

PAION AG, Aachen

Annual Financial Report

for the Fiscal Year 2019



PAION AG, Aachen

Consolidated Financial Statements

as of 31 December 2019 and

Group Management Report

for the Fiscal Year 2019

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Group management report for fiscal year 2019

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 developing and aiming to commercialize innovative drugs to be used in out-patient and 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, while the Group companies provide each other with development-related services. The activities of the PAION Group (hereinafter also referred to as PAION) are mainly determined by the development operations of the subsidiaries, particularly PAION UK Ltd, which are presented below.

PAION's portfolio exclusively comprises the drug candidate remimazolam. In January 2020, the first marketing approval was granted in Japan (after the balance sheet date).

For remimazolam, PAION has licensees in the U.S., China, South Korea, Southeast Asia, Canada, Russia/CIS, Turkey, the MENA region and Japan. For the use of remimazolam for procedural sedation, clinical development is completed; market approval dossiers have been filed in the U.S., EU and China. For the indication general anesthesia, remimazolam is in the final stage of clinical development and has already been completed for Japan and South Korea; market approval dossiers have been filed in both markets. The different indications for application of remimazolam will be described in detail in the following chapters.

Fiscal year 2019 was marked by the continuation of the development of remimazolam, regulatory as well as supply chain and pre-commercial activities, in particular the conduct of a Phase III study in general anesthesia in the EU and preparations and support for the market approval dossiers in the U.S., the EU and Japan.

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 subsequent commercialization of remimazolam. The progress of these activities is being documented and discussed continuously. PAION has already signed several regional license agreements. 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 is driven mainly by the research and development activities 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

German economy has continued its growth in the previous years also in 2019. Driver in particular was consumption. Private consumption increased by 1.6%, state expenditure on consumption increased by 2.6% compared to the prior year. With an increase of the gross domestic product (GDP) of 0.6% (2018: 1.5%), growth has lost momentum the second year in a row however.¹

A decrease in economic growth has also manifested in the Euro area: The GDP in the Euro zone only increased by 1.2% in 2019 after 1.9% growth in 2018. A further slowdown to 0.9% is expected for 2020. While in 2018, an increase in growth of the U.S. economy to 2.9% mainly borne by the U.S. tax reform had a soothing impact on the decrease of the world GDP, this trend did not

¹ Federal Statistical Office: Volkswirtschaftliche Gesamtrechnungen 2019: Wichtige Zusammenhänge im Überblick; 26 February 2020.

continue in 2019. U.S. GDP only increased by 2.3% in 2019 and a further slowdown to 1.7% is expected in 2020.² In terms of the world GDP, growth slowed down from 3.6% in 2018 to 2.9% in 2019. However, an increase of 3.3% is expected for 2020. While for the developed countries overall, a slightly lower growth of 1.6% in 2020 compared to 1.7% in 2019 is expected, the expected increase is mainly driven by stronger growth in the developing and emerging countries.³

There is major uncertainty in regard to international trade restrictions and tariffs, particularly with regard to the relations between the U.S. and China as well as in terms of economic relations between the EU and the United Kingdom after the transition period following the Brexit. Moreover, the short- and mid-term outlook is tarnished by geopolitical tensions.⁴ In addition, the Organisation for Economic Co-operation and Development (OECD) cautions against the impact of the Coronavirus spreading worldwide since the beginning of 2020 on the world economy and only expects a growth of 2.4% for the world GDP in 2020 under these conditions.⁵

On the stock markets however, an acceleration of stock price growth could be observed: The DAX registered an increase of 25.5% in 2019 in comparison to the prior year's end closing value; the EUROSTOXX 50 also closed 2019 with a considerable plus of 24.8% as compared to the previous year. The Dow Jones strongly increased, too, and closed 2019 with a plus of 22.3% in comparison to the prior year's end closing value.

b. Development of the pharmaceutical and biotechnology industry

The pharmaceutical and biotechnology industry continues 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 (gene) therapies which in turn are faced by increasingly lower income particularly due to higher competition, patent expiry of formerly high-selling products and price pressure from governmental regulation.⁶ Average development costs of a new drug increased by approx. 82% from 2010 to 2018 on average for big pharma companies while peak sales potential approximately halved.⁷

The consolidation pressure resulting from these trends has significantly materialized in the worldwide transaction volume in the pharmaceutical industry in 2019 that reached a new all-time high with USD 357 billion.⁸

The financing environment for the pharmaceutical and biotechnology industry was also good in 2019 but lagged behind the record year 2018. In 2019, USD 7.6 billion were raised through IPOs compared to USD 8.3 billion in 2018. However, the volume in 2019 was still approx.

