

# PAION AR # 2020

Annual Report of PAION AG, Aachen



# "Be the catalyst"

Remimazolam marketing activities started

## Key Consolidated Financial Figures, IFRS

(all figures in EUR K unless otherwise noted)	2020	2019
<b>Profit and loss statement</b>		
Revenues	19,655	8,000
Research and development expenses	-10,288	-13,099
General administrative and selling expenses	-7,523	-5,023
<b>Net result</b>	<b>2,222</b>	<b>-7,016</b>
Personnel expenses included therein	-5,668	-5,374
Number of shares outstanding (weighted average, basic)	65,721,395	63,918,752
Number of shares outstanding (weighted average, diluted)	66,133,456	64,035,132
Earnings per share in EUR (basic)	0.03	-0.11
Earnings per share in EUR (diluted)	0.03	-0.11
<b>Balance sheet</b>		
Intangible assets	1,829	2,137
Cash and cash equivalents	19,666	18,787
Equity	21,290	14,732
Current liabilities	6,845	10,154
<b>Balance sheet total</b>	<b>28,150</b>	<b>24,912</b>
<b>Cash flow</b>		
Cash flow from operating activities	906	-2,847
Cash flow from investing activities	-14	-14
Cash flow from financing activities	-24	4,414
<b>Employees</b>		
Group employees (average)	43	44

# PAION AR # 2020

Annual Report of PAION AG



## Dr. James (Jim) Phillips, Chief Executive Officer

- Graduated physician who also holds an MBA from the Cass Business School in London
- Over 20 years of experience in the international pharma business, with positions held in various projects especially in the build-up of commercial structures
- Responsible inter alia for Strategy, Commercial activities, Licensing, Business Development, IT and Fundraising



## Abdelghani Omari, Chief Financial Officer

- Degree in Business Administration
- Has been responsible for and accompanied various capital market transactions and licensing agreements
- Round about 20 years of experience in finance, before joining PAION he worked in audit and consulting at KPMG for several years
- Responsible inter alia for Finance and Accounting, Controlling, Tax, Legal and Compliance, Human Resources and Investor Relations



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## 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 and China for procedural sedation and in Japan and South Korea for general anesthesia.

In addition to Byfavo® (remimazolam), PAION is preparing to launch the two products GIAPREZA® (angiotensin II) and XERAVA® (eravacycline) in Europe. 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 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).

PAION is listed at the Frankfurt Stock Exchange (Prime Standard Regulated Market, Stock Symbol PA8, ISIN DE000A0B65S3).

## 2020 at a glance

### January

- PAION grants remimazolam license for Southeast Asia to Hana Pharm
- Licensee Mundipharma receives market approval for Anerem® (remimazolam) in general anesthesia

### June

- PAION announces approval of compassionate use for remimazolam in Italian hospital

### July

- U.S. FDA approval of remimazolam (BYFAVO™) for the indication and maintenance of procedural sedation
- Licensee Yichang Humanwell receives market approval for remimazolam in procedural sedation in China
- U.S. license agreement for BYFAVO™ (remimazolam) between PAION and Cosmo assigned from Cosmo to Acacia
- PAION announces successful product launch of Anerem® (remimazolam) in Japan by Mundipharma

### August

- Approval of compassionate use program for remimazolam in Belgium
- Licensee Yichang Humanwell launches Ruima® (remimazolam) in China

### November

- Positive remimazolam topline data in EU Phase III trial in general anesthesia

## Letter to Shareholders



Dr. Jim Phillips  
Chief Executive Officer of PAION AG

### Dear Shareholders and Friends of PAION,

The year 2020 was transformational for PAION as remimazolam was approved and successfully launched in countries around the globe and we took key steps towards becoming a commercial specialty pharma organization. Perhaps what makes this transformation particularly noteworthy is that we were in the midst of a global pandemic affecting our families, businesses and the world as a whole. As we all know too well, while there is now a light at the end of the tunnel, the pandemic continues, and its effects will be with us for some time to come. I am grateful to our employees and to our partners, who achieved so much despite the challenging situation. Indeed, our strong progress continued in the first months of the new year with additional remimazolam launches, including in the U.S., the largest pharmaceutical market in the world. Also key to our future success, we successfully in-licensed two critical care products, enabling us to accelerate the buildout of our commercial organization in Europe to prepare to launch three products, each addressing important unmet medical needs.

#### **Significant progress with remimazolam with key market approvals and launches**

At this writing, remimazolam has now been approved in five countries or regions and launched in four of them. Most of this activity happened in 2020 and the first quarter of 2021. In the U.S., our licensee Acacia received marketing approval for remimazolam (BYFAVO™) in July 2020 for the induction and maintenance of procedural sedation in adults undergoing procedures lasting 30 minutes or less. Acacia launched the drug in January 2021 and is focused initially on ensuring that BYFAVO™ is listed on hospital formularies, based on the unmet needs it can address and the health economic benefits it can deliver. This important work will be crucial to the long-term success of BYFAVO™ in the U.S. and ensuring it is available to anesthesia providers and the millions of patients across the U.S. who require moderate sedation to undergo medical procedures each year. We are excited about the experienced team that Acacia has built in sales, marketing, medical education and operational support to address the U.S. hospital market.

In Japan, our licensee Mundipharma made strong progress following the 2020 approval and launch of remimazolam (Anerem®) for general anesthesia and was already able to report first commercial sales in 2020. At the end of the year, Mundipharma reported that approximately 400 hospitals had opened accounts, an important first step for a new hospital product, and exceeding their original target by close to 100%. In China, our licensee Yichang Humanwell received approval for remimazolam (Ruima®) in procedural sedation and successfully launched the product, which had already been introduced in hospitals in 31 provinces by year end 2020. In South Korea, our licensee Hana Pharm received market approval for Byfavo™ in general anesthesia in January 2021 and had already launched the drug by the end of March.

We are very proud of our partners and these great achievements. Our other partners for remimazolam continue to make good progress in advancing the program through the regulatory pathway and we look forward to additional news during the year ahead.

We also had our own regulatory success to report with the European Commission approval of Byfavo® in procedural sedation at the end of March 2021, paving the way for us to launch the drug during the course of this year. Based on the positive results in the Phase III trial in general anesthesia that we announced in November 2020, we plan to submit an extension of the Marketing Authorization Application for remimazolam for this indication by the end of 2021. The approval process for an extension application is generally faster than for a Marketing Authorization Application.

### **Expansion of European product portfolio supports build-up of commercial specialty pharma organization**

In January 2021, we entered into an exclusive license agreement with La Jolla Pharmaceutical for the intensive care unit products GIAPREZA® (angiotensin II) and XERAVA® (eravacycline). The agreement gave PAION rights to commercialize these already approved products in the European Economic Area, Switzerland and the United Kingdom. Coupled with Byfavo®, this agreement enables us to have three attractive market-stage hospital products in our portfolio, certainly a strong basis to launch our

European commercial organization and to build out our sales and marketing activities. Importantly, we can use a single, hospital-focused team in each country to sell these products, enabling a highly efficient commercialization effort. GIAPREZA® is already approved by the European Commission as a vasoconstrictor for the treatment of refractory hypotension in adults with septic or other distributive shock and offers the potential to be life saving. XERAVA® is an antibiotic approved for the treatment of complicated intra-abdominal infections in adults, another area where new options are needed. Both products are already launched in the U.S. and are showing growing revenues and strong potential also in times after the pandemic. With the pricing and reimbursement work already done and the initial interest we are hearing from European hospitals, we are excited about the opportunity for these products in our territories.

### **A bright future for PAION**

While launching products during a pandemic is of course challenging, we are excited about what lies ahead for our company. We have been laying the groundwork to become a commercial organization and we are ensuring we have sufficient funds in place to achieve our goals. We also have been building up the supply chain to ensure available supply of remimazolam API (active pharmaceutical ingredient) for our licensees as well as of finished drug product for our own commercialization. We have put in place the necessary structures and processes as well as obtained required pharmaceutical permits so we can get supply to where it is needed in an expeditious manner. We also have started to put in place our own commercial structures in certain core countries in Western Europe, including Germany, the UK, the Netherlands, and Denmark, with more countries to follow. Our plan is to launch all three of our products in a staggered manner by country beginning in the second half of 2021. Our goal is that, by the end of 2022, all three products will be launched in all of the initial selected European markets. We will look to license these products in other markets where we do not plan to build our own commercial infrastructure.

PAION closed fiscal year 2020 with a net profit of EUR 2.2 million after a net loss of EUR 7.0 million in the previous year. With remimazolam already launched in key global markets

and our own launch plans for our portfolio, we look forward to increasing sales revenues and royalties as these much-needed hospital products gain traction. With all of the commercial activities planned for 2021, you should expect to see us dip back into loss territory as we invest in the product rollouts. A big change on the revenue side this year will be that most of it will be product related – royalties and sales related to API, as well as direct sales from our launches in Europe. As we get to 2025 and 2026, we expect to see very fast growth and strong profitability, with EBITDA between EUR 75 million and EUR 100 million per year.

We are proud of what we achieved at PAION in 2020 and already in the first months of 2021. I would like to thank our shareholders for your continued support and the great trust you have placed in us. My sincere thanks also go to our partners, who have continued to work tirelessly to advance remimazolam and bring this product to market in their territories. I also would like to express my great appreciation for our employees and our retired Management Board member, Dr. Beck, who have played such a large role in PAION's success in the past year with their hard work and commitment. I look forward to working together as we transform PAION into a leading specialty pharmaceutical company in anesthesia and critical care and positively impact patient lives.

A handwritten signature in black ink, appearing to read 'Jim Phillips', with a long horizontal flourish extending to the right.

**Your Jim Phillips**  
**Chief Executive Officer**

## Business Model

### Strategic focus to become a specialty pharmaceutical company further continued

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 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.

### Remimazolam

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 and China for procedural sedation and in Japan and South Korea for general anesthesia.

In addition to procedural sedation and general anesthesia, intensive care unit (ICU) sedation is another possible indication for remimazolam.

Remimazolam is partnered in the U.S. (brand name BYFAVO™) with Acacia Pharma (Acacia), 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.

### Remimazolam Market

#### Overview

Procedural sedation is a technique of administering sedatives or dissociative agents, with or without analgesics, to induce a state that allows the patient to tolerate unpleasant procedures such as a colonoscopy while maintaining cardiorespiratory function.

General anesthesia leads to loss of consciousness and loss of sensation of patients through the administration of anesthetics in combination with opioid analgesics. This allows medical procedures such as major surgery, that would otherwise be unbearable, to be carried out with minimal discomfort and a positive risk-benefit profile.

The number of surgical procedures worldwide continues to grow driven by population growth and other factors such as obesity, low physical activity levels, dietary habits, smoking, and alcohol but also the medical progress. Current estimates place the number of surgical procedures at more than 230 million per year; the majority in the areas of general, orthopedic/trauma and obstetric/gynecological surgery.<sup>1</sup>

The market for sedation and anesthesia has been short on pharmaceutical development during the last decade and there remains room for innovation. Sedative and anesthetic safety is continuously reviewed as part of quality assessments and includes such elements as efficacy, unintended intra-operational awareness, respiratory depression, hemodynamic stability, post-operative/procedure emergence and recovery, long-term effects of anesthesia and patient morbidity. In sedation, it is important to avoid any significant cardiorespiratory side effects and, at the same time, to ensure a high treatment efficiency. The relevant parameters for general anesthesia as well as for procedural sedation offer a considerable potential for innovations, which PAION will use with remimazolam.

#### Procedural Sedation Market

For the U.S., local licensee Acacia estimates that currently more than 40 million procedural sedations are performed annually. The growth of the procedural sedation market in the U.S. has been driven for many years by the increase in medical

<sup>1</sup> The Lancet: Estimate of the global volume of surgery in 2012: an assessment supporting improved health outcomes

procedures involving procedural sedations, such as colonoscopies, as well as by an increasing general demand for screening. According to Acacia, approximately 25 million colonoscopies and endoscopies are performed annually in the United States. Acacia states that more than 80% of colonoscopies and endoscopies are performed in the presence of personnel trained in anesthesia. The wholesale acquisition cost (WAC) price is reported by Acacia to be USD 39 per dose. Overall, the total market in procedural sedation is more than USD 1.5 billion per year, according to Acacia.

In Europe, based on its own projections for procedural sedation, PAION currently estimates an annual peak sales potential of approx. EUR 50 million to approx. EUR 60 million. In contrast to the U.S. market which has a large freestanding ambulatory surgery healthcare infrastructure, procedural sedation in Europe is mainly a hospital-based activity where anesthesiologists have the overall responsibility for the sedation of patients. Important users, however, are also e.g. gastroenterologists. This entails a high potential for synergies with the planned commercialization of remimazolam for use in general anesthesia. In addition, the area of day surgery is also growing in Europe, so that PAION expects a steady growth of procedural sedation procedures in Europe as well. One driver of this development is the establishment and further spread of colorectal cancer screening (diagnostic colonoscopies).

### **General Anesthesia Market**

Based on publicly available European procedure statistics and market research, PAION estimates that in Europe, approximately 29 million procedures requiring general anesthesia are performed each year. Of these, approximately 10 million are performed for high-risk patients (American Society of Anesthesiologists (“ASA”) classifications III or higher) who are particularly prone to hemodynamic instability. Approx. 55% of all anesthesia are balanced anesthesia (a combination of intravenous agents for induction and volatile gases for maintenance), approx. 20% are total intravenous anesthesia (“TIVA”) using propofol, and the remaining approx. 25% include regional anesthesia (for example epidural administration). Based on PAION’s market research, in Europe, the current standard-of-care drugs for general anesthesia are propofol (especially for induction) and narcotic gases; mostly used in conjunction with intravenous opioids.

PAION anticipates an increasing number and complexity of medical interventions requiring induction and maintenance of anesthesia in Europe in the future particularly driven by an ongoing aging of the population and the progress of surgical techniques. General anesthesia is more frequently offered to elderly patients than in the past, therefore the choice of a tailored anesthesia is made depending on the type of surgery, the underlying disease, and an assessment of the general physical health of the patient, including co-morbidities.

Accordingly, PAION believes that in Europe the demand for safer agents with low respiratory and cardio-depressive effects will increase over the coming years, creating opportunities for anesthetics with an enhanced safety profile such as remimazolam, even at higher prices compared to existing generic drugs. In Europe, based on its own projections, PAION currently estimates an annual peak sales potential of approx. EUR 100 million for general anesthesia.

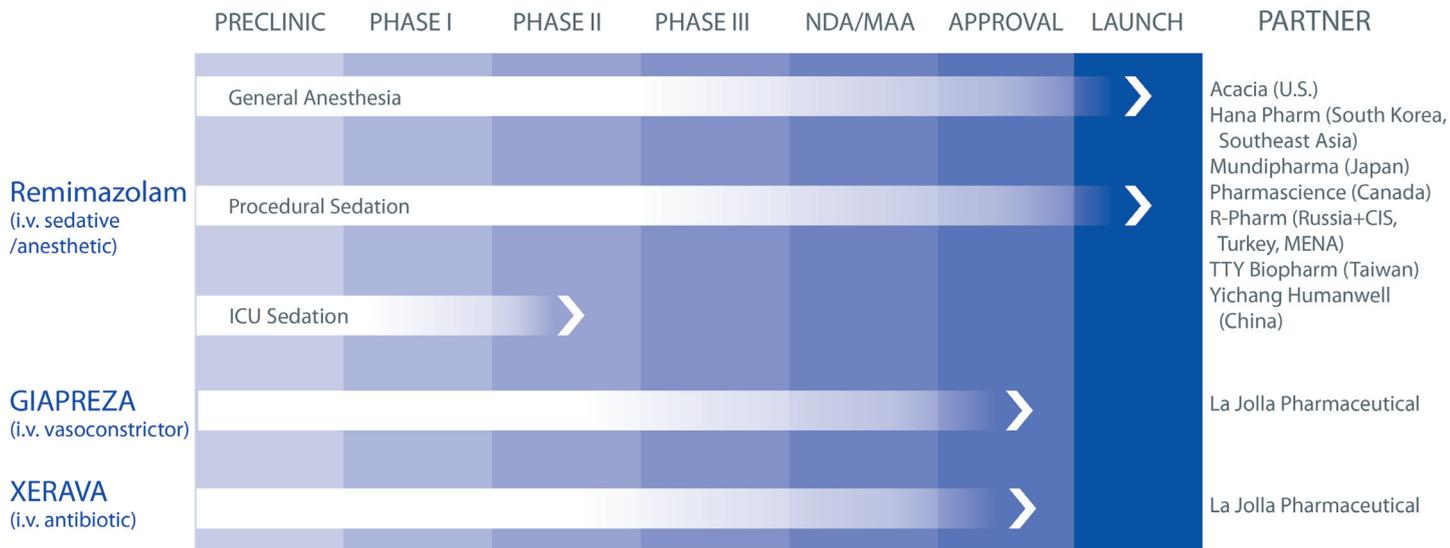
In adults, myocardial injury during noncardiac surgery (MINS) is the most common cardiovascular complication associated with such surgery. Investigations conclude that MINS occurs in about 8% of the approximately 200 million patients yearly worldwide and leads to an increased morbidity. Approximately 10% of patients suffering such injury die within 30 days after surgery. The suspected cause of this is, inter alia, a (too) low blood pressure and a concomitant temporary undersupply of the heart muscle with oxygen during the procedure.<sup>2</sup> Based on the safety data available to date, remimazolam could contribute significantly to reducing this mortality rate by reducing intraoperative blood pressure drops.

### **ICU Sedation Market**

Based on available information from 2012 published in Critical Care Medicine which estimates average days of care in ICUs per year in the U.S., and journal articles published in the Intensive Care Medicine in 2012, which records, among others, the volume of ICU admissions per year and the number of total adult beds in various countries in the EU, PAION estimates that there are at least 14 million ICU patient days requiring ICU sedation in the U.S. and Europe combined per year. A publication published in

<sup>2</sup> Khan, J. et al. (2014), Myocardial injury after noncardiac surgery, *Current Opinion in Cardiology*, 2014 Jul, 29(4):307-11; Abbott, T. E. F. et al. (2019): Depth of Anesthesia and Postoperative Delirium in JAMA, 2019, 321(5):459-460.

## Portfolio Overview



2013 on the basis of eight EU countries comes to an extrapolated figure of 17.5 million patient days for the EU alone.<sup>3</sup> PAION expects these numbers to increase in the years to come, driven by demand from the aging population both in the U.S. and in Europe. PAION believes that such development, in turn, will foster demand for safer agents such as remimazolam, given the fact that elderly patients are much more likely to suffer from systemic health problems.

## Remimazolam cooperations

Remimazolam is partnered in the U.S. (brand name BYFAVO™) with Acacia, 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, and in South Korea (brand name BYFAVO™) and Southeast Asia with Hana Pharm and in Taiwan with TTY Biopharm. For other markets except Western Europe, remimazolam is available for licensing.

For detailed information on partnering, please refer to page 37 et seq.

<sup>3</sup> Bittner et al. (2013): How is intensive care reimbursed? A review of eight European countries; Annals of Intensive Care, 3:37.

## Portfolio extension

With the addition of GIAPREZA® and XERAVA® to its commercial portfolio PAION has begun to establish its own commercial structures in certain core countries in Western Europe including Germany, UK, Netherlands and Denmark with more to follow to market GIAPREZA® and XERAVA® together with Byfavo®. PAION plans to launch all three products in a staggered manner by country beginning in the second half of 2021 so that by the end of 2022, launches will have been conducted in all selected European markets.

## GIAPREZA® (angiotensin II)

GIAPREZA® for injection is a vasoconstrictor and FDA-approved 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%).

Prescribing information for GIAPREZA® is available at [www.giapreza.com](http://www.giapreza.com). 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 currently plans the European commercial launch of GIAPREZA® in the second half of 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. "Complicated" means that the infection is difficult to treat because it has spread to the abdomen.

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 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 (another antibiotic). 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. Prescribing information for XERAVA® is available at [www.xerava.com](http://www.xerava.com).

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.



## Report of the Supervisory Board



Dr. Jörg Spiekerkötter  
Chairman of the Supervisory Board of PAION AG

Dear Shareholders,

during the 2020 fiscal year, the Supervisory Board performed its duties pursuant to the law, the company's articles of association and the by-laws and, in fulfilment of its advisory and supervisory function, closely followed the business conduct of the Management Board. The Supervisory Board was directly involved in all decisions of major importance to the company. In the course of fulfilling its duties, the Supervisory Board received regular, prompt and comprehensive written and verbal reports from the Management Board on the corporate planning, the state and development of the company and the group as well as all significant business transactions.

The Supervisory Board carefully examined, discussed and voted on the decisions or measures of the Management Board that, pursuant to the law, the articles of association or the by-laws of the Management Board, require its approval as well as other decisions of fundamental importance. In addition to receiving its reports, the Chairman of the Supervisory Board maintained continued contact with the Management Board. The Chairman kept himself informed of the current business development, the liquidity situation, the progress of the development activities with remimazolam and the possibilities of its optimal commercialization as well as other essential business transactions.

### **Meetings of the Supervisory Board and focus of deliberations**

The Supervisory Board held a total of five board meetings throughout fiscal year 2020. All board meetings were attended by all board members.

The Supervisory Board established an Audit Committee. Dr. Jörg Spiekerkötter, Dr. Chris Tanner and Dr. Markus Leyck Dieken are members of this committee. Dr. Chris Tanner is chair of the committee and fulfils all requirements of section 100(5) of the German Stock Corporation Act (AktG).

The Supervisory Board established a Human Resources and Nomination Committee. Dr. Jörg Spiekerkötter, Dr. Karin Dorrepaal and Dr. Chris Tanner are members of this committee. Dr. Karin Dorrepaal is chair of the committee.

The Supervisory Board established a Research and Development Committee. Dr. Karin Dorrepaal, Dr. Irina Antonijevic and Dr. Markus Leyck Dieken are members of this committee. Dr. Irina Antonijevic is chair of the committee.

No further committees were established.

The Supervisory Board focused on the following topics in particular during fiscal year 2020:

- The strategic positioning of the PAION group
- The funding of the PAION group
- The progress of filings for market approvals for remimazolam
- The Phase III development program of remimazolam in Europe
- The possibilities of an optimal commercialization of remimazolam, either with licensees or through own commercialization in selected territories
- The composition of the Management Board and the staffing of PAION group
- Impacts of the coronavirus pandemic on the business of PAION group

The 2020 corporate budget and the corporate budget planning for 2021 as developed by the Management Board were examined in detail and approved by the Supervisory Board. Based on mid- and long-term corporate planning, the strategic orientation was discussed, reviewed and adjusted. Specific attention was paid to both risk assessment and risk management.

The Management Board kept the Supervisory Board regularly informed of the net assets, financial position and results of operations of the PAION group. The basis for this were the timely presented monthly finance reports, quarterly statements, the half-year and annual financial report as well as variance analyses with regard to the planning.

The Audit Committee discussed the quarterly statements and the half-year financial report with the Management Board before publication.

In fiscal year 2020, no conflicts of interest arose involving the members of the Supervisory Board, as set out in recommendation E.1 of the German Corporate Governance Code in the version dated 16 December 2019.

The Audit Committee held four meetings in the fiscal year 2020 and focused on the following subjects:

- The accounting of the company and the PAION group

- Material accounting issues
- The award of the audit engagement to the auditor and the determination of the audit focus
- The monitoring of the accounting process, the effectiveness of the risk management system and the internal control system

With the exception of two meetings at each of which one member was absent, the meetings of the Audit Committee were attended by all its members.

The Human Resources and Nomination Committee held two meetings in fiscal year 2020 and focused on the composition of the Management Board and the Supervisory Board, the staffing of PAION group, the design of the Stock Option Plan 2020 of PAION group and the grant of stock options to members of the Management Board. The meetings of the Committee were attended by all its members.

The Research and Development Committee held one meeting in fiscal year 2020 and focused on the European remimazolam Phase III development program in the indication of general anesthesia. The meeting of the Committee was attended by all its members.

### **Changes in the Management Board**

Dr. Jürgen Beck was Chief Development Officer until 31 December 2020 and left the Management Board on 31 December 2020. The Supervisory Board thanks Dr. Beck for the trustful cooperation and his important contribution to the development of remimazolam.

### **Corporate Governance**

The concept of corporate governance stands for transparent business management that also aims to create long-term value. The Supervisory Board subscribes to the principles of the German Corporate Governance Code. In December 2020, the Supervisory Board and the Management Board jointly released an updated Declaration of Conformity in accordance with section 161 of the German Stock Corporation Act which was subsequently rendered available on the company's website at <http://www.paion.com/media-and-investors/corporate-governance/declaration-of-conformity/>. Since the last Declaration of Conformity in December 2019, PAION AG complied with all

recommendations of the Code in the version dated 07 February 2017. On 16 December 2019, the Government Commission on the German Corporate Governance Code agreed on a revised version of the Code that was published in the Federal Gazette on 20 March 2020. PAION AG complied with all recommendations of the revised Code, with the exception of the recommendation in C.5 regarding the number of mandates of Supervisory Board members. Information on corporate governance at PAION AG can be found in the joint declaration on Corporate Governance by the Supervisory Board and the Management Board. The declaration can be found in this annual report and is publicly available on the company's website at <http://www.paion.com/media-and-investors/corporate-governance/declaration-on-corporate-governance/>.

#### **Financial statements and consolidated financial statements**

Ernst & Young GmbH Wirtschaftsprüfungsgesellschaft, branch office Cologne, ("Ernst & Young") was appointed auditor and group auditor for the financial year 2020 by the Annual General Meeting on 27 May 2020 and subsequently mandated by the Supervisory Board. The independence of Ernst & Young was confirmed to us in writing prior to the Annual General Meeting. Ernst & Young has audited the Financial Statements and Consolidated Financial Statements of PAION AG prepared by the Management Board, the Management Report and the Group Management Report for the financial year 2020 and furnished them with an unqualified auditor's opinion. The Group Financial Statements were drawn up in accordance with section 315e of the German Commercial Code (HGB) on the basis of the International Financial Reporting Standards (IFRS).

All members of the Supervisory Board received the Financial Statements as well as the audit reports from the auditor well in advance of the Supervisory Board Meeting on 30 March 2021, in which the Financial Statements were discussed. They studied these documents in detail in preparation for this meeting. During the meeting, the Supervisory Board discussed and examined the Financial Statements and Consolidated Financial Statements of PAION AG, the Management Report and the Group Management Report. The assessments made by the Management Board in the Management Report and the Group

Management Report were consistent with both, those previously communicated in its reports to the Supervisory Board and independent assessments by the Supervisory Board. The auditor also took part in this meeting. He reported on the audit, especially that no major weaknesses in the internal control system and risk management system with respect to the accounting process existed, reported on the focal points of the audit and was available to answer questions and provide supplementary information to the Supervisory Board.

The Supervisory Board approves the audit reports on the Financial Statements and Consolidated Financial Statements as well as on the Management Report and the Group Management Report. The Supervisory Board does not raise any objections and authorizes the Financial Statements and Group Financial Statements prepared by the Management Board. The Financial Statements are therefore adopted.

The Supervisory Board would like to thank the members of the Management Board and all employees for their great commitment and their achievements during fiscal year 2020.

Aachen, March 2021

#### **For the Supervisory Board**



Dr. Jörg Spiekerkötter  
Chairman

## Declaration on Corporate Governance

The Declaration on Corporate Governance (Section 289f German Commercial Code) comprises the Declaration of Conformity, information on corporate governance practices and a description of the Management Board and Supervisory Board procedures. Our aim is to present PAION's corporate governance principles as clearly and concisely as possible. You will find the complete declaration on our webpage under <http://www.paion.com/media-and-investors/corporate-governance/declaration-on-corporate-governance>. The Management Board and the Supervisory Board jointly prepare the Declaration on Corporate Governance and are each responsible for the parts of the report that concern them.

The Declaration on Corporate Governance is combined for PAION AG and the Group. Accordingly, the statements apply equally to PAION AG and the Group, unless otherwise stated below.

### Explanation on Corporate Governance

The Supervisory Board and the Management Board of PAION AG are both committed to the principles of responsible management and governance aimed at sustainable value creation and set great store by these principles in their actions. In ensuring good and transparent corporate governance, the Supervisory Board and the Management Board of PAION AG are guided by the statutory provisions as well as the suggestions and recommendations of the Government Commission of the German Corporate Governance Code. The suggestions and recommendations laid down in the German Corporate Governance Code are based on internationally and nationally recognized standards of good and responsible business management.

In December 2020, the Supervisory Board and the Management Board released their annual Declaration of Conformity following the recommendations of the Government Commission of the German Corporate Governance Code in accordance with section 161 of the German Stock Corporation Act. The declaration is provided permanently on the company website (<http://www.paion.com/media-and-investors/>

[corporate-governance/declaration-of-conformity](#)) alongside now outdated Declarations of Conformity from previous years.

Since issuing the last declaration of conformity in December 2019, PAION AG has complied with all recommendations of the German Corporate Governance Code dated 7 February 2017. Furthermore, PAION AG declared that in the future it will comply with the recommendations of the German Corporate Governance Code dated 16 December 2019 (effective since publication in the Federal Gazette on 20 March 2020) with the exception of the recommendation in C.5 regarding the number of mandates of the members of the Supervisory Board. The Declaration of Conformity from December 2020 with the details is reproduced below.

### **Declaration of Conformity with German Corporate Governance Code**

"Pursuant to section 161 of the German Stock Corporation Act (AktG), the Management Board and the Supervisory Board of PAION AG have an obligation to annually declare that the company has complied and will comply with the recommendations of the latest version of the "Government Commission German Corporate Governance Code" (the "Code") published by the Federal Ministry of Justice in the official section of the Federal Gazette, or which of the recommendations have not been or are not being applied and why.

Pursuant to section 161 of the German Stock Corporation Act, the Management Board and the Supervisory Board of PAION AG declare: Since the last declaration of conformity in December 2019, PAION AG complied with all recommendations of the Code in the version dated 07 February 2017.

On 16 December 2019, the „Government Commission on the German Corporate Governance Code" agreed on a revised version of the Code that was published in the Federal Gazette on 20 March 2020. PAION AG will comply with all recommendations of the revised Code in the future, with the exception of the following non-compliance with the recommendation in C.5 regarding the number of mandates of Supervisory Board members:

- “Supervisory Board Members, who are members of the Management Board of a listed company, shall not have, in aggregate, more than two Supervisory Board mandates in non-group listed companies or comparable functions, and shall not accept the Chairmanship of a Supervisory Board in a non-group listed company” (Recommendation C.5 of the Code).

Dr. Chris Tanner, member of the Supervisory Board of PAION AG, is a member of the management board of a listed company and has currently more than two further Supervisory Board mandates in non-group listed companies or comparable functions. Dr. Tanner was elected in May 2017 to the Supervisory Board of PAION AG already and thus before the revised version of the Code dated 16 December 2019 entered into force.

In the future, the company intends, in principle, to follow this new recommendation of the Code. The company will only deviate from this new recommendation with a respective disclosure and explanation, if it should come to the conclusion, after examination in the individual case, that the additional mandates do not stand in the way of taking over the duties as member of the Supervisory Board of PAION AG, in particular in view of the workload for the Supervisory Board member resulting from the additional mandates.

