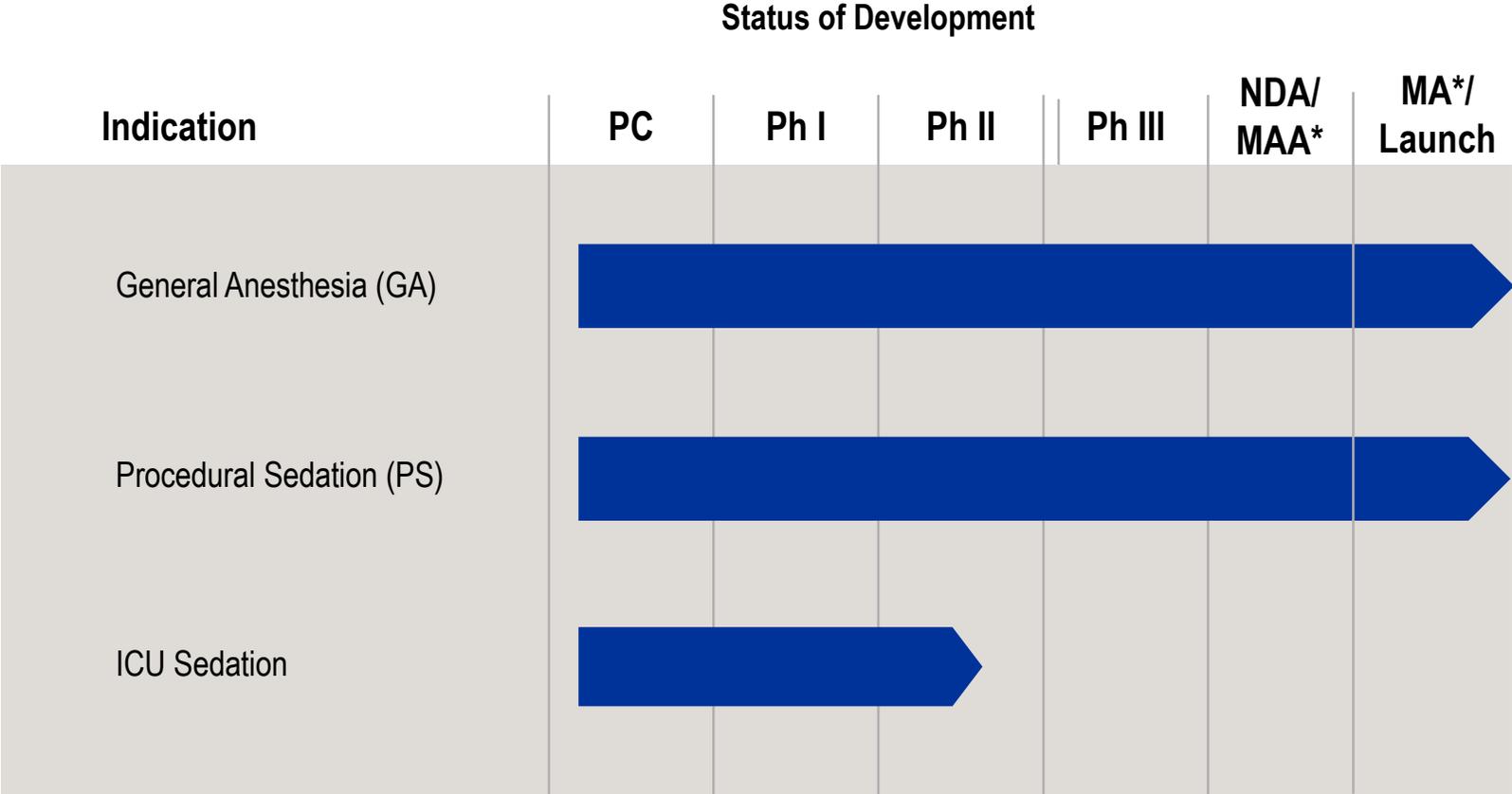
- In **August 2020**, the FAMHP granted approval for the compassionate use of remimazolam in **Belgium** for
 - sedation of intensive care unit patients with COVID-19
 - as a substitute for current standard of care in general anesthesia for which there are currently shortages due to the coronavirus pandemic
- The use is limited to physicians who have experience with remimazolam
- PAION will deliver the material initially free of charge