² Commerzbank Research: Economic and Market Monitor – Chart Book February 2020.

³ International Monetary Fund: World Economic Outlook Update, January 2020.

⁴ International Monetary Fund: World Economic Outlook Update, January 2020.

⁵ OECD Interim Economic Assessment: Coronavirus: The world economy at risk, 02 March 2020.

⁶ 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.

⁷ Deloitte Centre for Health Solutions: Unlocking R&D productivity: Measuring the return from pharmaceutical innovation 2018, 2018.

⁸ Ernst & Young: 2020 EY M&A Firepower report: How will deals done now deliver what the health ecosystem needs next?, 2019.

20% above the previous all-time high from 2014.⁹ With EUR 858 million of funds raised in total in 2019, German biotech companies also did not reach the all-time high of financing volume of EUR 1.3 billion from 2018, but the sum was still about 27% above the figure from 2017.¹⁰ The positive climate in the industry is also reflected in the valuation of pharma companies: The DAXsubsector Biotechnology Index increased by 29.7% in 2019 in comparison to the prior year's end closing value; the NASDAQ Biotechnology Index closed the year 2019 with a plus of 24.4%.

The significant competitive drivers in the pharmaceutical and biotechnology industry are likely to also persist in 2020 and to maintain consolidation pressure. In addition to intensifying competition and continuously increasing challenges for the industry, mainly in regard to digitalization, individualization of therapies and regulatory requirements, companies with a clear therapeutic focus are often more successful than their less focused competitors.¹¹ Under consideration of the availability of significant amounts of funds, an increasing concentration on therapeutic focus, a recently increased market volatility and a lower valuation of many small- and mid-sized biotech companies as compared to the 12-month average¹² as well as the central banks' continuing (and increasing) loose monetary policy, a high acquisition and transaction volume worldwide can be expected in the pharmaceutical industry also in 2020. However, it remains to be seen to what extent particularly the development of international trade restrictions and protective tendencies, political uncertainty mainly in the important U.S. market¹³ and last but not least the impact of the spread of the Coronavirus on the world economy have a damping effect on acquisition and transaction volumes.

2. Presentation of the course of business and development activities

The development portfolio of PAION Group essentially comprises remimazolam with its three indications procedural sedation, general anesthesia and ICU sedation.

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. In clinical studies, remimazolam demonstrated efficacy and safety in around 2,500 volunteers and

⁹ Morrison, C. (2019): Boom: 2018's biotech IPOs, in: Nature Reviews Drug Discovery, Vol. 18, January 2019; Morrison, C. (2020): 2019 biotech IPOs: party on, in: Nature Reviews Drug Discovery, Vol. 19, January 2020.

¹⁰ BIO Deutschland: Biotech-Branche: erneut gute Finanzierungszahlen; press release from 13 January 2020.

¹¹ 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.

¹² Ernst & Young: 2020 EY M&A Firepower report: How will deals done now deliver what the health ecosystem needs next?, 2019.

¹³ PwC Health Research Institute: Top health industry issues of 2020: Will digital start to show an ROI?, 2019; Evaluate: Vantage 2020 Preview, 2019.

patients. Data so far indicate that remimazolam has a rapid onset and offset of action combined with a favorable cardio-respiratory safety profile.

In Japan, licensee Mundipharma received market approval in general anesthesia in January 2020. In the U.S., licensee Cosmo Pharmaceuticals (Cosmo) submitted a New Drug Application (NDA) for procedural sedation in April 2019 for which the U.S. Food and Drug Administration (FDA) set 05 July 2020 (previously 05 April 2020) as target date for completion of the review under the Prescription Drug User Fee Act (PDUFA date) after announcement of an extension of the review period of up to three months for the evaluation of additional data. In China, licensee Yichang Humanwell filed for market approval in procedural sedation in November 2018. In South Korea, licensee Hana Pharm filed for market approval in general anesthesia in December 2019. In Europe, PAION submitted a Marketing Authorization Application (MAA) to the European Medicines Agency (EMA) in procedural sedation in November 2019 and a Phase III trial in general anesthesia is ongoing.

