

# PAION HI#2021

Consolidated Financial Interim Report for the First Half-Year 2021

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PAION AG



## About PAION AG

PAION AG is a publicly listed specialty pharmaceutical company with innovative drugs to be used in hospital-based sedation, anesthesia and critical care services. PAION's lead compound is remimazolam, an intravenous, ultra-short-acting and controllable benzodiazepine sedative/anesthetic. Remimazolam is partnered in multiple territories outside of Europe. Remimazolam is approved in the U.S., the EU/EEA/UK and China for procedural sedation and in Japan and South Korea for general anesthesia.

In addition to Byfavo® (remimazolam), PAION has two further products, GIAPREZA® (angiotensin II) and XERAVA® (eravacycline), in its portfolio. GIAPREZA® is 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, and was launched in July 2021. XERAVA® is a novel fluorocycline type of antibiotic indicated for the treatment of complicated intra-abdominal infections in adults.

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

PAION is headquartered in Aachen (Germany).

## Key Figures

(all figures in KEUR unless otherwise noted)	Q2 2021	Q2 2020	H1 2021	H1 2020
Revenues	413	20	3,617	3,520
Research and development expenses	-1,575	-2,669	-2,912	-6,399
General administrative and selling expenses	-4,875	-1,746	-8,706	-3,610
Earnings before interest and tax (EBIT)	-6,035	-4,592	-8,593	-6,682
Result for the period	-6,677	-4,341	-10,436	-6,052
Earnings per share in EUR for the period (basic)	-0.09	-0.06	-0.15	-0.09
Earnings per share in EUR for the period (diluted)	-0.09	-0.06	-0.15	-0.09

	H1 2021	H1 2020
Cash flows from operating activities	-6,979	-6,360
Cash flows from investing activities	-18,742	-2
Cash flows from financing activities	27,209	-22
Change in cash and cash equivalents	1,495	-6,373
Average number of group employees	47	43

	30-06-2021	31-12-2020
Intangible assets	19,804	1,829
Cash and cash equivalents	21,161	19,666
Equity	18,214	21,290
Current liabilities	9,123	6,845
Non-current liabilities	21,270	15
Balance sheet total	48,607	28,150

# Interim Group Management Report for the First Half-Year 2021

## The Reporting Period at a Glance

### January

Hana Pharm receives market approval for Byfavo™ (remimazolam) in general anesthesia in South Korea

PAION signs exclusive license agreement with La Jolla Pharmaceutical for GIAPREZA® (angiotensin II) and XERAVA® (eravacycline) in Europe

PAION receives positive CHMP opinion recommending approval of Byfavo® (remimazolam) in procedural sedation in the EU

Acacia Pharma launches BYFAVO™ (remimazolam) in the U.S. for procedural sedation in adults undergoing medical procedures lasting 30 minutes or less

### February

PAION draws EUR 12.5 million loan from European Investment Bank (EIB) from EUR 20 million loan facility

### March

PAION grants exclusive license to TTY Biopharm for development and commercialization of remimazolam in Taiwan

PAION to issue approx. 5 million shares at EUR 1.54 per share in capital increase with subscription rights

PAION receives European Commission approval of Byfavo® (remimazolam) for procedural sedation

### April

PAION announces product launch of Byfavo™ (remimazolam) in South Korea by Hana Pharm

PAION announces successful completion of capital increase with subscription rights

### June

PAION receives UK MHRA approval of Byfavo® for procedural sedation

Full draw of EUR 20 million EIB loan – third and final tranche in the amount of EUR 7.5 million

### July (after the reporting period)

PAION announces that NMPA accepts submission of New Drug Application for remimazolam in general anesthesia by chinese licensee Yichang Humanwell for review

PAION announces launch of GIAPREZA® for the treatment of refractory hypotension in adults with septic or other distributive shock in Germany

#### **August (after the reporting period)**

PAION announces launch of Byfavo® in the UK for procedural sedation

## **Update on business activity in the first half-year 2021**

### **Regulatory activities with remimazolam in Europe**

In Europe, remimazolam (trade name Byfavo®) has been approved in procedural sedation, and in addition PAION is seeking approval for general anesthesia.

Procedural sedation: The European Commission approved Byfavo® in the EU (including European Economic Area (EEA) countries) in March 2021. The decision of the UK Medicines & Healthcare products Regulatory Agency (MHRA) for approval in the United Kingdom followed in June 2021.

General anesthesia: Based on the positive results in the Phase III trial in general anesthesia and the approval in procedural sedation, PAION plans to submit an extension of the market approval application (MAA) for remimazolam for general anesthesia until the end of 2021. The approval process for an extension application is generally faster than for an MAA.

### **Remimazolam partner activities in the first half-year 2021**

Remimazolam licensees had product revenues in the amount of EUR 2.7 million in the first half of 2021. Sales of remimazolam in China are growing particularly well and China is currently the largest market globally, whilst in Japan the market is strong, but a previous batch recall and therefore limited supply hindered the sales in market. In the U.S. 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.

In the U.S., the launch of remimazolam (trade name BYFAVO™) by licensee Acacia Pharma (Acacia) was announced in January 2021. According to Acacia, initial market response was very positive despite the pandemic. At the end of June 2021, Acacia reported BYFAVO™ to be on track to meet its full year 2021 formulary acceptance goals. Until the end of June 2021, BYFAVO™ had been put on formulary in 47 accounts, against an expectation of 150 for the full year 2021; this represents an increase of 40 accounts since March 2021. For the indication general anesthesia, PAION is planning an advisory meeting with the FDA (U.S. Food and Drug Administration) on suitability of the European clinical program for a filing in the U.S. U.S. rights to develop and commercialize remimazolam in general anesthesia were originally subject to an option in the license agreement with Cosmo/Acacia. Since that option was not exercised by PAION's licensee, it has now lapsed and PAION will intensify discussion with interested parties after the FDA advice to execute a new license for the general anesthesia indication in the U.S.

PAION and Mundipharma have agreed on an amendment of the royalty calculation in the first half-year 2021. A corresponding contract amendment has been put in place. Under the terms of the amendment, PAION will receive 15.5% royalties on net sales. From mid-2023 onwards, the royalty rate could be reduced in case of (too) high cost of goods in relation to net sales, but not below 5%. The remaining royalties from the fiscal year 2020 of EUR 0.2 million were paid in the second quarter 2021 and are disclosed as revenue in the first half-

year 2021 accordingly. Mundipharma initiated a Phase II/III clinical trial in May 2021 to evaluate the efficacy and safety of remimazolam in Japanese patients undergoing gastrointestinal endoscopy. Following approval in general anesthesia, this will develop an additional indication in Japan.

In July 2021, the NDA for remimazolam in general anesthesia was accepted for review by the National Medical Products Administration (NMPA) in China. Yichang Humanwell had recently completed the clinical development for remimazolam in general anesthesia. In Shanghai, the first Securities Times journal's "Drug Innovation Award" ceremony was held on 10 June 2021. On site, Yichang Humanwell won the annual drug innovation achievement award. Ruima® (remimazolam) was selected for the "Annual Pharmaceutical Innovation Achievement Award". Supported by Yichang Humanwell, Chinese investigators are currently exploring the use of Ruima® in additional indications, in multi-center trials in intensive care unit (ICU) sedation of patients during and after mechanical ventilation. Another multi-center investigator-initiated trial (IIT) is studying Ruima® for use in spinal anesthesia, with a focus on elderly patients.

In South Korea, licensee Hana Pharm received market approval for Byfavo™ (remimazolam) in general anesthesia in January 2021 and launched in South Korea at the end of March 2021. Hana Pharm has recently reported that the domestic landing and market positioning strategy of Byfavo™ was successful in the three months after its launch. Hana Pharm has been conducting various academic activities and clinical trial promotion strategies to increase the accessibility of Byfavo™ starting from the Byfavo™ launch symposium held at the end of April 2021.

In March 2021, PAION and TTY Biopharm ("TTY") entered into a license agreement for remimazolam with PAION granting TTY an exclusive license for the development and commercialization of remimazolam in Taiwan.

#### **GIAPREZA® and XERAVA®**

In January 2021, PAION entered into an exclusive license agreement with La Jolla Pharmaceutical Company for the intensive care products GIAPREZA® (angiotensin II) and XERAVA® (eravacycline). The agreement grants PAION an exclusive license for the commercialization of these two approved products in the European Economic Area, the United Kingdom and Switzerland. GIAPREZA® is 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. XERAVA® is a novel fluorocycline type of antibiotic indicated for the treatment of complicated intra-abdominal infections in adults. In July 2021, GIAPREZA® was launched in Germany and can be ordered and delivered to customers through direct sales.