AGENDA

- 1 Corporate Overview
- 2 Remimazolam**
- 3 Financials

Remimazolam - Potential in three indications



* NDA = New Drug Application; MAA = Marketing Authorization Application; MA = Market Approval



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

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

 **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

Remimazolam (BYFAVO™ / Anerem® / Ruima®) – Status

Class	<ul style="list-style-type: none">• First-in-class ultra-short-acting intravenous benzodiazepine sedative/anesthetic
IP	<ul style="list-style-type: none">• 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
Safety	<ul style="list-style-type: none">• Extensive safety and efficacy database → ~ 2,900 volunteers/patients to date
Indications	<ul style="list-style-type: none">• Procedural Sedation in the U.S., EU & China• General Anesthesia in the EU, Japan, Russia, China and South Korea• Further potential in ICU sedation <p>→ Estimated market opportunity >\$500 m globally for each indication alone*</p>
Results to date indicate	<ul style="list-style-type: none">• Solid efficacy and safety in studied populations• Rapid onset and offset of action• Appropriate depth of sedation• Favorable hemodynamic stability

* PAION estimates

PAION's commercial partners

U.S. – Acacia



- **Lead indication: Procedural Sedation**
- Market approval received in July 2020
- Acacia plans to launch remimazolam in H2 2020

Japan – Mundipharma



- **Lead indication: General Anesthesia**
- Market approval received in January 2020
- Mundipharma successfully launched remimazolam in mid-2020 with first commercial product sales

China – Yichang Humanwell



- Indications General Anesthesia + Procedural Sedation
- Yichang Humanwell received market approval in Procedural Sedation in July 2020
- Yichang Humanwell launched remimazolam in July 2020
- Ongoing Phase III in general anesthesia

South Korea + Southeast Asia – Hana Pharm



- **Lead indication: General Anesthesia**
- Hana Pharm filed for market approval in December 2019; market approval expected in H2 2020
- Extended license territory by adding Southeast Asia in January 2020

Canada – Pharmascience



- **Lead indication: Procedural Sedation**
- PAION expects Pharmascience to use the U.S. market approval dossier as the basis for their own filing for market approval of remimazolam

R-Pharm (Russia, Turkey, MENA Region)



- R-Pharm successfully completed a Phase III trial in General Anesthesia in November 2018
- R-Pharm is currently preparing first market approval dossiers for the licensed territories

Japan (Anerem®): Launch Update (August 2020)

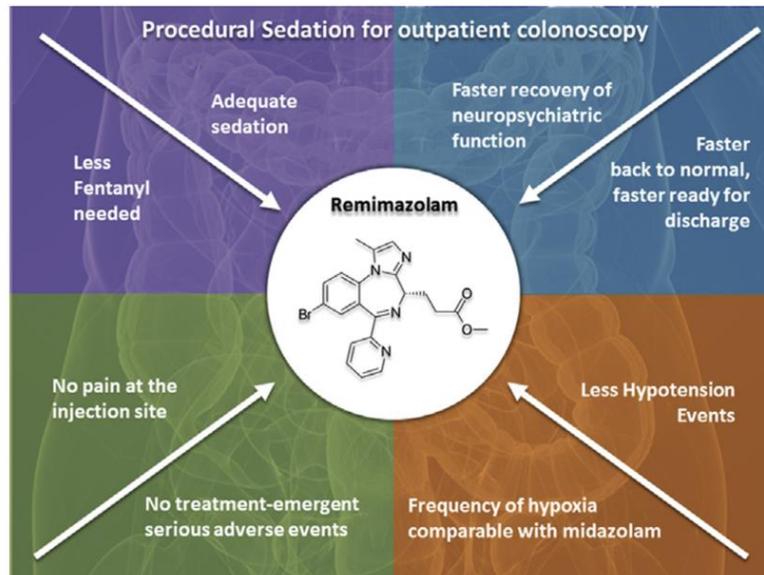
- NHI national reimbursed price of 2,218 yen per 50 mg vial (~ €18)
- 250- 300 hospitals are expected have product listed by year-end
- First royalties for PAION expected in Q4 2020