In addition to procedural sedation and general anesthesia, based on positive Phase II study results, ICU sedation is another possible indication.

Remimazolam is partnered in the U.S. (Cosmo Pharmaceuticals, sublicensed to Acacia Pharma), Japan (Mundipharma), China (Yichang Humanwell), Canada (Pharmascience), Russia/CIS, Turkey and the MENA region (R-Pharm) as well as South Korea and Southeast Asia (Hana Pharm). For all other markets including parts of the EU, remimazolam is available for licensing.

Procedural Sedation Market

Based on external sources (Symphony Health Solutions, Centers for Disease Control and Prevention) and own projections, PAION estimates that more than 40 million procedures using procedural sedation are currently taking place in the U.S. per year, predominantly outside the hospital setting.

The growth of the procedural sedation market in the U.S. has been driven for many years by the increase in medical interventions requiring procedural sedation, such as colonoscopies, as well as an increase in general demand for preventive screenings. According to iData Research, which examines historical trends and creates procedure forecasts in the U.S. drawing from an extensive collection of national- and state-level procedure databases, 26.7 million colonoscopy and endoscopy claims were reported in the U.S. in 2015. PAION estimates that 75% of the colonoscopies and endoscopies are conducted in an out-patient setting.

Regular colonoscopy screening for people aged 50 or older is recommended and covered by all major health insurance plans, including those under the Centers for Medicare and Medicaid Services (“CMS”), a U.S. federal agency that administers Medicare (the national social insurance program), since effective prevention is considered to reduce the likelihood of incidence of illnesses such as cancer, thereby reducing the suffering of patients and related financial burden to be borne by the payors. Statistics show that the rate at which people are diagnosed with colon cancer in the U.S. has dropped by approximately 30% in the recent years for those aged 50 years and older, partly due to more people getting recommended screening tests. Colorectal cancer is the third most diagnosed cancer and the third leading cause of cancer death in the U.S. Despite the decrease of

colorectal cancer death rates as a result of early screening and detection, it was reported in 2010 that only 59% of people aged 50 or older, for whom screening is recommended, reported having received colorectal cancer testing consistent with current guidelines. The market for endoscopies in gastroenterology represents the most important market segment for remimazolam in procedural sedation with approximately 20 million procedures per year in the U.S.

Currently, the most widely used products in procedural sedation are propofol and midazolam – both generic. PAION estimates that these two drugs each have a market share of approximately 50% in terms of volume of procedures performed in the out-patient market for colonoscopies in the U.S. The propofol label mandates the presence of an anesthesia professional throughout the procedure due to propofol's potential for respiratory- and cardio-depressive effects, which results in additional costs and higher risks, since there is no reversal agent available for propofol in order to be able to quickly stop sedation if required. For midazolam, these side effects are less pronounced and have a different relevance, since an undesirably deep sedation can be reversed with flumazenil. Midazolam has a slower onset and a longer duration of action which can impact patient throughput and overall efficiency.

In the U.S. increased enrollment and screenings are expected to result in a performance-based payment system that will seek to better align payments with high quality of care measures. This would imply that cost-efficient medicines with clinical value will be used more extensively and that continued premium prices will be paid for innovative medicines with strong clinical profile. Thus, PAION believes that concerns related to the overall cost of procedures, driven by the need for the presence of anesthesia professionals during procedures using agents such as propofol, will impact the choice of drug products for procedural sedation. Costs related to anesthesia services in gastrointestinal endoscopy procedures alone were estimated at USD 1.3 billion in 2009.¹⁴ Accordingly, PAION expects reimbursement regimes under national and commercial healthcare systems, such as Medicare, which differentiate the amounts reimbursed to physicians and/or patients depending on whether an anesthesia professional's service is used, may also positively impact the demand for products that do not require monitoring by an anesthesia professional.

PAION expects that remimazolam, subject to FDA approval with a safety labeling comparable to that of midazolam, would be able to offer a competitive alternative to midazolam. This is based on its enhanced efficiency profile compared to midazolam.

PAION submitted an MAA for procedural sedation to the EMA in November 2019 after it had been discussed in the course of a pre-submission meeting with the EMA held in February 2019 that the existing data package from the U.S. Phase III clinical development program will be sufficient for submitting an MAA in procedural sedation. An essential task to be completed prior to the MAA submission was EMA approval of the Pediatric Investigation Plan (PIP), which was granted in November 2019.