Aachen, December 2020

#### **Supervisory Board of PAION AG**

Dr. Jörg Spiekerkötter, Chairman of the Supervisory Board

#### **The Management Board of PAION AG**

Dr. James Phillips, Chairman of the Management Board

Dr. Jürgen Beck, Member of the Management Board

Abdelghani Omari, Member of the Management Board"

## Code of Conduct

PAION AG is a publicly listed specialty pharmaceutical company with innovative drugs to be used in hospital-based sedation, anesthesia and critical care services. As a listed company, PAION carries a major responsibility towards many stakeholders. Doctors and patients alike must be able to rely on our ability to

develop safe and effective products. Business partners, shareholders and investors must also be able to place trust on us that all our activities and relationships both with business partners and governmental authorities remain within the framework and principles of integrity in business relationships as recorded in our corporate “Code of Conduct”. Please visit <http://www.paion.com/media-and-investors/corporate-governance/code-of-conduct> for more information about the Code of Conduct at PAION.

## Information on Company management and supervision

In accordance with the provisions of the German Stock Corporation Act, PAION AG maintains a dual management and supervision structure formed by two bodies, the Management Board and the Supervisory Board. The Management Board currently consists of two members, who collectively bear all responsibility and are accountable for the company’s good management. The Supervisory Board, comprising five members, appoints, supervises and advises the Management Board and is directly involved in decisions that are of fundamental importance to the company. The Supervisory Board currently consists of the following members by name:

- Dr. Jörg Spiekerkötter (Chairman), Member of the Supervisory Board since 2007
- Dr. Karin Dorrepaal (Vice Chairman), Member of the Supervisory Board since 2012
- Dr. Chris Tanner, Member of the Supervisory Board since 2017
- Dr. Dr. Irina Antonijevic, Member of the Supervisory Board since 2017
- Dr. Markus Leyck Dieken, Member of the Supervisory Board since 2019

In overseeing and directing the composition of the Supervisory Board, the Supervisory Board pays attention to the principle of diversity, specifically the representation of women as well as different professional experience and internationality relevant for PAION AG. Moreover, the Supervisory Board has

determined that these goals are supposed to be considered for recommendations for the election of Supervisory Board members to the Annual General Meeting. The strategic objectives of the company are developed by the Management Board and coordinated with the Supervisory Board.

The Management Board and the Supervisory Board work together closely for the sole benefit of the company and its stakeholders. Taking into consideration the specific circumstances of PAION AG, the Supervisory Board adopted the following objectives regarding its composition. These objectives shall be considered by the Supervisory Board in its election recommendations to the Annual General Meeting for regular re-elections as well as for new elections.

The members of the Supervisory Board shall as a group possess the required knowledge, ability and expert experience required to complete the tasks of the Supervisory Board ("Competence Profile"). The competence profile includes:

- Experience and knowledge in corporate management, accounting, risk management and governance/compliance;
- Knowledge of the German and international capital markets;
- especially the knowledge relating to PAION AG in research and development, production and selling/distribution of pharmaceuticals;
- Knowledge of international cooperation models (e.g. licensing agreements, R&D agreements).

The Supervisory Board determined that the Supervisory Board shall have no more than one member who was a former member of the Management Board of the company. The Supervisory Board shall not have any members who act as board members or consultants for major competitors or have business or personal relations to the company or the Management Board members, which could give rise to a conflict of interest which is significant and not temporary. The Supervisory Board members shall have sufficient time to perform their mandate. Members who serve at the same time as active management board members shall have no more than three Supervisory Board mandates in total. The age limit for Supervisory Board members is 75 years. Tenure is limited to an aggregate total of fifteen years. Exceptions to this rule require a unanimous decision of

the Supervisory Board. The international nature of the company shall be adequately reflected in the composition of its Supervisory Board. Therefore, it is desired that at least one member possesses an international background. Furthermore, the Supervisory Board resolved that at least one of its five members must be female. This target shall be periodically reviewed and/or revised in accordance with current legal requirements.

During financial year 2020 all members were independent and younger than 75 years. The Supervisory Board takes the view that the Chairman of the Supervisory Board, Dr. Jörg Spiekerkötter, should be regarded as independent from the company and the Management Board, despite his tenure of more than 12 years as member of the Supervisory Board. The Supervisory Board believes that the Chairman's long-standing company-specific experience and expertise is conducive to the goals of advising and supervising the Management Board and coordinating the Supervisory Board's work in a lasting and objective manner. Moreover, there are no circumstances in his specific case that might cause a material and not merely temporary conflict of interests based on the tenure of his Supervisory Board membership. The Chairman of the Supervisory Board coordinates its work and chairs its meetings. The Chairman of the Supervisory Board maintains regular contact with the Management Board. In the By-Laws developed for the Management Board, the Supervisory Board laid down the duties of the Management Board. This includes the provision of information and reports, the allocation of duties, and further defines the necessary levels of co-operation within the Management Board including the processes and business transactions requiring approval by the Supervisory Board. The Supervisory Board established an Audit Committee chaired by Dr. Chris Tanner, an independent member of the Supervisory Board with specific knowledge and experience in the application of accounting principles and the auditing of financial statements. Furthermore, Dr. Jörg Spiekerkötter and Dr. Markus Leyck Dieken are members of the Audit Committee. The Supervisory Board established a Human Resources & Nomination Committee chaired by Dr. Karin Dorrepaal, an independent member of the Supervisory Board. Furthermore, Dr. Jörg Spiekerkötter and Dr. Chris Tanner are members of the Human Resources & Nomination Committee. In addition, the Supervisory Board established

a Research & Development (R&D) Committee chaired by Dr. Dr. Irina Antonijevic, also an independent member of the Supervisory Board. Dr. Karin Dorrepaal and Dr. Markus Leyck Dieken are members of the R&D Committee. Duties and tasks of the Supervisory Board and its committees are also regulated by specific rules of procedure. From time to time, the Supervisory Board reviews and assesses the work of the Supervisory Board and its committees using a checklist and questioning of the members of the Supervisory Board ("self-assessment"). The Supervisory Board lastly conducted such a self-assessment of the effectiveness of its work and the work of its committees in January 2021 using the checklist and questioning of the members of the Supervisory Board. Further details concerning the work of the Supervisory Board can be found in the Report of the Supervisory Board.

PAION AG has taken out a D&O insurance policy for the members of the Management Board and the Supervisory Board. This insurance policy provides partial coverage for the Management Board and the Supervisory. Insurance coverage is not provided in the event of fraudulent actions, omissions or deliberate breaches of duty.

The Supervisory Board has set an age limit of 65 for members of the Management Board. The Supervisory Board and the Management Board work together on long-term succession planning for the Management Board members. No succession topics are currently emerging. The Supervisory Board and the Management Board will continue to start the timely planning of successors in the future.

Conflicts of interest of the Management or Supervisory Board members must be disclosed immediately to the Supervisory Board. No conflicts of interest involving the members of the Supervisory Board, as set out in subsection 5.5 of the German Corporate Governance Code in the version dated 7 February 2017, and in accordance with Recommendation E.1 of the German Corporate Governance Code in the version dated 16 December 2019 were reported in financial year 2020.

Both members of the Management Board are also Managing Directors of PAION Deutschland GmbH, PAION Holdings UK Ltd and its subsidiaries as well as of PAION Netherlands B.V. Further mandates held by members of the Management Board

and Supervisory Board are listed in the notes to the Consolidated Financial Statements.

## Equal participation of Men and Women in executive positions

The Supervisory Board and the Management Board actively support the company in achieving an adequate representation of women in executive positions.

The Supervisory Board had determined a target of 30% to be achieved for the representation of women by 30 June 2017 in accordance with Section 111(5) Stock Corporation Act (AktG). This was based on the internal requirement that at least one member of the Supervisory Board shall be female. In the meantime the Supervisory Board was extended from three to five members by resolution of the Annual General Meeting held on 17 May 2017. On 30 June 2017 two of the five Supervisory Board members were female. The target was achieved. By resolution from June 2017 the Supervisory Board determined to maintain the target of at least one female Supervisory Board member. Consequently a target of 20% was defined for the reporting period commencing on 01 July 2017. The agreed deadline for reporting is 30 June 2022.

The Management Board of PAION AG comprises two members – Dr. James Phillips (CEO) and Mr. Abdelghani Omari (CFO). Effective 31 December 2020, Dr. Jürgen Beck retired from the Management Board, a successor was not appointed. There are no women represented on the Management Board. Given existing contractual obligations at the time, the Supervisory Board had determined, in accordance with Section 111(5) Stock Corporation Act (AktG), that no female representation was mandated for the Management Board of PAION AG until expiration of the reporting period on 30 June 2017. The target stood as achieved. By resolution dated 19 June 2017, the Supervisory Board determined that owed to the specific circumstances of the company no representation of women on the Management Board of PAION AG was mandated until 30 June 2019. By resolution dated 21 May 2019, the Supervisory Board extended this resolution until 30 June 2021.

In the reporting period that started on 1 July 2017, the Management Board of PAION AG had decided to reach a target of 20% share of women within the first and second management levels under the Management Board by 31 December 2019. The target was achieved with a quota of 31.6% as of 31 December 2019. In January 2020, the Management Board further decided to reach a target of 35% women by 31 December 2021. The target has already been achieved with a quota of 35.0% as of 31 December 2020. Thus, the company as a whole sees a successful path in its efforts to strengthen the participation of women in the first and second management levels.

## Compliance as a key management duty of the Management Board

Compliance, in the sense of measures designed to ensure adherence to statutory provisions and internal company policies including observance of these measures, represents a key obligation in the PAION group. Pursuant to Section 91(2) of the German Stock Corporation Act, the Management Board is obliged to implement effective measures – namely a monitoring system – to enable the early identification of any developments that may threaten the survival of the company. The German Corporate Governance Code stipulates the Management Board's responsibility for the implementation of a Compliance management system aligned with the company's risk situation ("Compliance Management System") and control system.

The Management Board of a joint stock corporation is jointly and severally liable for the fulfilment of its organizational duties, especially risk management and risk control. The Management Board must define an organizational structure for the company ensuring that its operations comply with legal requirements. Any infringement of rights and legally protected interests of third parties must reasonably be excluded. A Management Board is only eligible for exemption from liability if it provides evidence of compliance with its organizational obligations.

One of the organizational obligations for the Management Board is represented by the formal assignment of business responsibilities defining the individual areas of responsibility

for its members. This plan forms an integral part of the rules of engagement for the Management Board and must be approved by the Supervisory Board. In addition, regular meetings and consultations ensure that the members of the Management Board are well informed of any important developments. In case of any deficits and/or irregularities, the Management Board must collectively implement suitable counter-measures.

The Management Board must not delegate management tasks to lower levels of the organization. This excludes the vast majority of common operational tasks. The Management Board of PAION AG further delegated specific tasks to subordinate executives and expert members of staff in the Legal, Investor & Public Relations as well as Finance departments forming part of its efforts to comply with capital market statutes. These tasks and responsibilities are defined in the individual job descriptions. The members of staff that perform tasks related to compliance within capital market statutes are subject to ongoing monitoring, training and random checks.

All staff and members of the Management and Supervisory Board across the entire PAION Group of companies receive regular communications raising awareness of compliance with relevant financial market regulations. This includes, for example, the handling of sensitive confidential information, specifically insider information.

## Transparency and communication

Good corporate governance is distinguished by open, transparent and up-to-date communications. PAION AG ensures this by posting ad-hoc reports on the company's website and by forwarding without delay all relevant information for publication to the relevant service providers (Business Register, Deutsche Börse, Federal Gazette, Europe-wide publication).

All inside information according to Section 17 Market Abuse Regulation (MAR), Directors' dealings notifications according to Section 19 MAR, press releases, publications of voting right notifications according to Section 40 Securities Trading Act, financial reports, information on the Annual General Meeting as well as information on the company's corporate governance principles can be accessed by the public on the company's

website (<http://www.paion.com>). The website also features a financial calendar that provides information on the publication dates of the financial publications as well as an event calendar detailing upcoming presentations by the company. For all events and discussions, PAION AG ensures that no investor receives material information in a favorable manner and that the equal treatment of all shareholders is ensured. Information such as inside information announcements, press releases, quarterly releases, half-year reports and annual reports are also made available in English.

PAION AG reports regularly and promptly on the development of its business as well as the net assets, financial position and operational results for the entire group. The Annual Financial Report is published within 90 days from the end of the respective financial year.

Further information about transparency and communications can be found in the Investor Relations section of this Annual Report.

## Shareholders and Annual General Meeting

The shareholders of PAION AG are entitled to exercise their rights at the Annual General Meeting. Each share entitles the holder to one vote. The shareholders have the possibility to exercise their voting rights themselves or to appoint a proxy in writing. PAION AG implemented facilitating measures for the shareholders to exercise their voting rights by appointing a representative assisting in the exercise of shareholders' voting rights in accordance with their instructions. All reports and documents required to be made available for inspection in connection with the Annual General Meeting are also posted on the PAION webpage (<http://www.paion.com/media-and-investors/annual-general-meeting/>).

## Auditing of the financial statements

The consolidated financial statements of PAION AG are drawn up by the Management Board in accordance with the International Financial Reporting Standards. Following vote at the Annual General Meeting, Ernst & Young GmbH

Wirtschaftsprüfungsgesellschaft, branch office (Zweigniederlassung) Cologne, ("Ernst & Young") was commissioned by the Supervisory Board to audit the annual and consolidated financial statements of PAION AG. It was agreed upon between the Supervisory Board and Ernst & Young that the auditor would report to the Chairman of the Supervisory Board or to the Chairman of the Audit Committee, without delay all findings and events essential for the fulfilment of the duties of the Supervisory Board that were discovered during the audit. Furthermore, the auditor is required to inform the Supervisory Board and the Audit Committee, or to include a note in the auditor's report, if he discovers any facts during the audit that are not consistent with the Declaration of Compliance issued by the Management Board and the Supervisory Board in accordance with section 161 of the German Stock Corporation Act. In regard to the audit of the consolidated financial statements and the audit and adoption of the financial statements by the Supervisory Board we refer to the report of the Supervisory Board.

## Risk management

Good corporate governance involves the responsible handling of risks by the company. Details of the risk management system (Compliance Management System) implemented by the PAION group of companies are outlined in the Group Management Report. Please refer to the section "Report on risks and opportunities".

## Remuneration of the Management Board

The remuneration of the members of the Management Board Members is determined by the Supervisory Board. Regular reviews are conducted. The remuneration is comprised of a fixed component, a variable bonus, long-term performance-related remuneration components in the form of stock options, as well as contributions in terms of company car remuneration, insurance premiums and pension schemes.

In accordance with the statutory provisions, the remuneration of each individual member of the Management Board is disclosed in the Group Management Report under the

section “Remuneration Report – Management Board“. Moreover, this section includes explanations of the kind and structure of the remuneration of the Management Board as well as details on commitments in case of the termination of the contract of Management Board members. Reference is made to the detailed statements in the Group Management Report, which form an integral part of this Declaration on Corporate Governance.

## Remuneration of the Supervisory Board

The remuneration of the Supervisory Board is laid down in the Articles Of Association of PAION AG. Members of the Supervisory Board receive a basic remuneration and attendance fees in addition to the reimbursement of their expenses. Performance-related remuneration for the members of the Supervisory Board is not envisaged. The basic annual remuneration amounts to EUR 20,000 and the attendance fee to EUR 1,000 per meeting. Conference calls that are held between the meetings are not taken into consideration in the calculation of the attendance fee. The Chairman of the Supervisory Board receives double and the Vice Chairman one and a half times the basic remuneration and attendance fee. The attendance fee is paid for a maximum of five meetings per year. The remuneration paid to each individual member of the Supervisory Board is presented in the Group Management Report in the section “Remuneration Report – Supervisory Board“. Reference is made to the detailed statements in the Group Management Report, which at the same time form an integral part of this Declaration on Corporate Governance. The members of the Supervisory Board did not receive any remuneration or compensation for services rendered individually, in particular consultancy and agency services, in the financial year 2020.

## Share transactions by and shareholdings of the members of the Management Board and the Supervisory Board

In accordance with Section 19 MAR, members of the Management Board, the Supervisory Board and persons associated with them are required to disclose the selling or buying of PAION

AG shares if the value of the combined transactions reaches or exceeds EUR 20,000 in any calendar year. These transactions are published by PAION AG immediately on the company’s website and notified to the Federal Financial Supervisory Authority. In fiscal year 2020, notifiable transactions were reported by Dr. James Phillips on 24 January 2020 and on 08 June 2020. In fiscal year 2020, notifiable transactions were reported by Dr. Jürgen Beck and Mr. Abdelghani Omari on 24 January 2020.

As of 31 December 2020, Dr. James Phillips held 0.01% (8,750 voting rights) of the shares in PAION AG. Mr. Abdelghani Omari and the members of the Supervisory Board did not hold any shares in PAION AG as of 31 December 2020.

## Share-based incentive systems

PAION AG introduced the Stock Option Plans 2010, 2014, 2016, 2018 and 2020 as remuneration components with long-term incentives and risk characteristics. The Stock Option Plans allow for stock options to be granted to members of the Management Board as well as employees. The precise structure of the active plans, as e.g. waiting periods and exercise hurdles, as well as the options issued to date within the framework of these plans are presented in the notes to the Consolidated Financial Statements in section “Other Disclosures” under “Stock Option Plans“. Furthermore, the explanations in the Group Management Report in the section “Remuneration Report – Management Board” contain statements on the value of the options granted to the members of the Management Board. Reference is made to the statements in the notes to the Consolidated Financial Statements and the Group Management Report, which at the same time form an integral part of this Declaration on Corporate Governance.

Aachen, March 2021

**The Management Board of PAION AG**

Dr. James Phillips            Abdelghani Omari

**The Supervisory Board of PAION AG**

Dr. Jörg Spiekerkötter      Dr. Markus Leyck Dieken  
Dr. Karin Dorrepaal        Dr. Dr. Irina Antonijevic  
Dr. Chris Tanner



## Investor Relations

### Investor Relations

PAION's mission is to be a leading specialty pharmaceutical company in the fields of anesthesia & critical care by bringing novel products to market to benefit patients, doctors & other stakeholders in healthcare. In respect to corporate communications, we place great emphasis on transparent, comprehensive and timely communication. Information on significant developments within the company is made available immediately and simultaneously to all stakeholders.

PAION is listed in the Prime Standard segment of the Frankfurt Stock Exchange and therefore also fulfills extended disclosure requirements in addition to the ad-hoc disclosure obligations.

### Performance of PAION shares in 2020

PAION shares opened 2020 with a Xetra price of EUR 2.15 (Xetra closing price). The highest price in 2020 was marked on 06 July 2020 at EUR 3.06 (Xetra closing price). The low was EUR 1.40 on 19 March 2020 (Xetra closing price). The closing price on 30 December 2020 was EUR 2.40 (Xetra). This represents an increase of about 20% compared to the closing price of 30 December 2019 (EUR 1.98; Xetra).

The market capitalization of PAION AG at the end of the financial year amounted to EUR 159 million (31 December 2019: EUR 127 million).

### Xetra Stock Performance of the PAION share in 2020 (price and volume in EUR)



## Annual General Meeting and analyst conference

The Annual General Meeting, was held as a virtual meeting on 27 May 2020. The shareholders present owned around 8% of PAION's shares (previous year: 22%). All proposals were approved with a large majority.

As in previous years, PAION AG used the German Equity Capital Forum in November 2020 to host its annual analyst conference which made a great impression.

## Analyst coverage

The following analysts regularly publish reports on PAION:

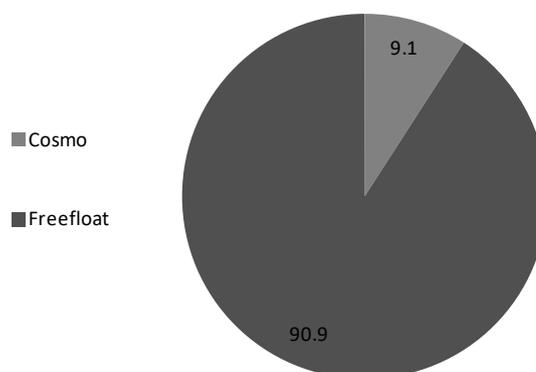
- Simon Scholes (First Berlin)
- Dr. Mohamed Vaseghi (FMR Frankfurt Main Research)
- Martial Descoutures (Oddo BHF Research)

Selected analyst reports are available under the investor relations section of the PAION website (<http://www.paion.com/media-and-investors/information-on-shares/analysts/>).

## Shareholder structure

PAION is characterized by a very high free float of approximately 91%. Cosmo Pharmaceuticals N.V., Amsterdam, Netherlands, is the largest single shareholder, owning 9.09% of PAION shares, pursuant to the available notifications (30 June 2016).

The current share capital amounts to EUR 71,336,992.00.



## Do you have any questions about PAION AG?

Please contact our investor and public relations team:

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# Group management report



# Group Management Report for Fiscal Year 2020

## Fundamental information of PAION AG and the PAION Group

### I. Business model of PAION AG and PAION Group

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 AG is a holding company exclusively providing management and other services to its subsidiaries. These services primarily focus on the development of the group strategy, administrative tasks, including accounting, legal, human resources, public relations, and controlling. In addition, PAION AG supports the financing of its subsidiaries' ongoing business activities, and the Group companies provide each other with services, mainly in the areas of development, supply chain and commercialization. The activities of the PAION Group (hereinafter also referred to as PAION) are mainly determined by the operations of the subsidiaries, which are presented below.

In the reporting period, PAION's portfolio exclusively comprised remimazolam. Remimazolam is already approved for procedural sedation in the U.S. and China and for general anesthesia in Japan and South Korea. After the balance sheet date, two additional products, GIAPREZA® and XERAVA®, were in-licensed for commercialization in the European Economic Area, the United Kingdom and Switzerland.

For remimazolam, PAION has licensees in the U.S., China, South Korea, Southeast Asia, Canada, Russia/CIS, Turkey, the MENA region, Japan and Taiwan. For the use of remimazolam for procedural sedation, clinical development is mostly completed. In the U.S. and China, remimazolam is approved for this indication and is already on the market; in the EU, a market approval dossier has been filed. The European Medicines Agency's (EMA) Committee for Medicinal Products for Human Use (CHMP) recommended approval in January 2021. For the indication general anesthesia, remimazolam is in the final stage of clinical development and has already been completed for Japan and South Korea; in both markets, remimazolam is approved for this indication and it is already on the market in Japan. The different indications for application of remimazolam will be described in detail in the following chapters.

Fiscal year 2020 was marked by the continuation of the further development of remimazolam, regulatory as well as supply chain and pre-commercial activities, in particular the conduct and completion of a Phase III study in general anesthesia in the EU, the build-up of a supply chain and support for the market approval dossier reviews in the EU and the U.S.

### 2. Internal management system of PAION AG and PAION Group

Financial performance indicators are liquidity (cash and cash equivalents from the balance sheet and cash flows from the cash flow statement), equity, revenues, research and development expenses, general administrative and selling expenses, and the number of employees. The financial management system of PAION and the PAION Group is based on monthly reports on a cost centre and cost unit basis that also show deviations from budget of the financial performance indicators. Significant deviations are updated in the short- and long-term corporate planning. Moreover, the planned development progress is checked against the planned budget. By simulating different scenarios, the planning tool used for this purpose enables management to identify and assess opportunities and risks at an early stage and determine their influence on the

future development of the group, particularly with regard to the key financial performance indicator liquidity.

The non-financial performance indicators essential for PAION's business activity mainly arise from the development and commercial activities. The clinical, non-clinical, regulatory and production development activities are characterized by the involvement of external service providers. The management of the development activities is based on using detailed project plans that contain defined work packages associated with specified reporting and information obligations. In this regard, the data generated in the course of the development of remimazolam in respect to positioning in comparison to competing products, the development progress as well as the relevant data for the targeted approvals in respect to safety and efficacy are of specific interest. The results are continuously processed in the internal project teams and reported to the Management Board.

Commercial and licensing activities aim at the commercialization of remimazolam. The progress of these activities is being documented and discussed continuously. PAION has already signed several regional license agreements and conducts preparatory pre-commercial activities for the planned own commercialization in selected European markets. The licensees operate independently in their respective license territory. However, the cooperation agreements require the partners to exchange relevant information.

The central coordination of the information flow worldwide between the licensees is managed by PAION. All activities are monitored and are being reviewed and reported to the Management Board continuously.

### **3. Business activity**

The business of PAION was mainly driven by the research and development activities as well as the preparation of commercialization for remimazolam in the reporting period which are described in detail in Section 2. "Presentation of the course of business and development activities".

## **Report on economic position**

### **I. Macroeconomic and sector-specific environment**

#### **a. Macroeconomic development**

The year 2020 was marked worldwide by the Covid-19 pandemic, which has been rampant since the spring. In Germany, the gross domestic product (GDP) decreased by 4.9% in 2020 year-on-year, the sharpest decline since 2009 (previous year: increase of 0.6%). Private consumption

decreased by 6.1% and investment fell by 6.9%, while state expenditure on consumption increased by 3.3%.<sup>1</sup>

Accordingly, there was also a decline in economic output internationally in 2020: In this context, GDP in the euro zone fell by 6.8% in 2020 following an increase of 1.3% in the previous year. In the U.S., economic output recorded a decline of 3.5% in 2020, while it still showed an increase of 2.2% in 2019.<sup>2</sup> Global GDP decreased by 3.5% in 2020 following an increase of 2.9% in 2019, with the developed economies recording a sharper decline of 4.9%, while economic output in the emerging and developing economies fell by only 2.4% in 2020.<sup>3</sup>

However, global GDP is expected to rise again by 5.5% in 2021. Growth of 4.3% is expected for the developed economies and 6.3% for the developing and emerging countries.<sup>4</sup>

The most significant uncertainty at present, not only for 2021 but also for periods further in the future, relates to the further development of the pandemic worldwide. For example, a rapid (global) supply of effective vaccines could induce a comparatively faster recovery of the global economy, while, for example, a delay in the supply of vaccine or the emergence of new (also potentially vaccine-resistant) mutations of the Coronavirus could have a more sustainable dampening effect on global economic performance.<sup>5</sup>

On the stock markets, on the other hand, a broad recovery was already evident in the course of 2020, particularly after massive price falls in the first quarter of 2020 in some cases in the context of the first wave of the pandemic and the start of the restrictions on public life. While the EUROSTOXX 50 closed 2020 with a minus of 5.1% as compared to the previous year, the DAX registered an increase of 3.5% and the Dow Jones as much as 7.2%.

## **b. Development of the pharmaceutical and biotechnology industry**

The pharmaceutical and biotechnology industry generally remains to be marked by steadily increasing costs for pharmaceutical development particularly due to increasingly extensive and challenging regulatory requirements as well as the strong trend to personalized therapies which in turn are faced by increasingly lower income e.g. due to higher competition and price pressure from governmental regulation.<sup>6</sup> In constant prices, average development costs of a new drug increased by approx. 5% from 2018 to 2019 on average for big pharma companies while peak sales potential decreased by close to 8% in 2019 and reached the lowest value of the past ten years.<sup>7</sup>

In 2020, the Covid-19 pandemic additionally had a massive impact on the pharmaceutical and biotechnology industry in particular. In addition to the numerous development projects for vaccines against the virus, the pandemic has above all massively accelerated the pace of

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<sup>1</sup> Federal Statistical Office: Volkswirtschaftliche Gesamtrechnungen 2020: Wichtige Zusammenhänge im Überblick; 01 March 2021.

<sup>2</sup> Commerzbank Research: Economic and Market Monitor – Chart Book February 2021.

<sup>3</sup> International Monetary Fund: World Economic Outlook Update, January 2021.

<sup>4</sup> International Monetary Fund: World Economic Outlook Update, January 2021.

<sup>5</sup> International Monetary Fund: World Economic Outlook Update, January 2021.

<sup>6</sup> DeloitteHealth: A new future for R&D? Measuring the return from pharmaceutical innovation, 2021; Deloitte Insights: 2020 global life sciences outlook, 2020; Ernst & Young: 2020 EY M&A Firepower report: How will deals done now deliver what the health ecosystem needs next?, 2019; PwC Health Research Institute: Top health industry issues of 2020: Will digital start to show an ROI?, 2019.

<sup>7</sup> DeloitteHealth: A new future for R&D? Measuring the return from pharmaceutical innovation, 2021.

innovation and digitization in healthcare systems, confronting the industry with major challenges.<sup>8</sup>

The consolidation pressure resulting from these trends was reflected in the global transaction volume in the pharmaceutical industry in 2020 despite the pandemic. While not reaching the volume of the record year 2019 of USD 306 billion, the transaction volume of USD 159 billion in 2020 was roughly on par with 2017 and 2018, with 2020 showing a clear trend towards alliances and smaller transactions that increase the therapeutic focus: By the end of November 2020, 261 partnerships had been agreed in the pharma and biotech sector for upfront and milestone payments of up to nearly USD 140 billion.<sup>9</sup>

The financing environment in the pharma and biotech sector was very good in 2020, with approximately USD 9.6 billion raised globally through IPOs; an increase of around 15% compared to the previous all-time high in 2018.<sup>10</sup> Also in Germany, a new high was reached in 2020, which was also largely driven by the development of vaccines against the Coronavirus: German biotech companies were able to raise funds totaling more than EUR 3 billion.<sup>11</sup>

The valuation of pharmaceutical companies also reflects a positive picture for the sector, which, following the share price losses observed here as well at the beginning of the year, appears to have benefited from the pandemic overall, at least to date, and to have continued the trend of rising valuations also observed in 2019 irrespective of the pandemic in 2020: The DAXsubsector Biotechnology Index increased by 36.1% in 2020 compared in comparison to the prior year's end closing value; the NASDAQ Biotechnology Index closed 2020 with a plus of 25.7%.

The significant competitive drivers in the pharmaceutical and biotechnology industry are likely to also persist in 2021 and to maintain consolidation pressure. In addition to intensifying competition and continuously increasing challenges for the industry, mainly in regard to digitization and individualization of therapies – not least pushed by the Covid-19 pandemic<sup>12</sup> –, companies with a clear therapeutic focus are often more successful than their less focused competitors.<sup>13</sup> Under consideration of the availability of significant amounts of funds, an increasing concentration on therapeutic focus as well as the central banks' continuing (and increasing as well as even more pushed by the pandemic) loose monetary policy, a high acquisition and transaction volume worldwide can be expected in the pharmaceutical industry also in 2021.<sup>14</sup> However, it remains to be seen to what extent the further development of the Covid-19 pandemic in particular will have an impact on the industry in 2021 (stimulating, but possibly also dampening).

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<sup>8</sup> Deloitte Insights: 2021 global health care outlook: Accelerating industry change, 2021.

<sup>9</sup> Ernst & Young: How the pandemic has changed the rules for life sciences deals, January 2021.

<sup>10</sup> Morrison, C. (2019): Boom: 2018's biotech IPOs, in: Nature Reviews Drug Discovery, Vol. 18, January 2019; Ernst & Young: How the pandemic has changed the rules for life sciences deals, January 2021.

<sup>11</sup> BIO Deutschland: Deutsche Biotechnologiebranche während der Pandemie – Rekordfinanzierung und hohe Erwartungen an die Politik; press release from 14 January 2021.

<sup>12</sup> DeloitteHealth: A new future for R&D? Measuring the return from pharmaceutical innovation, 2021.