#### **Commercial activities**

With the addition of GIAPREZA® and XERAVA® to its commercial portfolio, PAION has started to establish its own commercial structures in certain core countries in Western Europe including Germany, UK, Netherlands and Denmark to market GIAPREZA® and XERAVA® together with Byfavo®. PAION has started the commercialization of Byfavo® and GIAPREZA® in the second half of 2021 in a staggered manner by country so that by the end of 2022, launches are planned to have been conducted in most key European markets.

## Financial Overview

In the first half of 2021, revenues of EUR 3.6 million (prior-year period: EUR 3.5 million) were recognized, primarily resulting from milestones from remimazolam license agreements, the sale of remimazolam API (active pharmaceutical ingredient) to licensees as well as royalties from the commercialization of remimazolam. Research and development expenses amounted to EUR 2.9 million compared to EUR 6.4 million in the prior-year period and decreased as planned due to the completion of the EU Phase III study in general anesthesia in the previous year. General administrative and selling expenses increased as planned from EUR 3.6 million in the prior-year period to EUR 8.7 million in the first half of 2021, in particular due to commercialization and supply chain activities. Overall, earnings before interest and taxes (EBIT) amounted to EUR -8.6 million in the first half of 2021, compared to an EBIT of EUR -6.7 million in the prior-year period.

Cash and cash equivalents increased by EUR 1.5 million in the first half-year 2021 compared to 31 December 2020 and amounted to EUR 21.2 million as of 30 June 2021. Based on current planning, cash and cash equivalents secure a liquidity runway into the first half of 2022.

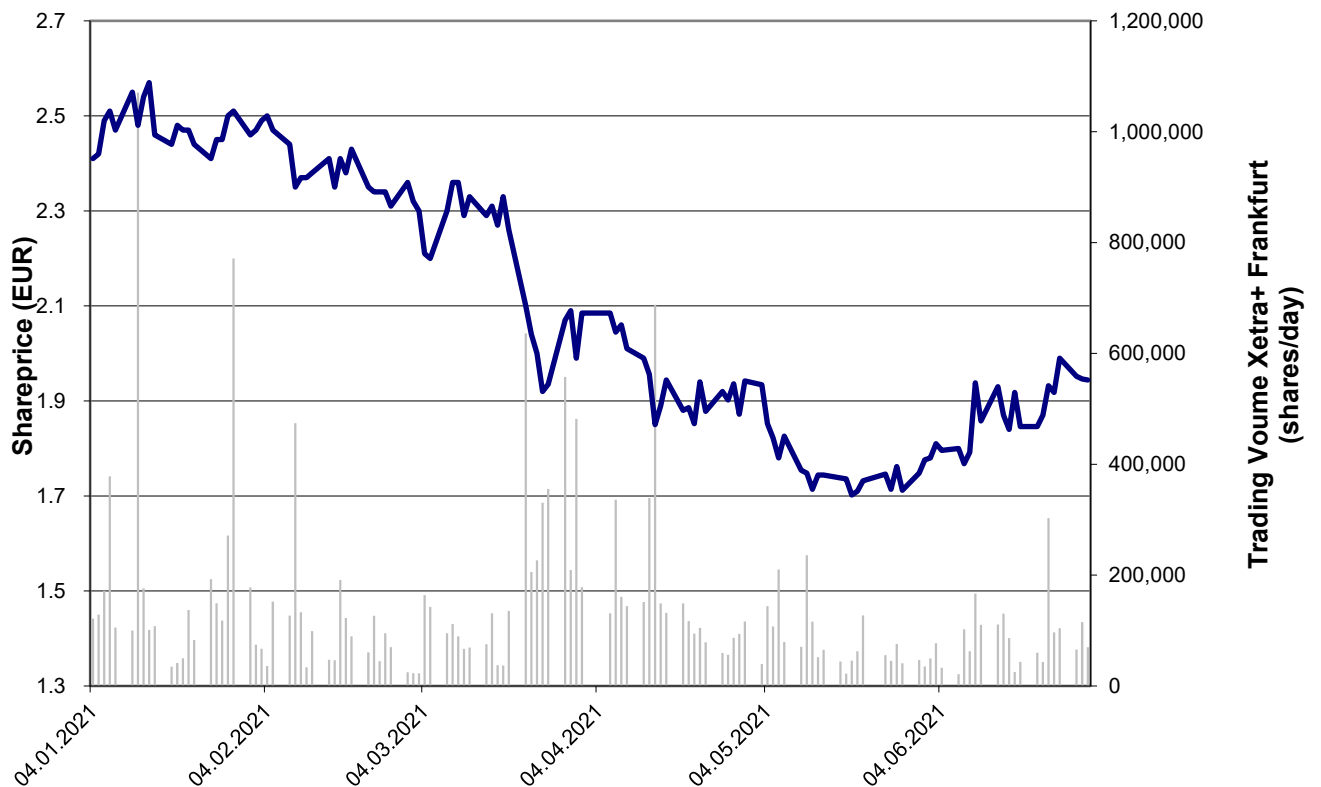
## Capital Market Environment and PAION Share Performance

The development of the German capital markets in the first half of 2021 was still mainly impacted by the Covid-19 pandemic. The DAXsubsector Biotechnology Index increased by about 8% and the NASDAQ Biotechnology Index also increased by approx. 10% in the first six months of 2021.

The PAION share started the year 2021 at a price of EUR 2.41 (Xetra closing price). The peak share price in the first half-year 2021 was marked on 11 January 2021 with EUR 2.55 based on Xetra closing prices. On 19 May 2021, the lowest price in the first half-year 2021 was marked at EUR 1.70 (Xetra closing price). The closing price on 30 June 2021 was EUR 1.94 (Xetra). This corresponds to a decrease of approx. 19% compared to the closing price on 30 December 2020 (EUR 2.40; Xetra).

The average daily trading volume in the first half of 2021 amounted to 136,025 shares (Xetra) and 125,124 shares (Tradegate) (full year 2020: 147,527 shares (Xetra) and 155,639 shares (Tradegate)).

### Development of the PAION Share Price and Volume (Xetra) in the First Half-Year 2021



## Presentation of the course of business and development activities

The product portfolio of PAION Group essentially comprises remimazolam (remimazolam besylate) (EU brand name: Byfavo®) with its three target indications procedural sedation, general anesthesia and ICU sedation, as well as the products GIAPREZA® and XERAVA®.

### Byfavo® (remimazolam besylate)

Remimazolam is an ultra-short-acting intravenous benzodiazepine sedative/anesthetic. In the human body, remimazolam is rapidly metabolized to an inactive metabolite by tissue esterases and is not metabolized by cytochrome-dependent hepatic pathways. Like other benzodiazepines, remimazolam can be reversed with flumazenil to rapidly terminate sedation or anesthesia if necessary. Data demonstrate that remimazolam has a rapid onset and offset of action combined with a favorable cardio-respiratory safety profile.

Remimazolam is approved in the U.S., the EU/EEA/UK and China for procedural sedation and in Japan and South Korea for general anesthesia.

In addition to procedural sedation and general anesthesia, ICU sedation is another possible indication for remimazolam.

Remimazolam is partnered in the U.S. (brand name BYFAVO™) with Acacia Pharma, in Japan (brand name Anerem®) with Mundipharma, in China (brand name Ruima®) with Yichang Humanwell, in Canada with Pharmascience, in Russia/CIS, Turkey and the MENA region with R-Pharm, in South Korea (brand name Byfavo™) and Southeast Asia with Hana Pharm and in Taiwan with TTY Biopharm. For all other markets except Western Europe, remimazolam is available for licensing.

## Clinical development

### Procedural sedation

The first U.S. Phase III trial was successfully completed in 2016, and the primary efficacy endpoint was achieved. The Phase III trial enrolled 461 patients at 13 U.S. sites and was designed to evaluate the efficacy and safety of remimazolam compared to placebo (with midazolam rescue) in patients undergoing proceduralist-administered sedation for colonoscopy. In addition, the trial had an open-label midazolam arm.

In addition to the above trial, the U.S. Phase III program included a second confirmatory, prospective, double-blind, randomized, placebo-controlled multi-center trial with an open-label midazolam arm in 446 patients undergoing bronchoscopies. The trial was successfully completed in 2017, and the primary efficacy endpoint was achieved. The Phase III trial was conducted at 15 U.S. sites and was designed to evaluate the efficacy and safety of remimazolam compared to placebo (with midazolam rescue medication) in patients undergoing bronchoscopy.

As part of the U.S. development program, also a safety trial in ASA III/IV (American Society of Anesthesiologists classification) patients undergoing colonoscopy (American Society of Anesthesiologists classification) was performed which was successfully completed in 2017. The trial enrolled 79 patients and was designed to evaluate the safety and efficacy of remimazolam compared to placebo (with midazolam rescue sedation) in patients undergoing proceduralist-supervised sedation for colonoscopy.