¹⁴ Liu, H. et al. (2012): Utilization of Anesthesia Services During Outpatient Endoscopies and Colonoscopies and Associated Spending in 2003-2009, *The Journal of the American Medical Association*, 2012 307(11):1178-1184; Al-Awabdy, B. and Wilcox, C.M. (2013): Use of anesthesia on the rise in gastrointestinal endoscopy, *World Journal of Gastrointestinal Endoscopy*, January 2013 5(1): 1-5.

In the EU, based on its own projections for procedural sedation, PAION currently estimates an annual peak sales potential of approx. EUR 50 million to approx. EUR 75 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. This entails a high potential for synergies with the planned commercialization of remimazolam for use in general anesthesia.

General Anesthesia Market

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. 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 the EU, the current standard-of-care drugs for general anesthesia are propofol (especially for induction) and narcotic gases; mostly used in conjunction with intravenous opioids.

Patient demographics in the EU will presumably continue to evolve driven by the aging population. PAION anticipates an increasing number and complexity of medical interventions requiring induction and maintenance of anesthesia in the EU in the future also driven by an ongoing aging of the population. 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 the EU 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. PAION also expects similar developments for the U.S. and other important international markets, subject to further market research. In the EU, based on its own projections, PAION currently estimates an annual peak sales potential of approx. EUR 150 million to approx. EUR 200 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.¹⁵ 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 the number of total adult beds in various countries in the EU, PAION estimates that there are approximately 14 million ICU patient days requiring ICU sedation in the U.S. and EU combined per year. PAION expects this number to increase in the years to come, driven by demand from the aging population in both regions. 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.

PAION is currently evaluating the risk-benefit ratio of developing remimazolam for ICU sedation.

¹⁵ 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.

Clinical Development

Overview of the studies conducted with remimazolam to date	
Phase II and III studies	Phase I studies
Procedural Sedation (U.S.) - completed	
Phase IIa Single bolus in upper GI endoscopy (100)	Phase I Single bolus in healthy volunteers (81)
Phase IIb Multiple bolus in colonoscopy (161)	Phase Ib Multiple bolus in volunteers undergoing colonoscopy (51)
Phase III in colonoscopy (461)	Phase I Renal Impairment (22)
Phase III ASA III/IV in colonoscopy (79)	Phase I Thorough QT (54)
Phase III in bronchoscopy (446)	Phase I Abuse Liability
	• Intravenous administration (40)
	• Oral bioavailability (14)
	• Oral administration with alcohol (20)
	• Intranasal administration (12)
General Anesthesia (Japan) - completed	
Phase II Induction and maintenance of anesthesia in general surgery (85)	Phase I Bolus in healthy volunteers (42)
Phase II/III Induction and maintenance of anesthesia in general surgery (375)	Phase Ib Infusion in healthy volunteers (10)
Phase III in ASA III or higher surgical patients (62)	Phase I Hepatic impairment (U.S.) (20)
General Anesthesia (EU)	
Phase II in cardiac surgery patients (90)	Phase I PK/PD modeling study (EEG) in healthy volunteers (20)
Phase III in cardiac surgery patients (23)*	
Phase III in general surgery (approx. 500)**	
ICU Sedation (Japan)	
Phase II in ICU patients (49)*	
Studies in other territories	
Phase III in general anesthesia - Russia (150)	Phase I single ascending dose in China (62)
Phase III in general anesthesia - South Korea (198)	Phase I continuous infusion in China (12)
Phase II in procedural sedation - China (150)	
Phase III in procedural sedation - China (480)	
Phase IIa dose finding study - China (24)	

Patient/volunteer numbers in brackets

*) Discontinued studies, no safety concerns

***) Ongoing study

Procedural sedation (U.S. + China)

With a total of eight Phase I, two Phase II and three Phase III trials, PAION deems the clinical development program for remimazolam in procedural sedation in the U.S. completed. In China, one Phase II and one Phase III trial have also been successfully conducted.

The first in-human trial explored a broad range of doses from no effect to loss of consciousness (not wanted for procedural sedation but indicative for induction of general anesthesia). Based on this trial, the next set of trials covered a colonoscopy study in healthy volunteers and a Phase IIa study in upper GI endoscopy. These studies confirmed the need for an approximately 50% dose reduction in combination with opioids (colonoscopy) and were the basis for the Phase IIb study in colonoscopy patients. In this study, a fixed dose regime consisting of starting dose and top-ups was tested with the lowest of the starting doses which was selected for use in the Phase III program.