<sup>13</sup> Ernst & Young: 2020 EY M&A Firepower report: How will deals done now deliver what the health ecosystem needs next?, 2019.

<sup>14</sup> Ernst & Young: How the pandemic has changed the rules for life sciences deals, January 2021.

## 2. 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, GIAPREZA® and XERAVA®.

### Byfavo® (remimazolam besylate)

Byfavo® is an ultra-short-acting intravenous benzodiazepine sedative/anesthetic. In the human body, remimazolam is rapidly metabolized to an inactive metabolite mainly 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. and China for procedural sedation and in Japan and South Korea for general anesthesia. In Europe, a final decision on the market approval application (MAA) by the EMA for procedural sedation is expected shortly after the CHMP of the EMA adopted a positive opinion recommending the approval of Byfavo® (remimazolam) for procedural sedation in adult patients in January 2021.

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 (Acacia), 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, and in South Korea (brand name BYFAVO™) and Southeast Asia with Hana Pharm and TTY Biopharm in Taiwan. For other markets except Western Europe, remimazolam is available for licensing.

### Procedural Sedation Market (U.S.<sup>15</sup> + Europe)

For the U.S., local licensee Acacia estimates that currently more than 40 million procedural sedations are performed annually. The growth of the procedural sedation market in the U.S. has been driven for many years by the increase in medical procedures involving procedural sedations, such as colonoscopies, as well as by an increasing general demand for screening. According to Acacia, approximately 25 million colonoscopies and endoscopies are performed annually in the United States. Acacia states that more than 80% of colonoscopies and endoscopies are performed in the presence of personnel trained in anesthesia. The wholesale acquisition cost (WAC) price is reported by Acacia to be USD 39 per dose. Overall, the total market in procedural sedation is more than USD 1.5 billion per year, according to Acacia.

In Europe, based on its own projections for procedural sedation, PAION currently estimates an annual peak sales potential of approx. EUR 50 million to approx. EUR 60 million. In contrast to the U.S. market which has a large freestanding ambulatory surgery healthcare infrastructure, procedural sedation in Europe is mainly a hospital-based activity where anesthesiologists have the overall responsibility for the sedation of patients. Important users, however, are also e.g. gastroenterologists. This entails a high potential for synergies with the

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<sup>15</sup> Source: Acacia Pharma: Non-Confidential Corporate Presentation January 2021.

planned commercialization of remimazolam for use in general anesthesia. In addition, the area of day surgery is also growing in Europe, so that PAION expects a steady growth of procedural sedation procedures in Europe as well. One driver of this development is the establishment and further spread of colorectal cancer screening (diagnostic colonoscopies).

### **General Anesthesia Market (Europe)**

Based on publicly available European procedure statistics and market research, PAION estimates that in Europe, approximately 29 million procedures requiring general anesthesia are performed each year. Of these, approximately 10 million are performed for high-risk patients (American Society of Anesthesiologists (“ASA”) classifications III or higher) who are particularly prone to hemodynamic instability. Approx. 55% of all anesthetics are balanced anesthesia (a combination of intravenous agents for induction and volatile gases for maintenance), approx. 20% are total intravenous anesthetics (“TIVA”) using propofol, and the remaining approx. 25% include regional anesthesia (for example epidural administration). Based on PAION’s market research, in Europe, the current standard-of-care drugs for general anesthesia are propofol (especially for induction) and narcotic gases; mostly used in conjunction with intravenous opioids.

PAION anticipates an increasing number and complexity of medical interventions requiring induction and maintenance of anesthesia in Europe in the future particularly driven by an ongoing aging of the population and the progress of surgical techniques. General anesthesia is more frequently offered to elderly patients than in the past, therefore the choice of a tailored anesthesia is made depending on the type of surgery, the underlying disease, and an assessment of the general physical health of the patient, including co-morbidities.

Accordingly, PAION believes that in Europe the demand for safer agents with low respiratory and cardio-depressive effects will increase over the coming years, creating opportunities for anesthetics with an enhanced safety profile such as remimazolam, even at higher prices compared to existing generic drugs. In Europe, based on its own projections, PAION currently estimates an annual peak sales potential of approx. EUR 100 million for general anesthesia.

In adults, myocardial injury during noncardiac surgery (MINS) is the most common cardiovascular complication associated with such surgery. Investigations conclude that MINS occurs in about 8% of the approximately 200 million patients yearly worldwide and leads to an increased morbidity. Approximately 10% of patients suffering such injury die within 30 days after surgery. The suspected cause of this is, inter alia, a (too) low blood pressure and a concomitant temporary undersupply of the heart muscle with oxygen during the procedure.<sup>16</sup> Based on the safety data available to date, remimazolam could contribute significantly to reducing this mortality rate by reducing intraoperative blood pressure drops.

### **Intensive Care Unit (ICU) Sedation Market**

Based on available information from 2012 published in Critical Care Medicine which estimates average days of care in ICUs per year in the U.S., and journal articles published in the Intensive Care Medicine in 2012, which records, among others, the volume of ICU admissions per year and

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<sup>16</sup> Khan, J. et al. (2014): Myocardial injury after noncardiac surgery, *Current Opinion in Cardiology*, 2014 Jul, 29(4):307-11; Abbott, T. E. F. et al. (2019): Depth of Anesthesia and Postoperative Delirium, in *JAMA*, 2019, 321(5):459-460.

the number of total adult beds in various countries in the EU, PAION estimates that there are at least 14 million ICU patient days requiring ICU sedation in the U.S. and Europe combined per year. A publication published in 2013 on the basis of eight EU countries comes to an extrapolated figure of 17.5 million patient days for the EU alone.<sup>17</sup> PAION expects these numbers to increase in the years to come, driven by demand from the aging population both in the USA and in Europe. PAION believes that such development, in turn, will foster demand for safer agents such as remimazolam, given the fact that elderly patients are much more likely to suffer from systemic health problems.

## 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.

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<sup>17</sup> Bittner et al. (2013): How is intensive care reimbursed? A review of eight European countries; *Annals of Intensive Care*, 3:37.

### 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. Preclinical data had suggested and clinical data confirmed that a better hemodynamic stability can be reached with remimazolam than with propofol.

The clinical development program completed 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 intensive care units (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 preclinical 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 further trials may be performed with increasingly younger children. The first of these trials in the indication procedural sedation is planned to be conducted together with the U.S. licensee Acacia and is currently in preparation.

### Regulatory activities

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

Procedural sedation: PAION submitted an MAA for procedural sedation to the EMA in November 2019. On 28 January 2021, the CHMP of the EMA adopted a positive opinion recommending the approval of Byfavo® (remimazolam) for procedural sedation in adult patients.

The European Commission will review the CHMP recommendation and a final decision on the MAA for Byfavo® in the EU (including European Economic Area (EEA) countries) is expected shortly. The UK Medicines & Healthcare products Regulatory Agency (MHRA) will also review the positive opinion for a potential approval in the UK.

General anesthesia: Based on the positive results in the Phase III trial in general anesthesia and assuming 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.

### Compassionate Use

Due to the Covid-19 pandemic, shortages of anesthetics emerged. As a result, PAION had been approached by one of its Phase III trial centers – San Raffaele Hospital in Milan, Italy – as well as Belgian authorities regarding the compassionate use of remimazolam. Remimazolam has been approved for compassionate use with certain restrictions at the San Raffaele Hospital as well as in Belgium, and PAION is providing product free of charge under these programs. Meanwhile, the planned five patients at San Raffaele Hospital were treated with remimazolam without complications.

### Commercial activities

With the addition of two more hospital products to its commercial portfolio after the balance sheet date, PAION has begun to establish its own commercial structures in certain core countries in Western Europe including Germany, UK, Netherlands, Denmark with more to follow to market GIAPREZA® and XERAVA® together with Byfavo® following its expected market approval in Europe. PAION plans to launch all three products in a staggered manner by country beginning in the second half of 2021 so that by the end of 2022, launches will have been conducted in all selected European markets.

### Partner activities

In the U.S., the U.S. Food and Drug Administration (FDA) granted marketing approval for remimazolam (trade name BYFAVO™) for the induction and maintenance of procedural sedation in adults undergoing procedures lasting 30 minutes or less on 2 July 2020. BYFAVO™ received its Schedule IV designation from the U.S. Drug Enforcement Administration (DEA) on 6 October

2020, finalizing the approval process and clearing the way for final packaging and shipping to the U.S. Market launch was then announced by licensee Acacia on 28 January 2021. U.S. rights to develop and commercialize remimazolam in general anesthesia were 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 is talking to Acacia and other parties to execute a new license for the general anesthesia indication in the U.S.

In Japan, licensee Mundipharma received market approval for Anerem® (remimazolam) for general anesthesia in January 2020 and has successfully launched Anerem® in mid-2020 with first commercial product sales. By the end of 2020, Mundipharma reported they had about 400 hospitals opening account. According to Mundipharma, this exceeded their original target by close to 100%. In addition, they are supporting Investigator Initiated Trials. Mundipharma plans to start a Phase II/III trial in the first half of 2021 to evaluate the efficacy and safety of remimazolam in Japanese patients undergoing gastrointestinal endoscopy. Following approval in general anesthesia, a further indication is now being developed in Japan.

In China, licensee Yichang Humanwell received market approval for Ruima® (remimazolam) in procedural sedation in July 2020 and successfully launched Ruima® in the third quarter 2020 as well. By the end of 2020, Yichang Humanwell reported having launched Ruima® to hospitals in 31 Chinese provinces. In July 2020, Yichang Humanwell had initiated a Phase III trial in general anesthesia. The Phase III trial was a multicentre, single-blind randomized comparative clinical trial of efficacy and safety of remimazolam versus propofol in induction and maintenance of general anesthesia in 516 elective surgery patients. Patient enrolment was completed on schedule in December 2020 and headline data are expected in mid-2021.

In South Korea, licensee Hana Pharm received market approval for BYFAVO™ (remimazolam) in general anesthesia in January 2021 and plans to begin marketing in South Korea mid-2021. In January 2020, PAION and Hana Pharm extended their license agreement for remimazolam to include Southeast Asia (Indonesia, Malaysia, Philippines, Singapore, Thailand, Vietnam). Hana Pharm conducts the regulatory process in each country with local partners.

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 shortly.

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 submitted and/or approved:

Licensee, Country	Indication	Market approval	Royalty rate
Mundipharma, Japan	General anesthesia	Granted 01/2020	15.5%
Yichang Humanwell, China	Procedural sedation	Granted 07/2020	5%
Acacia Pharma, U.S.	Procedural sedation	Granted 07/2020	20–25% <sup>1</sup>
Hana Pharm, S. Korea	General anesthesia	Granted 01/2021	10%
PAION, EU	Procedural sedation	Expected H1/2021	-

1. Subject to adjustments under specific circumstances, but not below 15% of net sales

Remimazolam sales in Japan and China combined have reached EUR 2.6 million in 2020. This generally translates to EUR 0.3 million royalties based on the agreed royalty rates, of which EUR 0.1 million could be recorded as revenues in fiscal year 2020. After the balance sheet date, PAION and Mundipharma have agreed on an amendment of the royalty calculation. A corresponding contract amendment is currently being put in place based on which the remaining EUR 0.2 million royalties will be recognized as revenues in fiscal year 2021.

### GIAPREZA® and XERAVA®

In January 2021, PAION AG and PAION Deutschland GmbH entered into an exclusive license agreement with La Jolla Pharmaceutical Company 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.

La Jolla is entitled to an upfront payment in the amount of USD 22.5 million. In addition, 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 but PAION is examining whether this study is required and will coordinate this in discussion with the EMA.

### GIAPREZA® (angiotensin II)

GIAPREZA® for injection is a vasoconstrictor and FDA-approved 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%).

Prescribing information for GIAPREZA® is available at [www.giapreza.com](http://www.giapreza.com). 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 currently plans the European commercial launch of GIAPREZA® in the second half of 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. "Complicated" means that the infection is difficult to treat because it has spread to the abdomen.

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 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 (another antibiotic). 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. Prescribing information for XERAVA® is available at [www.xerava.com](http://www.xerava.com).

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.

### Supply chain activities

In the reporting period, PAION continued to build up the supply chain to ensure the regular supply of remimazolam API to licensees as well as of finished remimazolam drug product for PAION's own commercialization. Activities included setting up and establishing the structures and processes as well as obtaining necessary pharmaceutical permits. On this basis, the regular supply of remimazolam API to licensees can now take place as planned.

### 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 loan is available until June 2021 and can be drawn down in three tranches. The first two tranches amounting to EUR 12.5 million in total were drawn down in February 2021 after the balance sheet date. The third tranche in the amount of EUR 7.5 million will be drawn down after completion of the currently ongoing capital increase with subscription rights. Each tranche has a term of five years and is repaid starting in the 39<sup>th</sup> month after disbursement. Interest comprises a current cash interest component of 6% to 7.5%, a deferred bullet interest component of 3% to 5% and a performance-related component.

In August 2019, in addition, PAION entered into an agreement with a U.S. institutional investor for the issue convertible notes in the amount of up to EUR 15 million, divided into up to three tranches. The first tranche of convertible notes with a total nominal amount of EUR 5 million was issued to the investor in September 2019 under exclusion of subscription rights. The convertible notes were fully converted into a total of 2,363,350 new PAION shares until 8 July 2020. A further issuance of convertible bonds under this agreement is not planned.

On 19 March 2021, a capital increase with subscription rights with planned gross proceeds of EUR 7.8 million was resolved, the completion of which is planned for 9 April 2021. By means of this capital increase, the share capital of PAION AG is planned to be increased by

EUR 5,095,499.00 from EUR 66,241,493.00 to EUR 71,336,992.00 by utilization of the Authorized Capital 2020 by issuing 5,095,499 new shares. After the rights issue, the Authorized Capital 2020 will amount to EUR 21,039,429.00.

### 3. Net assets, financial position and results of operations

#### a. Results of operations

	2020 KEUR	2019 KEUR	Change in result KEUR
Revenues	19,655	8,000	11,655
<b>Gross Profit</b>	<b>19,655</b>	<b>8,000</b>	<b>11,655</b>
Research and development	-10,288	-13,099	2,811
General administrative and selling	-7,523	-5,023	-2,500
Other income (expenses)	-261	796	-1,057
<b>Operating expenses</b>	<b>-18,072</b>	<b>-17,326</b>	<b>-746</b>
<b>Operating result</b>	<b>1,583</b>	<b>-9,326</b>	<b>10,909</b>
Financial result	-152	-122	-30
Income taxes	791	2,432	-1,641
<b>Net result</b>	<b>2,222</b>	<b>-7,016</b>	<b>9,238</b>

**Revenues** recognized in the reporting period amounted to KEUR 19,655 and primarily resulted from milestone payments in connection with the market approvals of remimazolam in the U.S. and Japan as well as the license extension signed with Hana Pharm in January 2020 to include six additional countries in Southeast Asia. Revenues in the previous year related to the remimazolam license agreements with Cosmo and R-Pharm.

**Research and development expenses** amounted to KEUR 10,288 and mainly relate to the EU Phase III trial in general anesthesia completed in the reporting period. The decrease of KEUR 2,811 compared to the prior year mainly results from lower expenses for this study as well as lower expenses for production development.

**General administrative and selling expenses** amounted to KEUR 7,523 and increased by KEUR 2,500 compared to the previous year. Administrative expenses decreased by KEUR 255 to KEUR 3,177 while selling expenses increased by KEUR 2,755 to KEUR 4,346. The increase of

selling expenses is mainly in connection with pre-commercial activities and the build-up of a supply chain for remimazolam. The decrease of administrative expenses mainly results from expenses recognized in the prior year in connection with the conclusion of a loan agreement with the EIB and the issue of convertible notes that were not incurred in the reporting period.

**Other income (expenses) (net)** primarily results from recharges to licensees and obligations towards licensees.

The **financial result** amounts to KEUR -152 and decreased by KEUR 30 compared to the previous year. This is mainly attributable to higher negative interest on bank balances.

**Income taxes** of the fiscal year 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 is mainly due to a cap of the claim based on the net result of PAION UK Ltd.

PAION closes fiscal year 2020 with a **net profit** of KEUR 2,222 after a net loss of KEUR 7,016 in the previous year.

#### b. Net assets

	31 Dec. 2020 KEUR	31 Dec. 2019 KEUR	Change KEUR
Non-current assets	1,872	2,262	-390
Current assets	26,278	22,650	3,628
<b>Assets</b>	<b>28,150</b>	<b>24,912</b>	<b>3,238</b>
Equity	21,290	14,732	6,558
Non-current liabilities	15	26	-11
Current liabilities	6,845	10,154	-3,309
<b>Equity and liabilities</b>	<b>28,150</b>	<b>24,912</b>	<b>3,238</b>

**Non-current assets** mainly comprise the book value of the development project remimazolam (KEUR 1,808; 31 December 2019: KEUR 2,096) resulting from the purchase price allocation in the course of the CeNeS acquisition in 2008 reduced by scheduled amortization.

Compared to 31 December 2019, **current assets** increased by KEUR 3,628 to KEUR 26,278 and comprised cash and cash equivalents (KEUR 19,666), prepaid expenses and other assets (KEUR 4,338), inventories (KEUR 1,774) as well as trade receivables (KEUR 500) as of 31 December 2020. The increase of KEUR 3,628 compared to 31 December 2019 is attributable to an increase of cash and cash equivalents by KEUR 879, of prepaid expenses and other assets by KEUR 975 and of inventories by KEUR 1,774. The increase of prepaid expenses and other assets mainly results from the tax claims for reimbursement of parts of the research

and development expenses from the British tax authorities for the reporting period as well as higher VAT refund claims compared to 31 December 2019.

The increase in **equity** by KEUR 6,558 compared to 31 December 2019 mainly results from the net profit of the year and the issue of a total of 1,955,907 new shares from the conversion of the remaining part of convertible notes issued in the prior year. The equity ratio amounts to 75.6% as of 31 December 2020 (31 December 2019: 59.1%).

**Non-current liabilities** entirely result from lease liabilities.

As of 31 December 2020, **current liabilities** comprise trade payables, provisions, lease liabilities and other liabilities. The decrease of KEUR 3,309 to KEUR 6,845 mainly on the one hand results from the conversion of the remaining convertible notes with a book value of KEUR 4,354 as of 31 December 2019 issued in the prior year into shares of PAION AG in the reporting period, as well as from an increase of provisions by KEUR 1,936 to KEUR 2,206 due to higher bonuses and obligations towards licensees on the other hand. Moreover, trade payables decreased by KEUR 936 to KEUR 3,907 as planned primarily in the course of completion of the EU Phase III study.

#### c. Financial position

Compared to 31 December 2019, **cash and cash equivalents** increased by KEUR 879 to KEUR 19,666 as of 31 December 2020. The change in cash and cash equivalents stems from the following areas:

	2020 KEUR	2019 KEUR	Change KEUR
Cash flow from operating activities	906	-2,847	3,753
Cash flow from investing activities	-14	-14	0
Cash flow from financing activities	-24	4,414	-4,438
Effect of exchange rate changes	11	7	4
<b>Change in cash and cash equivalents</b>	<b>879</b>	<b>1,560</b>	<b>-681</b>

The **cash flow from operating activities** mainly results from the net profit of KEUR 2,222 as well as changes in the working capital.

The **cash flow from financing activities** results from the exercise of stock options (KEUR 26) and the principal portion of lease payments (KEUR -50).

#### d. Overall appraisal

The net result of EUR 2.2 million is within the forecast range of approx. EUR -1 million to approx. EUR 3 million projected for fiscal year 2020 in the previous year.

Recognized revenues of EUR 19.7 million meet the amount of approx. EUR 20 million forecasted per prior year for 2020 since particularly the milestones underlying the planning were mostly achieved.

General administrative and selling expenses of EUR 7.5 million are within the range of approx. EUR 7 million to approx. EUR 9 million forecasted per prior year for 2020 as pre-commercial activities and the build-up of a supply chain for remimazolam were continued as planned.

With EUR 10.3 million, research and development expenses are also within the forecast range of approx. EUR 10 million to approx. EUR 12 million projected for fiscal year 2020 in the previous year.

Tax income of EUR 0.8 million is slightly above the prior-year forecast for 2020 of up to EUR 0.5 million since the commencement date of a change in calculation and capping rules already enacted was postponed by one year at short notice during the reporting period.

In total, results of operations, net assets and financial position have evolved as expected in the reporting period.

Since PAION's products Byfavo®, GIAPREZA® and XERAVA® are not being marketed by PAION yet and commercial structures are still being established in Europe for this purpose, PAION will (continue to) incur losses for the time being.

## Headcount

In fiscal year 2020, PAION had an average of 43 employees (previous year: 44 employees). Of these 43 employees, 30 worked in development and 13 in administration and sales. PAION UK Group had an average headcount of ten employees. As of 31 December 2020, the headcount was 43 (31 December 2019: 45).

## 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 effectively prevent the disease from currently spreading forms of the virus; on the other hand, the number of infections is nevertheless increasing (significantly) again in many places (so-called "third 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 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.

To date, the pandemic has only had a minor 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 not yet commercialized its own products and no regular supply of commercially manufactured product has happened yet, the pandemic has not had any direct impact in this respect either. Operationally, the pandemic led to an earlier completion of patient recruitment for the EU Phase III study in general anesthesia. However, as a large proportion of the originally planned number of patients had already been recruited for the study by this time, there were no significant effects on the study.

Overall, the direct impact of the pandemic on the PAION Group's net assets, financial position and results of operations has been minor to date. Based on the factual situation at the time of this report, only minor direct effects on the operating business are assumed for the future, so that in particular no planning adjustments due to the Covid-19 pandemic arise at the present time. However, any impact of the pandemic on the general financing environment could limit PAION's ability to obtain necessary financing. PAION does not expect the pandemic to have a material impact on the planned commercialization of Byfavo®, GIAPREZA® and XERAVA® in the second half of 2021. However, it is currently unknown in how far particularly our licensees' business activities will be restrained by the pandemic potentially leading to revenues from milestones or royalties being recognized not at all, in a lower amount or delayed.

## Remuneration report

### I. Management Board

The remuneration paid to Management Board members comprises fixed annual remuneration, a variable bonus, a long-term performance-based remuneration component in the form of stock options as well as other remuneration in terms of company car remuneration, insurance premiums and pension contributions. All stock options granted to Management Board members so far have a ten-year term. The variable bonus depends on the achievement of long-term and sustainable financial and strategic corporate goals which are determined by the Supervisory Board at the beginning of each fiscal year. The level of goal achievement and the related amount of the variable remuneration is assessed and determined by the Supervisory Board. Bonuses are not subject to a minimum but are limited to a maximum amount and are paid depending on individual goal achievement. Moreover, the Supervisory Board is entitled to grant special remuneration to individual members of the Management Board in exceptional cases based on dutiful discretion.

The compensation as Management Board member covers also the managing director function at the subsidiaries.

From the Stock Option Plan 2010 approved by the Annual General Meeting on 19 May 2010, a total of 324,000 stock options were granted to acting Management Board members at the time of the grant. The Supervisory Board determined the number of stock options to be allocated

to the Management Board. The four-year waiting period before stock options can be exercised acts as a long-term incentive to increase the company's value. The exercise price of stock options granted to current Management Board members is EUR 1.31 per stock option and is based on the average price of the shares in a certain time period before the allocation and potentially necessary adjustments in accordance with the terms of the stock option plan. As of 31 December 2020, the exercise hurdle was EUR 2.43.

From the Stock Option Plan 2014 approved by the Annual General Meeting on 21 May 2014, a total of 333,000 stock options were granted to acting Management Board members at the time of the grant. The Supervisory Board determined the number of stock options to be allocated to the Management Board. The four-year waiting period before stock options can be exercised acts as a long-term incentive to increase the company's value. The exercise price of stock options granted to current Management Board members is EUR 1.99 or EUR 2.30 per stock option, depending on the date of issue of the stock options, and is based on the average price of the shares in a certain time period before the allocation and potentially necessary adjustments in accordance with the terms of the stock option plan. As of 31 December 2020, the exercise hurdle was EUR 2.44 or EUR 2.98, depending on the grant date.

From the Stock Option Plan 2016 approved by the Annual General Meeting on 25 May 2016, a total of 378,000 stock options were granted to acting Management Board members at the time of the grant. The Supervisory Board determined the number of stock options to be allocated to the Management Board. The four-year waiting period before stock options can be exercised acts as a long-term incentive to increase the company's value. The exercise price of stock options granted to current Management Board members is EUR 2.00 or EUR 2.25 per stock option, depending on the date of issue of the stock options, and is based on the average price of the shares in a certain time period before the allocation and potentially necessary adjustments in accordance with the terms of the stock option plan. As of 31 December 2020, the exercise hurdle was EUR 2.08 or EUR 2.53, depending on the grant date.

From the Stock Option Plan 2018 approved by the Annual General Meeting on 23 May 2018, a total of 391,500 stock options were granted to acting Management Board members at the time of the grant. The Supervisory Board determined the number of stock options to be allocated to the Management Board. The four-year waiting period before stock options can be exercised acts as a long-term incentive to increase the company's value. The exercise price of stock options granted to current Management Board members is EUR 2.00 per stock option, depending on the date of issue of the stock options, and is based on the average price of the shares in a certain time period before the allocation and potentially necessary adjustments in accordance with the terms of the stock option plan. As of 31 December 2020, the exercise hurdle was EUR 2.08.

The stock option agreements with the individual members of the Management Board limit the numbers of stock options which can be granted. With the exception of minimum increases in value, no restrictions have been imposed in respect of the performance of the stock options, which is directly linked to PAION's share price performance.

The remuneration of the individual Management Board members in fiscal year 2020 can be gathered from the following table:

Compensation in EUR	Dr. James Phillips CEO		Abdelghani Omari CFO	
	2019	2020	2019	2020
Fixed compensation	128,952 *	305,000	180,000	202,500
Other remuneration	4,977	15,712	15,127	15,127
<b>Total</b>	<b>133,928</b>	<b>320,712</b>	<b>195,127</b>	<b>217,627</b>
One-year variable compensation	0	102,000	36,000	85,000
Multi-year variable compensation				
Stock Option Plan 2016 - Grant 2020 ** (Waiting period 2020 to 2024)	0	100,125	0	0
Stock Option Plan 2018 – Grant 2020 ** (Waiting period 2020 bis 2024)	0	124,875	0	112,500
<b>Total</b>	<b>133,928</b>	<b>647,712</b>	<b>231,127</b>	<b>415,127</b>
Service cost	0	0	0	0
<b>Total remuneration</b>	<b>133,928</b>	<b>647,712</b>	<b>231,127</b>	<b>415,127</b>

\*) Dr. Phillips' prior-year fixed compensation relates to the time period since joining the Management Board and includes a signing bonus for lost compensation from his previous employment as well as a yearly bonus which was not variable for 2019 and is therefore disclosed as part of the fixed compensation.

\*\*) Applicable fair value at the time of issuance, calculated using the Black/Scholes option pricing model

The "other remuneration" item contains company car remuneration, insurance premiums and pension contributions paid by PAION.

Management Board remuneration in fiscal year 2020 amounted to KEUR 1,394 in total (previous year: KEUR 956) and is composed as follows:

In EUR	2020	2019
Fixed remuneration	707,500	754,924
Other remuneration	45,967	74,277
<b>Total non-performance based remuneration</b>	<b>753,467</b>	<b>829,201</b>
Short-term variable remuneration	246,500	126,611
<b>Total short-term remuneration</b>	<b>999,967</b>	<b>955,812</b>
Long-term variable remuneration	393,750	0
<b>Total long-term remuneration</b>	<b>393,750</b>	<b>0</b>
<b>Total remuneration</b>	<b>1,393,717</b>	<b>955,812</b>

The increase of total remuneration mainly results from the grant of stock options in the reporting period while no stock options were granted in the prior year.

**Dr. Jürgen Beck**  
**CDO**  
 until 31 December 2020

<b>2019</b>	<b>2020</b>
200,000	200,000
15,127	15,127
<b>215,127</b>	<b>215,127</b>
28,000	59,500
0	0
0	56,250
<b>243,127</b>	<b>330,877</b>
0	0
<b>243,127</b>	<b>330,877</b>

Current Management Board members held the following stock options as of 31 December 2020:

Status of non-exercised stock options as of 31 December 2020:		Dr. James Phillips	Abdelghani Omari
Stock options 2010	No.	0	80,000
Stock options 2010 - fair value*	EUR	-	133,600
Stock options 2014	No.	0	111,000
Stock options 2014 - fair value*	EUR	-	119,325
Stock options 2016	No.	133,500	100,000
Stock options 2016 - fair value*	EUR	100,125	102,000
Stock options 2018	No.	166,500	150,000
Stock options 2018 - fair value*	EUR	124,875	112,500

\* Applicable fair value at the time of issuance, calculated using the Black/Scholes option pricing model

In the event of a change of control and the termination of employment within a certain period after the change of control, the Management Board members are each entitled to contractual termination benefits, which correspond to an amount of two annual fixed basic remunerations. For Dr. Phillips, a claim to termination benefits in connection with a change of control can only be exerted if the change of control also entails a significant change in business strategy, in responsibilities or in regard to the company domicile.

In the event of early termination of the employment relationship relating to any other circumstance than a change of control, potential termination benefits must not exceed the amount of two annual fixed basic remunerations and must not compensate more than the remaining time of the employment contract. The employment contracts of Management Board members do not provide for transitional benefits upon expiry.

The Supervisory Board is entitled to reduce the total compensation of the Management Board members to the appropriate level according to the applicable provisions under stock corporation law in case of a significant degradation of the company's position if the continuation of granting the compensation were inequitable for the company.

Pursuant to the terms of the Stock Option Plans 2010, 2014, 2016 and 2018, in the event of a change of control, for all stock options issued to Management Board members for which the waiting period has not expired yet at the date of the change of control, the entitlement to subscribe to shares is converted into an entitlement to a cash settlement based on the share price on the day the controlling acquisition comes into effect. The corresponding stock options lapse. The company may choose to grant listed shares in the acquiring company instead of the cash settlement.

## 2. Supervisory Board

Supervisory Board remuneration comprises basic remuneration and per-meeting fees. The members of the Supervisory Board do not receive performance-based remuneration. The Chairman of the Supervisory Board receives twice the basic remuneration and per-meeting fee, his deputy receives one-and-a-half times these amounts. The per-meeting fee is paid for a maximum of five meetings per year. Supervisory Board remuneration for fiscal year 2020 can be gathered from the following table:

	<b>Basic remuneration EUR</b>	<b>Per-meeting fees EUR</b>	<b>Total EUR</b>
Dr. Jörg Spiekerkötter	40,000	10,000	50,000
Dr. Karin Dorrepaal	30,000	7,500	37,500
Dr. Dr. Irina Antonijevic	20,000	5,000	25,000
Dr. Hans Christoph Tanner	20,000	5,000	25,000
Dr. Markus Leyck Dieken	20,000	5,000	25,000

Supervisory Board remuneration in fiscal year 2020 amounted to KEUR 163. In the previous year the remuneration amounted to KEUR 162.