China (Ruima®): Launch Update (July 2020)



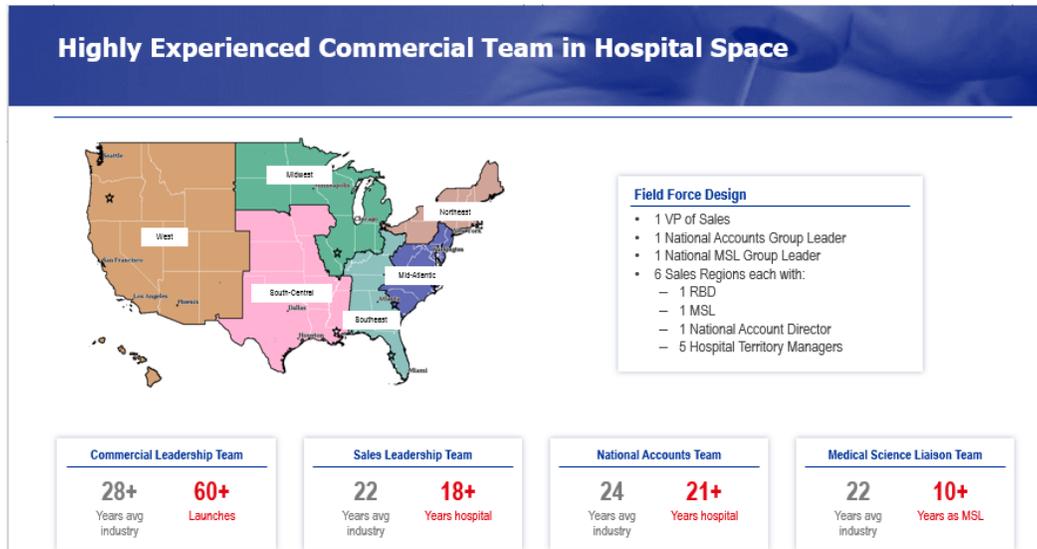
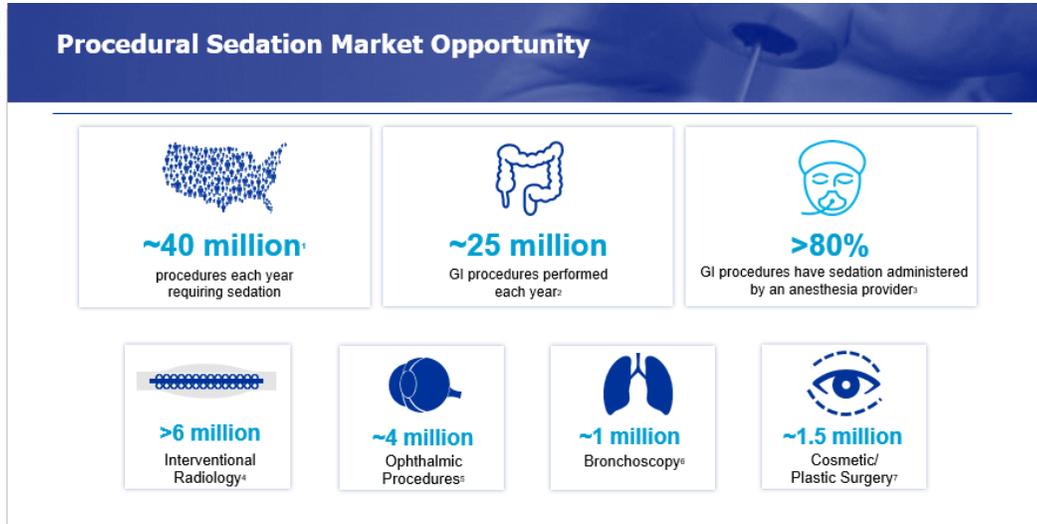
- Pricing at launch 139 RMB / Vial (~ €17)
- Currently in clinical use in China and already being sold to hospitals in some provinces
- Several Chinese KOL support differentiation compared to competition
 - “[...] four major advantages: low impact on blood pressure, heart rate and respiratory depression, 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