The first U.S. Phase III study 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 study had an open-label midazolam arm.

The primary outcome measure was a composite endpoint defined as: no need for rescue medication, completion of the procedure and no more than 5 doses within any 15-minute window. The primary endpoint was reached in 91.3% of the patients in the remimazolam arm and 1.7% in the placebo (including midazolam rescue) arm.

Important secondary endpoints in the remimazolam arm showed a median time from start of medication to start of procedure of 4.0 minutes (placebo 19.5 minutes) and a mean time from end of procedure to return to full alertness of 7.2 minutes (placebo 21.3 minutes). Additionally, time from last dose to “back to normal” as reported by patients on remimazolam was 331 minutes (placebo 572 minutes).

There were no treatment-emergent serious adverse events in the trial. Hypotension was 44.3% with remimazolam and 47.5% with placebo and accounted for most of the adverse events in all study arms. Hypoxia occurred in 1.0% of patients given remimazolam, 3.4% in the placebo arm.

On the Hopkins Verbal Learning Test administered five minutes after reaching the fully alert status, the total raw score, delayed recall, memory retention, and recognition discrimination scores were all better with remimazolam compared to placebo.

Patient satisfaction was similar in all arms of the study.

The open-label midazolam patients showed a median time from start of medication to start of procedure of 19.0 minutes and a mean time from end of procedure to return to full alertness of 15.7 minutes. Midazolam patients took 553 minutes to be back to normal.

In addition to the above study, the U.S. Phase III program includes a second confirmatory, prospective, double-blind, randomized, placebo-controlled multi-center trial with an open-label midazolam arm in 446 patients undergoing bronchoscopies.

The study was successfully completed in 2017, and the primary efficacy endpoint was achieved. The Phase III trial enrolled 446 patients at 15 U.S. sites and was designed to evaluate the

efficacy and safety of remimazolam compared to placebo (with midazolam rescue medication) in procedural sedation in patients undergoing bronchoscopy.

The primary outcome measure was a composite endpoint defined as: no need for rescue medication, completion of the procedure and no more than 5 doses within any 15-minute window for remimazolam/placebo and no more than 3 doses within any 12-minute window for midazolam. The primary endpoint was reached in 82.5% of the patients treated in the remimazolam arm and 3.4% in the placebo arm (p-value of <0.0001). Important secondary endpoints included median time from start of medication to start of procedure (5.0 minutes in the remimazolam arm versus 17.0 minutes for placebo) and median time from end of procedure to return to full alertness (remimazolam 6.0 minutes versus placebo 14.0 minutes). Additionally, the patients' subjective impression of time from last dose to "back to normal" was a median of 404 minutes for remimazolam versus 935 minutes for placebo.

In the open-label midazolam arm, procedural success was achieved in 34.8% of patients. Midazolam patients showed a median time from start of medication to start of procedure of 16.0 minutes and a median time from end of procedure to return to full alertness of 12.0 minutes. Additionally, time from last dose to "back to normal" as reported by patients on midazolam was a median of 479 minutes.

As part of the U.S. development program, also a safety study 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 efficacy and safety of remimazolam compared to placebo (with midazolam 'rescue' sedation) in patients undergoing proceduralist-supervised sedation for colonoscopy. This study also included an open-label arm in which midazolam was dosed according to U.S. label. The trial confirmed remimazolam's safety profile and tolerability shown in all previous studies in a more vulnerable patient population. Overall, remimazolam demonstrated good respiratory and cardiovascular stability as compared to placebo with midazolam rescue. No adverse events of concern were observed in either group. In addition, the efficacy and efficiency improvements were comparable to the two positive pivotal U.S. Phase III trials in colonoscopy and bronchoscopy patients. Success of the procedure (including no requirement for rescue medication and the application of not more than five doses in any 15-minute interval) was achieved in 84.4% of patients in the remimazolam arm and 0% in the placebo arm. Other relevant endpoints showed a median time from start of medication to start of procedure of 5.0 minutes for remimazolam (placebo: 18.5 minutes) and a median time from end of procedure to return to full alertness of 3.0 minutes (placebo: 5.0 minutes). By comparison, procedural success was achieved in 12.9% of the midazolam patients. Midazolam patients showed a median time from start of medication to start of procedure of 19.0 minutes and a median time from end of procedure to return to full alertness of 7.0 minutes.