## Disclosures pursuant to section 315 a (I) HGB and explanatory report

### **Composition of subscribed capital**

As of 31 December 2020, PAION AG had a subscribed capital of EUR 66,241,493.00, divided into 66,241,493 no-par value shares, each representing a notional share in the share capital of EUR 1.00. The shares are issued to the bearer and are fully paid in. Shareholders are not entitled to demand share certificates for their shares under Art. 6 (2) of the Articles of Incorporation. All shares carry the same rights and duties. Each share carries the right to one vote at the Annual General Meeting and also forms the basis of the holder's share in profit. More information on the individual rights and duties of shareholders can be found in the German Stock Corporation Act (*Aktiengesetz*, AktG), in particular Sections 12, 53a *et seqq.*, 118 *et seqq.* and 186.

### **Restrictions relating to voting rights or the transfer of shares**

Pursuant to German legislation and the Articles of Incorporation of PAION AG, no restrictions are imposed on the voting rights or transferability of the shares. The Management Board of PAION AG is also not aware of any voting rights or share transfer restrictions at shareholder level.

### **Equity interests exceeding 10% of voting rights**

The German Securities Trading Act (*Wertpapierhandelsgesetz*, WpHG) stipulates that any shareholder who achieves, exceeds or falls short of specific shares in the voting rights in the company through the purchase or sale of shares or by other means, must notify the company and the German Federal Financial Supervisory Authority (*Bundesanstalt für Finanzdienstleistungsaufsicht*, BaFin) accordingly. The lowest threshold for this reporting obligation is 3%. Direct or indirect shares in the company's capital that equaled or exceeded 10% of the voting rights as of 31 December 2020 were not reported to the company.

### **Shares with special rights conferring powers of control**

The bearers of PAION AG shares have not been granted any special rights by the company, in particular with regard to powers of control.

### **Type of control of voting rights when employees are shareholders and do not directly exercise their control rights**

The share options issued to employees and members of the Management Board can be exercised once the defined waiting period has expired and the other conditions have been met by the beneficiaries. Shares acquired in this way give the beneficiaries the same rights as other shareholders and are not subject to any voting rights control.

### **Legal provisions and provisions of the Articles of Incorporation on the appointment and removal of members of the Management Board and amendments to the Articles of Incorporation**

Members of the Management Board are appointed and removed in accordance with Sections 84 and 85 AktG and the supplementary provisions of the Supervisory Board's rules of procedure, which stipulate an age limit of 65 years for Management Board members. Pursuant to Section 84 AktG, members of the Management Board can be elected for a maximum of five years by the Supervisory Board. Re-appointments or extensions of the term of office for up to a maximum of

five years at a time are permissible. Pursuant to Art. 8 (1) of the Articles of Incorporation, the Management Board must comprise at least one member. The Supervisory Board determines the number of members on the Management Board. Furthermore, pursuant to Section 84 (2) AktG and Art. 8 (2) of the Articles of Incorporation, the Supervisory Board may appoint a member of the Management Board as CEO.

Amendments to the Articles of Incorporation are effected in accordance with Sections 179 and 133 AktG in conjunction with Art. 27 of PAION AG's Articles of Incorporation. The shareholder resolution required for any amendment to the Articles of Incorporation can, under PAION AG's Articles of Incorporation, be adopted by a simple majority of the share capital represented at the adoption of the resolution, provided this is permitted by law.

#### **Authority of the Management Board to issue or buy back shares**

The Management Board is authorized to increase the share capital on or prior to 26 May 2025, with the consent of the Supervisory Board, on one or more occasions, by up to EUR 26,134,928.00 in total by issuing up to 26,134,928 new no-par value bearer shares in return for cash contributions or contributions in kind (Authorized Capital 2020). For information on the partial utilization of the authorization after the balance sheet date, please refer to the Report on post-balance sheet date events. In the case of capital increases against contributions in kind, the Management Board may also exclude pre-emptive rights, subject to the Supervisory Board's consent. Shareholders must be granted pre-emptive rights if the capital is to be increased against payments in cash. The new shares may also be taken by one or more financial institutions on condition that they offer them to shareholders. The Management Board may, subject to the Supervisory Board's consent, exclude fractional shares from shareholders' pre-emptive rights. The Management Board is also authorized to exclude shareholders' pre-emptive rights, subject to the consent of the Supervisory Board, if the issue price of the new shares is not significantly less than the market price and the shares issued in return for cash contributions with pre-emptive rights excluded pursuant to Section 186 (3) Sentence 4 AktG do not exceed 10% of the share capital as of 27 May 2020 and the time of the exercise of the authorization. The Management Board is moreover authorized to exclude shareholders' pre-emptive rights, subject to the consent of the Supervisory Board, to the extent necessary to grant pre-emptive rights to holders of convertible bonds, participation rights or options as defined in Section 221 AktG. Due to the conversion of convertible notes into shares of PAION AG in the reporting period, the amount of Authorized Capital 2020 that can be used under exclusion of pre-emptive rights is EUR 6,149,011.00 as of 31 December 2020.

Furthermore, subject to the consent of the Supervisory Board, the Management Board is authorized to issue on or before 21 May 2024, on one or more occasions, bearer or registered convertible bonds, warrant-linked bonds, profit participation rights and/or participating bonds (or combinations thereof; hereinafter collectively "Bonds") of up to an aggregate of EUR 125,000,000.00 with or without a limited maturity period and to grant the holders or beneficiaries of the Bonds conversion rights or options to new shares in PAION AG with a proportionate amount of the share capital of up to EUR 26,200,000.00 in total (Conditional Capital 2019). Conditional Capital 2019 was utilized in an amount of EUR 2,363,350.00 in total by conversion of convertible notes issued under exclusion of pre-emptive rights in the prior year into shares of PAION AG and amounts to EUR 23,836,650.00 as of 31 December 2020. Conditional

Capital 2019 can be used under exclusion of pre-emptive rights in an amount of EUR 4,022,464.00 as of 31 December 2020. Furthermore, the company is authorized to issue 281,093 shares (Conditional Capital 2008 I), 700,000 shares (Conditional Capital 2010 I), 740,000 shares (Conditional Capital 2014), 840,000 shares (Conditional Capital 2016), 900,000 shares (Conditional Capital 2018 II) and 1,200,000 shares (Conditional Capital 2020) in connection with the Stock Option Plans 2008, 2010, 2014, 2016, 2018 and 2020.

**Material arrangements of the company dependent on a change in control in the event of a takeover bid**

In case of a change of control, the EIB has the right to terminate the existing loan agreement and to demand an early repayment of tranches drawn down.

**Compensation agreements entered into by the company with members of the Management Board and employees in the event of a takeover bid**

The terms of the Stock Option Plans 2008, 2010, 2014, 2016, 2018 and 2020 stipulate both for members of the Management Board and for employees that in case of a change of control, the waiting period for all options for which the waiting period has not expired yet at the date of the change of control, the entitlement to subscribe to shares is converted into an entitlement to a cash settlement based on the share price on the day the change of control comes into effect; the corresponding stock options lapse. The company may choose to grant listed shares in the acquiring company instead of the cash settlement.

For information on further existing compensation agreements with Management Board members, please refer to the comments in the section "Remuneration Report".

**Statement on Corporate Governance pursuant to Section 289 f HGB**

The Statement on Corporate Governance pursuant to Section 289 f HGB has been published on PAION AG's website (<http://www.paion.com/media-and-investors/corporate-governance/declaration-on-corporate-governance/>).

## Report on risks and opportunities

### I. Risk Management

As a specialty pharma company, PAION is exposed to the segment and market risks that are typically associated with the development and commercialization of pharmaceutical products. In accordance with the German Law on Control and Transparency in Business (Gesetz zur Kontrolle und Transparenz im Unternehmensbereich, KonTraG), PAION has implemented a group-wide comprehensive and effective risk management system which is integrated into the operating processes and flexibly adaptable to the changing environment. The task of the risk management system is to promote the conscious and responsible handling of risks, and to enable the early identification, monitoring, analysis, evaluation and management of future developments with inherent risks. Involving all management levels and project management in the process of strategic and business development creates a shared awareness of the critical success factors and related risks.

PAION's risk management system comprises an internal control system, an early warning system for the detection of risks and a controlling system. These three sub-systems interact directly with each other and also take on tasks from each of the other sub-systems.

The financial accounting and cost accounting software „Microsoft Dynamics NAV“ and an enterprise planning tool in Excel customized for PAION form the basis for controlling. Monthly internal reporting is performed on a cost centre and cost unit basis, allowing deviations from the budget to be identified at an early stage. Short-, mid- and long-term corporate planning (cost centre planning, cost unit and project planning, budget income statement, budget balance sheet and budget cash flow statement) is conducted using the Excel-based planning tool. Using this planning tool, management and the controlling department are in a position to simulate various scenarios to identify, assess and determine the impact of opportunities and risks on the future development of the company, particularly with regard to the key financial performance indicator liquidity.

The implemented internal control system includes rules for the management of business activities as well as arrangements for monitoring compliance with these rules. The primary tasks of the internal control system include application of the dual control principle, determining which types of business transactions require approval, limiting the issuance of signing and banking authority, standardizing workflows using procedural instructions, monitoring compliance with process steps by using checklists and establishing measures for the protection of data and IT systems. Furthermore, PAION commissioned an auditing firm with carrying out the tasks of an internal audit department in the past. Internal Audit works on the basis of a multi-year audit plan, which was developed by Internal Audit in collaboration with the Management Board based on a risk-oriented audit approach and materiality aspects. The internal auditors report promptly on the audit procedures carried out and any findings there from. In the reporting period, no audit was carried out by the internal auditors. In addition, PAION has appointed an internal Compliance Officer. The Compliance Officer monitors the compliance of the group-wide compliance policies and reports once a year on his activities and any findings there from. Both the audit plan and the reports of Internal Audit as well as the report of the Compliance Officer are forwarded to the Supervisory Board for information and discussion.

PAION has implemented a matrix organisation which combines both project organisation and department organisation. Detailed reporting and information structures have been set up within these organisational structures to ensure the early identification and communication of risks. The individual projects are managed and monitored by project teams. The project teams regularly provide the individual department heads and management with reports – also in writing – on the current progress of projects and potential risks.

The risk management system is reviewed once per year and discussed with the Supervisory Board. The risk analysis is updated during the year and presented to the Supervisory Board. Special risks are communicated ad-hoc. A comprehensive risk inventory is conducted on a yearly basis. The internal control system is reviewed continuously with regard to the effectiveness of the controls and is adjusted if required. The risk management system and the internal control system were audited by Internal Audit in line with a multi-year audit plan.

## **2. Risk management and internal control system relevant for the financial reporting process**

The risk management system and the internal control system also involve the financial reporting processes and aim to ensure compliance and reliability of the consolidated financial statements, the group management report and the released quarterly statements and half-year financial statements.

The risk management and internal control system relevant for the financial reporting process address the risk of significant misstatements in the annual and interim financial statements. Essential measures and controls in financial reporting are the clear assignment of responsibilities, the dual control principle, the segregation of duties, the use of an appropriate financial accounting system with a corresponding authorization concept as well as the use of checklists and work instructions. Furthermore separate and consolidated financial statements are prepared every month for internal purposes. The monthly, interim and annual financial statements are analyzed by means of the group-wide controlling with regard to plan/actual variances and implausibilities and inconsistencies in the accounting. The monthly finance report is forwarded to the Supervisory Board. The quarterly statements as well as half-year and annual financial statements are published and are discussed with the Audit Committee of the Supervisory Board or the Supervisory Board prior to publication.

Significant issues in connection with the preparation of financial statements are discussed promptly with the audit committee. Furthermore, the audit committee determines additional audit topics and key audit procedures for the auditor.

In addition, the auditor is obligated to report to the Supervisory Board on risks and control deficiencies relevant for the financial reporting process as well as other deficiencies of the risk management system and the internal control system that he becomes aware of in the course of his audit.

## **3. Significant risks**

Within the framework of the risk early warning system, risks are initially assessed as gross risks in terms of potential damage levels and likelihoods of occurrence before taking into account any

risk-mitigating measures. Net risks are assessed in terms of damage level and likelihood under consideration of implemented risk-reducing actions and are classified based on the resulting expected value. For the evaluation of potential risks, company-internal as well as known relevant external factors are taken into account based on their respective relevance. Applied categories for likelihoods of occurrence and damage levels as well as the classification of resulting net risks are illustrated in the following table:

Likelihood of occurrence	Damage level				
	Very low < KEUR 100	Low KEUR 100 - KEUR 500	Moderate KEUR 500 - EUR 1 mill.	High EUR 1 mill. - EUR 5 mill.	Very high > EUR 5 mill.
Highly probable > 90%	Very low risk	Moderate risk	Increased risk	Very high risk	Very high risk
Very probable 60%-90%	Very low risk	Low risk	Increased risk	High risk	Very high risk
Probable 30%-60%	Very low risk	Low risk	Moderate risk	High risk	High risk
Possible 15%-30%	Very low risk	Very low risk	Low risk	Increased risk	High risk
Unprobable < 15%	Very low risk	Very low risk	Low risk	Moderate risk	Increased risk

In the following, identified risks will be outlined together with respective implemented risk-reducing measures and classified according to the illustrated table above. The classification is based on net risks under consideration of risk-mitigating activities. Risks potentially posing a threat to the continued existence of the group are defined as risks with a potential damage level of more than EUR 5 million in case of occurrence. Risks potentially posing a threat to the continued existence of the group are separately denoted accordingly. Net risks with an assessment as “Very low risk” and “Low risk” are not depicted since these do not significantly influence the decisions of a reasonable addressee. In the course of the necessary aggregation of risks, some of the risks depicted in the following may comprise individual partial risks. In this case, the classification of the risk always relates to the highest of the underlying partial risks. Potential changes of risk classifications compared to the previous year are denoted accordingly. If risks disclosed in the prior year do not exist anymore or if risks are presented for the first time in the reporting period, this is not outlined separately.

#### a. Risks in connection with the development and commercialization of the product portfolio

Due to the complete concentration of all resources on remimazolam so far, PAION is highly dependent on its successful development and subsequent commercialization. After the reporting

date, the two new products GIAPREZA® and XERAVA® were in-licensed for the European market. The risks listed below relate explicitly to remimazolam, but also apply in part to the products in-licensed after the reporting date accordingly. No separate reference is made to this in the individual risks.

#### aa) Development and approval risks

Before remimazolam can be approved and marketed, its safety and efficacy must be proven in appropriate and carefully monitored clinical and non-clinical studies. As is common practice in the pharmaceutical industry, Clinical Research Organizations (CROs) are assigned to conduct the studies. PAION performs monitoring and control functions which are in line with practice in the pharmaceutical industry. Despite supervision, there is a risk that an inadequate conduct of studies only becomes evident once the study data are available or after filing for market approval in the course of study site inspections conducted by the respective authorities requiring rework amendments and causing delays in the approval process. In order to reduce this risk, CROs are carefully being selected based on defined processes and criteria and are regularly audited. Moreover, the conduct of clinical studies in the respective study centers as well as generated study data are monitored and checked by independent third parties. This is an industry-specific high risk. In case of occurrence of this risk, the potential damage level could pose a threat to the continued existence of the group. Among the industry, nearly 40% of all Phase III projects do not directly lead to approval.<sup>18</sup>

In order to ensure timely filings for market approval of remimazolam, PAION cooperates with experienced regulatory service providers. PAION regularly evaluates the rendered services also taking into account external data for comparison but is not in a position to entirely assess the adequacy and compliance with regulatory requirements due to the highly specialized expertise of the service providers. In spite of the professional track record of the contracted service providers there is a risk that regulatory requirements, as e.g. in respect to documentation or quality assurance prerequisites, are not met sufficiently which is only revealed during the review of market approval dossiers by the respective authorities leading to a delay of market approval. This is an increased risk. In case of occurrence, the potential damage level could pose a threat to the continued existence of the group.

PAION regularly conducts clinical trials. There is a risk that in future trials, patients cannot be recruited fast enough or at all. The resulting delay, necessary amendment or discontinuation of the respective study would usually (e.g. in case of the initiation of a new study) lead to higher costs and delayed market approval. Insights from all clinical studies conducted so far particularly in regard to recruitment of certain patient populations are regularly taken into account for the study designs in order to guarantee optimal patient recruitment. In the course of study monitoring, PAION analyzes potential alternative and prevention scenarios on a need basis in order to be able to initiate these in a timely manner in case of occurrence of this risk. In addition, PAION cooperates closely with its licensees, for example to jointly conduct studies and share findings from previous studies. This is a moderate risk.

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<sup>18</sup> Thomas, D. W. et al. (2016): BIO Industry Analysis: Clinical Development Success Rates 2006-2015.

The results of clinical and non-clinical studies are not predictable. There is always the danger that unexpected serious adverse events occur or that promising results achieved in prior studies may not be confirmed to the same degree in subsequent studies and primary and secondary study endpoints defined in advance cannot be achieved. Reasons for the latter could be the inadequacy of the drug candidate for the planned indication or the respective study designs. If this risk occurs, further development could be delayed considerably or development of the drug candidate may be discontinued altogether. These are typical development risks which can only be influenced to a minor extent. In regard to unexpected serious adverse events, thorough dose finding and careful monitoring of safety aspects of the studies are carried out, and with respect to the results of studies and the achievement of primary and secondary endpoints, a thoroughly chosen study design defined in advance under consultation with external experts and/or in the course of the study potential dosage modifications and amendments to clinical trial protocols if there are indications for their necessity mitigate the risk as far as possible. Unexpected serious adverse events are a moderate risk. The risk classification decreased by one category compared to the previous year. Insufficient study outcomes are a high risk. In case of occurrence, the potential damage level could pose a threat to the continued existence of the group.

In the course of the development of remimazolam for adults, in the U.S. as well as in the EU the subsequent development for pediatric use is a requirement. Should the conduct of this development not be possible within the timetable agreed with the EMA due to delays, there is a risk that the grant of market approval for procedural sedation and/or acceptance of filing of an extension for general anesthesia in the EU is denied by the EMA at first. PAION works on the implementation of the pediatric development plan in the EU in order to minimize this risk. This is a high risk. In case of occurrence, the potential damage level could pose a threat to the continued existence of the group.

There is also a risk that authorities impose additional regulatory requirements exceeding the needs PAION originally planned for. Tightening of clinical thresholds for safety and efficacy evaluations, or changes in the way regulators evaluate clinical data could lead to cost increases or significant delays in the conduct also of ongoing studies or necessitate the initiation of additional studies in order to be able to file for market approval. Assessments of individual authorities might also differ. Data sets regarded as sufficient in one country might be deemed insufficient by an authority in a different country. Also after filing of a market approval dossier, there is a risk that the competent authority rejects a dossier e.g. due to formal reasons and demands rework, appoints external expert committees for the evaluation of single issues and/or initially rejects dossiers demanding the conduct of further studies. This may lead to significant delays in the approval process, higher than initially planned costs (e.g. in case of the necessity to conduct additional studies) and discontinuation of further development of the product candidate (in the respective market) in the worst case. This is a typical drug development risk that can only be influenced by PAION to a minor degree. However, in order to reduce the risk to the highest possible extent, PAION and its licensees in all important markets consult the regulatory authorities informally as well as within the frame of official consultations, as e.g. in pre-NDA meetings. Moreover, PAION consults regulatory experts. This is a high risk. In case of occurrence, the potential damage level could pose a threat to the continued existence of the group.

Moreover, there is a risk that product defects and deficiencies in the manufacturing process of remimazolam or certain incidents at PAION's contractual manufacturers entail regulatory consequences or insufficient supply volumes that lead to the interruption and/or delay of studies or a constraint also of commercial usability of product already manufactured. PAION's quality assurance maintains a close cooperation with PAION's contractual manufacturers and regularly conducts audits in order to ensure a constantly high quality of the manufacturing. Insights from interactions with the different authorities are considered for the evaluation in the course of audits as well as for the definition of relevant quality requirements on an ongoing basis. In addition, a safety stock of product is maintained. This is an increased risk. In case of occurrence, the potential damage level could pose a threat to the continued existence of the group.

Additionally, authorities regularly conduct pre-approval inspections in terms of (the manufacturing of) drugs before granting respective market approval. There is a risk that quality deficiencies at PAION, PAION's contractual manufacturers or other service providers contracted by PAION in this context are identified within the scope of such inspections which might lead to delays of market approval. In order to minimize this risk, PAION maintains a close cooperation with its contractual manufacturers and service providers and regularly conducts own audits in order to ensure a constantly high quality of the manufacturing and the processes and documentation in this context. PAION also works with renowned and experienced external service providers for this purpose. This is an increased risk.

Apart from market approval per se, particularly the exact conditions of the received label play an important role for successful commercial usability of remimazolam. There is a risk that remimazolam will not be granted this target label e.g. in the EU significantly reducing or entirely eliminating commercial usability. In order to reduce this risk, PAION considers the relevant aspects in the respective study designs and performs additional analyses if necessary. This is a high risk and the potential damage level could pose a threat to the continued existence of the group in case of occurrence.

#### **bb) Commercialization risks**

With a constantly progressing degree of the development status and first filings of market approval dossiers and grants of market approvals for remimazolam, (potential) commercialization is closing in as well and imposes several risks.

PAION has already conducted comprehensive market research as a basis for assessing different market potentials and analyzes market access in different markets in Europe. There is a risk for all regions that assumed prices or other assumptions such as expected market share underlying the business plan and thus remimazolam's full potential cannot be realized. This risk can – particularly in regard to partnered regions – only be influenced to a minor degree. For Europe, it is planned to potentially conduct additional smaller studies for specific markets which clearly emphasize the value added by remimazolam in the respective indication in the affected market in order to allow for commercialization in the respective target groups as planned. Moreover, measures to reduce the manufacturing costs of remimazolam are planned. This is a high risk. In case of occurrence, the potential damage level could pose a threat to the continued existence of the group.

There is also a risk that PAION or PAION's licensees will not be able to sufficiently prepare the market for launch by means of pre-marketing and market access activities as for example communication and exchange with the scientific community, and will therefore not be able to sell the anticipated volumes of remimazolam at the market. In order to reduce this risk, PAION works on the preparation of the relevant markets, including bringing in external consultants for communication with the scientific community, collaboration with key opinion leaders and the establishment and expansion of the internal commercial team. Moreover, there is regular information exchange with the U.S. licensee Acacia and the licensees in the other regions. Moreover, it is planned to initially launch remimazolam in a different indication than planned as main indication in single countries in Europe in order to support later commercialization in the main indication in these markets. Since a large number of planned examinations and procedures were initially canceled or postponed due to the Covid-19 pandemic, subsequent catch-up and the resulting induced increased need for sedatives and/or anesthetics may support the successful launch of remimazolam. This is a high risk. In case of occurrence, the potential damage level could pose a threat to the continued existence of the group.

In order to be able to successfully commercialize remimazolam upon market approval, PAION's (for an own commercialization in parts of Europe) and licensees' distribution set-ups, if not existent yet, need to be fully established. There is a risk that this process will not have been (entirely) completed until market approval or, depending on the respective region and regulatory process, the theoretically earliest possible date of commercialization after market approval. In order to reduce this risk to the highest possible degree, PAION has analyzed potential distribution set-ups and is working on the implementation also under consultation of external experts. Moreover, there is a regular information exchange with the U.S. licensee Acacia and the licensees in the other regions. This is a high risk. In case of occurrence, the potential damage level could pose a threat to the continued existence of the group.

The health care sector is exposed to governmental regulations of different degrees depending on the respective region, which are often subject to changes or tightening over time. There is a risk that the rules of access, reimbursement, promotion and distribution for pharmaceutical products will be changed significantly to the disfavor of the pharmaceutical industry. This risk cannot be influenced by PAION. This is a high risk. In case of occurrence, the potential damage level could pose a threat to the continued existence of the group.

### cc) Production and purchase risks

For the preparation of commercialization, PAION has successfully completed so-called scale-up processes for the manufacture of remimazolam together with experienced and renowned contract manufacturing organizations (CMOs) that serve the purpose of validating the technical feasibility of production also of higher quantities of remimazolam. However, commercial production has not been proven as a regular process yet implying the risk that it might not be possible to manufacture remimazolam at commercial scale fast enough, in sufficient quantity and/or quality and/or at competitive cost for the market. In order to reduce this risk, PAION closely cooperates with the CMOs to identify possible saving potentials and opportunities to increase efficiency as e.g. the increase of batch sizes on the one hand and to detect and address potential weaknesses in the processes at an early stage on the other hand. Moreover, PAION

maintains a safety stock of product. This is a high risk. In case of occurrence, the potential damage level could pose a threat to the continued existence of the group.

Moreover, (additional) requirements of the authorities might delay manufacturing of market material and thus lead to a delay of commercialization. This is also an inherent risk in drug development and can barely be influenced. Still, the contractual manufacturers PAION works with are experienced in the adoption of additional regulatory requirements. Moreover, PAION has considered feedback from the respective regulatory authorities from formal and informal consultations in the product development program for remimazolam accordingly. This is an increased risk.

There is a risk that large amounts of remimazolam get lost due to events like fire, theft, accidents or comparable incidents. PAION chooses all of its contractors along the supply chain thoroughly and places great importance on high security requirements. Also, PAION has hedged against potential damages to a high degree by industry typical insurances. This is a moderate risk.

PAION has started but not yet entirely completed the implementation of a supply chain. If the complete build-up of the supply chain should not be completed in time, the timely availability of remimazolam manufactured at commercial scale could be at risk. PAION is working on the implementation of the supply chain in cooperation with its CMOs. This is a moderate risk.

PAION partially supplies licensees in different regions with remimazolam API. In the course of commercialization, PAION is exposed to product liability risks. This also applies to the planned own commercialization of remimazolam in certain European markets. PAION works with experienced and renowned CMOs for the production of both the API and the final and applicable drug product (DP), and the production process is regularly monitored by PAION's quality assurance based on predefined processes and requirements and in close cooperation with the CMOs and licensees. Contractual liability arrangements are in place with both CMOs and licensees. In addition, PAION has taken out product liability insurance to reduce the risk to a large extent and to limit any damage. This is a high risk. In case of occurrence, the potential damage level could pose a threat to the continued existence of the group.

#### dd) Risks in relation to patents and other intellectual property

PAION's business operations are largely dependent on its ability to secure extensive patent protection and other intellectual property protection for the individual substances and to defend these against third parties without violating their rights. There can be no assurance that current or future patent applications will be granted or that any patents issued or licensed to PAION will be valid and sufficiently extensive to provide PAION and its licensees with adequate legal protection or any commercial advantage. PAION continuously collaborates with an experienced patent law firm to secure the protection of PAION's intellectual property and to identify and address potential threats at an early stage as well as to make sure to not infringe any other third parties' patents itself. This is an increased risk. The risk classification increased by one category compared to the previous year.

#### ee) Risks in relation to licensees

In light of the progress of the development activities for remimazolam, increasingly bigger clinical studies are being conducted by licensees and important regulatory coordinations, meetings with the respective regulatory authorities, filings of market approval dossiers and preparations for potential commercialization are increasingly in the focus for PAION's licensees. There is a risk that results from clinical studies, discussions with the authorities or evaluations of market approval dossiers by the authorities render the further development and/or commercialization of remimazolam unattractive for existing licensees in their respective licensed region and that they terminate their license for this reason. In order to reduce this risk, PAION is in regular exchange with all licensees and engages in the evaluation of development plans, market approval dossiers and strategies and analyses for pricing discussions with authorities as appropriate, in order to share the comprehensive set of experience in the clinical development of remimazolam and regulatory interactions with authorities in this regard to thus guarantee the successful conduct of clinical trials and compliance with the respective regional regulatory requirements in regard to studies as well as market approval dossiers and the best possible preparation of potential commercialization. This is an increased risk. The risk classification decreased by one category compared to the previous year.

There is also a risk that there are delays in the development, regulatory review and/or subsequent potential commercialization of remimazolam in the licensed territories leading to a delay or omission of milestone and/or royalty payments. Since the underlying original risks, which are already depicted in the other sections, are diverse and heterogeneous among the different licensees, this risk is not classified in this section.

### b. Finance risks

#### aa) Financing risks

PAION expects future payments from existing and possible future cooperation agreements as well as from tax credits to partially cover its short- and mid-term financing needs. However, PAION needs additional funding for further development and the planned commercialization of remimazolam, XERAVA® and GIAPREZA® in Europe. Funding requirements in addition to the above may also arise due to delays or cost increases in development and commercialization. Milestone payments and royalties could be delayed or cancelled entirely if targets agreed with the licensees are not met.

PAION's ability to secure additional funding depends on the success of PAION's and its licensees' commercial and development activities, licensee and partnering activities, the situation on the capital markets, in particular also the impact of the Covid-19 pandemic on the financing environment, and other factors. If PAION is unable to raise financing in the short- to mid-term, it will be forced to reduce its operating expenses by delaying, reducing or discontinuing the development and commercialization of its products.

PAION conducts short-, mid- and long-term planning of the financing requirements and updates it continuously in order to identify additional financing requirements in due time and to

take measures accordingly. Moreover, PAION maintains regular and close contact to investors as well as (potential) pharma partners and licensees. PAION has entered into a loan agreement with the EIB which has already been drawn down partially after the balance sheet date. This is a very high risk. In case of occurrence, the potential damage level could pose a threat to the continued existence of the group. The risk classification increased by one category compared to the previous year.

#### bb) Currency risks

Some of PAION's contracts are based on foreign currencies, mainly on the U.S. dollar and the pound sterling. A strong rise of these currencies in respect to the euro could increase the costs for development and commercialization of remimazolam. In order to reduce this risk, PAION does maintain foreign currency funds in U.S. dollars and pound sterling. Currency risks also arise from potential future royalties which will be payable in different currencies by licensees depending on the respective licensed market, particularly in U.S. dollars from the potential commercialization in the U.S., as well as from translating the British subsidiaries' separate financial statements from pound sterling into euros because the pound sterling is the functional currency of the UK subsidiaries.

Currency risks are systematically recorded and monitored based on short- and mid-term planning. With the consent of the Supervisory Board of PAION AG, the Management Board has drawn up clear rules governing the hedging instruments that may be used to limit currency risks. Hedging contracts are transacted or foreign currency funds are held under certain circumstances for foreign currency items, for which the amounts and due dates of cash flows are relatively certain. This is a moderate risk.

#### cc) Liquidity and default risks

PAION's cash and cash equivalents are held at different banks. There is a risk that PAION is not able to retrieve invested funds in case of a default of one or more of these banks. In order to minimize this risk, wherever applicable, only investments with the lowest possible risk safeguarded by deposit protection fund and/or other protection systems are made. This is an increased risk. In case of occurrence, the potential damage level could pose a threat to the continued existence of the group.

#### dd) Tax risks

PAION AG and its subsidiaries have considerable tax losses carried forward available. PAION assumes that based on the current German and British tax legislation, these losses can be carried forward indefinitely and offset against future earnings according to the relevant tax regulations (e.g. minimum taxation). If the usage of tax losses is partly or completely disallowed, for example due to changes in legislation, changes in capitalization or ownership structure as well as other events, higher income tax payments than expected would become due on the expected earnings if

remimazolam is developed and commercialized successfully. This is an increased risk. In case of occurrence, the potential damage level could pose a threat to the continued existence of the group.

Based on current tax legislation in Great Britain, PAION receives tax credits in connection with the development costs for remimazolam. The calculation of the refund claims is based on the calculation method agreed in previous years between PAION and the British tax authorities. Should the tax authorities change the calculation method or not accept current methods anymore, the tax credits might be significantly lower than expected or might not be received at all in the future. Tax claims already recognized in the accounts could not be recoverable anymore in such a case and received tax credit payments not finally reviewed by the British tax authorities yet could become repayable. Due to a legislation change already enacted, tax credits will be significantly lower for PAION from fiscal year 2021 onwards. This is a moderate risk.