Summary of key results from the three Phase III trials:

	Remimazolam	Placebo	Midazolam (Open Label) *
Primary endpoint achieved (ITT)	80.6–91.3%	0.0–4.8%	12.9–32.9%
Time from start of medication to start of procedure	4.0–5.0 min	17–19.5 min	15.5–19.0 min
Time from end of procedure to fully alert	3.0–6.0 min	5.3–15.0 min	7.0–13.0 min
Time to back to normal	192–402 min	348–936 min	366–444 min

\* Only partially relevant for the label claim

### General Anesthesia

In the clinical program, specific attention was paid to hemodynamic stability, which addresses a current need in general anesthesia. Nonclinical data had suggested and clinical data confirmed that a better hemodynamic stability can be reached with remimazolam than with propofol.

The clinical development program in Europe and Japan demonstrated safety and efficacy as an anesthetic as well as an improved hemodynamic profile compared to propofol.

In Europe, a randomized, single-blind, propofol-controlled, confirmatory Phase III trial enrolled 424 ASA III/IV patients (American Society of Anesthesiologists classification III to IV) undergoing planned surgery at more than 20 European sites. The primary objective of the trial was to demonstrate non-inferiority of remimazolam compared to propofol for the induction and maintenance of general anesthesia during elective surgery. The key secondary objective was to show improved hemodynamic stability compared to propofol. In the trial, remimazolam met both the primary and key secondary endpoints.

### ICU sedation

PAION's former licensee in Japan, Ono, independently initiated a Phase II trial for sedation in ICUs. Higher than expected plasma concentrations by pure calculation of remimazolam were observed in isolated cases after long-term treatment as is known from similar substances, and Ono discontinued this exploratory trial in 2013. Patients were sedated successfully and no significant unexpected adverse events were reported.

The observed phenomenon of elevated remimazolam plasma concentrations was subsequently thoroughly investigated using a series of nonclinical tests and pharmacokinetic models. None of these experiments was able to reproduce the findings or provide a mechanistic explanation for the elevated plasma concentrations. Further analysis has revealed that such pharmacokinetic deviations are common for utilization of sedatives like midazolam and propofol on the ICU and the most likely explanation is the underlying serious condition of patients presenting on the ICU. Further development of this indication is currently not being conducted.

### Pediatric development

In 2018, PAION submitted a PIP (Pediatric Investigation Plan) to the EMA which was approved in November 2019. In this development plan, various trials are planned to be carried out over several years, starting with procedural sedation. The clinical trials will initially be conducted with adolescents and with increasingly younger children being

enrolled in a stepwise approach. The first of these trials in the indication procedural sedation is planned to be conducted together with the U.S. licensee Acacia and will start shortly.

## Regulatory activities

In Europe, remimazolam (trade name Byfavo®) is approved in procedural sedation and in addition PAION is seeking approval for general anesthesia.

Procedural sedation: The European Commission approved Byfavo® in the EU (including EEA countries) in March 2021. The decision of the MHRA for approval in the United Kingdom followed in June 2021.

General anesthesia: Based on the positive results in the Phase III trial in general anesthesia and the approval in procedural sedation, PAION plans to submit an extension of the MAA for remimazolam for general anesthesia until the end of 2021. The approval process for an extension application is generally faster than for an MAA.

## Commercial activities

With the addition of GIAPREZA® and XERAVA® to its commercial portfolio, PAION has started to establish its own commercial structures in certain core countries in Western Europe including Germany, UK, Netherlands and Denmark to market GIAPREZA® and XERAVA® together with Byfavo®. PAION has started the commercialization of Byfavo® and GIAPREZA® in the second half of 2021 in a staggered manner by country so that by the end of 2022, launches are planned to have been conducted in most key European markets.

## Partner activities

Remimazolam licensees had product revenues in the amount of EUR 2.7 million in the first half of 2021. Sales of remimazolam in China are growing particularly well and China is currently the largest market globally, whilst in Japan the market is strong, but a previous batch recall and therefore limited supply hindered the sales in market. In the U.S. 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.

In the U.S., the launch of remimazolam (trade name BYFAVO™) by licensee Acacia was announced in January 2021. According to Acacia, initial market response was very positive despite the pandemic. At the end of June 2021, Acacia reported BYFAVO™ to be on track to meet its full year 2021 formulary acceptance goals. Until the end of June 2021, BYFAVO™ had been put on formulary in 47 accounts, against an expectation of 150 for the full year 2021; this represents an increase of 40 accounts since March 2021. For the indication general anesthesia, PAION is planning an advisory meeting with the FDA on suitability of the European clinical program for a filing in the U.S. U.S. rights to develop and commercialize remimazolam in general anesthesia were originally subject to an option in the license agreement with Cosmo/Acacia. Since that option was not exercised by PAION's licensee, it has now lapsed and PAION will intensify discussion with interested parties after the FDA advise to execute a new license for the general anesthesia indication in the U.S.

PAION and Mundipharma have agreed on an amendment of the royalty calculation in the first half-year 2021. A corresponding contract amendment has been put in place. Under the terms of the amendment, PAION will receive 15.5% royalties on net sales. From mid-

2023 onwards, the royalty rate could be reduced in case of (too) high cost of goods in relation to net sales, but not below 5%. The remaining royalties from the fiscal year 2020 of EUR 0.2 million were paid in the second quarter 2021 and are disclosed as revenue in the first half-year 2021 accordingly. Mundipharma initiated a Phase II/III clinical trial in May 2021 to evaluate the efficacy and safety of remimazolam in Japanese patients undergoing gastrointestinal endoscopy. Following approval in general anesthesia, this will develop an additional indication in Japan.

In July 2021, the NDA for remimazolam in general anesthesia was accepted for review by the National Medical Products Administration (NMPA) in China. Yichang Humanwell had recently completed the clinical development for remimazolam in general anesthesia. In Shanghai, the first Securities Times journal's "Drug Innovation Award" ceremony was held on 10 June 2021. On site, Yichang Humanwell won the annual drug innovation achievement award. Ruima® (remimazolam) was selected for the "Annual Pharmaceutical Innovation Achievement Award". Supported by Yichang Humanwell, Chinese investigators are currently exploring the use of Ruima® in additional indications, in multi-center trials in intensive care unit (ICU) sedation of patients during and after mechanical ventilation. Another multi-center investigator-initiated trial (IIT) is studying Ruima® for use in spinal anesthesia, with a focus on elderly patients.

In South Korea, licensee Hana Pharm received market approval for Byfavo™ (remimazolam) in general anesthesia in January 2021 and launched in South Korea at the end of March 2021. Hana Pharm has recently reported that the domestic landing and market positioning strategy of Byfavo™ was successful in the three months after its launch. Hana Pharm has been conducting various academic activities and clinical trial promotion strategies to increase the accessibility of Byfavo™ starting from the Byfavo™ launch symposium held at the end of April 2021.

In Russia, licensee R-Pharm announced the successful completion of a Phase III trial in general anesthesia in November 2018. As the regulatory requirements for remimazolam API (active pharmaceutical ingredient) in Russia differ from those in the EU, PAION and R-Pharm are currently working together to create the necessary conditions for the submission of a marketing authorization application in Russia.

In Canada, PAION expects that its licensee Pharmascience can use the U.S. market approval dossier as the basis for filing for market approval for remimazolam. PAION is currently in discussions with Pharmascience in order to achieve a potentially speedy submission of the marketing authorization application and subsequent launch in Canada, which are expected to be completed very soon.

In March 2021, PAION and TTY Biopharm ("TTY") announced that they entered into a license agreement for remimazolam with PAION granting TTY an exclusive license for the development and commercialization of PAION's lead drug candidate, remimazolam, in Taiwan. Under the terms of the agreement, TTY has the right and obligation to further develop remimazolam in all indications in Taiwan with PAION's support. TTY will bear all cost for market authorization and distribution. PAION will receive a EUR 1.1 million upfront payment, is entitled to payments from regulatory and commercial milestones of up to EUR 3.1 million and will supply drug product at a percentage of the net selling price in Taiwan with minimum supply price guarantees.