Ruima =
Running Horse



USA (BYFAVO™): FDA approval in July 2020 Commercial launch planned in H2-2020



- Commercial synergy with BARHEMSYS® (U.S. approved for treatment and prophylaxis of PONV)
- Target prescribers: anesthesiologists and proceduralists in hospitals and ambulatory surgery centers
- Substantial clinical data shows compelling efficacy and safety in colonoscopies and bronchoscopies, including least fit patients

Remimazolam in Europe - Planned indications: Procedural Sedation & General Anesthesia

- PAION submitted an MAA in Procedural Sedation based on the completed U.S. development program in **November 2019**
- EU Phase III study in General Anesthesia (ASA III/IV)
 - Multicenter, randomized and active-controlled European (EU) Phase III trial in 424 patients undergoing elective surgery
 - Countries: Germany, France, Italy, Switzerland, The Netherlands, UK, Belgium
 - Due to the coronavirus pandemic, patient recruitment was completed in April 2020 with 424 patients enrolled, as agreed to by the Data Monitoring Committee
 - Topline data of the trial are expected in the **H2 2020**
- Following approval in procedural sedation, an extension of the dossier to also include general anaesthesia is planned. This would allow for an abbreviated application for general anesthesia that is generally processed faster

- Evaluation of efficacy and safety incl. hemodynamic stability

- Comparison between remimazolam and propofol

Primary objective: Efficacy (non-inferiority of remimazolam compared to propofol)

Key secondary objective: Improved hemodynamic stability compared to propofol

EU Launch Planning and Market Access activities ongoing

Potential Launch Timetable Procedural Sedation EU

April 2021	May-July 2021	June 2021	July 2021	September 01 2021
MAA from EMA	Final Packaging / Labelling	Formulary / MSL Work begins	KAM Training	Formal Launch

Market Access activities:

- Development of Global Value Dossier (GVD) and economic modelling for procedural sedation
- EU country discussions commencing on reimbursement

Marketing activities: Brand name in EU will also be Byfavo^{®*} Logo & brandbook available

byfavo[®] 
remimazolam

EU/partner logo US allows for global branding

byfavo[®]  remimazolam | 
byfavo[®] (remimazolam)
injection 2.5 mg/mL

*Byfavo has no marketing approval yet in the EU

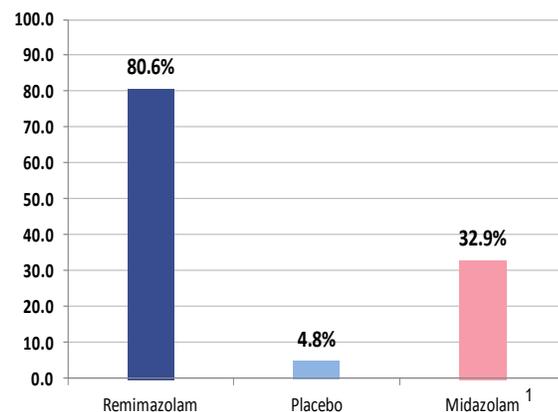
Remimazolam: Clinical development program successfully completed in Procedural Sedation in the U.S. and China

Three U.S. trials with positive results*

Phase III trial in Procedural Sedation in patients undergoing bronchoscopy (n = 446)

Phase III bronchoscopy (ASA I-III)

Success of procedure

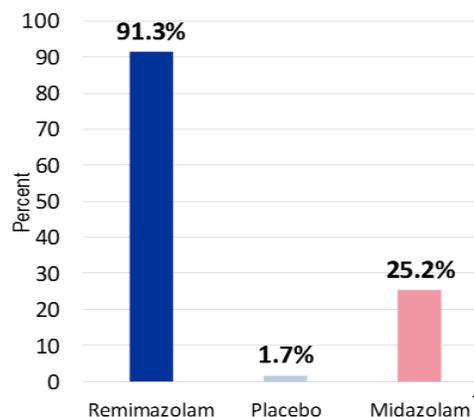


1. Open label

Phase III trial in Procedural Sedation in patients undergoing colonoscopy (n = 461)