Within the PAION Group, there is a diverse exchange of services between the companies, also across national borders. Due to the increasing complexity of the service relationships, especially against the background of the planned commercialization of remimazolam, GIAPREZA® and XERAVA®, there is a risk that the transfer prices applied and the underlying transfer pricing methods are not (fully) accepted by tax authorities and that litigation costs and/or possible (higher) tax payments (than planned) may be incurred. This is an increased risk.

The British subsidiary PAION UK Ltd, which holds the rights to remimazolam, is expected to generate significant income from licenses in the future if remimazolam is successfully marketed in the various territories. As a result of the final configuration of the UK's exit from the EU contractually fixed end of 2020, PAION could be subject to additional taxation in Germany on the basis of this income (according to controlled foreign corporation rules), which could lead to significant additional tax payments for PAION due to the considerably higher tax rate in Germany and more restrictive minimum taxation compared to the UK. These tax payments would have a corresponding negative impact on liquidity. This is a very high risk. In case of occurrence, the potential damage level could pose a threat to the continued existence of the group.

PAION continuously monitors the relevant tax legislation and jurisdiction and consults external tax consultants for all material issues in order to identify and address tax risks at an early stage.

#### ee) Risk of insolvency

There is a risk that one or several subsidiaries could go into insolvency. The occurrence of this risk would lead to substantial impairment losses on the equity investments in subsidiaries and the loans to subsidiaries. This would accordingly reduce the equity of PAION AG. Furthermore, difficulties in financing or a default of expected payments from licensees, e.g. milestone payments or royalties, or from subsidiaries, e.g. loan repayments, could lead to the insolvency of PAION.

For the purpose of monitoring the financial position, results of operations and cash flows of PAION AG and the operative subsidiaries, a monthly reporting with a balance sheet and profit and loss statement is conducted for these companies. The liquidity is monitored on a daily basis for each company. This is a high risk. In case of occurrence, the potential damage level could pose a threat to the continued existence of the group.

### c. IT risks

As a globally acting group, PAION has implemented complex IT systems providing instantaneous exchange of data via stationary as well as mobile devices which are crucial for PAION's business activity. There is a risk that external third parties gain unauthorized access and delete, corrupt or misuse confidential data to PAION's disadvantage or damage the IT infrastructure on purpose. This could be carried out via direct attacks, access via mobile devices or by bringing in malware which is then involuntarily installed or executed by users. PAION has implemented an integrated multiple-level security concept that reduces this risk to a high degree. This is an increased risk. In case of occurrence, the potential damage level could pose a threat to the continued existence of the group.

Substantial parts of the IT infrastructure are hosted by external service providers. There is a risk that incidents at the providers such as hardware failures lead to the breakdown of essential parts of the IT system rendering PAION unable to e.g. fulfill contractual or regulatory obligations in time and/or leading to the unrecoverable loss of data. In order to significantly reduce this risk, PAION works with experienced and renowned IT service providers with redundant and physically separated systems to ensure undisturbed functionality of the IT infrastructure also in a damage case. Data is backed up on a daily basis. In addition, the existing IT infrastructure is currently being transformed into a cloud-based environment. This is an increased risk. The risk classification increased by one category compared to the previous year.

### d. Legal and Compliance risks

PAION cooperates with a variety of external partners in different regions, exchanges confidential data on a regular basis and conducts clinical trials in various countries with different jurisdictions inducing several risks.

There is a risk that confidential information is being forwarded, published or misused. PAION has implemented internal guidelines for dealing with confidential information and only exchanges information with external third parties based on confidentiality agreements. All employment contracts contain clauses with confidentiality obligations. This is a moderate risk.

Conducting clinical studies always bears a liability risk, for example in case of unexpected physical damage for volunteers or patients. PAION generally purchases country-specific insurance policies for all clinical trials. This is a moderate risk. For the risk from the commercial supply/commercialization of medicines, please see section a.cc) Production and purchase risks.

### e. Risks in relation to the "Brexit"

With the end of the transition period on 31 December 2020, the United Kingdom ultimately left the European Union (so-called "Brexit"). The precise contractual regulations for economic relations between the two parties for periods from 2021 onwards were decided only a few days before the end of the transition period. In various areas, the actual legal and economic consequences of the Brexit for individual cases will therefore only crystallize in detail over time. As a result, there are still potential risks for PAION in connection with the Brexit, which, however,

cannot necessarily be fully assessed due to the uncertainties that still exist. For this reason, potential risks are not categorized.

Regulatory requirements for market approval of new drugs could change rendering currently conducted or planned development programs inadequate for regulatory approval of remimazolam in the UK without amendments and consequentially additional costs and longer development times resulting thereof. In case of market approval, trade restrictions of any kind as well as customs or other duties could restrict PAION's competitiveness in the UK or reduce potential proceeds based on the commercial structures within the PAION group at that time.

As remimazolam is a product of the English group company PAION UK Ltd and there is a variety of intercompany service provision within the group, restrictions in that regard might occur preventing a reasonable and efficient exchange of services within the group. This could e.g. relate to organizational, logistical, tax, personnel and financial aspects. Among others, free movement of employees of the PAION Group could be restrained.

#### **f. Risks in relation to the Covid-19 pandemic**

The Covid-19 pandemic that has been rampant since the beginning of 2020 has internationally led to regionally different, partly massive and now as before existing constraints of public life and economic output. At the present time, it is not possible to predict when the direct and indirect restrictions caused by the pandemic will cease to exist and when and to what extent normalization will occur in the various areas of life and the economy.

Limitations of public life (as e.g. in regard to travel restrictions or the like) could directly affect PAION's business activity and its results of operations, net assets and financial position. Among others, development and manufacture of PAION's products, regulatory reviews and authority decisions or commercialization in certain markets could be delayed. There is a risk that other risks detailed in this risk report become more likely and potentially occur. In light of the high uncertainty in respect of the further course of the pandemic and the resulting impact on public life and the global economy, this risk cannot be classified.

## **4. Market opportunities**

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 & stakeholders in healthcare.

Essentially, the anesthesia market is regarded as sufficiently supplied, and there have been no relevant innovations for decades. Nonetheless, remimazolam's properties either show safety or efficacy advantages in certain interventions providing attractive market opportunities. Demand for innovative anesthesia solutions is growing because of an aging population with an increasing number and complexity of surgical interventions for which existing products show certain safety deficiencies. PAION intends to make use of this fact. Most big pharma companies have withdrawn from actively promoting their product range in this therapeutic field. Market research has shown that the highest medical need in this field is provision of substances which have a superior safety profile. Furthermore, anesthesiologists often express the desire for a short-

acting, safe and well controllable agent. PAION has responded to this medical need with the development of remimazolam.

PAION has made the strategic decision to commercialize remimazolam on its own in selected European markets. In order to realize synergies in the build-up of its own distribution structures, PAION in-licensed the two approved products GIAPREZA® and XERAVA® for exclusive commercialization in the European Economic Area, Switzerland and the United Kingdom after the balance sheet date. Both products – GIAPREZA® as an intravenously administered vasoconstrictor to increase blood pressure, for example in case of a septic shock, and XERAVA® as an intravenously administered antibiotic for complicated intra-abdominal infections – are indicated for use in critical care and are therefore ideally suited as complementary additions to PAION's product portfolio.

PAION assumes that the build-up of an own distribution infrastructure for the hospital market in selected European markets will provide the opportunity to acquire or in-license additional products in the future in order to further increase both revenues and profitability.

### Remimazolam besylate

Clinical development of remimazolam in procedural sedation is mostly completed. In the U.S. and China, remimazolam is approved for this indication and is already on the market. In the EU, an MAA was filed in November 2019. A final decision by the EMA on the MAA for procedural sedation is expected shortly after the CHMP adopted a positive opinion recommending the approval of Byfavo® (remimazolam) for procedural sedation in adult patients in January 2021. Based on its own projections, PAION currently estimates an annual peak sales potential of approx. EUR 50 million to approx. EUR 60 million for procedural sedation in Europe.

Development in general anesthesia is already completed in Japan and South Korea. The Japanese licensee Mundipharma received market approval in January 2020 and successfully launched Anerem® (remimazolam) in mid-2020. PAION's South Korean licensee Hana Pharm received market approval for remimazolam in South Korea in January 2021. Based on the positive results in the Phase III trial in general anesthesia and assuming 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. Based on publicly available European procedure statistics and market research, PAION estimates that in the EU, approximately 29 million procedures requiring general anesthesia are performed each year. Based on its own projections, PAION currently estimates an annual peak sales potential of approx. EUR 100 million for general anesthesia in Europe.

PAION benefits from the progress of the development of remimazolam in the licensed territories financially in the form of milestone payments and royalties from launch onwards as well as in the form of additional development data. All license agreements in place bear royalties upon commercialization ranging from 5% up to over 20% of net sales based on the respective territory that could reach a total of approx. EUR 60 million per year at peak. For selected European markets, an own commercialization is planned. For all other regions, it is targeted to find licensees or distribution partners, and PAION is well positioned to find further licensees. Pharmaceutical companies have a growing need to add drugs to their pipeline that have already demonstrated proof of concept in advanced stages of clinical trials or are already approved and also provide a commercially viable alternative in a global healthcare environment characterized

by increasing cost consciousness. PAION has partnering discussions with potential further licensees in order to allow for swift commercialization of remimazolam after potential market approval.

Overall, PAION has the chance of generating significant license income or income from the potential commercialization of remimazolam. Based on the results of the market research activities performed so far, remimazolam is an excellent candidate for developing a commercial platform in anesthesia.

### **GIAPREZA® und XERAVA®**

With the in-licensing of the two products GIAPREZA® and XERAVA®, which are already approved in Europe, after the balance sheet date, PAION has expanded its product portfolio by two products highly complementary to remimazolam that offer essential application possibilities in critical care and are already successfully marketed by the licensor in the U.S. As PAION needs to build-up appropriate distribution structures for the planned own commercialization of remimazolam in selected markets in Europe, which can also be used for the distribution of the now in-licensed products, the cost efficiency of establishing this infrastructure increases significantly. PAION currently plans the European launch of GIAPREZA® and XERAVA® in the second half of 2021. Based on its own projections, PAION currently estimates an annual peak sales potential in Europe of approx. EUR 75 million to approx. EUR 90 million for GIAPREZA® and of approx. EUR 25 million to approx. EUR 35 million for XERAVA®. Thus, the planned commercialization of both products offers attractive revenue potentials.

### **Overall evaluation of opportunities and risks**

The development of remimazolam was again significantly advanced in the reporting year. In Japan, China and the U.S., market approvals were granted for the respective first indication; in South Korea, market approval was granted shortly after the balance sheet date. In addition, remimazolam is already being marketed in Japan, China and the U.S. In Europe, a recommendation for approval in the first indication in the EU was issued by the CHMP after the balance sheet date, so that the first approval is also expected here in the short term, which would allow for a launch in selected European markets soon. The risk of failure of the development of remimazolam has thus been further reduced, while the chances of successful commercialization in an increasing number of regions worldwide have increased significantly. The addition of the two products GIAPREZA® and XERAVA® to the product portfolio after the balance sheet date raises the prospect of additional substantial and sustainable revenues through an own commercialization of these products together with remimazolam in selected European markets, while increasing cost efficiency by using the same distribution infrastructure for all three products. Overall, the opportunity situation has improved compared to the previous year.

The planned own commercialization in parts of Europe requires the establishment of a distribution infrastructure in particular. However, the costs for the build-up cannot yet be covered by revenues from product sales or royalties thus inducing a substantial need for additional financing in the short- to medium-term. To this end, PAION has drawn down the first two tranches of the loan agreement with the EIB in the amount of EUR 12.5 million after the balance sheet date and has initiated a capital increase with subscription rights with expected gross proceeds of approx. EUR 8 million, which is expected to be completed shortly after the

publication of this report, and plans to draw down the third tranche of the EIB loan in the amount of EUR 7.5 million shortly. However, PAION will need additional funds to successfully market the product portfolio in Europe. The financing risk has thus increased compared to the previous year. The expansion of the product portfolio has reduced the dependence on the success of a single product accordingly and had a risk-reducing effect. Overall, the risk situation has however worsened compared to the previous year.

As no sustainable revenues of a significant amount are currently generated, PAION will continue to incur losses for the time being.

## Report on post-balance sheet date events

On 12 January 2021, PAION entered into a license agreement with La Jolla Pharmaceutical Company and further subsidiaries of this company which grants PAION the rights for exclusive commercialization of the two approved products GIAPREZA® and XERAVA® in the European Economic Area, Switzerland and the United Kingdom.

On 28 January 2021, the CHMP of the EMA adopted a positive opinion recommending the approval of Byfavo® (remimazolam) for procedural sedation in adult patients.

On 12 February 2021, PAION AG drew down the first two tranches of the financing agreement with the EIB amounting to EUR 12.5 million in total.

On 5 March 2021, PAION granted an exclusive license for development and commercialization of remimazolam in Taiwan to TTY Biopharm.

On 19 March 2021, a capital increase with subscription rights with planned gross proceeds of EUR 7.8 million was resolved, the completion of which is planned for 9 April 2021. By means of this capital increase, the share capital of PAION AG is planned to be increased by EUR 5,095,499.00 from EUR 66,241,493.00 to EUR 71,336,992.00 by utilization of the Authorized Capital 2020 by issuing 5,095,499 new shares. After the rights issue, the Authorized Capital 2020 will amount to EUR 21,039,429.00.

There were no further significant events in the period between the reporting date, 31 December 2020, and the preparation of this report.

## Report on expected developments

### Business outlook

PAION's focus in 2021 will be on preparing the commercialization of its product portfolio, consisting of remimazolam (Byfavo®), which is in the approval process, as well as the already approved products GIAPREZA® and XERAVA®, and on building a distribution infrastructure in selected European countries. In addition, PAION plans to submit the MAA for Byfavo® for general anesthesia by the end of 2021. PAION plans to launch all three products in a staggered manner by country beginning in the second half of 2021 so that by the end of 2022, launches will have been conducted in all selected 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 and China, 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. Furthermore, PAION expects the launch of remimazolam in South Korea in mid-2021.

### Financial outlook 2021

PAION expects revenues of about EUR 8 million to about EUR 9.5 million in 2021. Approx. EUR 7.5 million to approx. EUR 9 million of the revenues are expected from existing licensees, thereof approx. EUR 5 million to approx. EUR 6 million from the sale of remimazolam API as well as royalties from the commercialization of remimazolam, and approx. EUR 2.5 million to approx. EUR 3 million from milestones. Revenues from the own commercialization of Byfavo®, GIAPREZA® and XERAVA® are expected in an amount of approx. EUR 0.5 million. Cost of revenues will amount to approx. EUR 3.5 million to approx. EUR 4 million.

Focus of the activities will be 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 -16.5 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, expected cash inflows from the recently launched rights issue of almost EUR 8 million and the outstanding loan tranche of EUR 7.5 million from the EIB, 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 planned 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, 30 March 2021

PAION AG



Dr. James Phillips



Abdelghani Omari

# Consolidated Financial Statements

PAION AG

## Consolidated Balance Sheet as of 31 December 2020

ASSETS	Note	31 Dec. 2020 EUR	31 Dec. 2019 EUR
<b>Non-current assets</b>			
Intangible assets	1	1,829,398.87	2,137,302.29
Equipment	2	16,280.54	45,860.19
Right-of-use assets	11	26,118.72	79,075.61
Other assets		13.92	14.05
		<b>1,871,812.05</b>	<b>2,262,252.14</b>
<b>Current assets</b>			
Trade receivables	3	500,000.00	500,000.00
Inventories	4	1,774,252.00	0.00
Prepaid expenses and other assets	5	4,337,443.69	3,362,893.03
Cash and cash equivalents	6	19,666,309.58	18,786,680.89
		<b>26,278,005.27</b>	<b>22,649,573.92</b>
<b>Total assets</b>		<b>28,149,817.32</b>	<b>24,911,826.06</b>

<b>EQUITY AND LIABILITIES</b>	<b>Note</b>	<b>31 Dec. 2020 EUR</b>	<b>31 Dec. 2019 EUR</b>
Equity	7		
Share capital		66,241,493.00	64,265,586.00
Capital reserve		141,906,632.49	139,421,819.80
Translations reserve		-1,009,793.75	-884,259.03
Loss carryforward		-188,070,648.97	-181,054,833.90
Result for the period		2,222,143.55	-7,015,815.07
		<b>21,289,826.32</b>	<b>14,732,497.80</b>
Non-current liabilities			
Lease liabilities	11	15,429.23	25,632.41
Current liabilities			
Trade payables	9	3,906,828.93	4,843,429.10
Provisions	8	2,205,803.34	270,042.03
Lease liabilities	11	11,430.64	54,579.74
Financial debt	12	0.00	4,354,136.41
Other current liabilities	10	720,498.86	631,508.57
		<b>6,844,561.77</b>	<b>10,153,695.85</b>
<b>Total equity and liabilities</b>		<b>28,149,817.32</b>	<b>24,911,826.06</b>

## Consolidated Statement of Comprehensive Income for Fiscal Year 2020

	Note	2020 EUR	2019 EUR
Revenues	13	19,655,104.70	8,000,000.00
Gross profit		19,655,104.70	8,000,000.00
Research and development expenses		-10,288,176.99	-13,099,393.66
General administrative and selling expenses		-7,523,324.04	-5,022,729.37
Other income (expenses), net	14	-260,804.73	796,271.78
Operating expenses		-18,072,305.76	-17,325,851.25
Operating result		1,582,798.94	-9,325,851.25
Financial income		10,605.75	975.69
Financial expenses		-162,924.79	-123,391.51
Financial result	15	-152,319.04	-122,415.82
Result for the period before taxes		1,430,479.90	-9,448,267.07
Income taxes	16	791,663.65	2,432,452.00
<b>Result for the period</b>		<b>2,222,143.55</b>	<b>-7,015,815.07</b>
of which attributable to other shareholders		0.00	0.00
of which attributable to shareholders of PAION AG		2,222,143.55	-7,015,815.07
Foreign currency translation of subsidiaries		-125,534.72	-172,228.31
Total income and expense recognized directly in equity that will be reclassified to profit or loss when specific conditions are met		-125,534.72	-172,228.31
Other comprehensive income		-125,534.72	-172,228.31
<b>Total comprehensive income</b>		<b>2,096,608.83</b>	<b>-7,188,043.38</b>
of which attributable to other shareholders		0.00	0.00
of which attributable to shareholders of PAION AG		2,096,608.83	-7,188,043.38
Earnings per share (basic)	17	0.03	-0.11
Earnings per share (diluted)	17	0.03	-0.11

## Consolidated Cash Flow Statement for Fiscal Year 2020

	2020 EUR	2019 EUR
<b>Cash flows from operating activities:</b>		
Net result for the year	2,222,143.55	-7,015,815.07
Reconciliation of net profit (loss) for the period to cash flows from operating activities:		
Income taxes	-791,663.65	-2,432,452.00
Amortization/depreciation and non-cash changes of fixed assets	342,909.55	118,148.48
Loss/Profits from the disposal of non-current assets	8,256.09	-1,023.51
Interest expenses and interest income	152,319.04	122,415.82
Expenses from stock option plans	285,665.48	334,972.25
Transaction costs and fair value adjustments in connection with financing activities	61,653.04	210,923.80
Changes in assets and liabilities which are not attributable to investing or financing activities:		
Inventories	-1,774,252.00	0.00
Trade receivables	0.00	1,000,000.00
Prepaid expenses and other assets	-543,785.17	272,517.31
Trade payables	-936,600.17	2,625,450.04
Provisions	1,935,761.31	-359,464.23
Other current liabilities	86,903.06	-22,900.16
Non-cash exchange losses/gains	-86,914.49	-126,523.35
	962,395.64	-5,273,750.62
Interest paid	-66,874.63	-9,187.25
Interest received	10,605.75	954.17
Tax payments received	0.00	2,435,055.74
<b>Cash flows from operating activities</b>	<b>906,126.76</b>	<b>-2,846,927.96</b>
<b>Cash flows from investing activities:</b>		
Cash paid for investments in intangible assets and equipment	-13,682.44	-15,264.44
Proceeds from Sale of Property, Plant and Equipment	0.00	1,023.51
<b>Cash flows from investing activities</b>	<b>-13,682.44</b>	<b>-14,240.93</b>
<b>Cash flows from financing activities:</b>		
Capital increase	20,000.00	0.00
Contributions to the capital reserve	6,200.00	0.00
Principal portion of lease payments	-50,660.71	-52,076.05
Proceeds from the issue of convertible bonds	0.00	4,750,000.00
Transaction costs in connection with the issue of convertible bonds	0.00	-277,840.00
Payments in connection with raising capital	0.00	-6,400.00
<b>Cash flows from financing activities</b>	<b>-24,460.71</b>	<b>4,413,683.95</b>
Change in cash and cash equivalents	867,983.61	1,552,515.06
Effect of exchange rate changes on cash	11,645.08	7,507.63
Cash and cash equivalents at beginning of period	18,786,680.89	17,226,658.20
<b>Cash and cash equivalents at end of the period</b>	<b>19,666,309.58</b>	<b>18,786,680.89</b>
Composition of cash and cash equivalents at the end of the period:		
<b>Cash and cash equivalents</b>	<b>19,666,309.58</b>	<b>18,786,680.89</b>

## Consolidated Statement of Changes in Equity for Fiscal Year 2020

EUR	Share capital	Capital reserve	Translation reserve	Loss carryforward	Equity
<b>31 Decemer 2018</b>	<b>63,858,143.00</b>	<b>138,730,764.25</b>	<b>-712,030.72</b>	<b>-181,054,833.90</b>	<b>20,822,042.63</b>
Total comprehensive income	0.00	0.00	-172,228.31	-7,015,815.07	-7,188,043.38
Issue of shares	407,443.00	0.00	0.00	0.00	407,443.00
Contribution to the capital reserve	0.00	434,662.28	0.00	0.00	434,662.28
Cost of raising capital	0.00	-78,578.98	0.00	0.00	-78,578.98
Additional contribution to the capital reserve due to the issue of options	0.00	334,972.25	0.00	0.00	334,972.25
<b>31 December 2019</b>	<b>64,265,586.00</b>	<b>139,421,819.80</b>	<b>-884,259.03</b>	<b>-188,070,648.97</b>	<b>14,732,497.80</b>
Total comprehensive income	0.00	0.00	-125,534.72	2,222,143.55	2,096,608.83
Issue of shares	1,975,907.00	0.00	0.00	0.00	1,975,907.00
Contribution to the capital reserve	0.00	2,466,082.50	0.00	0.00	2,466,082.50
Cost of raising capital	0.00	-266,935.29	0.00	0.00	-266,935.29
Additional contribution to the capital reserve due to the issue of options	0.00	285,665.48	0.00	0.00	285,665.48
<b>31 Dcember 2020</b>	<b>66,241,493.00</b>	<b>141,906,632.49</b>	<b>-1,009,793.75</b>	<b>-185,848,505.42</b>	<b>21,289,826.32</b>

# Consolidated Notes

PAION AG

# Notes to the consolidated financial statements for Fiscal Year 2020

## General disclosures

The consolidated financial statements comprise PAION AG as the parent company, registered at Martinstrasse 10-12, 52062 Aachen, Germany, and the following wholly-owned and fully consolidated subsidiaries:

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

PAION AG is a holding company that provides various services to the subsidiaries. The PAION Group specializes in developing and commercializing medical innovations for procedural sedation, anesthesia and critical care services.

PAION AG shares are admitted to trading on the Frankfurt Stock Exchange and are listed in the Prime Standard of the Regulated Market.

The consolidated financial statements as of 31 December 2020 are scheduled for authorization and approval for publication by the Supervisory Board in its meeting on 30 March 2021.

## Basis of accounting

The consolidated financial statements have been prepared according to Section 315e of the German Commercial Code (Handelsgesetzbuch, HGB) in accordance with the International Financial Reporting Standards (IFRSs) as adopted by the European Union (EU), and the interpretations of the International Financial Reporting Interpretations Committee (IFRIC). PAION applied all IFRSs that had been issued by the International Accounting Standards Board (IASB), London, UK, and were effective as of the balance sheet date of 31 December 2020, and which had been adopted by the European Commission for application in the EU at the time of preparing the consolidated financial statements. Assets and liabilities are recognized and measured using those standards that were mandatory as of 31 December 2020 according to IAS 1.

The following new and/or revised standards, amendments and interpretations were applied for the first time in the fiscal year:

- Amendments to References to the Conceptual Framework in IFRS Standards
- Amendments to IFRS 3 “Business Combinations”
- Amendments to IFRS 9, IAS 39 and IFRS 7 (Interest Rate Benchmark Reform)
- Amendments to IAS 1 and IAS 8 (Definition of Material)

The application of these standards and interpretations applicable for the first time did not necessitate the provision of additional disclosures and did not influence the Group’s net assets, financial position or results of operations.

The following standards, amendments, clarifications and interpretations which have already been issued will be applied as soon as they become effective, provided they are adopted by the European Commission:

- IFRS 17 “Insurance Contracts” (including Amendments to IFRS 17): This standard is effective for fiscal years beginning on or after 1 January 2023. Earlier adoption is allowed. The adoption by the EU is still pending.
- Amendments to IAS 1 “Presentation of Financial Statements” (Classification of Liabilities as Current or Non-current): The amendments are effective for fiscal years beginning on or after 1 January 2023. Earlier adoption is allowed. The adoption by the EU is still pending.
- Amendments to IAS 1 “Presentation of Financial Statements” and IFRS Practice Statement 2 (Disclosure of Accounting policies): The amendments are effective for fiscal years beginning on or after 1 January 2023. Earlier adoption is allowed. The adoption by the EU is still pending.
- Amendments to
  - IFRS 3 “Business Combinations”
  - IAS 16 “Property, Plant and Equipment”
  - IAS 37 “Provisions, Contingent Liabilities and Contingent Assets”
  - Annual Improvements 2018-2020The amendments are effective for fiscal years beginning on or after 1 January 2022. Earlier adoption is allowed. The adoption by the EU is still pending.
- Amendments to IAS 8 “Accounting policies, Changes in Accounting Estimates and Errors” (Definition of Accounting Estimates): The amendments are effective for fiscal years beginning on or after 1 January 2023. Earlier

adoption is allowed. The adoption by the EU is still pending.

- Amendments to IFRS 9, IAS 39 and IFRS 7 (Interest Rate Benchmark Reform – Phase 2): The amendments are effective for fiscal years beginning on or after 1 January 2021. Earlier adoption is allowed.
- Amendments to IFRS 4 “Insurance Contracts” (Deferral of IFRS 9): The amendments are effective for fiscal years beginning on or after 1 January 2021. Earlier adoption is allowed.
- Amendment to IFRS 16 “Leases” (Covid 19-Related Rent Concessions): The amendments are effective for fiscal years beginning on or after 1 June 2020. Earlier adoption is allowed.

The application of these new and/or revised standards and interpretations may, in some cases, result in additional disclosure obligations in future consolidated financial statements. The amendments will presumably not have any effects on the Group’s net assets, financial position and results of operations.

The consolidated financial statements are prepared in Euros. Amounts are stated in Euro or KEUR.

The income statement has been prepared using the cost of sales method. Research and development expenses are reported separately in the income statement in light of their material importance.

In accordance with IAS 1 “Presentation of Financial Statements”, the balance sheet distinguishes between non-current and current assets and non-current and current liabilities. Assets, liabilities and provisions are deemed to be current if they mature within one year.

The consolidated financial statements do not contain any segment information as no reportable segments according to IFRS 8 could be identified.

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

The estimations and discretionary valuations made in the course of preparing the consolidated financial statements apply primarily to the measurement of intangible assets, provisions and revenues. The

development project remimazolam that was capitalized following the acquisition of the PAION UK group is amortized over the useful life based on forward-looking assumptions in respect of the time at which regulatory approval is obtained and of patent protection. PAION’s revenues to date mainly result from license agreements which usually comprise the transfer of so far generated data, the achievement of development milestones as well as royalty payments depending on the commercial success. Revenues relating to technology access fees (e.g. in form of upfront payments), the achievement of milestones and services to be provided in that regard are recognized once the Management Board deems the underlying criteria for revenue recognition according to IFRS as satisfied based on a scientific, technical and economic evaluation including the involvement of the relevant specialized departments. Provisions are recognized for current obligations if they originated in the past and are uncertain in regard to maturity and amount, and if it is probable after consideration and evaluation of all relevant information that these obligations will have to be satisfied by an outflow of resources that represent an economic benefit and if the amount of the obligations can be reliably estimated.

The consolidation principles and accounting policies adopted in the previous year have been maintained and incorporate the new and/or revised standards and interpretations. The application of the new and/or revised standards and interpretations did not result in additional disclosure obligations and did not have an influence on the net assets, financial position or results of the Group’s operations.

### Consolidation principles

The consolidated financial statements include PAION AG, its subsidiaries PAION Deutschland GmbH, PAION Netherlands B.V. and PAION Holdings UK Ltd, and the latter’s subsidiary companies as listed in “General disclosures”. The financial statements of the companies included in the consolidated financial statements have been prepared in accordance with uniform accounting policies. Accounts receivable and payable, income and expenses and interim profits from intra-Group transactions have been eliminated.

## Foreign currency translation

The consolidated financial statements are shown in Euros, 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 whereas the UK-based companies use the pound sterling as their functional currency. All items on the respective financial statements of each company are initially translated into the functional currency at the exchange rate applicable on the transaction date. Monetary assets and liabilities denominated in a foreign currency are translated to the functional currency on the reporting date at the exchange rate applicable on that date. All ensuing currency differences are recognized 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 recognized directly in equity.

The assets and liabilities of the foreign companies are translated into euro on the balance sheet date at the exchange rate applicable on that date (exchange rate as of 31 December 2020: 0.8993 GBP/EUR; exchange rate as of 31 December 2019: 0.8500 GBP/EUR). 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 (bandwidth in 2020 from 0.8419 GBP/EUR to 0.9105 GBP/EUR; bandwidth in 2019 from 0.8476 GBP/EUR to 0.9153 GBP/EUR). The resulting currency differences are accounted for separately within equity.

## Accounting policies

### Business combinations before 1 January 2010

Business combinations are accounted for using the acquisition method. The cost of an acquisition is measured as the aggregate of the consideration transferred, measured at acquisition date fair value. Acquisition costs also include the costs directly attributable to the acquisition as well as liabilities arising from the acquisition. Assets, liabilities and contingent liabilities identifiable in the context of a

business combination are measured at acquisition date fair value for first time consolidation.

There were no business combinations after 1 January 2010.

### Intangible assets

Acquired intangible assets are measured at cost. They are subject to amortization over their respective useful life using the straight-line method and tested for possible impairment if there are any indications that the intangible asset may be impaired. A useful life of between three and five years is defined for software, while research and marketing rights for compounds are amortized over the term of the respective patent.