The following table provides a status overview of remimazolam in the various territories where MAAs have already been approved:

Licensee, Country	Indication	Market approval	Royalty rate
Mundipharma, Japan	General anesthesia	Granted 01/2020	15.5% <sup>1</sup>
Yichang Humanwell, China	Procedural sedation	Granted 07/2020	5%
Acacia Pharma, U.S.	Procedural sedation	Granted 07/2020	20–25% <sup>2</sup>
Hana Pharm, S. Korea	General anesthesia	Granted 01/2021	10%
PAION, EU	Procedural sedation	Granted 04/2021	-
PAION, United Kingdom	Procedural sedation	Granted 06/2021	-

1. From mid-2023 onwards, the royalty rate could be reduced in case of (too) high cost of goods in relation to net sales, but not below 5%.
2. Subject to adjustments under specific circumstances, but not below 15% of net sales

## GIAPREZA® and XERAVA®

In January 2021, PAION AG and PAION Deutschland GmbH entered into an exclusive license agreement with La Jolla Pharmaceutical Company, San Diego, U.S., and certain of its wholly-owned subsidiaries (collectively La Jolla) for GIAPREZA® (angiotensin II) and XERAVA® (eravacycline). The agreement grants PAION an exclusive license for the commercialization of these two approved products in the European Economic Area, the United Kingdom and Switzerland.

In addition to an upfront payment in the amount of USD 22.5 million, La Jolla is entitled to receive additional payments of up to USD 109.5 million contingent upon the achievement of certain commercial milestones of which the majority are dependent on the respective first achievement of significant sales revenues.

These are in detail as follows for GIAPREZA®:

- USD 5 million for annual sales > EUR 20 million
- USD 5 million for annual sales > EUR 50 million
- USD 15 million for annual sales > EUR 100 million
- USD 60 million for annual sales > EUR 250 million

and for XERAVA®:

- USD 2 million for annual sales > EUR 15 million
- USD 2.5 million upon EMA approval of a second indication for XERAVA®
- USD 5 million for annual sales > EUR 50 million
- USD 15 million for annual sales > EUR 100 million

La Jolla is also entitled to royalties on PAION's own net sales in Europe in the amount of 15% for XERAVA® and between 18% and 24% for GIAPREZA® (18% until end of 2021, 20% from 2022 to 2023, and 24% starting 2024) and a share of revenues from indirect sales.

La Jolla had agreed with the EMA to conduct pediatric trials for XERAVA® and for GIAPREZA® and a Phase IV trial for GIAPREZA®. For the Phase IV trial, a protocol approved by the EMA already exists. PAION is examining the specifics of the study and will coordinate these in discussion with the EMA.

## GIAPREZA® (angiotensin II)

GIAPREZA® for injection is an FDA-approved vasoconstrictor to increase blood pressure in adults with septic or other distributive shock. GIAPREZA® is approved by the European Commission and the UK Medicines Agency 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. GIAPREZA® mimics the body's endogenous angiotensin II peptide, which is central to the renin-angiotensin-aldosterone system, which in turn regulates blood pressure.

Angiotensin II raises blood pressure by vasoconstriction; increased aldosterone release via direct action of angiotensin II on the vessel wall is mediated by binding to the G-protein-coupled angiotensin II receptor type 1 on vascular smooth muscle cells which stimulates Ca<sup>2+</sup>/calmodulin dependent phosphorylation of myosin and causes smooth muscle contraction.

The pivotal phase III trial of angiotensin II for the treatment of high-output shock (ATHOS-3) was a randomized, placebo-controlled, double-blind, international, multicenter Phase III safety and efficacy trial in which 321 adults with septic shock or other distributive shock who had hypotension despite fluid and vasopressor therapy were randomized 1:1 to GIAPREZA® or placebo. The primary efficacy endpoint, an increase in blood pressure, was achieved by 70% of patients randomized to GIAPREZA® compared with 23% of patients treated with placebo;  $p < 0.0001$  (a treatment effect of 47%).

The European Summary of Product Characteristics is available on the EMA website: [www.ema.europa.eu/en/medicines/human/EPAR/giapreza](http://www.ema.europa.eu/en/medicines/human/EPAR/giapreza).

PAION launched GIAPREZA® in Germany in July 2021. In Europe, PAION currently estimates a peak sales potential of approximately EUR 75 million to approximately EUR 90 million per year based on its own projections.

## XERAVA® (eravacycline)

XERAVA® (eravacycline) for injection is a novel fluorocycline of the tetracycline class. XERAVA® is an antibiotic used to treat complicated intra-abdominal infections (cIAI) in adults. According to the Infectious Diseases Society of America (IDSA), cIAI is defined as an infection that extends beyond the wall of a hollow viscus of origin into the abdominal cavity while being associated with an abscess or peritonitis.<sup>1</sup>

The mechanism of action of eravacycline is to interfere with bacterial protein synthesis by binding to the ribosomal subunit 30S, thereby preventing the incorporation of amino acid residues into extended peptide chains.

XERAVA® has been shown to be as effective as alternative antibiotics in two main trials in adults with cIAI. The main indicator of efficacy in both trials was the cure rate of

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<sup>1</sup> Solomkin JS, Mazuski JE, Bradley JS: Diagnosis and management of complicated intra-abdominal infection in adults and children: guidelines by the Surgical Infection Society and the Infectious Diseases Society of America. Clin Infect Dis. 2010;50:133-164.

infections. In the first trial, involving 538 patients, XERAVA® was compared with ertapenem (another antibiotic). After about one month, 87% of patients treated with XERAVA® were cured of their infection, compared with 89% of patients treated with ertapenem. In the second trial, involving 499 patients, XERAVA® was compared with meropenem (a carbapenem antibiotic commonly used in Europe in this indication). After about one month, 92% of patients treated with XERAVA® and 92% of patients treated with meropenem were cured of their infection.

XERAVA® is FDA-approved for the treatment of complicated abdominal infections in patients 18 years of age and older. XERAVA® is approved by the European Commission and the UK Medicines Agency for the treatment of abdominal infections in adults. Consideration should be given to official guidance on the appropriate use of antibacterial agents.

The European Summary of Product Characteristics is available on the EMA website: [https://www.ema.europa.eu/en/documents/product-information/xerava-epar-product-information\\_en-0.pdf](https://www.ema.europa.eu/en/documents/product-information/xerava-epar-product-information_en-0.pdf).

PAION currently plans the European commercial launch of XERAVA® in the second half of 2021. In Europe, PAION currently estimates a peak sales potential of approximately EUR 25 million to approximately EUR 35 million annually based on its own projections.

## Financing activities

In June 2019, PAION signed a financing agreement for a loan of up to EUR 20 million with the European Investment Bank (EIB). The first two tranches amounting to EUR 12.5 million in total were drawn down in February 2021. The third tranche in the amount of EUR 7.5 million was drawn down in June 2021.

In April 2021, a rights issue was successfully completed with gross proceeds of EUR 7.8 million. The subscription rate was over 92%. Thereby, the share capital of PAION AG was increased to EUR 71,336,992.00 by using the Authorized Capital 2020 through the issuance of 5,095,499 new shares.

## Net Assets, Financial Position, and Results of Operations

### Results of Operations

	Q2 2021	Q2 2020	H1 2021	H1 2020
	KEUR	KEUR	KEUR	KEUR
Revenues	413	20	3,617	3,520
Cost of sales	0	0	-466	0
Gross profit	413	20	3,151	3,520
Research and development expenses	-1,575	-2,669	-2,912	-6,399
General administrative and selling expenses	-4,875	-1,746	-8,706	-3,610
Other income (expenses)	2	-197	-126	-193
Operating expenses	-6,448	-4,612	-11,744	-10,202
Operating result	-6,035	-4,592	-8,593	-6,682
Financial result	-961	-48	-2,242	-110
Income taxes	319	299	399	740
Net result for the period	-6,677	-4,341	-10,436	-6,052

**Revenues** in the first half-year 2021 amounted to KEUR 3,617 of which KEUR 2,600 resulted from milestone payments and KEUR 1,017 from remimazolam API sales to licensees (KEUR 546) and royalties (KEUR 471). In the prior-year period, revenues amounted to KEUR 3,520 and mainly resulted from milestone payments.

**Cost of sales** amounted to KEUR 466 in the first half-year 2021.

**Research and development expenses** in the first half-year 2021 amounted to KEUR 2,912 (prior-year period: KEUR 6,399) and decreased as planned particularly due to the completion of the EU Phase III study in general anesthesia in the previous year.

**General administrative and selling expenses** increased by KEUR 5,096 to KEUR 8,706 in the first half-year 2021 compared to the prior-year period. General administrative expenses increased by KEUR 863 to KEUR 2,548 and selling expenses increased by KEUR 4,233 to KEUR 6,158. The increase in general administrative expenses is mainly related to financing activities and the expansion of IT systems and infrastructure. Selling expenses increased as planned particularly due to commercialization and supply chain activities for the three products Byfavo®, GIAPREZA® and XERAVA® in Europe.

**Earnings before interest and tax** amounted to KEUR -8,593 in the first half-year 2021 and decreased by KEUR 1,911 compared to the prior-year period (earnings before interest and tax in the prior-year period: KEUR -6,682).