Phase III colonoscopy (mostly ASA I-III)

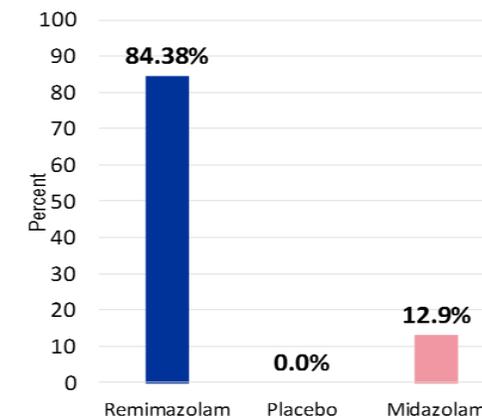
Success of procedure



Safety study in ASA III/IV (high-risk) patients undergoing colonoscopy (n = 79)

ASA III/IV patients

Success of procedure



* Phase III trials performed by PAION

U.S. pivotal Phase III study in colonoscopy: Supports business case (ability to treat more patients)

Time from start of medication to start of procedure		minutes
Remimazolam – 5.0/2.5 mg		4.0
Midazolam – 1.75/1.0 mg (1.0/0.5 mg in the elderly and debilitated)		19.0

Time from end of procedure to fully alert		minutes
Remimazolam – 5.0/2.5 mg		6.0
Midazolam – 1.75/1.0 mg		13.0

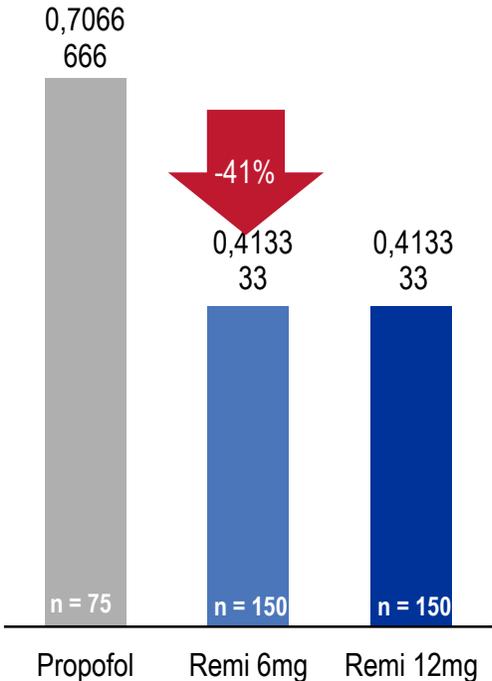
→ With an average reduction of 22 min/procedure and an average number of procedures of 10/day/doctor with midazolam, centers could increase throughput significantly

Remimazolam clinical data (General Anesthesia – ASA I/II): Phase IIb/III pivotal trial: post hoc analyses