### Equipment

Equipment is measured at cost less cumulative depreciation. These assets are subject to depreciation over their expected useful life using the straight-line method; their expected useful life is between three and twenty years. The recoverability of assets is always tested when events have occurred or circumstances have changed, which could have an effect on the recoverability of the assets. The recoverability of the assets held and used by the company is measured on the basis of a comparison between the carrying amount and the higher of fair value less cost to sell and its value in use. If an asset is measured below its carrying amount, it is written down to the higher of fair value less cost to sell and its value in use. These impairment losses are reversed if the reasons for the prior impairments cease to exist.

### Leases

Leased equipment and intangible assets that meet certain requirements defined in IFRS 16 "Leases" is recognized as an asset and the present value of the leasing payment obligations is recognized as a liability. Leased assets that are recognized as assets are subject to depreciation/amortization over the term of the lease using the straight-line method.

### Financial assets

Standard market purchases or sales of financial assets are recognized on the trading date, i.e. on the day on which the Group undertakes to purchase or sell the asset.

### **Financial Instruments**

The fair value of financial instruments is determined according to the three hierarchy levels defined in IFRS 13 based on the availability of respective input factors:

- Level 1: The fair value is determined based on quoted prices in active markets.
- Level 2: The fair value is determined based on valuation models depending on price-relevant information.
- Level 3: The fair value is determined based on valuation models that do not incorporate price-relevant information.

Changes in fair value are recognized through profit and loss.

### **Receivables and other assets**

Trade receivables and other assets are measured at amortized cost. Receivables denominated in a foreign currency are translated at the rate applicable on the balance sheet date. Exchange rate gains or losses are recognized in profit or loss.

### **Inventories**

Inventories comprise finished goods and advance payments on inventories and are measured at the lower of cost or net realizable value.

### **Cash and cash equivalents**

Cash and cash equivalents comprise cash balances, bank account balances and current deposits with an original residual term of less than three months. Cash and cash equivalents are measured at amortized cost.

### **Equity**

The costs directly associated with the issuance of equity are not expensed in the income statement but deducted straight from the added equity after taking into account potential tax effects.

### **Provisions**

Provisions for current obligations (legal or constructive), which originated in the past and whose maturity and amount are uncertain, are recognized to the extent to which these obligations will probably have to be satisfied by an outflow of resources that represent an economic benefit, and to which the amount of the obligations can be reliably

estimated. Provisions with a term of more than one year are recognized at present value.

### **Financial Debt**

Financial debt is initially measured at fair value (deducting potential transaction costs directly attributable to the acquisition if financial debt is not recognized at fair value through profit or loss). Financial debt is generally recognized at amortized cost. In case of hybrid contracts containing embedded derivatives, based on the specific contractual conditions, the embedded derivatives are either separated and recognized at fair value through profit or loss and the host contract is recognized at amortized cost if the embedded derivatives are not closely related to the host contract, or the entire hybrid contract is recognized at fair value through profit or loss.

### **Trade payables/other liabilities**

Trade payables and other liabilities are measured at repayment cost. Liabilities denominated in a foreign currency are measured at the exchange rate applicable on the reporting date. Exchange rate gains or losses are recognized in profit or loss.

### **Deferred income**

Non-refundable payments received in connection with out-licensing agreements are either directly recognized as income or reported as deferred income and recognized in profit over the period in which the corresponding underlying service is being rendered or over the probable development life of the respective product/indication, in each case depending on the individual contractual regulations.

### **Revenues**

Revenues are recognized as realized during the fiscal year according to IFRS 15. Income is realized once PAION's performance obligation has been satisfied by transfer of the promised good or service. Such an asset is deemed transferred when the customer obtains control of it and is therefore able to direct the use of and substantially obtain the remaining benefits from it. Some performance obligations are satisfied over time while others are satisfied at a point in time.

Since PAION is currently not selling products at the market itself yet, revenues are essentially realized by means of selling or outlicensing substances or drug candidates. Processually, the sale or outlicensing of substances or technological knowledge regularly starts with an extensive technology and know-how access by the buyer or licensee. Depending on the strategy of the licensee, subsequent services like the (support in regard to the) implementation of a production process, the conduct and completion of clinical trials in other regions or e.g. providing dossiers for market approvals from other regions are contractually agreed. Revenues from performance obligations satisfied at a point in time are realized at the time of satisfaction. Revenues from performance obligations satisfied over time, comprising research and development activities and/or milestones and for which PAION owes a successful completion are only recognized once all services to be delivered based on the contractual agreements have been carried out completely in the respective period due to the high inherent risk in the development of medical and pharmaceutical products. Revenues in connection with performance obligations which are satisfied over time, quantifiable and for which PAION does not owe a success, are recognized based on the stage of completion in the respective reporting period. Sales-based royalties from licensees are recognized as revenues as soon as the underlying sales by licensees have occurred.

For the assessment of the respective magnitude of revenues to be recognized, the contractual agreements, the complexity and specificity of the service, the potential costs for the licensee/buyer in case of an alternative purchase, the costs (incurred) as well as revenues from comparable transactions are being considered.

#### **Research and development expenses**

Research costs are recognized as expenditure in the period in which they are incurred. Pursuant to IAS 38 "Intangible Assets", development costs must be capitalized depending on the possible outcome of the development activities and when specific cumulative conditions are met. These conditions are not met at present, which is why all development costs are recognized as expenses in the period in which they occur.

#### **Interest income/expense**

Interest income/expense is recognized in the period in which it occurs. Any necessary deferrals are calculated using the effective interest method.

#### **Income taxes/deferred taxes**

Deferred taxes are recognized in accordance with IAS 12 "Income Taxes". They are recognized by applying enacted statutory tax rates applicable to future years to temporary differences between the IFRS carrying amounts and the tax bases of existing assets and liabilities. The effects of a change in the enacted tax rates on deferred taxes is recognized in the period in which the change is enacted. Deferred taxes are also recognized for losses carried forward. No deferred tax assets are recognized if it is probable that some portion or all of the deferred tax assets may not be recoverable. Tax reimbursements from the British tax authorities for subsidized research and development activities are disclosed under income taxes.

#### **Share-based payment transactions**

Stock options (equity-settled share-based payment instruments) are measured at fair value at the time they are granted. The fair value of the obligations is recognized both as a personnel expense and an increase in equity over the vesting period. The fair value is calculated using internationally accepted valuation methods (Black/Scholes).

## Consolidated balance sheet disclosures

### (I) Intangible assets

Intangible assets developed as follows:

in EUR	Industrial rights and similar rights and assets
Acquisition cost	
01 Jan. 2019	12,589,393.55
Additions	8,625.00
Disposals	0.00
Reclassifications	0.00
Exchange rate differences	678,687.42
31 Dec. 2019	13,276,705.97
Additions	0.00
Disposals	0.00
Reclassifications	0.00
Exchange rate differences	-711,513.77
31 Dec. 2020	12,565,192.20
Accumulated amortization, depreciation and impairment losses	
01 Jan. 2019	10,376,916.75
Additions	203,424.28
Disposals	0.00
Exchange rate differences	559,062.65
31 Dec. 2019	11,139,403.68
Additions	194,725.26
Disposals	0.00
Exchange rate differences	-598,335.61
31 Dec. 2020	10,735,793.33
<b>Carrying amounts 31 Dec. 2019</b>	<b>2,137,302.29</b>
<b>Carrying amounts 31 Dec. 2020</b>	<b>1,829,398.87</b>

The intangible assets mainly comprise the asset remimazolam (KEUR 1,808; 31 December 2019: KEUR 2,096). This asset is being written off over the expected useful life until mid-2031 based on forward-looking assumptions in respect of the expected time at which regulatory approval is obtained, and of patent protection.

Amortization of intangible assets substantially relates to remimazolam and is recognized as research and development expenses during the development period. A minor portion of the amortization of intangible assets relates to software and is recognized partly in the research and development expenses and partly in the general administrative and selling expenses.

## (2) Equipment

Equipment developed as follows:

in EUR	Plant and machinery	Other plan, factory and office equipment	Total
<b>Acquisition cost</b>			
01 Jan. 2019	172,585.59	789,774.08	962,359.67
Additions	2,825.71	3,813.73	6,639.44
Disposals	2,481.96	0.00	2,481.96
Reclassifications	0.00	0.00	0.00
Exchange rate differences	0.00	13,235.47	13,235.47
31 Dec. 2019	172,929.34	806,823.28	979,752.62
Additions	13,682.44	0.00	13,682.44
Disposals	168,990.81	316,345.70	485,336.51
Reclassifications	0.00	0.00	0.00
Exchange rate differences	0.00	-13,875.63	-13,875.63
31 Dec. 2020	17,620.97	476,601.95	494,222.92
<b>Accumulated amortization, depreciation and impairment losses</b>			
01 Jan. 2019	164,010.80	724,779.03	888,789.83
Additions	2,434.96	35,426.42	37,861.38
Disposals	2,481.96	0.00	2,481.96
Exchange rate differences	0.01	9,723.17	9,723.18
31 Dec. 2019	163,963.81	769,928.62	933,892.43
Additions	3,811.46	29,798.40	33,609.86
Disposals	164,562.27	312,518.15	477,080.42
Exchange rate differences	0.00	-12,479.49	-12,479.49
31 Dec. 2020	3,213.00	474,729.38	477,942.38
<b>Carrying amounts 31 Dec. 2019</b>	<b>8,965.53</b>	<b>36,894.66</b>	<b>45,860.19</b>
<b>Carrying amounts 31 Dec. 2020</b>	<b>14,407.97</b>	<b>1,872.57</b>	<b>16,280.54</b>

### (3) Trade receivables

Trade receivables entirely relate to the remimazolam license agreement with licensee R-Pharm.

### (4) Inventories

Inventories amount to KEUR 1,774 (previous year: KEUR 0) as of 31 December 2020 and comprise finished goods (remimazolam API) in the amount of KEUR 974 as well as advance payments on inventories (remimazolam API) in the amount of KEUR 800. No allowance on inventories was recognized in the reporting period.

### (5) Prepaid expenses and other assets

Prepaid expenses and other assets substantially comprise claims for reimbursement from the British tax authorities for subsidized research and development activities (KEUR 3,216; previous year: KEUR 2,567), VAT refund claims (KEUR 829; previous year: KEUR 196) as well as prepaid expenses relating to insurance contributions, rents and other prepayments (KEUR 226; previous year: KEUR 159).

### (6) Cash and cash equivalents

Cash and cash equivalents are comprised of the following:

	31 Dec. 2020 KEUR	31 Dec. 2019 KEUR
Current deposits	4,200	7,870
Bank balance and cash in hand	15,466	10,917
	19,666	18,787

Bank balances earn interest at the variable rates for call money. Current deposits are made for periods ranging from one to three months. These earn interest at the respective applicable interest rate for current deposits.

### (7) Equity

As of 31 December 2020, the share capital amounts to EUR 66,241,493.00 (previous year: EUR 64,265,586.00); it is divided into 66,241,493 no-par value shares (previous

year: 64,265,586 shares). The increase of the share capital in the total amount of EUR 1,975,907.00 results from the conversion of convertible notes issued in the prior year in the amount of EUR 1,955,907.00 and from the exercise of stock options in the amount of EUR 20,000.00. For a partial amount of the increase of the share capital in the reporting period of EUR 346,185.00, registration in the Commercial Register took place on 27 February 2020. For the remaining amount of the share capital increase of EUR 1,629,722.00, registration in the Commercial Register took place after the balance sheet date on 18 February 2021.

The capital reserve amounts to EUR 141,906,632.49 as of 31 December 2020 (previous year: EUR 139,421,819.80) and contains the share premium from the issuance of shares and expenses in the amount of the fair value of granted stock options recognized over the vesting period. Moreover, cost of raising equity according to IAS 32.35 were directly offset from the capital reserve in the course of capital increases.

By virtue of a resolution adopted by the Annual General Meeting on 27 May 2020, the Management Board was authorized to increase the share capital on or prior to 26 May 2025, with the consent of the Supervisory Board, on one or more occasions, by up to EUR 26,134,928.00 in total by issuing up to 26,134,928 new no-par value bearer shares in return for cash contributions or contributions in kind (Authorized Capital 2020). For information on the partial utilization of the authorization after the balance sheet date, please refer to the Report on post-balance sheet date events. Furthermore, the Management Board was authorized to use up to EUR 6,579,591.00 of the Authorized Capital 2020 to issue new shares for cash by excluding pre-emptive rights. Due to the conversion of convertible notes into shares of PAION AG in the reporting period, the amount of Authorized Capital 2020 that can be used under exclusion of pre-emptive rights is EUR 6,149,011.00 as of 31 December 2020. The still available Authorized Capital 2019 in the amount of EUR 31,929,071.00 was revoked.

By virtue of a resolution adopted by the Annual General Meeting on 22 May 2019, subject to the consent of the Supervisory Board, the Management Board was authorized to issue on or before 21 May 2024, on one or more occasions, bearer or registered convertible bonds, warrant-linked bonds, profit participation rights and/or

participating bonds (or combinations thereof; hereinafter collectively "Bonds") of up to an aggregate of EUR 125,000,000.00 with or without a limited maturity period and to grant the holders or beneficiaries of the Bonds conversion rights or options to new shares in PAION AG with a proportionate amount of the share capital of up to EUR 26,200,000.00 in total (Conditional Capital 2019). Furthermore, the Management Board was authorized to use up to EUR 6,385,814.00 of the Conditional Capital 2019 for Bonds against cash by excluding pre-emptive rights. In the reporting period, Conditional Capital 2019 was utilized in an amount of EUR 1,955,907.00 by conversion of convertible notes issued under exclusion of pre-emptive rights in the prior year into shares of PAION AG and amounts to EUR 23,836,650.00 as of 31 December 2020. Conditional Capital 2019 can be used under exclusion of pre-emptive rights in an amount of EUR 4,022,464.00 as of 31 December 2020.

A resolution was adopted by the Annual General Meeting on 5 May 2008 to conditionally increase the share capital of PAION AG by an aggregate of up to EUR 815,000.00 by issuing an aggregate of up to 815,000 new no-par value bearer shares (Conditional Capital 2008 I). A resolution was adopted by the Annual General Meeting on 19 May 2010 to adjust the Conditional Capital 2008 I to EUR 760,235.00. The conditional capital increase may be executed only to the extent that the holders of options granted by PAION AG in connection with the Stock Option Plan 2008 exercise their options. Under the Stock Option Plan 2008, no stock options were issued anymore as of 31 December 2020. A total of 479,142 stock options from the Stock Option Plan 2008 were exercised. As of 31 December 2020, Conditional Capital 2008 I amounts to EUR 281,093.00.

A resolution was adopted by the Annual General Meeting on 19 May 2010 to conditionally increase the share capital of PAION AG by an aggregate of up to EUR 720,000.00 by issuing an aggregate of up to 720,000 new no-par value bearer shares (Conditional Capital 2010 I). The conditional capital increase may be executed only to the extent that the holders of options granted by PAION AG in connection with the Stock Option Plan 2010 exercise their options. Under the Stock Option Plan 2010, 676,626 stock options were issued to current and former

Management Board members and employees of the PAION Group as of 31 December 2020. To date, 20,000 stock options from the Stock Option Plan 2010 have been exercised, thereof 20,000 in the reporting period. The exercises led to cash inflows of KEUR 26. As of 31 December 2020, Conditional Capital 2010 I amounts to EUR 700,000.00.

A resolution was adopted by the Annual General Meeting on 21 May 2014 to conditionally increase the share capital of PAION AG by an aggregate of up to EUR 740,000.00 by issuing an aggregate of up to 740,000 new no-par value bearer shares (Conditional Capital 2014). The conditional capital increase may be executed only to the extent that the holders of options granted by PAION AG in connection with the Stock Option Plan 2014 exercise their options. Under the Stock Option Plan 2014, 530,010 stock options were issued to current and former Management Board members and employees of the PAION Group as of 31 December 2020. No stock options have been exercised yet.

A resolution was adopted by the Annual General Meeting on 25 May 2016 to conditionally increase the share capital of PAION AG by an aggregate of up to EUR 840,000.00 by issuing an aggregate of up to 840,000 new no-par value bearer shares (Conditional Capital 2016). The conditional capital increase may be executed only to the extent that the holders of options granted by PAION AG in connection with the Stock Option Plan 2016 exercise their options. Under the Stock Option Plan 2016, 702,672 stock options were issued to former and current Management Board members and employees of the PAION Group as of 31 December 2020. No stock options have been exercised yet.

A resolution was adopted by the Annual General Meeting on 23 May 2018 to conditionally increase the share capital of PAION AG by an aggregate of up to EUR 900,000.00 by issuing an aggregate of up to 900,000 new no-par value bearer shares (Conditional Capital 2018 II). The conditional capital increase may be executed only to the extent that the holders of options granted by PAION AG in connection with the Stock Option Plan 2018 exercise their options. Under the Stock Option Plan 2018, 806,250 stock options were issued to former and current Management Board members and employees of the PAION

Group as of 31 December 2020. No stock options have been exercised yet.

A resolution was adopted by the Annual General Meeting on 27 May 2020 to conditionally increase the share capital of PAION AG by an aggregate of up to EUR 1,200,000.00 by issuing an aggregate of up to 1,200,000 new no-par value bearer shares (Conditional Capital 2020). The conditional capital increase may be executed only to the extent that the holders of options granted by PAION AG in connection with the Stock Option Plan 2020 exercise their options. Under the Stock Option Plan 2020, no stock options were issued yet as of 31 December 2020.

The currency translation reserve amounts to KEUR -1,010 as of 31 December 2020 (previous year: KEUR -884). Of these, KEUR 7,486 concern cumulative exchange rate gains (as of 31 December 2019 cumulative exchange rate gains of KEUR 6,301) arising from the translation of the financial statements of the British subsidiaries from GBP into EUR, KEUR -6,319 concern cumulative exchange rate losses (as of 31 December 2019 cumulative exchange rate losses of KEUR -6,319) from (parts of) the loans granted to the British subsidiaries by PAION AG which were swapped into shares in the respective entities in fiscal year 2018, and KEUR -2,177 concern cumulative exchange rate losses (as of 31 December 2019 cumulative exchange rate losses of KEUR -866) incurred on the loan from PAION AG to the British subsidiary PAION UK Ltd. As of 31 December 2020, the loan granted to PAION UK Ltd amounts to KEUR 17,750 (31 December 2019: KEUR 23,142).

## (8) Provisions

Provisions developed as follows:

in KEUR	Premiums/ Management Bonuses	Obligations from license agreements	Others	Total
31 Dec. 2018	534	0	96	630
Utilization	533	0	0	533
Addition	173	0	0	173
Release	3	0	0	3
Exchange rate differences	2	0	1	3
31 Dec. 2019	173	0	97	270
Utilization	171	0	0	171
Addition	609	1,515	0	2,124
Release	0	0	0	0
Exchange rate differences	-1	-15	-1	-17
31 Dec. 2020	610	1,500	96	2,206

## (9) Trade payables

Trade payables amount to KEUR 3,907 as of 31 December 2020 (previous year: KEUR 4,843). These liabilities do not bear interest and are generally due for payment within 30 days after invoicing. In case of accrued liabilities as of the balance sheet date, the maturity may be later than 30 days after the balance sheet date, depending on the respective invoice date.

## (10) Other current liabilities

Other current liabilities comprise the following:

	31 Dec. 2020 KEUR	31 Dec. 2019 KEUR
Refund liabilities	441	250
Wage taxes	125	217
Holiday allowances	102	110
Supervisory Board remuneration	34	35
Others	18	20
<b>Total</b>	<b>720</b>	<b>632</b>

## (II) Leases

PAION has rented office space and leased parts of its factory and office equipment. The underlying contracts usually have a term between six months and seven years (partly with special termination rights after expiry of a certain minimum term) and in some cases include an automatic extension unless the respective contract is terminated by one of the two contract parties at a certain point in time prior to its expiry.

Leases are accounted for initially recognizing a right-of-use asset and corresponding lease liability at the date the lease asset is being made available to PAION for utilization. Short-term leases and leases of low value are not recognized on the balance sheet based on IFRS 16.6. In this case, lease payments are linearly recognized as operating expenses over the term of the respective underlying lease.

Following items in connection with leases are included in the balance sheet:

	31 Dec. 2020 KEUR	31 Dec. 2019 KEUR
<b>Right-of-use assets</b>		
Land, land rights and buildings	0	42
Other plant, factory and office equipment	26	37
<b>Total</b>	<b>26</b>	<b>79</b>
<b>Lease liabilities</b>		
Short-term	11	26
Long-term	15	54
<b>Total</b>	<b>27</b>	<b>80</b>

There were no additions to right-of-use assets in fiscal year 2020.

Following items in connection with leases are included in the income statement:

	2020 KEUR	2019 KEUR
<b>Depreciation of right-of-use assets</b>		
Land, land rights and buildings	40	48
Other plant, factory and office equipment	10	7
<b>Total</b>	<b>50</b>	<b>55</b>
Interest expenses	2	3
Expenses for short-term leases according to IFRS 16.6	256	240

Total payments for leases amounted to KEUR 308 in fiscal year 2020. Future minimum lease payments from unexpired short-term leases, leases of low value and leases already contracted that will lead to recognition of right-of-use assets and lease liabilities in fiscal year 2021 amount to KEUR 473 as of 31 December 2020.

## (12) Financial debt

In August 2019, PAION entered into an agreement with U.S. investment firm Yorkville Advisors (Yorkville) for the issue of convertible notes of up to EUR 15 million in up to three tranches. Under the terms of the agreement, Yorkville is obligated to purchase convertible notes in a total nominal amount of up to EUR 15 million at an issue price corresponding to 95% of the nominal amount until June 2022. PAION may, at its own discretion, issue the next tranche of convertible notes to Yorkville under certain conditions each time once 75% of the previous tranche have been converted. The unsecured convertible notes each have a term of 15 months and are convertible into PAION shares at any time by the holder of the convertible notes. PAION can extend the term of the notes by up to 24 months against a cash fee. The conversion price is determined taking into account a 5% discount on the volume-weighted 5-day average trading price of the PAION share

immediately prior to conversion but may not be lower than 80% of the volume-weighted 10-day average price of the PAION share prior to PAION's Management Board's resolution to issue the convertible notes. Interest is not paid during the term of the notes.

The first tranche of convertible notes with a total nominal amount of KEUR 5,000 was issued to Yorkville at an issue price of KEUR 4,750 under exclusion of pre-emptive rights on 12 September 2019. The minimum conversion price was EUR 1.91 per share.

Due to the variable conversion price and the consequential variable number of shares to be issued upon (potential) conversion, the convertible notes were to be classified as debt entirely according to IAS 32.16(b) in connection with IAS 32.AG27. The entire hybrid contract is recognized at fair value based on IFRS 9.4.3.5. Initially, financial debt was recognized on the balance sheet in an amount of KEUR 5,263. The difference of KEUR 513 between the fair value and the transaction price was capitalized as a so-called day-one loss based on IFRS 9.B5.1.2A b). In the course of conversions, the day-one loss was partially amortized by direct offset of these costs of raising capital from the capital reserve according to IAS 32.35. Moreover, it was amortized as financial expenses based on the change of the time factor.

In the prior year, convertible notes with a nominal amount of KEUR 800 were converted into 407,443 PAION shares. In the reporting period, all remaining convertible notes issued in the course of this tranche with a nominal amount of KEUR 4,200 were converted into 1,955,907 shares of PAION AG.

## Consolidated statement of comprehensive income disclosures

### (13) Revenues

Revenues amount to KEUR 19,655 and primarily result from milestone payments in connection with the market approvals of remimazolam in the U.S. and Japan as well as the license extension signed with Hana Pharm in January 2020 to include six additional countries in Southeast Asia. Revenues in the previous year related to the remimazolam license agreements with Cosmo and R-Pharm.

#### Disaggregation of revenues

Revenues in the reporting period result from consideration from licensees for data and know-how transfers, the achievement of (development) milestones as well as the grant of licenses for development and commercialization (of remimazolam) in certain geographical regions. Moreover, revenues include consideration from licensees for supply with remimazolam API. Revenues of the reporting period are therefore disaggregated based on geographical regions in the following overview. Revenues are allocated to a certain region if they result from contracts with licensees for the respective region.

#### Revenues per region:

U.S.: KEUR 15,346

Asia (incl. Russia): KEUR 4,309

#### Contract balances and performance obligations

Contract balances at the beginning and end of the reporting period were as follows:

	31 Dec. 2019 KEUR	31 Dec. 2020 KEUR
Trade receivables	500	500
Refund liabilities	250	441

In the reporting period, no revenues were realized from (parts of) consideration recognized on the balance sheet as of 31 December 2019. Revenues amounting to

KEUR 17,750 were recognized in the reporting period from performance obligations partially satisfied in prior years.

As a specialty pharma group, PAION develops new product candidates in anesthesia and intensive care aiming at outlicensing these and potentially commercializing these itself in certain regions. In addition to the grant of the license for development and commercialization, typical performances in the course of outlicensing product candidates and entering into license agreements regularly comprise extensive data, technology, process and/or know-how transfers, development services, the achievement of (regulatory) milestones and the provision of market approval dossiers from other regions.

Based on the development stage of PAION's only product candidate remimazolam as of the balance sheet date which has been granted first market approvals in single regions in the reporting period but which is still in development or in approval processes in other regions, PAION generates first revenues in the form of sales-based royalties which are however not yet sustainable. Before the potential recognition of royalties upon commercialization of remimazolam, there are basically mostly upfront payments at the beginning of the contract regularly compensating – depending on the respective development stage for the specific (regulatory) requirements of the respective region – an extensive data, technology, process and/or know-how transfer as the typically first performance obligation in the course of entering into license agreements and/or the license (with a right to use) itself. Based on the respective contract, this performance can either be carried out at a point in time or over time. In case of satisfaction of the performance obligation at a point in time, payment regularly occurs shortly before the services are rendered or closely around the time the performance is carried out. In case of satisfaction of the performance obligation over time, payment regularly occurs before completion of the performance, and deferred income is being recognized for the part of the consideration that is not to be recognized as revenue yet which is then being realized as revenue over the time of the satisfaction of the performance obligation. Revenue is regularly either being recognized over a contractually defined period or over a period resulting from (planned) development steps in this case.

Chronologically following upfront payments, the license contracts regularly include consideration linked to the achievement of certain (development) milestones (see above). These can either compensate development services to be carried out or development results to be achieved by PAION or the license itself. Due to the high risk of failure in drug development, underlying revenues are only being recognized upon complete and successful achievement of the defined milestones. Therefore, no contract assets or liabilities are being recognized during the time of satisfaction of the performance obligation. Upon achievement of the milestone, revenue and corresponding trade receivables are being recognized. Achievement of a milestone is in close timely relation to the corresponding consideration to be paid by the licensee.

Payments are usually due within 30 days either after satisfaction of the performance obligation or after contract signature in case of upfront payments. There is a potential refund liability in the amount of (net) KEUR 441 from the license contract with Yichang Humanwell which can be (potentially partially) set off against royalties. The license agreements regularly do not comprise guarantees and do not include further material obligations in addition to a regular data exchange with the licensees, potential support of the licensees in their regulatory and development activities and the contractually defined performance obligations, in the course of which however not only the sole rendering of services but also the successful result of the underlying (development) performance may be owed, as e.g. the successful conduct of studies under achievement of primary and secondary endpoints as defined in advance.

The transaction price allocated to (partially) unsatisfied performance obligations is KEUR 0 for all existing license contracts as of 31 December 2020. Performance obligations existing as of 31 December 2020 entirely relate to variable consideration which is either constrained according to IFRS 15.56 or which is in the form of sales-based royalties according to IFRS 15.B63 and therefore not included in the transaction price due to the high risk of pharmaceutical development.

Material changes of contract balances in the reporting period relate to the increase of refund liabilities due to the receipt of a milestone payment from Yichang

Humanwell in the reporting period (after set off against royalties).

### **Significant judgements**

Each performance obligation is individually being analyzed in regard to the point in time or the timeframe of satisfaction. In case of satisfaction of a performance obligation over time, output methods are regularly being used for recognition of revenue. For data, technology, process and/or know-how transfers, a finalization date is typically defined until which revenues are being realized on a straight-line basis, or revenue is recognized over the timeframe resulting from the (planned) development steps otherwise. Due to the objective verifiability for the licensor as well as for the licensee, these methods depict an appropriate state of the transfer of the services. For performance obligations for which successful satisfaction contractually requires the achievement of defined milestones, revenues are only being recognized at the point in time of complete achievement of the respective defined milestone in spite of the service being rendered over time since variable consideration for these services is constrained according to IFRS 15.56. As it is not certain if milestones can be achieved or not before actual achievement of these milestones due to the high risk of pharmaceutical development, actual achievement of the milestones depicts the best measurement for revenue recognition.

Performance obligations satisfied at a point in time regularly exist for data, technology, process and/or know-how transfers on the one hand, and for the grant of licenses with a right to use on the other hand. In the case of satisfaction of performance obligations from data, technology, process and/or know-how transfers at a point in time, this point in time is regularly contractually defined and both parties confirm the successful transfer in writing allowing for a clear determination of when the control has been transferred. For the grant of licenses with a right to use according to IFRS 15.B56b), the license is regularly deemed granted at the time of conclusion of the contract and thus control of it is deemed transferred.

For determination of the transaction price of a contract, all potential payments from a contract are initially being analyzed and included in the calculation of a potential transaction price. Variable consideration is then being

analyzed in regard to a potential constraint according to IFRS 15.56 et seqq. This regularly leads to variable consideration from the achievement of (development) milestones not being included in the transaction price. Moreover, sales-based royalties according to IFRS 15.B63 are not included in the transaction price. Each variable consideration is individually analysed and evaluated in this context under consideration of the specific contractual background and the conditions for which fulfillment is required for receipt of the respective variable consideration. The high risk environment of the pharmaceutical industry in particular is taken into account for this evaluation. Within the contracts which are negotiated highly individually for the respective regions, variable consideration for the individual performance obligations is already depicted in the contractually defined payments linked to those performances. The transaction price at the time of conclusion of a contract regularly only includes the first payment mostly linked to a data, technology, process and/or know-how transfer and/or the grant of a license with a right to use which then consequentially the transaction price is allocated to. As soon as performance obligations have been satisfied by achievement of certain development steps or milestones and variable consideration is not constrained anymore, the total transaction price increases in the amount of the variable consideration which is not constrained anymore. This increase of the transaction price is allocated to the (development) performance (usually the achievement of a milestone) the variable consideration is linked to.

Returns, refunds and other similar obligations are evaluated individually based on the specific contracts and do not require estimations or measurements based on the contracts in place.

#### **Assets recognized from costs to obtain or fulfill a contract and practical expedients**

Since there are regularly no costs to obtain a contract that are only incurred in case of conclusion of a contract, no additional costs in connection with obtaining contracts have been capitalized.

#### **(14) Other income (expenses), net**

Other income (expenses) in the fiscal year includes income from recharges to licensees in the amount of KEUR 1,444 (previous year: KEUR 503) as well as expenses from obligations towards licensees in the amount of KEUR 1,575 (previous year: KEUR 121).

#### **(15) Financial result**

Financial income of KEUR 11 (previous year: KEUR 1) mainly results from interest received for receivables paid after the due date.

Financial expenses of KEUR 163 (previous year: KEUR 123) relate to the amortization (change of the time factor) of the day-one loss capitalized in the prior year in the course of the issue of convertible bonds based on IFRS 9.B5.1.2A b) in an amount of KEUR 94, to negative interest on bank balances and current deposits in an amount of KEUR 67 and to the compounding of lease liabilities in an amount of KEUR 2.