The **financial result** amounted to KEUR -2,242 in the first half of 2021 (prior-year period: KEUR -110) and mainly comprises expenses in connection with the EIB loan drawn down in the reporting period totaling KEUR 20,000. In the prior-year period, the financial result mainly comprised expenses in connection with convertible notes issued in fiscal year 2019.

**Income taxes** amounted to KEUR 399 in the first half-year 2021 (prior-year period: KEUR 740) and mainly relate to tax claims for reimbursement of parts of the research and development expenses from the British tax authorities. The decrease in comparison to the prior-year period is mainly due to lower research and development expenses.

The **net result** for the first half-year 2021 amounted to KEUR -10,436 compared to a net result of KEUR -6,052 in the prior-year period. This corresponds to a decrease of the net result in the amount of KEUR 4,384 compared to the first half-year 2020 which is mainly attributable to lower expenses for research and development on the one hand and higher financial expenses as well as general administrative and selling expenses than in the prior-year period on the other hand.

## Net Assets

	30-06-2021	31-12-2020	Change
	KEUR	KEUR	KEUR
Non-current assets	20,721	1,872	18,849
Current assets	27,886	26,278	1,608
Total Assets	48,607	28,150	20,457
Equity	18,214	21,290	-3,076
Non-current liabilities	21,270	15	21,255
Current liabilities	9,123	6,845	2,278
Total Equity and liabilities	48,607	28,150	20,457

**Non-current assets** mainly comprise the commercialization rights for the products GIAPREZA® and XERAVA® in Europe (KEUR 17,818) acquired in the reporting period under the license agreement concluded with La Jolla Pharmaceutical, the development project remimazolam (KEUR 1,804) and right-of-use assets for office space (KEUR 769).

**Current assets** comprise cash and cash equivalents (KEUR 21,161), inventories (KEUR 3,025), other assets and prepaid expenses (KEUR 2,542) as well as trade receivables (KEUR 1,158). The increase of KEUR 1,608 compared to 31 December 2020 is due to an increase in cash and cash equivalents of KEUR 1,495, in inventories of KEUR 1,250 and in trade receivables of KEUR 658 on the one hand and a decrease in other assets and prepaid expenses of KEUR 1,795 on the other hand. The decrease in other assets and prepaid expenses is mainly due to a KEUR 1,859 lower tax claim for reimbursement of parts of the research and development expenses from the British tax authorities compared to 31 December 2020.

The decrease in **equity** of KEUR 3,076 compared to 31 December 2020 mainly results from the net result of the first half-year 2021 in the amount of KEUR -10,436 on the one hand and the issue of 5,095,499 new shares in the course of a rights issue with gross proceeds of KEUR 7,847 completed in April 2021 on the other hand. As of 30 June 2021, the equity ratio was 37.5% (31 December 2020: 75.6%).



**Non-current liabilities** comprise the non-current part of the loan drawn down from the EIB (KEUR 20,645) as well as lease liabilities (KEUR 625).

**Current liabilities** increased by KEUR 2,278 compared to 31 December 2020. This increase mainly results from an increase of trade payables by KEUR 990 as well as an increase of financial debt by KEUR 1,317 which relates entirely to the loan drawn down from the EIB.

## Financial Position

Compared to 31 December 2020, **cash and cash equivalents** increased by KEUR 1,495 to KEUR 21,161 at the end of the current reporting period. The change in cash and cash equivalents stems from the following areas:

	H1 2021 KEUR	H1 2020 KEUR
Cash flows from operating activities	-6,979	-6,360
Cash flows from investing activities	-18,742	-2
Cash flows from financing activities	27,209	-22
Effects of exchange rate changes	7	11
Change in cash and cash equivalents	1,495	-6,373

The **cash flows from operating activities** in the first half-year 2021 were KEUR -6,979 and primarily resulted from the net result for the period, adjusted for non-cash items, as well as changes of the working capital.

The **cash flows from investing activities** amounted to KEUR -18,742 in the first half-year 2021 and mainly resulted from the acquisition of the commercialization rights for the products GIAPREZA® und XERAVA® in Europe in the amount of KEUR 18,493.

The **cash flows from financing activities** of KEUR 27,209 in the first half-year 2021 mainly resulted from complete draw-down of the loan from the EIB (KEUR 20,000), gross proceeds from the rights issue completed in April 2021 (KEUR 7,847) as well as the incurred costs of funds in this context (KEUR 586).

## Personnel Development

On average, PAION employed 47 employees in the first six months of 2021 (fiscal year 2020: 43 employees). As of 30 June 2021, the headcount was 50.

## Impact of the Covid-19 pandemic on the PAION Group

Since the beginning of 2020, a new form of Coronavirus (SARS-CoV-2) causing the respiratory disease Covid-19 has spread internationally. The pandemic has led to partially massive restrictions in public life worldwide, as well as significant declines in economic output. The

success of containment measures, the resulting rate of spread of the virus and the respective restrictions based on this, particularly in public areas, partly differ significantly by region. At the time of this report, there is still uncertainty about the further course of the pandemic. On the one hand, various vaccines have already been approved also internationally, which relatively effectively prevent the disease from currently spreading forms of the virus while a decrease of efficacy is already observable for the newest mutations of the virus; on the other hand, the number of infections is nevertheless partly increasing (significantly) again in many places (so-called "fourth wave"), and mutations, some of which are more infectious and dangerous to humans, are spreading, so that there is also a risk of further mutations developing which may be increasingly resistant to currently available vaccines. In light of this, it is currently not possible to accurately assess the short- and medium-term consequences for the economic development.

The Covid-19 pandemic is severely restricting access to the market in some territories like the U.S., whilst in others like China the effects are not significant. This remains a key commercial risk as healthcare systems globally struggle to cope with both the pandemic and the extra healthcare costs it has brought, as well as the back-log of work. PAION will continue to as far as possible work to mitigate these risks with our global partners.

To date, the pandemic has had a modest direct impact on the PAION Group. On the one hand, PAION currently still recognizes a significant portion of its revenues from milestone payments. The underlying milestones are largely independent from the general economic development. On the other hand, PAION was and is able to continue its business activity also under significant restrictions in public life with barely any changes since office presence of employees is not necessary for the normal continuation of the business in the vast majority of time. In addition, PAION is largely independent from the general economic development in the short- to medium-term, since in the worst case, development and commercial activities could be reduced in order to increase the cash reach. As PAION has only started commercializing its own products and therefore only a small amount of supplies of commercially manufactured product has occurred yet, the pandemic has not had a major impact in this respect either. However, a lack of production capacities at Contract Manufacturing Organizations (CMOs) and very long order times for certain materials (e.g. glass vials) can be observed and have partially impacted the business of our licensees. Furthermore, access to clinics and prescribers has been limited by Covid-19 effects on the healthcare system, leading to partially moderate product sales. PAION is hoping to see growth accelerating in the second half of 2021.

Overall, the direct impact of the pandemic on the PAION Group's net assets, financial position and results of operations has been moderate to date. Due to the limited access to clinics and prescribers, PAION currently expects a moderate negative impact of the pandemic on the own commercialization of Byfavo®, GIAPREZA® and XERAVA®. As such, based on the factual situation at the time of this report, moderate direct effects on the own operating business are assumed for the future. It is currently unknown in how far particularly our licensees' business activities will be (further) restrained by the pandemic potentially leading to revenues from milestones or royalties being recognized not at all, in a lower amount or delayed. However, PAION currently expects a moderate impact on its licensees' business overall as well leading to moderate planning adjustments due to the Covid-19 pandemic at the present time. Any impact of the pandemic on the general financing environment could limit PAION's ability to obtain necessary financing.

## Risks and Opportunities

Material risks and opportunities relating to future development are presented in detail in the group management report for the fiscal year 2020. The overall evaluation of opportunities and risks has not changed significantly in the first half-year 2021.

## Significant Events Occurring After the Balance Sheet Date

There were no significant events in the period between the reporting date, 30 June 2021, and the preparation of this report.

## Report on expected developments

### Business Outlook

PAION's focus in 2021 remains on preparing and starting the commercialization of its product portfolio, consisting of Byfavo®, GIAPREZA® and XERAVA®, and on further building a distribution infrastructure in selected European countries. In addition, PAION plans to submit the MAA for Byfavo® for general anesthesia in Europe by the end of 2021. PAION has started launching its products in a staggered manner by country beginning in the second half of 2021 so that by the end of 2022, launches are planned to have been conducted in most key European markets.

It is planned to grant the commercialization rights for Byfavo®, GIAPREZA® and XERAVA® to licensees in selected territories in Europe where no own commercialization is planned, and to also out-license remimazolam for additional markets outside Europe as well.