Summary of headline data of the three Phase III studies:

	Remimazolam	Placebo	Midazolam (Open Label)*
Primary endpoint achieved	82.5–91.3%	0.0–3.4%	12.9–34.8%
Time from start of medication to start of procedure	4.0–5.0 min	17–19.5 min	16.0–19.0 min
Time from end of procedure to fully alert	3.0–7.2 min	5.0–21.3 min	7.0–15.7 min
Time to back to normal	331–404 min	572–935 min	478.5–553 min

*) not part of label claim

Based on the results of preclinical and Phase I studies and in consultation with the FDA, PAION conducted additional Phase I studies to further assess the abuse potential of remimazolam. Two aspects were being studied: if remimazolam could inappropriately be used as a knock-out cocktail in combination with alcohol and if it could be abused intranasally. PAION deems the clinical development program for remimazolam in procedural sedation in the U.S. completed, and Cosmo filed for market approval in April 2019.

General anesthesia (Japan, EU, Russia, China + South Korea)

A total of six Phase I, three Phase II and four Phase III trials have been completed for use of remimazolam in 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 Japanese program started with a comparative Phase I study building on PAION's first human trial and showed an identical pharmacokinetic and pharmacodynamic profile. The next step was a continuous infusion Phase I study to define induction and maintenance doses for anesthesia. The doses for induction and maintenance identified as safe and effective in the Phase II study subsequently conducted were then used in the Japanese Phase III studies, which confirmed remimazolam's efficacy and safety as a general anesthetic and its favorable hemodynamic profile compared to propofol.

In order to allow using the Japanese data for filing in the EU, the same induction and maintenance doses were used in the Phase II trial performed in Germany in 2014 as part of the European development program, delivering further evidence for a potentially beneficial hemodynamic profile of remimazolam. The primary efficacy endpoint for general anesthesia was achieved in 98% of patients in the remimazolam dose groups and 96% in the propofol/sevoflurane group demonstrating an excellent efficacy rate across all treatment groups. As expected, the onset and offset of action profile was comparable between all treatment groups, showing that remimazolam indeed shares the fast-acting sedative profile of propofol.

One of the key targets of this trial was to assess the hemodynamic stability during cardiac surgery with remimazolam when compared to propofol/sevoflurane, both of which are known to

cause cardiac depression. The study evaluated a substantial number of parameters to analyse these effects. Remimazolam confirmed the improved hemodynamic stability that had already been shown in the Ono Phase III study.

Based on these positive data, a multi-national, multi-center, randomized, single-blind, propofol-controlled, confirmatory Phase III study in patients undergoing major cardiac surgery was started in the EU in August 2015. Due to the complex study design in cardiac surgery, the trial faced recruitment challenges. Despite intensive efforts to enhance patient recruitment, the trial proved to be difficult to implement in practice. Therefore, in February 2016, PAION decided to discontinue the trial in order to avoid a long and expensive study with the existing design. No drug-related serious adverse events were observed.

Subsequently, PAION evaluated how to resume the clinical development of remimazolam in the EU. In consultation with key opinion leaders in general anesthesia, PAION has successfully conducted a Phase I trial which served as a means to define key elements and sample size calculation for the planned Phase III trial. Based on the results of this study, subsequent simulations and scientific advice obtained from the European authority EMA for defining the new European Phase III program, PAION has started an EU Phase III clinical trial with remimazolam for the induction and maintenance of general anesthesia in July 2018.

The randomized, single-blind, propofol-controlled, confirmatory Phase III trial is expected to enroll approx. 500 ASA III/IV patients (American Society of Anesthesiologists classification III to IV) undergoing planned surgery. The primary objective of the trial is to demonstrate the non-inferiority of remimazolam compared to propofol for the induction and maintenance of general anesthesia during elective surgery. The key secondary objective is to show improved hemodynamic stability (avoidance of intraoperative drop of blood pressure and vasopressor usage) compared to propofol. Currently, 424 patients have been enrolled in the study. Due to the Coronavirus pandemic, completion of patient recruitment previously planned in the first half of 2020 will be delayed until hospitals which are currently increasingly working to capacity with the treatment of patients infected with the Coronavirus will have capacities for the recruitment of patients for planned interventions available again.