#### **(16) Income taxes/Deferred taxes**

As of 31 December 2020, the tax losses carried forward by PAION Germany group (PAION AG and PAION Deutschland GmbH) amounted to about EUR 81 million (previous year: EUR 80 million). According to current German tax legislation, these losses can be carried forward indefinitely and offset against future earnings according to the relevant tax regulations (e.g. minimum taxation).

The tax losses carried forward by the British subsidiaries amount to GBP 111 million as of 31 December 2020 (equivalent to EUR 123 million if translated at the exchange rate applicable on the reporting date). In the previous year, these amounted to GBP 111 million or EUR 130 million, respectively. According to British tax legislation, these can be carried forward indefinitely and a large portion of them can be offset against future earnings according to the relevant tax regulations (e.g. minimum taxation).

The tax loss carried forward by the Dutch subsidiary amounts to slightly less than EUR 2 million as of 31 December 2020. According to Dutch tax legislation, it can be carried forward for six years and can be offset

against future earnings according to the relevant tax regulations.

Overall, the losses carried forward within the Group amount to EUR 206 million (previous year: EUR 211 million). No deferred tax assets were recognized regarding a partial amount of EUR 205 million (previous year: EUR 209 million) of the total tax losses carried forward.

The composite German corporate income tax rate is 32.45% resulting from a corporate income tax rate of 15.0%, the solidarity surcharge of 5.5% that is levied on corporate income tax, and the trade earnings tax rate of 16.625%. The corporate income tax rate in Great Britain is 19%. The corporate income tax in the Netherlands is 16.5% or 25% respectively for taxable earnings above KEUR 200 for calendar year 2020. Corporate income tax in the Netherlands will be 15% or 25% respectively for taxable earnings above KEUR 245 starting 2021. The expected tax rate for the Group overall is 30%.

Intangible assets were recognized in an amount of KEUR 13,844 as part of the purchase price allocation of PAION UK Group, which was acquired in 2008. The measurement of these development projects resulted in deferred tax liabilities in an amount of KEUR 3,876 based on the British income tax rate of 28% applicable at that time. These were offset by the same amount of deferred tax assets on losses carried forward. Deferred tax assets and liabilities are written down in line with the amortization of the development projects. Deferred taxes are reported as net balances in both the balance sheet and the statement of comprehensive income. As of the balance sheet date, deferred tax assets and liabilities each amounted to KEUR 344 (previous year: KEUR 356) after currency translation; these relate to the intangible asset remimazolam (deferred tax liabilities) as well as in the same amount to deferred taxes on losses carried forward (deferred tax assets).

If the combined income tax rate that is currently applicable in Germany was applied to the tax losses carried forward in Germany as of 31 December 2020, the resulting deferred tax assets would amount to EUR 26 million (previous year: EUR 26 million). Based on the income tax rate of 19% applicable in Great Britain, the losses carried forward in Great Britain as of 31 December 2020 would

produce deferred tax assets in an amount of GBP 21 million (equivalent to EUR 23 million if translated at the rate applicable on the reporting date). In the previous year, these amounted to GBP 19 million or EUR 22 million, respectively (based on the applicable tax rate of 17% at that time for periods starting 1 April 2020). In the Netherlands, only immaterial deferred tax assets of less than KEUR 500 would result from the tax losses carried forward regardless of the assumed timing and consequentially applicable tax rate. The temporary differences between the tax base and the IFRS carrying amount would produce a net balance as of 31 December 2020 of deferred tax assets in an amount of KEUR 265 (previous year: KEUR 254), of which Germany accounts for KEUR 0 (previous year: KEUR 5), Great Britain for KEUR 265 (previous year: KEUR 249) and the Netherlands for KEUR 0 (previous year: KEUR 0). The depicted differences in carrying amounts relate mainly to fixed assets and provisions. Total deferred tax assets would amount to EUR 50 million (previous year: EUR 48 million).

In the fiscal year, PAION Deutschland GmbH and PAION UK Ltd. reported a profits; the other companies of the PAION Group have reported losses. In coming years, further losses are expected to be generated. As a result, the realizability of the deferred tax assets mentioned above is not considered sufficiently likely before a sustainable and successful launch of remimazolam as well as the two products GIAPREZA® and XERAVA® in-licensed after the balance sheet date for Europe. In line with IAS 12.34 "Income Taxes", the excess assets of the deferred tax assets on losses carried forward and the excess assets of deferred taxes on temporary differences are therefore not recognized.

In the reporting period, also the other comprehensive income (foreign currency translation of foreign subsidiaries) does not have any tax effects.

Based on an anticipated Group tax rate of 30%, the reconciliation of anticipated and actual income taxes is as follows:

In KEUR	2020	2019
<b>Result for the period before taxes</b>	<b>1,430</b>	<b>-9,448</b>
Anticipated tax expense (+)/income (-)	429	-2,834
Adjustment non-recognition of deferred taxes on tax losses due to tax rate changes	2,469	0
Non-recognition of deferred taxes on tax losses	790	725
Expenses in connection with stock options	94	102
Deferred taxes on adjusted tax losses from previous years	71	0
Non-deductible expenses	28	31
Non-recognition of deferred taxes on temporary differences	0	-5
Cost in connection with capital increases	-11	-2
Effect of convertible notes	-11	0
Non-recognition of deferred taxes on adjusted tax losses from previous years	-71	0
Tax losses used	-74	-78
Effect of tax rate changes	-93	7
Difference between anticipated Group tax rate and actual local tax rates	-171	664
Effects from currency translation	-390	257
Effects from tax credits	-1,386	-1,300
Revaluation of tax losses due to tax rate changes	-2,469	0
Others	3	1
<b>Actual tax expense (+)/income (-)</b>	<b>-792</b>	<b>-2,432</b>

The actual tax income results from the expected reimbursement of research and development costs through British tax authorities. The expected tax credits reduced the tax losses carried forward accordingly.

## (17) Earnings per share

In accordance with IAS 33 "Earnings per Share", the earnings per share were calculated on the basis of the net result for the year and the weighted average number of shares outstanding. The underlying weighted average number of ordinary shares is derived as follows:

	2020	2019
Shares outstanding as of 1 January	64,265,586	63,858,143
Weighted average number of shares issued	1,455,809	60,609
<b>Weighted average number of ordinary shares</b>	<b>65,721,395</b>	<b>63,918,752</b>

The calculation of basic and diluted earnings per share is based on the following figures:

	2020	2019
<b>Net result for the year in EUR</b>	<b>2,222,143.55</b>	<b>-7,015,815.07</b>
Weighted average number of ordinary shares for basic earnings per share	65,721,395	63,918,752
Weighted average number of ordinary shares for diluted earnings per share	66,133,456	64,035,132
<b>Earnings per share in EUR:</b>		
<b>Basic</b>	<b>0.03</b>	<b>-0.11</b>
<b>Diluted</b>	<b>0.03</b>	<b>-0.11</b>

Potential ordinary shares from the exercise of stock options only have a dilutive effect if the new ordinary shares from the exercise of stock options led to a lower net profit per share. Under consideration of the net result of the PAION group, potential new ordinary shares did therefore not induce a dilutive effect in the prior year.

## Consolidated cash flow statement disclosures

The consolidated cash flow statement shows how additions and disposals have changed the cash and cash equivalents held by PAION over the course of the fiscal year. In accordance with IAS 7 “Statement of Cash Flows”, a distinction is made between cash flows from operating activities, from investing activities and from financing activities. The cash and cash equivalents reported in the consolidated cash flow statement are comprised of cash and bank balances, together with current deposits that mature within three months from investment. PAION owns leased right-of-use assets which are being accounted for based on IFRS 16 and are thus not depicted in the cash flow statement in the course of their acquisition. For details see note (11) of the consolidated balance sheet disclosures.



## Other disclosures

### Stock Option Plans

PAION has implemented a total of five active stock option plans in the course of which stock options can be/have been granted to Management Board members and employees of PAION AG and its subsidiaries at the time of the grant. The stock options are accounted for in accordance with the provisions of IFRS 2. All stock option plans include vesting periods, waiting periods and exercise hurdles. The respective exercise price is based on the average stock price during a certain period of time before the grant and potentially required adjustments. Details of the individual plans can be found in the following table (the presentation of Stock Option Plan 2008, of which the last stock options lapsed in the reporting period, as well as the presentation of Stock Option Plan 2020, from which no stock options have been granted yet, are omitted):

	Stock Option Plan 2010 Approved 19 May 2010	Stock Option Plan 2014 Approved 21 May 2014
Underlying Capital	Conditional Capital 2010 I	Conditional Capital 2014
Term of the options	10 years	10 years
Vesting period	2 years	2–4 years
Waiting period	4 years	4 years
Number of outstanding options for which the waiting period has expired as of 31 December 2020	676,626	474,510
Exercise condition	Cumulative stock price increase of 5% per year since grant in relation to exercise price	Cumulative stock price increase of 5% per year since grant in relation to exercise price
Exercise price *	EUR 1.31 * <sup>1</sup>	EUR 1.99 to EUR 2.60
Weighted average exercise price *	EUR 1.31 * <sup>1</sup>	EUR 2.21
Exercise hurdle as of 31 Dec. 2020 *	EUR 2.43 * <sup>1</sup>	EUR 2.44 to EUR 3.08
Weighted average remaining term as of 31 Dec. 2020	3.1 years	5.0 years
Further grants possible? (as of 31 Dec. 2020)	No	No
Number of totally granted options until 31 Dec. 2020	720,000	740,000
Number of outstanding options as of 31 Dec. 2020 * <sup>2</sup>	676,626	530,010
granted to employees	372,876	231,697
granted to Management Board members	303,750	298,313
Number of totally lapsed options as of 31 Dec. 2020	23,374	209,990
thereof lapsed in the reporting period	0	0
Number of totally exercised options until 31 Dec. 2020	20,000	0
thereof exercised in the reporting period	20,000	0
Personnel expenses in the reporting period	EUR 0	KEUR 3
Fair value per option at the time of the grant * <sup>3</sup>	EUR 1.67	EUR 1.02 to EUR 1.39
Elements of calculation		
Valuation model	Black/Scholes	Black/Scholes
Risk-free rate	0.7%	-0.26% to 0.08%
Volatility	73.75%	72.34% to 83.76%
Staff turnover * <sup>4</sup>	10% per year	9% per year
* in relation to outstanding options as of 31 Dec. 2020		
* <sup>1</sup> adjusted based on terms of the Stock Option Plan		
* <sup>2</sup> in relation to employee/Management Board member status at the time of the grant		
* <sup>3</sup> in relation to totally granted options		
* <sup>4</sup> turnover last used for update of the quantity structure conducted until the end of the respective vesting period		

**Stock Option Plan 2016**  
**Approved 25 May 2016**

**Stock Option Plan 2018**  
**Approved 23 May 2018**

Conditional Capital 2016

Conditional Capital 2018 II

10 years

10 years

2-4 years

2-4 years

4 years

4 years

0

0

Cumulative stock price increase of 5%  
per year since grant in relation to  
exercise price

Cumulative stock price increase of 5%  
per year since grant in relation to  
exercise price

EUR 2.00 to EUR 2.60

EUR 2.00 to EUR 2.35

EUR 2.28

EUR 2.19

EUR 2.08 to EUR 2.98

EUR 2.08 to EUR 2.44

7.5 years

9.3 years

No

Yes

840,000

886,500

702,672

806,250

353,838

458,500

348,834

347,750

137,328

80,250

41,600

80,250

0

0

0

0

KEUR 110

KEUR 173

EUR 0.75 to EUR 1.70

EUR 0.75 to EUR 0.84

Black/Scholes

Black/Scholes

-0.40% to -0.14%

-0.44% to -0.40%

39.03% to 81.61%

39.03% to 56.15%

9% per year

9% per year

### Other financial obligations/Contingent liabilities

Based on assigning the conduct of (non-)clinical studies to Clinical Research Organizations (CROs) and having contractual manufacturers perform the production (development) and manufacture the (study) medication, PAION has contractually committed financial obligations in the amount of approx. EUR 6.7 million as of the balance sheet date. The underlying contracts have variable notice periods of several months at the maximum. If contracts were terminated, the depicted financial obligations would decrease.

### Headcount and personnel expenses

In fiscal year 2020, PAION had an average of 43 employees (previous year: 44 employees). Of these 43 employees, 30 worked in development and 13 in administration and sales. PAION UK Group had an average headcount of ten employees. As of 31 December 2020, the headcount was 43 (31 December 2019: 45).

The following personnel expenses were incurred in fiscal years 2020 and 2019:

	2020 KEUR	2019 KEUR
Wages and salaries	5,062	4,772
Social security contributions	606	602
<b>Total</b>	<b>5,668</b>	<b>5,374</b>

The personnel expenses stated above include (net) expenses from the granting of stock options in connection with the Stock Option Plans 2014, 2016 and 2018 in an amount of KEUR 286 (previous year: KEUR 335). The figures also include contributions to the German and British social insurance schemes in an amount of KEUR 533 (previous year: KEUR 536) and expenses for defined contribution plans in the amount of KEUR 66 (previous year: KEUR 56).

### Related parties

In accordance with IAS 24 "Related Party Disclosures", information must be provided on related parties. Members of both the Management Board and the Supervisory Board, and

shareholders, are classified as related parties in the context of IAS 24.9. As far as the remuneration paid to and equity interests owned by the members of the Management and Supervisory Board are concerned, please refer to the explanations in the subsections "Members of the Management Board" and "Members of the Supervisory Board" in this section.

No relationships with related parties existed otherwise.

### Objectives and methods of financial risk management

PAION's business activities currently focus on completion of the clinical and production development for remimazolam as well as regulatory activities. Moreover, PAION is working on building up a supply chain and conducting pre-commercial activities for remimazolam. Since these activities are not yet generating (sustainable) revenues from (own) sales of launched products, losses are still scheduled in the coming years. PAION aims at commercializing remimazolam and the products GIAPREZA® and XERAVA® in-licensed after the balance sheet date either itself or through partners depending on the respective market as well as to ensure the availability of the requisite short-term and mid-term funding. This funding is primarily secured by means of equity and/or debt as well as through cooperation agreements, pursuant to which the cooperation partners effect milestone payments and assume direct and indirect responsibility for the development and/or commercialization. Future possibilities to attract additional equity and debt will depend to a large extent on the positive progress of the regulatory process of remimazolam, mainly in Europe, as well as the success of (later) commercialization of remimazolam in the U.S. and Europe and the two products GIAPREZA® and XERAVA® in-licensed after the balance sheet date in Europe. PAION's management therefore concentrates on managing and monitoring the individual development projects, its liquidity and its future liquidity requirements.

The financial liabilities are comprised of provisions, trade payables and part of the other liabilities. PAION owns various financial assets, such as trade receivables, part of the other assets as well as bank balances and current deposits. These financial assets and liabilities are direct products of PAION's business operations and/or are used to finance ongoing business activities. For all financial assets it is

intended to collect the original cash flows. These only include the original claim and potential interest.

PAION AG uses derivative financial instruments in the context of foreign exchange risk management. In doing so, only financial instruments with an explicit hedging relationship are used.

The financial instruments expose PAION to the following risks:

PAION is exposed to currency risks arising from the loan granted to the British subsidiary PAION UK Ltd. as well as from its trade payables to a currently only minor degree anymore. Liquid assets are mainly invested in euros, but to a low extent, also funds in Pound Sterling and U.S. dollar are held.

The loan granted by PAION AG to its British subsidiary PAION UK Ltd produced exchange rate gains of KEUR 1,311 in fiscal year 2020 which were recognized in equity. If the EUR/GBP exchange rate had been 5% higher on the balance sheet date, the currency component recognized in equity in the reporting period would have decreased by KEUR 896 compared to the change in the currency component actually recognized in equity in 2020. If the EUR/GBP exchange rate had been 5% lower on the balance sheet date, the currency component recognized in equity in the reporting period would have increased by KEUR 896 compared to the change in the currency component actually recognized in equity in 2020.

PAION's bank balances and current deposits are mainly held with two major German banks, a savings bank and a major British bank. The choice of short-term capital investments is based on various security criteria (e.g. rating, capital guarantee, safeguarded by the deposit protection fund (Einlagensicherungsfonds)). In light of these selection criteria and the ongoing monitoring of its capital investments, PAION deems the occurrence of a counterparty credit risk in this area improbable. The amounts stated in the balance sheet always represent the maximum possible default risk.

PAION uses a customized business planning tool to monitor and manage its cash flows; this tool comprises both short- and medium-term, and long-term business planning. Liquidity risks are identified at an early stage by simulating different scenarios and conducting sensitivity analyses. Current liquidity is recorded and monitored on a daily basis.

The interest earned on bank balances and current deposits is dependent on the development of market interest rates. As such, these assets held by PAION are exposed to the risk of changing interest rates. A reduction of 10 basis points in the interest rates on bank balances and current deposits would have reduced the consolidated result by KEUR 17 in fiscal year 2020.

The other assets mainly comprise claims for tax refunds from the tax authorities in Great Britain in connection with the partial reimbursement of research and development costs. The calculation of the refund claims is based on the calculation method agreed in previous years between the PAION UK companies and the British tax authorities. A final review of the tax credit recognized for 2020 by the British tax authorities has however not taken place as of the balance sheet date.

## Financial instruments

The following table shows the carrying amounts and fair values of the financial instruments included in the consolidated financial statements:

in KEUR	Carrying amount		Fair value		
	31 Dec. 2020	31 Dec. 2019	31 Dec. 2020	31 Dec. 2019	
<b>Financial assets:</b>					
Cash and cash equivalents	(1)	19,666	18,787	19,666	18,787
Trade receivables	(1)	500	500	500	500
Other assets	(1)	59	101	59	101
<b>Financial liabilities:</b>					
Trade payables	(1)	3,907	4,843	3,907	4,843
Provisions	(1)	2,206	270	2,206	270
Lease liabilities		27	80	27	80
Financial debt	(2)	0	4,354	0	4,354
Other liabilities	(1)	596	415	596	415

Measurement category according to IFRS 9:

(1) Recognized at amortized cost

(2) Recognized at fair value through profit or loss

Cash and cash equivalents, trade receivables, other assets, trade payables, provisions and other liabilities have short residual terms and their carrying amounts are equivalent to the fair values as of the balance sheet date. The determination of the fair values of these financial instruments was thus based on unobservable input factors (input factors of level 3 according to IFRS 13). The determination of the fair value of financial debt was based on quoted prices in an active market (input factor of level 1 according to IFRS 13).

In fiscal year 2020, 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.

### Members of the Management Board

The members of the company's Management Board in the reporting period are/were:

- Dr. James Phillips, CEO, Chairman

Memberships in comparable/other domestic and foreign control boards:

- Herantis Pharma plc, Espoo/Finland

- Abdelghani Omari, CFO
- Dr. Jürgen Beck, CDO (until 31 December 2020)

Management Board remuneration totalled

KEUR 1,394 in fiscal year 2020. As of 31 December 2020, a total of 741,000 stock options (fair value at time of granting: EUR 692,425) had been issued to active Management Board members as of 31 December 2020. For more information on Management Board remuneration, please see the disclosures in the remuneration report, which is part of the group management report.

All Management Board members are also Managing Directors of PAION Deutschland GmbH, PAION Holdings UK Ltd and its subsidiaries as well as of PAION Netherlands B.V. All Management Board members work full-time for the company and its subsidiaries.

As of 31 December 2020, Dr. Phillips owned 0.01% (8,750 voting rights) of the shares in PAION AG.

### Members of the Supervisory Board:

The members of the Supervisory Board in the reporting period are/were:

- Dr. Jörg Spiekerkötter, Berlin/Germany, Chairman; Managing Partner of JSP-Invest GmbH, Potsdam/Germany

Memberships in comparable/other domestic and foreign control boards:

- Dr. Loges + Co. GmbH, Winsen (Luhe)/Germany (Chairman) (until 31 August 2020)

- Dr. Karin Louise Dorrepaal, Amsterdam/The Netherlands, Vice Chairman; Chairman of the HR and Nomination Committee, former Member of the Management Board of Schering AG

Memberships in Supervisory Boards according to German legal regulations:

- Gerresheimer AG, Dusseldorf/Germany

Memberships in comparable/other domestic and foreign control boards:

- Almirall S.A., Barcelona/Spain
- Triton Beteiligungsberatung GmbH, Frankfurt/Germany
- Kerry Group plc, Tralee/Ireland
- Van Eeghen & Co B.V., Amsterdam/The Netherlands (since 24 June 2020)
- Julius Clinical Research BV, Zeist/The Netherlands
- Intravacc B.V., Bilthoven/ The Netherlands (since 1 January 2021)

- Dr. Dr. Irina Antonijevic, Boston, MA/U.S., Chairman of the Research and Development Committee; Chief Medical Officer at Triplet Therapeutics, Inc., Cambridge, MA/U.S.

Memberships in Supervisory Boards according to German legal regulations:

- 4SC AG, Planegg-Martinsried (Munich)/Germany

- Dr. Hans Christoph Tanner, Horgen/Switzerland, Chairman of the Audit Committee, former Head of Transactions of Cosmo Pharmaceuticals N.V., Amsterdam/The Netherlands, and former Chief Financial Officer & Head of Investor Relations of Cassiopea SpA, Milan/Italy

Memberships in Supervisory Boards according to German legal regulations:

- CureVac AG, Tübingen/Germany (until 14 August 2020)

Memberships in comparable/other domestic and foreign control boards:

- CureVac N.V., Tübingen/Germany (since 14 August 2020)
- Cosmo Pharmaceuticals N.V., Amsterdam/The Netherlands
- DKSH Holding AG, Zurich/Switzerland
- Joimax GmbH, Karlsruhe/Germany
- Qvanteq AG, Zurich/Switzerland
- Wyss Zurich (ETH Zürich), Zurich/Switzerland

- Dr. Markus Leyck Dieken, Berlin/Germany, Member of the Supervisory Board, Managing Director of gematik Gesellschaft für Telematikanwendungen der Gesundheitskarte mbH, Berlin/Germany

Remuneration of the Supervisory Board totalled KEUR 163 in fiscal year 2020. For more information on Supervisory Board remuneration, please see the disclosures in the remuneration report of the group management report.

As of 31 December 2020, none of the members of the Supervisory Board owned shares in PAION AG.

### Financial statements auditor

The Annual General Meeting on 27 May 2020 appointed Ernst & Young GmbH Wirtschaftsprüfungsgesellschaft, Cologne office, Germany, as auditor of the annual and consolidated financial statements for fiscal year 2020. The auditor has received or will invoice the following fees for services rendered to PAION AG and its subsidiaries in fiscal year 2020:

	2020 KEUR	2019 KEUR
Audits of financial statements	105	96
	<b>105</b>	<b>96</b>

The fees for audits of financial statements include remuneration for reviewing the interim financial statements in the amount of KEUR 12 (previous year: KEUR 11).

### Corporate Governance

The Supervisory Board and Management Board of PAION AG declare that they are committed to responsible and transparent management and control of the company focused on adding value in the long term.

In December 2020, the Supervisory Board and the Management Board issued the Declaration of Conformity with the Corporate Governance Code pursuant to Section 161 AktG.

The Declaration of Conformity is published on PAION AG's website (<http://www.paion.com/media-and-investors/corporate-governance/declaration-of-conformity/>).

### Report on post-balance sheet date events

On 12 January 2021, PAION entered into a license agreement with La Jolla Pharmaceutical Company and further

subsidiaries of this company which grants PAION the rights for exclusive commercialization of the two approved products GIAPREZA® and XERAVA® in the European Economic Area, Switzerland and the United Kingdom.

On 28 January 2021, the Committee for Medicinal Products for Human Use (CHMP) of the European Medicines Agency (EMA) adopted a positive opinion recommending the approval of Byfavo® (remimazolam) for procedural sedation in adult patients.

On 12 February 2021, PAION AG drew down the first two tranches of the financing agreement with the European Investment Bank (EIB) amounting to EUR 12.5 million in total.

On 5 March 2021, PAION granted an exclusive license for development and commercialization of remimazolam in Taiwan to TTY Biopharm.

On 19 March 2021, a capital increase with subscription rights with planned gross proceeds of EUR 7.8 million was resolved, the completion of which is planned for 9 April 2021. By means of this capital increase, the share capital of PAION AG is planned to be increased by EUR 5,095,499.00 from EUR 66,241,493.00 to EUR 71,336,992.00 by utilization of the Authorized Capital 2020 by issuing 5,095,499 new shares. After the rights issue, the Authorized Capital 2020 will amount to EUR 21,039,429.00.

There were no further significant events in the period between the reporting date, 31 December 2020, and the preparation of this report.

Aachen, Germany, 30 March 2021

PAION AG

  
Dr. James Phillips

  
Abdelghani Omari

Responsibility Statement (Bilanzzeit) in accordance with section 117 no.1 of the Wertpapierhandelsgesetz (WpHG – German Securities Trading Act) in conjunction with sections 297(2) sentence 4 and 315(1) sentence 5 of the Handelsgesetzbuch (HGB – German Commercial Code)

„To the best of our knowledge, and in accordance with the applicable reporting principles, the consolidated financial statements give a true and fair view of the assets, liabilities, financial position and profit or loss of the group, and the group management report 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.“

Aachen, Germany, 30 March 2021

PAION AG



Dr. James Phillips



Abdelghani Omari

## Reproduction of the auditor's report

### “Independent auditor's report

To PAION AG, Aachen

### Report on the audit of the consolidated financial statements and of the group management report

#### Opinions

We have audited the consolidated financial statements of PAION AG, Aachen, and its subsidiaries (the Group), which comprise the consolidated balance sheet as at 31 December 2020, and the consolidated statement of comprehensive income, consolidated statement of changes in equity and consolidated cash flow statement for the fiscal year from 1 January 2020 to 31 December 2020, and notes to the consolidated financial statements, including a summary of significant accounting policies. In addition, we have audited the group management report of PAION AG for the fiscal year from 1 January 2020 to 31 December 2020. In accordance with the German legal requirements, we have not audited the content of the group statement on corporate governance that is part of the group management report and was published on the website cited in the group management report. Furthermore, we have not audited the content of sub-section “Clinical development” of section “Economic report” of the group management report which relates to extraneous information. This relates to any information whose disclosure in the group management report is not required pursuant to Secs. 315, 315a HGB [“Handelsgesetzbuch”: German Commercial Code] or Secs. 315b to 315d HGB.

In our opinion, on the basis of the knowledge obtained in the audit,

- the accompanying consolidated financial statements comply, in all material respects, with the IFRSs as adopted by the EU, and the additional requirements of German commercial law pursuant to Sec. 315e (1) HGB and, in compliance with these requirements, give a true and fair view of the assets, liabilities and financial position of the Group as at 31 December 2020 and of its financial performance for the fiscal year from 1 January 2020 to 31 December 2020, and
- the accompanying group management report as a whole provides an appropriate view of the Group's position. In all

material respects, this group management report is consistent with the consolidated financial statements, complies with German legal requirements and appropriately presents the opportunities and risks of future development. Our opinion on the group management report does not cover the content of the group statement on corporate governance referred to above or the subsection “Clinical development” in section “Economic report” of the group management report referred to above.

Pursuant to Sec. 322 (3) Sentence 1 HGB, we declare that our audit has not led to any reservations relating to the legal compliance of the consolidated financial statements and of the group management report.

#### Basis for the opinions

We conducted our audit of the consolidated financial statements and of the group management report in accordance with Sec. 317 HGB and the EU Audit Regulation (No 537/2014, referred to subsequently as “EU Audit Regulation”) and in compliance with German Generally Accepted Standards for Financial Statement Audits promulgated by the Institut der Wirtschaftsprüfer [Institute of Public Auditors in Germany] (IDW). We performed the audit of the consolidated financial statements in supplementary compliance with the International Standards on Auditing (ISAs). Our responsibilities under those requirements, principles and standards are further described in the “Auditor's responsibilities for the audit of the consolidated financial statements and of the group management report” section of our auditor's report. We are independent of the group entities in accordance with the requirements of European law and German commercial and professional law, and we have fulfilled our other German professional responsibilities in accordance with these requirements. In addition, in accordance with Art. 10 (2) f) of the EU Audit Regulation, we declare that we have not provided non-audit services prohibited under Art. 5 (1) of the EU Audit Regulation. We believe that the audit evidence we have obtained is sufficient and appropriate to provide a basis for our opinions on the consolidated financial statements and on the group management report.

## **Key audit matters in the audit of the consolidated financial statements**

Key audit matters are those matters that, in our professional judgement, were of most significance in our audit of the consolidated financial statements for the fiscal year from 1 January 2020 to 31 December 2020. These matters were addressed in the context of our audit of the consolidated financial statements as a whole, and in forming our opinion thereon; we do not provide a separate opinion on these matters.

Below, we describe what we consider to be the key audit matters:

### **1. Recognition and measurement of the tax credit for certain research and development expenses in the UK**

#### **1.1 Reasons why the matter was determined to be a key audit matter**

The research and development activities for the main product remimazolam are performed by PAION UK Ltd. For the incurred research and development costs the company requests for tax reliefs from the UK tax authorities. There is a risk that the research and development expenses incurred during the fiscal year will be only partially or not at all recognised by the UK tax authorities as tax-privileged research and development expenses. Tax recognition depends on the categorisation of the individual cost components as well as the other requirements of UK tax law. There is therefore a risk that, in the event of an incorrect categorisation of the cost components, research and development expenses will be only partially or not at all recognised, which would mean that the receivable from the UK tax authorities reported as of 31 December 2020 would be only partially or not at all recoverable. The potential non-recognition of the research and development expenses and the corresponding resulting lack of cash inflow would give rise to higher financing requirements on the part of PAION. In light of this and the related use of judgement, the recoverability of the tax credit for certain research and development expenses was a key audit matter.

#### **1.2 Auditor's response**

With regard to the calculation of refundable research and development expenses, we analysed the process implemented within the Group and the related controls in connection with the full and correct categorisation of the cost components. We obtained an understanding of the composition, completeness and origination of the research and development expenses by comparing the individual cost components with accounting evidence on a sample basis, examining whether the type and amount of the costs agree with the evidence. Additionally, we analysed the tax return of PAION UK for 2020 prepared by an external tax advisor by checking the tax return for arithmetical accuracy and also assessed whether the return was prepared in accordance with the requirements of the UK tax law. We also involved our tax specialists in the UK for this purpose. Additionally, we compared the figures in the tax return with the figures from the financial accounts.

Our audit procedures did not lead to any reservations regarding the recognition and measurement of the tax credit for certain research and development expenses in the UK.

#### **1.3 Reference to related disclosures**

With regard to the accounting bases applied to the tax credits as well as other disclosures, refer to section "Accounting policies, paragraph: Income taxes/deferred taxes" and section "Consolidated balance sheet disclosures, (5) Prepaid expenses and other assets" in the notes to the Company's consolidated financial statements.

#### **Other information**

The executive directors are responsible for the other information. The other information comprises the group statement on corporate governance referred to above and the sub-section "Clinical development" of section "Economic report" of the group management report referred to above, as well as the "Responsibility statement pursuant to Sec. 297 (2) Sentence 4 HGB and statement on the consolidated financial statements and group management report pursuant to Sec. 315 (1) Sentence 5 HGB", which will be included in the annual report and of which we obtained a version prior to issuing this auditor's report.