Research and development activities are planned to a minor extent and mainly relate to final evaluations and documentation of the Phase III study with remimazolam in general anesthesia and the subsequent submission of the MAA for this indication. In addition, minor work is taking place in the area of production development.

After the already conducted launches of remimazolam in the U.S., Japan, China and South Korea with total product revenues in the amount of EUR 2.7 million in the first half of 2021, PAION expects that the good market acceptance observed so far will translate into further increasing product sales and correspondingly increasing revenues of our licensees and resulting royalties for PAION.

## Financial outlook 2021

PAION expects revenues of about EUR 8 million to about EUR 9.5 million in fiscal year 2021. Approx. EUR 4 million to approx. EUR 4.5 million (previous guidance: approx. EUR 5 million to approx. EUR 6 million) relate to the sale of remimazolam API as well as royalties from the commercialization of remimazolam, and approx. EUR 4 million to approx. EUR 5 million (previous guidance approx. EUR 2.5 million to approx. EUR 3 million) relate to milestones and upfront payments including potential new license agreements in minor territories. Revenues from the own commercialization of Byfavo®, GIAPREZA® and XERAVA® are not included in this revenue guidance since commercialization has only just started, and are expected in an amount of up to EUR 0.2 million (previous guidance: approx. EUR 0.5 million). Cost of revenues will amount to approx. EUR 3 million (previous guidance: approx. EUR 3.5 million to approx. EUR 4 million).

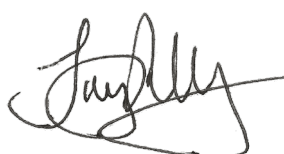
Focus of the activities is on marketing and distribution in 2021 so that general administrative and selling expenses of approx. EUR 18 million to approx. EUR 20 million are expected, depending on the progress of commercial activities. Research and development expenses will amount to between approx. EUR 4.5 million and approx. EUR 5.5 million. Earnings before interest and tax of approx. EUR -16 million to approx. EUR -20.5 million (previous guidance: approx. EUR -16.5 million to approx. EUR -21.5 million) are expected for 2021.

This outlook assumes that PAION and licensee activities progress as expected. In case of delays, essential cost blocks and/or revenues would shift into 2022 or subsequent periods. Plans are also based on the current status of discussions with regulatory authorities. Additional unexpected requirements by regulatory authorities could lead to higher costs than planned and to delays in approvals and revenues based thereon. Also, potential effects of the Covid-19 pandemic on our business and the business of our partners could lead to delays and a shift of revenues and/or costs.


PAION expects increasing revenues in the coming years, both from license agreements and from its own commercialization in parts of Europe, and, based on current planning, a break-even towards the end of 2023 or beginning of 2024. Cash and cash equivalents at hand as well as expected payments from revenues secure a liquidity runway into the first half of 2022 based on current planning. Additional funds will be required particularly for the further build-up of the distribution infrastructure, the staggered launch in Europe by countries as well as post-approval commitments towards the respective regulatory authorities, as e.g. possible Phase IV studies after approval or market launch of the products. Based on current planning, there is a financing requirement in the mid double-digit million range in the coming years until break-even, which could be raised through different financing measures and further partnerships.

Aachen, Germany, 23 August 2021

PAION AG



Dr. James Phillips



Abdelghani Omari

## Condensed Consolidated Interim Financial Statements

### Consolidated Balance Sheet

ASSETS	30 June 2021	31 Dec. 2020
	EUR	EUR
Non-current assets		
Intangible assets	19,804,494.91	1,829,398.87
Equipment	133,035.59	16,280.54
Right-of-use assets	783,558.31	26,118.72
Other assets	14.03	13.92
	<b>20,721,102.84</b>	<b>1,871,812.05</b>
Current assets		
Trade receivables	1,158,195.68	500,000.00
Inventories	3,024,614.10	1,774,252.00
Prepaid expenses and other assets	2,542,731.99	4,337,443.69
Cash and cash equivalents	21,160,537.76	19,666,309.58
	<b>27,886,079.53</b>	<b>26,278,005.27</b>
<b>Total assets</b>	<b>48,607,182.37</b>	<b>28,149,817.32</b>

EQUITY AND LIABILITIES	30 June 2021 EUR	31 Dec. 2020 EUR
Equity		
Share capital	71,336,992.00	66,241,493.00
Capital reserve	144,230,751.55	141,906,632.49
Translation reserve	-1,069,024.33	-1,009,793.75
Loss carryforward	-185,848,505.42	-188,070,648.97
Result for the period	-10,436,087.97	2,222,143.55
	<b>18,214,125.83</b>	<b>21,289,826.32</b>
Non-current liabilities		
Financial debt	20,644,844.95	0.00
Lease liabilities	624,973.66	15,429.23
	<b>21,269,818.61</b>	<b>15,429.23</b>
Current liabilities		
Trade payables	4,897,210.35	3,906,828.93
Provisions	1,910,426.39	2,205,803.34
Financial debt	1,316,533.90	0.00
Lease liabilities	161,088.58	11,430.64
Other current liabilities	837,978.71	720,498.86
	<b>9,123,237.93</b>	<b>6,844,561.77</b>
<b>Total equity and liabilities</b>	<b>48,607,182.37</b>	<b>28,149,817.32</b>

## Consolidated Statement of Comprehensive Income

EUR	1 April – 30 June 2021	1 April – 30 June 2020	1 January – 30 June 2021	1 January – 30 June 2020
Revenues	412,634.15	19,876.24	3,616,918.33	3,519,876.24
Cost of sales	0.00	0.00	-466,349.91	0.00
<b>Gross profit</b>	<b>412,634.15</b>	<b>19,876.24</b>	<b>3,150,568.42</b>	<b>3,519,876.24</b>
Research and development expenses	-1,575,112.76	-2,669,570.52	-2,912,103.49	-6,399,162.67
General administrative and selling expenses	-4,875,574.48	-1,745,392.53	-8,706,108.97	-3,609,833.17
Other income (expenses), net	2,930.07	-196,567.81	-125,825.50	-192,879.25
<b>Operating expenses</b>	<b>-6,447,757.17</b>	<b>-4,611,530.86</b>	<b>-11,744,037.96</b>	<b>-10,201,875.09</b>
<b>Operating result</b>	<b>-6,035,123.02</b>	<b>-4,591,654.62</b>	<b>-8,593,469.54</b>	<b>-6,681,998.85</b>
Financial income	0.00	0.17	141.70	64.58
Financial expenses	-960,757.97	-48,003.64	-2,242,521.58	-109,966.82
<b>Financial result</b>	<b>-960,757.97</b>	<b>-48,003.47</b>	<b>-2,242,379.88</b>	<b>-109,902.24</b>
<b>Result for the period before taxes</b>	<b>-6,995,880.99</b>	<b>-4,639,658.09</b>	<b>-10,835,849.42</b>	<b>-6,791,901.09</b>
<b>Income taxes</b>	<b>318,800.24</b>	<b>299,110.87</b>	<b>399,761.45</b>	<b>739,988.18</b>
<b>Result for the period</b>	<b>-6,677,080.75</b>	<b>-4,340,547.22</b>	<b>-10,436,087.97</b>	<b>-6,051,912.91</b>
of which attributable to other shareholders	0.00	0.00	0.00	0.00
of which attributable to shareholders of PAION	-6,677,080.75	-4,340,547.22	-10,436,087.97	-6,051,912.91
Foreign currency translation	-3,854.64	-66,669.17	-59,230.58	-185,788.26
Total income and expense recognized directly in equity that will be reclassified to profit or loss when specific conditions are met	-3,854.64	-66,669.17	-59,230.58	-185,788.26
<b>Other comprehensive income</b>	<b>-3,854.64</b>	<b>-66,669.17</b>	<b>-59,230.58</b>	<b>-185,788.26</b>
<b>Total comprehensive income</b>	<b>-6,680,935.39</b>	<b>-4,407,216.39</b>	<b>-10,495,318.55</b>	<b>-6,237,701.17</b>
of which attributable to other shareholders	0.00	0.00	0.00	0.00
of which attributable to shareholders of PAION	-6,680,935.39	-4,407,216.39	-10,495,318.55	-6,237,701.17
Earnings per share (basic)	-0.09	-0.06	-0.15	-0.09
Earnings per share (diluted)	-0.09	-0.06	-0.15	-0.09