In Hypotension

Patients with MAP < 60 mm Hg
First hour after intubation

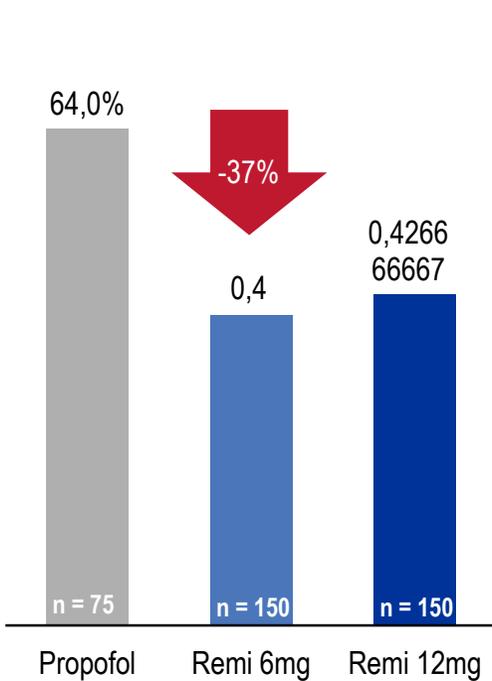
NNT = 3.4



Need for Vasopressors

Share of patients with any
vasopressor entire study

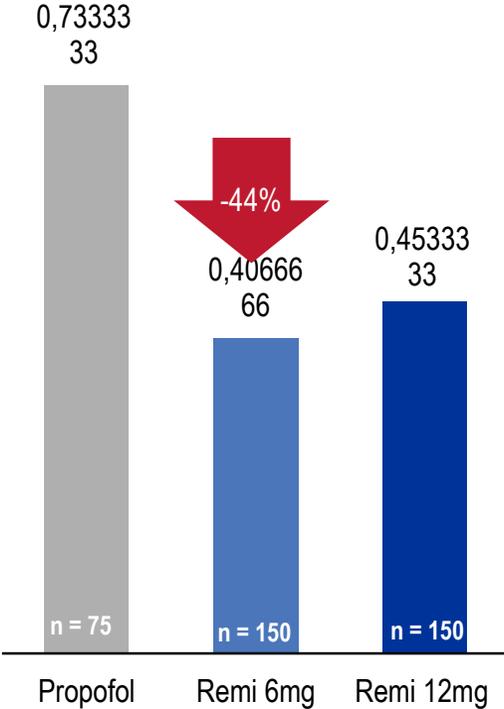
NNT = 4.2



Too deep sedation

Share of patients with BIS score
below 40 until 1 h after
intubation

NNT = 3.1





AGENDA

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EIB Financing Agreement / Yorkville convertible notes

EIB Financing Agreement:

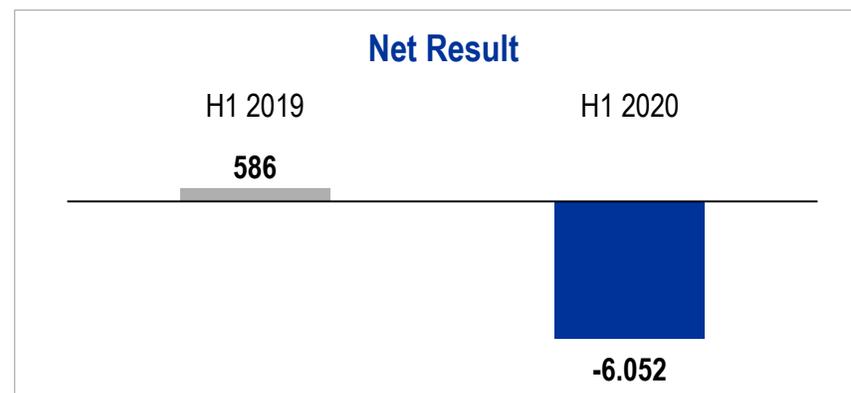
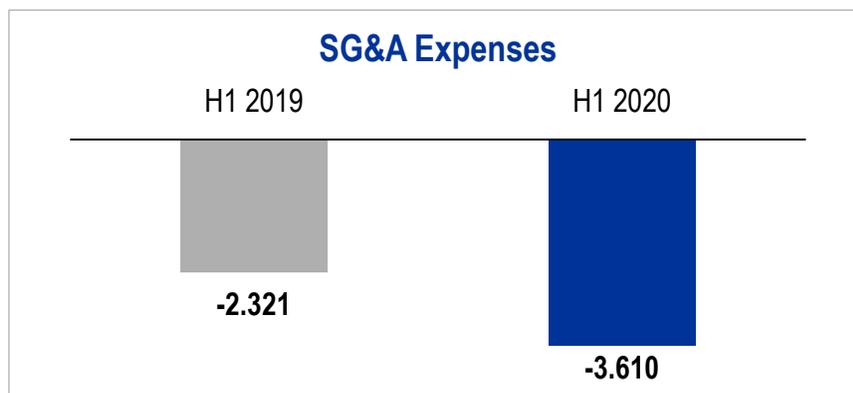
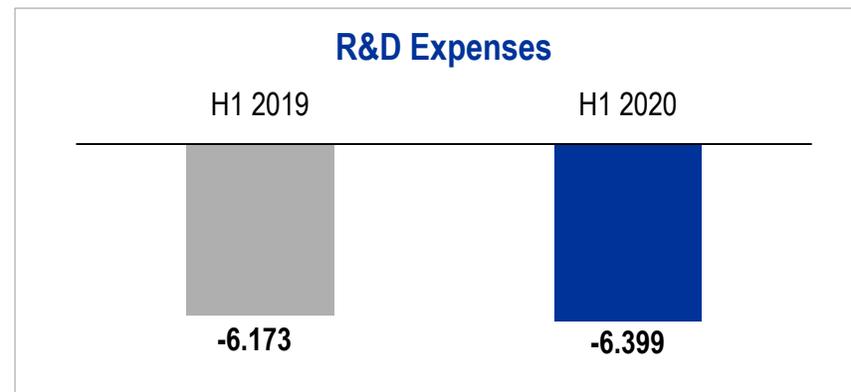
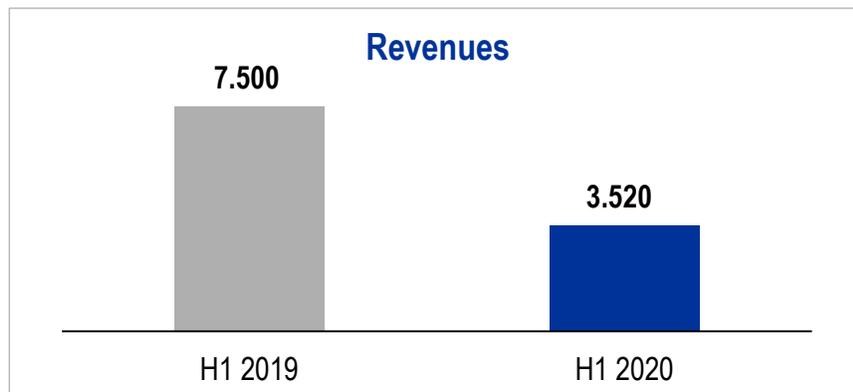
- Unsecured loan of up to EUR 20 million
- Can be drawn down in a total of three tranches based on certain conditions as e.g. the achievement of operational milestones
- Available until June 2021
- The first tranche of the loan is already available and the two further tranches could become available in 2020
- PAION has not drawn down the loan yet