Our opinions on the consolidated financial statements and on the group management report do not cover the other information, and consequently we do not express an opinion or any other form of assurance conclusion thereon.

In connection with our audit, our responsibility is to read the other information and, in so doing, to consider whether the other information

- is materially inconsistent with the consolidated financial statements, with the group management report or our knowledge obtained in the audit, or
- otherwise appears to be materially misstated.

#### **Responsibilities of the executive directors and the Supervisory Board for the consolidated financial statements and the group management report**

The executive directors are responsible for the preparation of the consolidated financial statements that comply, in all material respects, with IFRSs as adopted by the EU and the additional requirements of German commercial law pursuant to Sec. 315e (1) HGB, and that the consolidated financial statements, in compliance with these requirements, give a true and fair view of the assets, liabilities, financial position, and financial performance of the Group. In addition, the executive directors are responsible for such internal control as they have determined necessary to enable the preparation of consolidated financial statements that are free from material misstatement, whether due to fraud or error.

In preparing the consolidated financial statements, the executive directors are responsible for assessing the Group's ability to continue as a going concern. They also have the responsibility for disclosing, as applicable, matters related to going concern. In addition, they are responsible for financial reporting based on the going concern basis of accounting unless there is an intention to liquidate the Group or to cease operations, or there is no realistic alternative but to do so.

Furthermore, the executive directors are responsible for the preparation of the group management report that, as a whole, provides an appropriate view of the Group's position and is, in all material respects, consistent with the consolidated financial statements, complies with German legal requirements, and appropriately presents the opportunities and risks of future development. In addition, the executive directors are responsible for such arrangements and measures (systems) as they have

considered necessary to enable the preparation of a group management report that is in accordance with the applicable German legal requirements, and to be able to provide sufficient appropriate evidence for the assertions in the group management report.

The Supervisory Board is responsible for overseeing the Group's financial reporting process for the preparation of the consolidated financial statements and of the group management report.

#### **Auditor's responsibilities for the audit of the consolidated financial statements and of the group management report**

Our objectives are to obtain reasonable assurance about whether the consolidated financial statements as a whole are free from material misstatement, whether due to fraud or error, and whether the group management report as a whole provides an appropriate view of the Group's position and, in all material respects, is consistent with the consolidated financial statements and the knowledge obtained in the audit, complies with the German legal requirements and appropriately presents the opportunities and risks of future development, as well as to issue an auditor's report that includes our opinions on the consolidated financial statements and on the group management report.

Reasonable assurance is a high level of assurance, but is not a guarantee that an audit conducted in accordance with Sec. 317 HGB and the EU Audit Regulation and in compliance with German Generally Accepted Standards for Financial Statement Audits promulgated by the Institut der Wirtschaftsprüfer (IDW) and in supplementary compliance with ISAs will always detect a material misstatement. Misstatements can arise from fraud or error and are considered material if, individually or in the aggregate, they could reasonably be expected to influence the economic decisions of users taken on the basis of these consolidated financial statements and this group management report.

We exercise professional judgment and maintain professional scepticism throughout the audit.

We also:

- Identify and assess the risks of material misstatement of the consolidated financial statements and of the group management report, whether due to fraud or error, design and perform audit procedures responsive to those risks,

and obtain audit evidence that is sufficient and appropriate to provide a basis for our opinions. The risk of not detecting a material misstatement resulting from fraud is higher than for one resulting from error, as fraud may involve collusion, forgery, intentional omissions, misrepresentations, or the override of internal control.

- Obtain an understanding of internal control relevant to the audit of the consolidated financial statements and of arrangements and measures (systems) relevant to the audit of the group management report in order to design audit procedures that are appropriate in the circumstances, but not for the purpose of expressing an opinion on the effectiveness of these systems.
- Evaluate the appropriateness of accounting policies used by the executive directors and the reasonableness of estimates made by the executive directors and related disclosures.
- Conclude on the appropriateness of the executive directors' use of the going concern basis of accounting and, based on the audit evidence obtained, whether a material uncertainty exists related to events or conditions that may cast significant doubt on the Group's ability to continue as a going concern. If we conclude that a material uncertainty exists, we are required to draw attention in the auditor's report to the related disclosures in the consolidated financial statements and in the group management report or, if such disclosures are inadequate, to modify our respective opinions. Our conclusions are based on the audit evidence obtained up to the date of our auditor's report. However, future events or conditions may cause the Group to cease to be able to continue as a going concern.
- Evaluate the overall presentation, structure and content of the consolidated financial statements, including the disclosures, and whether the consolidated financial statements present the underlying transactions and events in a manner that the consolidated financial statements give a true and fair view of the assets, liabilities, financial position and financial performance of the Group in compliance with IFRSs as adopted by the EU and the additional requirements of German commercial law pursuant to Sec. 315e (1) HGB.
- Obtain sufficient appropriate audit evidence regarding the financial information of the entities or business activities

within the Group to express opinions on the consolidated financial statements and on the group management report. We are responsible for the direction, supervision and performance of the group audit. We remain solely responsible for our audit opinions.

- Evaluate the consistency of the group management report with the consolidated financial statements, its conformity with [German] law, and the view of the Group's position it provides.
- Perform audit procedures on the prospective information presented by the executive directors in the group management report. On the basis of sufficient appropriate audit evidence we evaluate, in particular, the significant assumptions used by the executive directors as a basis for the prospective information, and evaluate the proper derivation of the prospective information from these assumptions. We do not express a separate opinion on the prospective information and on the assumptions used as a basis. There is a substantial unavoidable risk that future events will differ materially from the prospective information.

We communicate with those charged with governance regarding, among other matters, the planned scope and timing of the audit and significant audit findings, including any significant deficiencies in internal control that we identify during our audit.

We also provide those charged with governance with a statement that we have complied with the relevant independence requirements, and communicate with them all relationships and other matters that may reasonably be thought to bear on our independence and where applicable, the related safeguards.

From the matters communicated with those charged with governance, we determine those matters that were of most significance in the audit of the consolidated financial statements of the current period and are therefore the key audit matters. We describe these matters in our auditor's report unless law or regulation precludes public disclosure about the matter.

## **Other legal and regulatory requirements**

### **Report on the assurance in accordance with § 317 Abs. 3b HGB on the electronic reproduction of the consolidated financial statements and the group management report prepared for publication purposes**

#### **Reasonable assurance opinion**

We have performed assurance work in accordance with § 317 Abs. 3b HGB to obtain reasonable assurance about whether the reproduction of the consolidated financial statements and the group management report (hereinafter the "ESEF documents") contained in the attached electronic file Paion\_AG\_KA+KLB\_ESEF-2020-12-31.ZIP and prepared for publication purposes complies in all material respects with the requirements of § 328 Abs. 1 HGB for the electronic reporting format ("ESEF format"). In accordance with German legal requirements, this assurance only extends to the conversion of the information contained in the consolidated financial statements and the group management report into the ESEF format and therefore relates neither to the information contained in this reproduction nor to any other information contained in the above-mentioned electronic file.

In our opinion, the reproduction of the consolidated financial statements and the group management report contained in the above-mentioned attached electronic file and prepared for publication purposes complies in all material respects with the requirements of § 328 Abs. 1 HGB for the electronic reporting format. We do not express any opinion on the information contained in this reproduction nor on any other information contained in the above-mentioned file beyond this reasonable assurance opinion and our audit opinion on the accompanying consolidated financial statements and the accompanying group management report for the financial year from 1 January 2020 to 31 December 2020 contained in the "Auditor's report on the consolidated financial statements and on the group management report" above.

#### **Basis for the reasonable assurance opinion**

We conducted our assurance work on the reproduction of the consolidated financial statements and the group management report contained in the above-mentioned attached electronic file in accordance with § 317 Abs. 3b HGB

and the Exposure Draft of IDW Assurance Standard: Assurance in Accordance with § 317 Abs. 3b HGB on the Electronic Reproduction of Financial Statements and Management Reports Prepared for Publication Purposes (ED IDW AsS 410). Accordingly, our responsibilities are further described below in the "Group auditor's responsibilities for the assurance work on the ESEF Documents" section. Our audit firm has applied the IDW Standard on Quality Management 1: Requirements for Quality Management in the Audit Firm (IDW QS 1).

#### **Responsibilities of the executive directors and the supervisory board for the ESEF documents**

The executive directors of the company are responsible for the preparation of the ESEF documents including the electronic reproduction of the consolidated financial statements and the group management report in accordance with § 328 Abs. 1 Satz 4 Nr. 1 HGB and for the tagging of the consolidated financial statements in accordance with § 328 Abs. 1 Satz 4 Nr. 2 HGB.

In addition, the executive directors of the company are responsible for such internal control as they have considered necessary to enable the preparation of ESEF documents that are free from material intentional or unintentional non-compliance with the requirements of § 328 Abs. 1 HGB for the electronic reporting format.

The executive directors of the company are also responsible for the submission of the ESEF documents together with the auditor's report and the attached audited consolidated financial statements and audited group management report as well as other documents to be published to the operator of the Federal Gazette.

The supervisory board is responsible for overseeing the preparation of the ESEF documents as part of the financial reporting process.

#### **Group auditor's responsibilities for the assurance work on the ESEF documents**

Our objective is to obtain reasonable assurance about whether the ESEF documents are free from material intentional or unintentional non-compliance with the requirements of § 328 Abs. 1 HGB. We exercise professional judgment and maintain professional skepticism throughout the assurance work. We also

- Identify and assess the risks of material intentional or unintentional non-compliance with the requirements of § 328 Abs. 1 HGB, design and perform assurance procedures responsive to those risks, and obtain assurance evidence that is sufficient and appropriate to provide a basis for our assurance opinion.
- Obtain an understanding of internal control relevant to the assurance on the ESEF documents in order to design assurance procedures that are appropriate in the circumstances, but not for the purpose of expressing an assurance opinion on the effectiveness of these controls
- Evaluate the technical validity of the ESEF documents, i.e., whether the electronic file containing the ESEF documents meets the requirements of the Delegated Regulation (EU) 2019/815 on the technical specification for this electronic file.
- Evaluate whether the ESEF documents enables an XHTML reproduction with content equivalent to the audited consolidated financial statements and to the audited group management report.
- Evaluate whether the tagging of the ESEF documents with Inline XBRL technology (iXBRL) enables an appropriate and complete machine-readable XBRL copy of the XHTML reproduction.

**Further information pursuant to Art. 10 of the EU Audit Regulation**

We were elected as group auditor by the Annual General Meeting on 27 May 2020. We were engaged by the Supervisory Board on 27 May 2020. We have been the group auditor of PAION without interruption since fiscal year 2004.

We declare that the opinions expressed in this auditor’s report are consistent with the additional report to the Audit Committee pursuant to Art. 11 of the EU Audit Regulation (long-form audit report).

**German Public Auditor responsible for the engagement**

The German Public Auditor responsible for the engagement is Titus Zwirner.”

Cologne, 30 March 2021

Ernst & Young GmbH  
Wirtschaftsprüfungsgesellschaft

Zwirner  
Wirtschaftsprüfer  
[German Public Auditor]

Conrad  
Wirtschaftsprüfer  
[German Public Auditor]

## Management Board

### **Dr. James Phillips**

Chief Executive Officer of PAION AG, Managing Director of PAION Deutschland GmbH, the UK subsidiaries and PAION Netherlands B.V.

Dr. James Phillips is Chief Executive Officer of PAION AG since October 2019, and within the Management Board, he is responsible inter alia for Strategy, Commercial activities, Licensing, Business Development, IT and Fundraising.

Dr. James Phillips is a registered physician who also holds an MBA from the City University Business School in London. Previously, he was the Managing Director of Imevax since 2018 and prior to that CEO of Midatech Pharma for five years. In Europe, Dr. Phillips holds a directorship at Herantis Pharma. He was President of EUSA Pharma Europe in its key growth phase prior to its sale to Jazz Pharma in 2012 and CEO and founder of Talisker Pharma (founded in 2004 and sold to EUSA Pharma in 2006). Dr. Phillips was also Chairman of Prosonix between 2007 and 2012 prior to its successful sale to Circassia. Before that, Dr. Phillips worked for Johnson & Johnson and Novartis as a senior executive.

### **Abdelghani Omari**

Chief Financial Officer of PAION AG, Managing Director of PAION Deutschland GmbH, the UK subsidiaries and PAION Netherlands B.V.

Abdelghani Omari joined PAION in 2008 as Vice President Finance. In 2014 he was appointed Chief Financial Officer of PAION AG. Mr. Omari is responsible inter alia for Finance and Accounting, Controlling, Tax, Legal and Compliance, Human Resources and Investor Relations.

Mr. Omari has round about 20 years of experience in Finance. At KPMG, he advised international clients on accounting, post-merger integration and financial reporting. Previously, he worked several years in the audit department of KPMG with a focus on the chemical industry.

He holds a degree in Business Administration from the University of Aachen.

Mr. Omari has been instrumental in financings and partnering deals, particularly for remimazolam. He has raised over EUR 100 million through capital increases and debt financings and concluded a total of eleven license agreements with more than EUR 110 million in upfront and milestone payments.

## Supervisory Board

### **Dr. Jörg Spiekerkötter**

Chairman of the  
Supervisory Board

Dr. Jörg Spiekerkötter is a member of PAION's Supervisory Board since June 2007 and the Supervisory Board appointed Dr. Spiekerkötter as Chairman on 19 May 2010.

Dr. Jörg Spiekerkötter has many years of experience in the pharmaceutical industry where he has held executive positions in the areas of finance, law and human resources. Until May 2007, he was the Chief Financial Officer of Organon BioSciences N.V., Oss (Netherlands). He left after the acquisition of the company by the U.S. pharmaceutical company Schering-Plough. Until September 2006, he was the Chief Financial Officer at Schering AG in Berlin (Germany), and before that he was Head of the Legal Department at Hoechst Schering AgrEvo GmbH in Berlin (Germany). Dr. Spiekerkötter is Managing Partner of JSP-Invest GmbH. Dr. Spiekerkötter studied in Bielefeld (Germany), Lausanne (Switzerland) and Freiburg (Germany) and has a PhD in law. Until December 2010, he was the Chief Financial Officer of Conergy AG, Hamburg (Germany).

### **Dr. Karin Dorrepaal**

Vice Chairman of the  
Supervisory Board,  
Chairman of the Human  
Resources & Nomination  
Committee

Dr. Karin Dorrepaal is a member of PAION's Supervisory Board since October 2012.

She has broad experience in the Life Science Industry. After four years as a research fellow at the Netherlands Cancer Institute, Dr. Dorrepaal received her PhD from the Free University of Amsterdam, Netherlands. She went on to study at the Rotterdam School of Management where she obtained an MBA. In 1990, Dr. Dorrepaal joined Booz Allen Hamilton, Management Consultants. She specialized in the pharmaceutical industry and advised major companies on issues regarding strategy, sales, marketing and supply chain. In 2000, Dr. Dorrepaal was appointed Vice President of Booz Allen.

In 2004, the Supervisory Board of Schering AG appointed Dr. Dorrepaal to the Board of Executive Directors of Schering AG.

After Bayer AG acquired Schering AG, Dr. Dorrepaal left the company in 2006 and since that time she holds several non-executive roles in Germany, Ireland, Spain and the Netherlands.

### **Dr. Dr. Irina Antonijevic**

Chairman of the  
Research and Development  
Committee

Dr. Dr. Irina Antonijevic is a member of PAION's Supervisory Board since June 2017.

Dr. Dr. Irina Antonijevic has more than 20 years of drug development experience in different pharmaceutical organizations, with a focus on neuropsychiatric and rare diseases. She completed her medical studies at the Technical University of Munich (1991), received her MD from the Max Planck Institute in Munich (1992) and her PhD from the University of Edinburgh, UK (1995).

She completed her residency at the Max Planck Institute of Psychiatry in Munich and received her Venia Legendi from the Charité, Berlin, in 2004. Dr. Dr. Antonijevic has been a regular reviewer for the German Ministry of Research (BMBF) since 2006 and currently holds the position of Chief Medical Officer at Triplet Therapeutics, Inc., Cambridge (MA, U.S.).

**Dr. Chris Tanner**

Chairman of the Audit  
Committee

Dr. Chris Tanner is a member of PAION's Supervisory Board since June 2017.

Dr. Chris Tanner was a member of the Executive Board since 2005 and has been a member of the Supervisory Board of Cosmo Pharmaceuticals N.V. since 2006 for which he conducted the IPO as Chief Financial Officer and Head of Investor Relations. In 2015, Cosmo spun off the daughter Cassiopea SpA where he acted as Chief Financial Officer and Head of Investor Relations until end of 2020. He is a member of the board of directors or advisory board (Beirat) of listed DKSH Holding AG, Cosmo Pharmaceuticals N.V. and CureVac N.V. and the private medtec companies Qvanteq AG and Joimax GmbH. From 1998 to 2001, he was a partner of Dr. Ernst Mueller-Moehl and co-founder of the 20 Minutes group of newspapers and founded A&A Active Investor, a SIX-listed investment company. From 1992 to 1998, he was the Head of Corporate Finance & Capital Markets at UBS in Zurich, and from 1976 to 1991 he had various functions in the Corporate Banking Department at UBS in Zurich, Madrid and Los Angeles. Dr. Tanner has a PhD in economics and a diploma as economist from the University of St. Gallen.

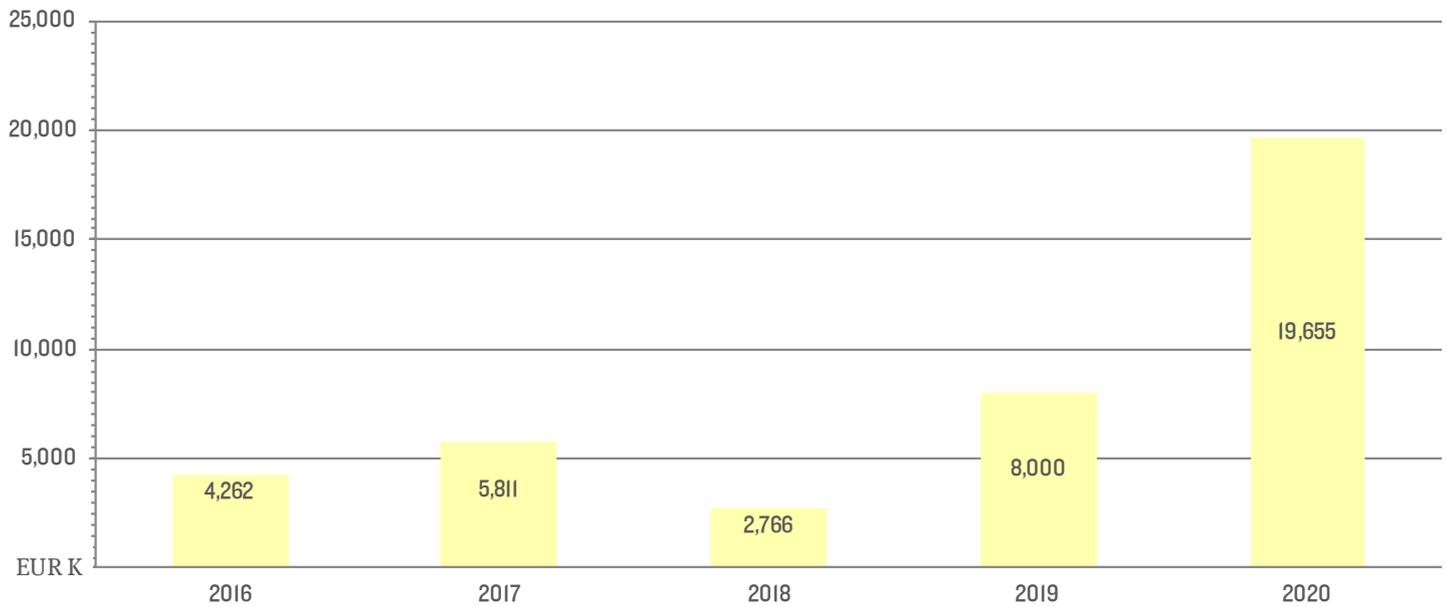
**Dr. Markus Leyck Dieken**

Dr. Leyck Dieken is a member of PAION's Supervisory Board since May 2019.

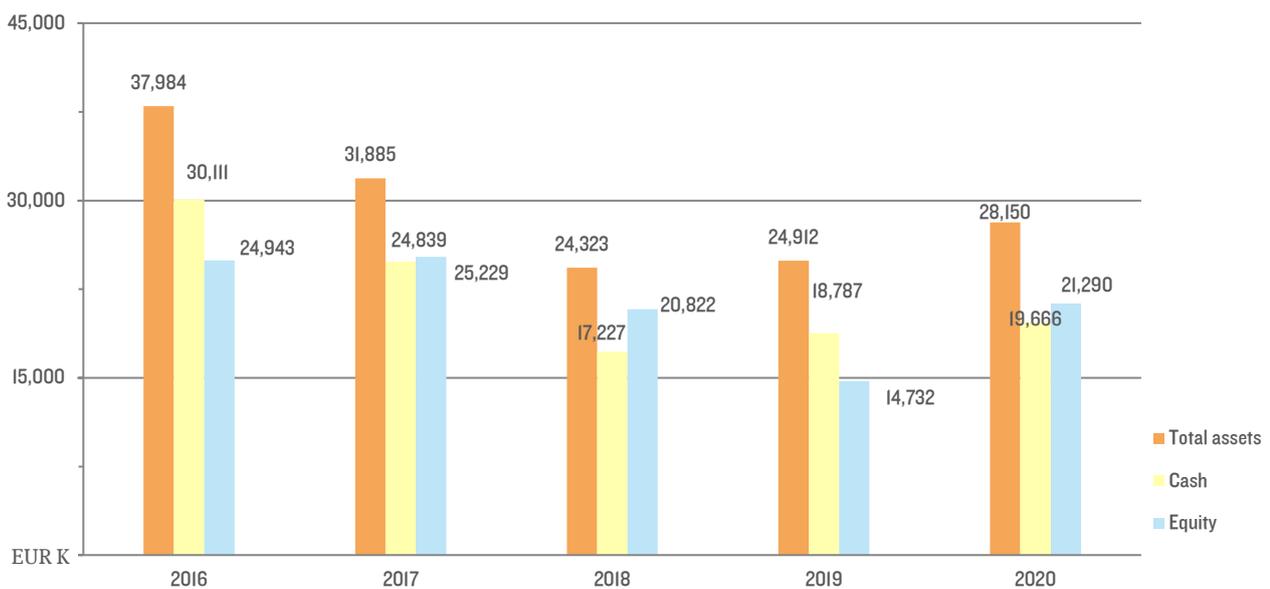
He has over 20 years of experience in the European pharma business in various positions. Since 2019 the graduated physician is Managing Director of gematik GmbH. Before that, Dr. Leyck Dieken was Senior Vice President and Managing Director of Shionogi Europe Central and inter alia has been working for Teva in various global and European leadership positions for many years, was Europe Head of the Novartis Vaccine Division, Senior Vice President of InterMune and Vice President of Novo Nordisk.

## Development of Selected Consolidated Financial Key Figures (IFRS)

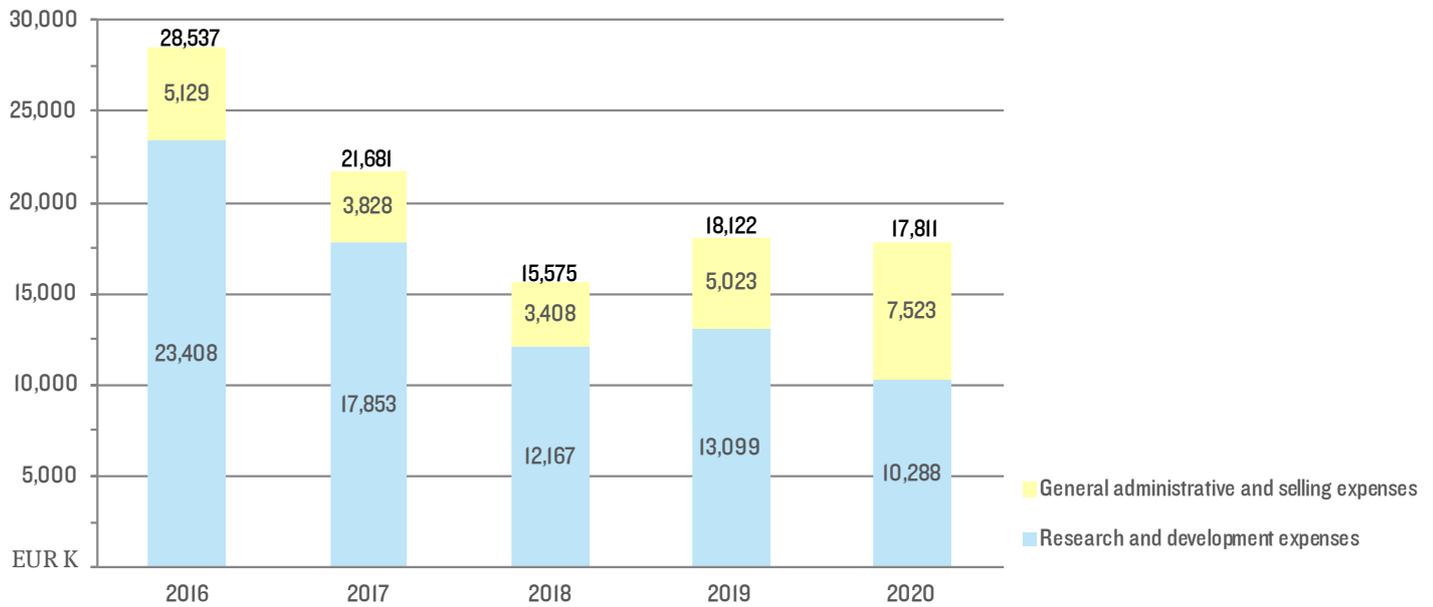
### Revenues



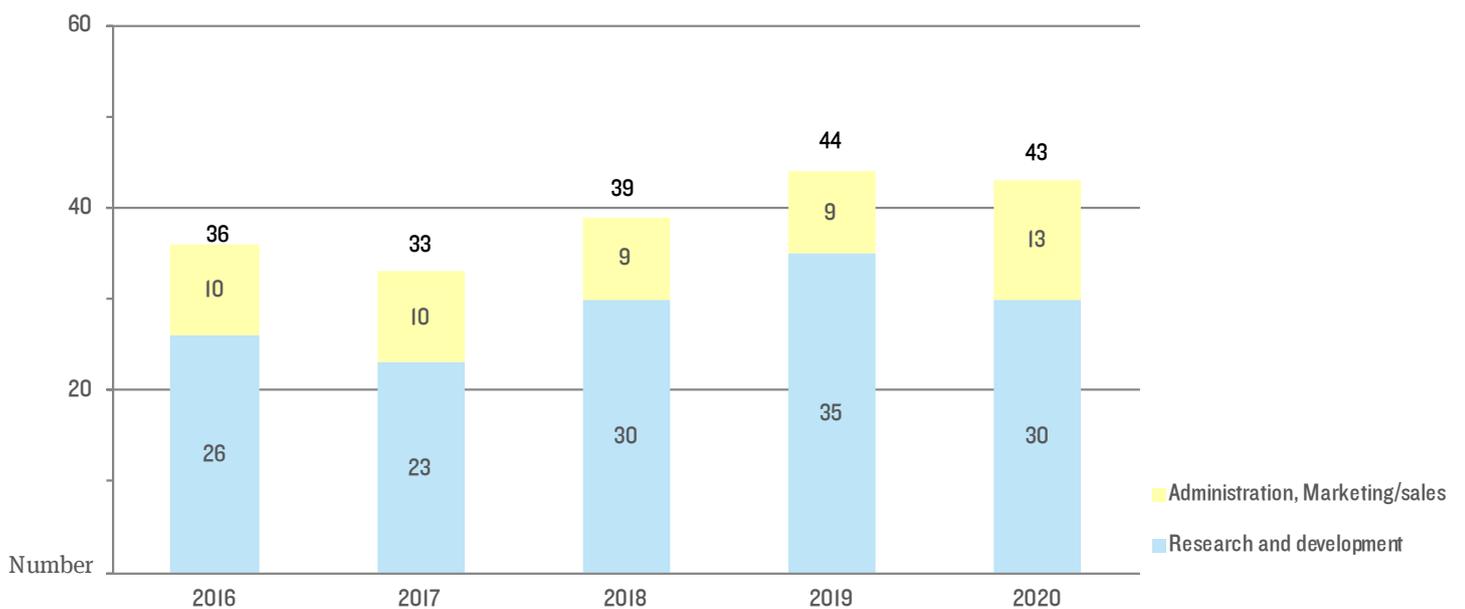
### Total Assets / Cash and Cash Equivalents / Equity



## Breakdown of expenses



## Employee Structure



## Five-Year Comparison of Key Consolidated Financial Figures (IFRS)

(all figures in EUR K unless otherwise noted)	2020	2019	2018	2017	2016
<b>Profit and loss statement</b>					
Revenues	19,655	8,000	2,766	5,811	4,262
Research and development expenses	-10,288	-13,099	-12,167	-17,853	-23,408
General administrative and selling expenses	-7,523	-5,023	-3,408	-3,828	-5,129
Net result	2,222	-7,016	-9,939	-12,093	-20,118
Personnel expenses included therein	-5,668	-5,374	-5,080	-4,166	-5,375
Number of shares outstanding (weighted average, basic)	65,721,395	63,918,752	62,512,375	59,118,686	53,245,632
Number of shares outstanding (weighted average, diluted)	66,133,456	64,035,132	62,754,424	59,558,627	53,491,803
Earnings per share in EUR (basic)	0.03	-0.11	-0.16	-0.20	-0.38
Earnings per share in EUR (diluted)	0.03	-0.11	-0.16	-0.20	-0.38
<b>Balance sheet</b>					
Intangible assets	1,829	2,137	2,212	2,415	2,688
Cash and cash equivalents	19,666	18,787	17,227	24,839	30,111
Equity	21,290	14,732	20,822	25,229	24,943
Current liabilities	6,845	10,154	3,501	6,656	13,040
Balance sheet total	28,150	24,912	24,323	31,885	37,983
<b>Cash flow</b>					
Cash flow from operating activities	906	-2,847	-12,813	-17,720	-11,586
Cash flow from investing activities	-14	-14	-13	-25	-192
Cash flow from financing activities	-24	4,414	5,214	12,494	9,212
<b>Employees</b>					
Group employees (average)	43	44	39	33	36

## 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 BHF

Key figures	2020	2019
Numbers of shares at year-end	66,241,493	64,265,586
Average daily trading volume (Xetra, FSE, in shares)	154,533	61,483
Year high (Xetra closing price)	EUR 3.06 (06 Jul 2020)	EUR 2.58 (10 Jul 2019)
Year low (Xetra closing price)	EUR 1.40 (19 Mar 2020)	EUR 1.90 (27 Dec 2019)
Share price at year-end	EUR 2.40	EUR 1.98
Market capitalization at year-end (Xetra)	EUR 159 million	EUR 127 million

## Imprint

### Editor, Conception, Design & Text

PAION AG, Heussstrasse 25, 52078 Aachen

## Corporate Calendar 2021

30 March 2021	Publication of financial results 2020
12 May 2021	Publication of the financial results for the first quarter 2021
27 May 2021	Annual general meeting
11 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 first nine months 2021

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