## Consolidated Cash Flow Statement

EUR	1 January – 30 June 2021	1 January – 30 June 2020
<b>Cash flows from operating activities:</b>		
Result for the period	-10,436,087.97	-6,051,912.91
<b>Reconciliation of result for the period to cash flows from operating activities:</b>		
Income taxes	-399,761.45	-739,988.18
Amortization/depreciation and non-cash changes of fixed assets	642,771.93	250,786.93
Interest expenses and interest income	2,242,379.88	109,902.24
Expenses from stock option plans	158,605.00	192,431.67
Gain/loss on disposal of assets	7,518.66	0.00
Transaction costs and fair value adjustments in connection with financing activities	0.00	61,653.04
<b>Change in assets and liabilities which are not attributable to investing or financing activities:</b>		
Trade receivables	-658,195.68	0.00
Inventories	-1,250,362.10	-356,360.00
Prepaid expenses and other assets	-120,756.10	-1,779,933.28
Trade payables	990,381.42	466,966.98
Provisions	-345,376.95	1,663,447.50
Other current liabilities	117,090.60	6,406.23
Non-cash exchange losses/gains	38,100.43	-167,907.86
	-9,013,692.33	-6,344,507.64
Tax payments received	2,315,229.25	0.00
Interest paid	-280,753.48	-15,368.96
Interest received	141.70	64.58
<b>Cash flows from operating activities</b>	<b>-6,979,074.86</b>	<b>-6,359,812.02</b>
<b>Cash flows from investing activities:</b>		
Cash paid for investments in intangible assets and equipment	-18,742,141.79	-1,543.66
<b>Cash flows from investing activities</b>	<b>-18,742,141.79</b>	<b>-1,543.66</b>
<b>Cash flows from financing activities:</b>		
Capital increase	5,095,499.00	5,000.00
Contributions to the capital reserve	2,751,569.46	1,550.00
Payments in connection with raising capital	-586,055.40	0.00
Drawdown of loans	20,000,000.00	0.00
Principal portion of lease payments	-51,530.77	-28,254.94
<b>Cash flows from financing activities</b>	<b>27,209,482.29</b>	<b>-21,704.94</b>
Change in cash and cash equivalents	1,488,265.64	-6,383,060.62
Effect of exchange rate changes on cash	5,962.54	10,283.42
Cash and cash equivalents at beginning of the period	19,666,309.58	18,786,680.89
<b>Cash and cash equivalents at end of the period</b>	<b>21,160,537.76</b>	<b>12,413,903.69</b>
<b>Composition of cash and cash equivalents at the end of the period:</b>		
Cash and cash equivalents	21,160,537.76	12,413,903.69



## Consolidated Statement of Changes in Equity

EUR	Share capital	Capital reserve	Translation reserve	Loss carryforward	Equity
31 December 2019	64,265,586.00	139,421,819.80	-884,259.03	-188,070,648.97	14,732,497.80
Total comprehensive income	0.00	0.00	-185,788.26	-6,051,912.91	-6,237,701.17
Issue of shares	1,530,327.00	0.00	0.00	0.00	1,530,327.00
Contribution to the capital reserve	0.00	1,734,117.76	0.00	0.00	1,734,117.76
Cost of raising capital	0.00	-219,216.13	0.00	0.00	-219,216.13
Additional contribution to the capital reserve due to the issue of options	0.00	192,431.67	0.00	0.00	192,431.67
30 June 2020	65,795,913.00	141,129,153.10	-1,070,047.29	-194,122,561.88	11,732,456.93
Total comprehensive income	0.00	0.00	60,253.54	8,274,056.46	8,334,310.00
Issue of shares	445,580.00	0.00	0.00	0.00	445,580.00
Contribution to the capital reserve	0.00	731,964.74	0.00	0.00	731,964.74
Cost of raising capital	0.00	-47,719.16	0.00	0.00	-47,719.16
Additional contribution to the capital reserve due to the issue of options	0.00	93,233.81	0.00	0.00	93,233.81
31 December 2020	66,241,493.00	141,906,632.49	-1,009,793.75	-185,848,505.42	21,289,826.32
Total comprehensive income	0.00	0.00	-59,230.58	-10,436,087.97	-10,495,318.55
Issue of shares	5,095,499.00	0.00	0.00	0.00	5,095,499.00
Contribution to the capital reserve	0.00	2,751,569.46	0.00	0.00	2,751,569.46
Cost of raising capital	0.00	-586,055.40	0.00	0.00	-586,055.40
Additional contribution to the capital reserve due to the issue of options	0.00	158,605.00	0.00	0.00	158,605.00
30 June 2021	71,336,992.00	144,230,751.55	-1,069,024.33	-196,284,593.39	18,214,125.83

# Selected Explanatory Notes to the Consolidated Interim Financial Statements as of 30 June 2021

## General

The half-year financial report of PAION AG includes interim consolidated financial statements and an interim group management report in accordance with the provisions of Sec. 115 (2) WpHG [“Wertpapierhandelsgesetz”: German Securities Trading Act] in conjunction with Sec. 117 WpHG as well as a statement of the management board according to Secs. 264 (2) sentence 3 and 289 (1) sentence 5 HGB [“Handelsgesetzbuch”: German Commercial Code]. The consolidated financial statements were prepared in accordance with the provisions of the International Financial Reporting Standards (IFRSs) for interim financial reporting. The interim group management report was prepared in accordance with the relevant provisions of the German Securities Trading Act.

The interim consolidated financial statements comprise PAION AG as the parent company, registered at Heussstrasse 25, 52078 Aachen, Germany, and the wholly-owned subsidiaries, which are fully consolidated:

- PAION Deutschland GmbH, Aachen/Germany
- PAION Holdings UK Ltd, Cambridge/UK
- PAION UK Ltd, Cambridge/UK
- PAION Netherlands B.V., Heerlen/The Netherlands
- PAION Scandic ApS, Odense/Denmark
- TheraSci Limited, Cambridge/UK

PAION Scandic ApS was founded in March 2021 and is being accounted for using the full consolidation.

## Basis of Accounting

The interim consolidated financial statements have been prepared in accordance with Sec. 315e (1) HGB [“Handelsgesetzbuch”: German Commercial Code] and IFRSs, as adopted by the EU, and the interpretations of the International Financial Reporting Interpretations Committee (IFRIC). The consolidation principles and accounting policies adopted in the preparation of the interim condensed consolidated financial statements are consistent with those followed in the preparation of the

Group’s annual consolidated financial statements for the year ended 31 December 2020, except for the adoption of the following new or revised standards effective for the current reporting period:

- Amendments to IFRS 9, IAS 39 and IFRS 7 (Interest Rate Benchmark Reform – Phase 2)
- Amendments to IFRS 4 “Insurance Contracts”
- Amendment to IFRS 16 “Leases” (Covid 19-Related Rent Concessions)

The application of these new and/or revised standards may, in some cases, result in additional disclosure obligations in future consolidated financial statements. All disclosure obligations in interim consolidated financial statements resulting from first-time adoption of new standards in the current reporting period have been met accordingly. The amendments did not have any effects on the Group’s net assets, financial position and results of operations.

The provisions of IAS 34, “Interim Financial Reporting”, have been applied. The interim financial statements as of 30 June 2021 should be read in conjunction with the consolidated financial statements as of 31 December 2020.

The preparation of interim consolidated financial statements in accordance with IFRSs requires management to make estimates and assumptions which have an effect on the amount of recognised assets and liabilities, income and expenses and contingent liabilities. Actual amounts may differ from these estimates.

The interim consolidated financial statements do not contain any segment information as no material reportable segments could be identified.

## Foreign Currency Translation

The consolidated financial statements are shown in Euro, which is the functional currency of PAION AG and the reporting currency of the Group. Each company within the Group defines its own functional currency. This is the Euro in the case of the German companies and the Dutch

company, Pound Sterling for the UK-based companies and Danish Croner for the Danish entity. All items on the respective financial statements of each company are initially converted to the functional currency at the exchange rate applicable on the transaction date. Monetary assets and liabilities denominated in a foreign currency are translated into the functional currency on the reporting date at the exchange rate applicable on that date. All ensuing currency differences are recognised in profit or loss with the exception of exchange rate gains and losses from intra-Group loans classified in accordance with IAS 21 as net investments in foreign business operations; these are recognised in equity.

The assets and liabilities of the foreign companies are translated into Euro on the balance sheet reporting date at the exchange rate applicable on that date. These include any goodwill in connection with the acquisition of a foreign company and any fair value adjustments to the carrying amounts of the foreign company's assets and liabilities. Equity components are translated into Euro at historical rates at the time of initial consolidation. Expenses and income are translated into Euro at average monthly exchange rates. The resulting currency differences are accounted for separately within equity.