Yorkville Growth Financing:

- EUR 5 million convertible notes completely converted into a total of 2,363,350 new shares
- No convertible notes outstanding as of today
- A further issue of convertible notes under this agreement is not planned

Consolidated statement of comprehensive income

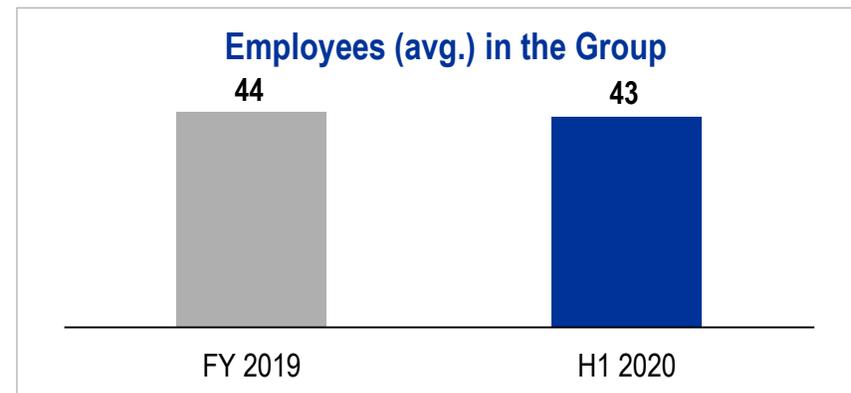
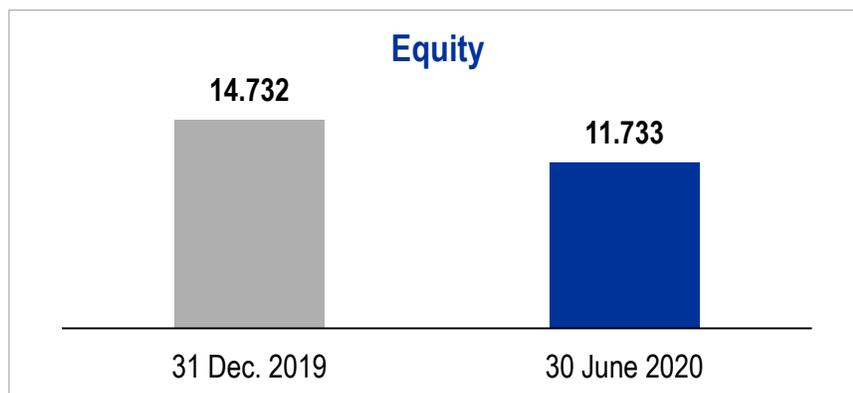
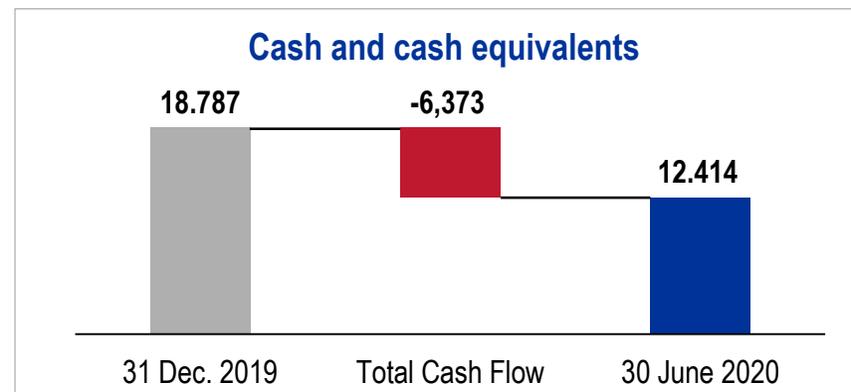
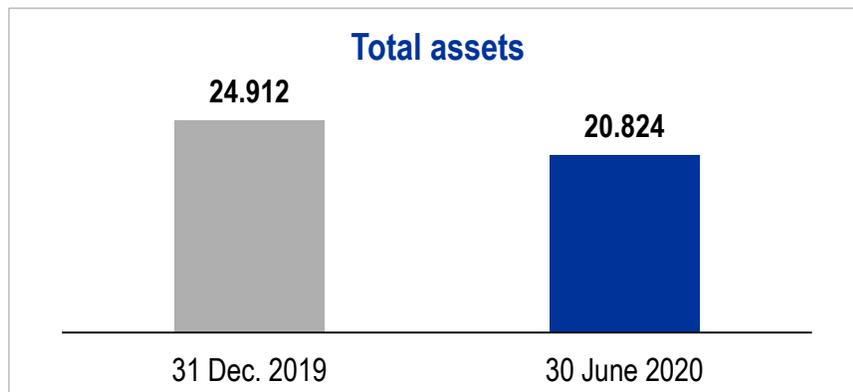
In accordance with IFRS (all figures in EUR k)



- R&D expenses mainly relate to the EU Phase III study in general anesthesia for which the data analysis is currently ongoing
- SG&A expenses increased particularly due to pre-commercial activities and build-up of a supply chain

Consolidated balance sheet and employees

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



→ Equity ratio as of 30 June 2020 was 56.3%

Financial Outlook 2020

	Actual FY 2019 EUR million	Plan FY 2020 EUR million	Comments	
Revenues	€ 8.0m	~ € 20m	EUR 15m from market approval in the U.S.; further revenues from market approvals in Japan & China, license extension with Hana Pharm and in connection with potential market approval in South Korea	
Expenses	R&D	€ 13.1m	~ € 10m – ~ € 12m	R&D expenses mainly due to continuation of development program of remimazolam including EU Phase III study
	SG&A	€ 5.0m	~ € 7m – ~ € 9m	SG&A expenses increase due to pre-commercial activities and build-up of supply chain
Tax credits	€ 2.4m	~ € 1m – ~ € 1.5m	Tax credits on portion of R&D expenses from UK tax authorities	
Net result	€ -7.0m	~ € 0.5m – ~ € 4m	Positive net result expected	

Cash Runway



Cash reach is at least into the second half of 2021 based on current planning



Q&A

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