## Equity

On 19 March 2021, the Management Board decided with the approval of the Supervisory Board and based on the authorization by the General Meeting to issue 5,095,499 new, no-par value bearer shares at a subscription price of EUR 1.54 per share, granting pre-emptive rights to existing shareholders. The existing shareholders were able to subscribe the new shares at a subscription ratio of 13:1 in the subscription period from 24 March 2021 to 6 April 2021. A U.S. institutional investor had committed to acquire any new shares not subscribed for by existing shareholders or other investors in connection with the rights offering at the subscription price. Upon completion of the capital increase, the company's share capital increased from EUR 66,241,493.00 by EUR 5,095,499.00 to EUR 71,336,992.00 through the issuance of 5,095,499 new shares. The capital increase with gross proceeds of EUR 7.8 million was recorded in the commercial register on 9 April 2021. Authorized Capital 2020 correspondingly decreased to EUR 21,039,429.00.

## Intangible assets

Intangible assets amount to KEUR 19,804 as of 30 June 2021 (31 December 2020: KEUR 1,829). In the reporting period, the commercialization rights for the products GIAPREZA® and XERAVA® in Europe were capitalized with acquisition costs of KEUR 18,493 under the license agreement concluded with La Jolla Pharmaceutical. Both assets are amortized over their expected useful lives until the end of 2034 for GIAPREZA® and mid-2033 for XERAVA®, respectively, based on the currently expected period of the respective patent protection.

Intangible assets relate to assets in development in the amount of KEUR 50 as of 30 June 2021 (31 December 2020: KEUR 0).

## Right-of-use assets

In the reporting period, right-of-use assets with acquisition costs of KEUR 810 were capitalized in accordance with IFRS 16 in connection with newly leased office space.

## Inventories

Inventories amount to KEUR 3,025 (31 December 2020: KEUR 1,774) as of 30 June 2021 and comprise finished goods in the amount of KEUR 1,025 as well as advance payments on inventories (remimazolam API) in the amount of KEUR 2,000. No allowance on inventories was recognized in the reporting period.

## Financial debt

In February 2021, the first two tranches of the loan agreement concluded with the EIB in June 2019 in the amount of EUR 12.5 million were drawn down. In June 2021, the third and final tranche of the loan agreement in the amount of EUR 7.5 million was drawn down. Each tranche has a term of five years and is repaid from the 39th month after disbursement. The interest rate consists of a current cash interest component of 6% to 7.5%, a deferred bullet interest component of 3% to 5% and a performance-based bullet component depending on the market capitalization.

The loan is measured at amortized cost using the effective interest method, with the exception of the performance-based component, which is an embedded

derivative that must be separated. This performance-based bullet component is measured at fair value through profit or loss based on the market capitalization at the reporting date and discounted to the reporting date using a market interest rate in line with the remaining term to maturity.

Financial debt amounts to KEUR 21,961 as of 30 June 2021 in total, of which KEUR 1,655 relate to the performance-based component measured at fair value through profit or loss.

## Revenues

Revenues recognized in the first half-year 2021 relate to following categories:

- Royalties: KEUR 471
- API sales: KEUR 546
- Milestones: KEUR 2,600

## Stock options

In connection with the stock options granted from Stock Option Plans 2016 and 2018, personnel expenses in the amount of KEUR 159 were recognized in the first half-year 2021.

## Tax Effects on Other Comprehensive Income

In the reporting period the Other Comprehensive Income (foreign currency translation of foreign subsidiaries) did not have any tax effects.

## Financial instruments

As of 30 June 2021 and as of 31 December 2020, the fair value of financial assets and liabilities was identical to the respective book value.

in KEUR	Book value		Fair Value		
	30 June 2021	31 Dec. 2020	30 June 2021	31 Dec. 2020	
<b>Financial assets</b>					
Cash and cash equivalents	(1)	21,161	19,666	21,161	19,666
Trade receivables	(1)	1,158	500	1,158	500
Other assets	(1)	235	59	235	59
<b>Financial liabilities</b>					
Trade payables	(1)	4,897	3,907	4,897	3,907
Provisions	(1)	1,910	2,206	1,910	2,206
Financial debt	(1)	20,306	0	20,306	0
Financial debt	(2)	1,655	0	1,655	0
Lease liabilities		786	27	786	27
Other liabilities	(1)	657	596	657	596

Measurement categories according to IFRS 9:

- (1) Recognized at amortized cost
- (2) Recognized at fair value through profit or loss

The determination of the fair value of the financial instruments was based on unobservable input factors (Level 3 inputs according to IFRS 13). In the first half-year 2021, there were no movements between the hierarchy levels.

Recoverability of financial assets was assessed based on historical and expected payment defaults. No default risks were identified and no impairment was recognized.

## Related Parties

The relationships with related parties have not changed in comparison to those applied in the consolidated financial statements as of 31 December 2020.

**Declaration of the Management Board  
pursuant Secs. 264 para. 2 sentence 3 and  
289 para.1 sentence 5 HGB [German  
Commercial Code]**

“To the best of our knowledge and in accordance with the applicable reporting principles for interim financial reporting, the consolidated interim financial statements give a true and fair view of the assets, liabilities, financial position and profit or loss of the group, and the interim management report of the group includes a fair review of the development and performance of the business and the position of the group, together with a description of the principal opportunities and risks associated with the expected development of the group for the remaining months of the financial year.”

Aachen, Germany, 23 August 2021

PAION AG

The image shows two handwritten signatures in black ink. The signature on the left is for Dr. James Phillips and the one on the right is for Abdelghani Omari. Both signatures are fluid and cursive.

Dr. James Phillips

Abdelghani Omari

# Review Report

## To PAION AG:

We have reviewed the condensed consolidated interim financial statements of PAION AG, Aachen - comprising the condensed statement of financial position, the condensed statement of comprehensive income, the condensed statement of cash flows, the condensed statement of changes in equity and selected explanatory notes - together with the interim group management report of PAION AG, Aachen, for the period from January 1 to June 30, 2021, part of the six-monthly financial report pursuant to § (Article) 115 WpHG ("Wertpapierhandelsgesetz": German Securities Trading Act). The executive directors are responsible for the preparation of the interim condensed consolidated financial statements in accordance with IFRSs on interim financial reporting as adopted by the EU and of the interim group management report in accordance with the requirements of the WpHG applicable to interim group management reports. Our responsibility is to issue a report on the interim condensed consolidated financial statements and the interim group management report based on our review.

We conducted our review of the interim condensed consolidated financial statements and of the interim group management report in compliance with German Generally Accepted Standards for the Review of Financial Statements promulgated by the Institut der Wirtschaftsprüfer [Institute of Public Auditors in Germany] (IDW). Those standards require that we plan and perform the review to obtain a certain level of assurance in our critical appraisal to preclude that the interim condensed consolidated financial statements are not prepared, in all material respects, in accordance with IFRSs on interim financial reporting as adopted by the EU and that the interim group management report is not prepared, in all material respects, in accordance with the requirements of the WpHG applicable to interim group management reports. A review is limited primarily to making inquiries of the Company's employees and analytical assessments and therefore does not provide the assurance obtainable from an audit of financial statements. Since, in accordance with our engagement, we have not performed an audit of financial statements, we cannot issue an auditor's report.

Based on our review, nothing has come to our attention that causes us to believe that the interim condensed consolidated financial statements are not prepared, in all material respects, in accordance with IFRSs on interim financial reporting as adopted by the EU or that the interim group management report is not prepared, in all material respects, in accordance with the provisions of the WpHG applicable to interim group management reports.

Cologne, Germany, August 23, 2021

Ernst & Young GmbH

Wirtschaftsprüfungsgesellschaft

(s) Zwirner

(s) Conrad

Wirtschaftsprüfer

Wirtschaftsprüfer

[German Public Auditor] [German Public Auditor]

## Information on PAION Shares

Market segment	Regulated market – Prime Standard Frankfurt Stock Exchange
Ticker symbol	PA8
Reuters symbol	PA8G.DE (Xetra)
Bloomberg	PA8 GY (Xetra)
ISIN	DE000A0B65S3
First day of trading	11 February 2005
Designated sponsor	Oddo Seydler

Key figures	H1 2021	2020
Numbers of shares at the end of the period	71,336,992	66,241,493
Average daily trading volume (Xetra, Tradegate, in shares)	261,149	303,166
Year high (Xetra closing price)	EUR 2.55 (11 Jan. 2021)	EUR 3.06 (06 July 2020)
Year low (Xetra closing price)	EUR 1.70 (19 May 2021)	EUR 1.40 (19 Mar. 2020)
Share price at the end of the period (Xetra)	EUR 1.94	EUR 2.40
Market capitalization at the end of the period (Xetra)	EUR 138 million	EUR 159 million

## Corporate Calendar

30 March 2021	Publication of the financial results 2020
12 May 2021	Publication of the financial results of the first quarter 2021
27 May 2021	Annual General Meeting
23 August 2021	Publication of the financial results for the first half-year 2021
10 November 2021	Publication of the financial results for the third quarter and the first nine months of 2021



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