Based on Scientific Advice obtained from the EMA in January 2018, PAION expects that a positive Phase III trial in combination with previously completed clinical studies in Europe and Japan should be sufficient for market approval in the indication of general anesthesia in the EU.

In November 2018, PAION's licensee R-Pharm announced the successful completion of a Phase III trial in general anesthesia and PAION's licensee Hana Pharm also successfully completed a Phase III trial in general anesthesia in October 2018.

ICU sedation

PAION's former licensee in Japan, Ono, independently initiated a Phase II trial for sedation in intensive care units (ICUs). Higher than by Ono expected plasma concentrations 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 being evaluated.

Pediatric development

Another field of high clinical need is pediatric use.

The aims of sedation and general anesthesia are the same in both adults and children: to enable diagnostic, surgical or dental procedures to be carried out safely and successfully while minimizing distress and discomfort to the patient. Advances in the diagnostics and treatment of pediatric diseases has led to an increase in the number of painful or distressing procedures for which many children need effective sedation or general anesthesia. While in adults many procedures can be undertaken with local anesthesia and verbal reassurance, this is often not possible with children and teenagers. Particularly for children, procedures are often too frightening, too painful, or need to be performed in children who are uncooperative, ill or in pain. In 2018, PAION submitted a PIP 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, followed by general anesthesia and finally ICU sedation. The clinical trials will initially be conducted with adolescents and further studies will be performed with increasingly younger children. At the same time, while at the beginning less serious diseases are included in the trials, increasingly severe diseases will be included in the trials in the later course of the development program.

Partnerships, regulatory and commercial activities

Development and commercialization collaborations with partners with local expertise or with a specific therapeutic focus with respect to remimazolam are an effective way of funding and advancing remimazolam's development and of assisting PAION with its commercialization in international markets where PAION does not intend to directly conduct sales and marketing activities. The local further development of remimazolam leads to additional data and potential milestone payments for PAION. PAION has partnering discussions with potential further licensees in order to allow for swift commercialization of remimazolam after potential market approval. In order to exploit remimazolam's full potential, PAION is evaluating commercializing remimazolam on its own in selected European markets after a potential market approval.

PAION is starting to build up a supply chain for remimazolam. Process validation of the manufacture of remimazolam at commercial scale has been completed successfully and commercial production contracts have been signed with the contract manufacturers. On this basis, the planned development of the structures, establishment of the processes and obtaining all pharmaceutical permits should be implemented in the second half of 2020 to an extent that allows for regular supply of the licensees with remimazolam.

In the U.S., the NDA in procedural sedation was prepared together with licensee Cosmo and submitted to the FDA by Cosmo in April 2019. The FDA informed Cosmo in June 2019 that the filing had been accepted. After announcement of an extension of the review period of up to three months for the evaluation of additional data, the FDA set 05 July 2020 (previously 05 April 2020) as PDUFA date. Under this timeline, market approval and subsequent launch of remimazolam in the U.S. can be expected in 2020 assuming a regular approval process.

In January 2020, Cosmo announced that its remimazolam (ByFavo) U.S. rights were sub-licensed to Acacia Pharma (Acacia). Going forward, Acacia will be responsible for the marketing of remimazolam in the U.S. In 2016, PAION entered into a U.S. license agreement for remimazolam (ByFavo) with Cosmo which remains unchanged.

Also in January 2020, PAION and Hana Pharma extended their license agreement for remimazolam to include Southeast Asia (Indonesia, Malaysia, Philippines, Singapore, Thailand, Vietnam), and Hana Pharm will be responsible for the development and marketing approval process in these markets. PAION and Hana Pharm entered into an exclusive remimazolam license agreement for South Korea in 2013.

In Europe, PAION is seeking approval for remimazolam in general anesthesia and in procedural sedation.

Procedural sedation: PAION submitted an MAA for procedural sedation to the EMA in November 2019 after it had been discussed in the course of a pre-submission meeting with the EMA held in February 2019 that the existing data package from the U.S. Phase III clinical development program will be sufficient for submitting an MAA in procedural sedation. Market approval is currently expected in the beginning of 2021 at the earliest.

General anesthesia: Assuming approval in procedural sedation and positive results in the Phase III trial in general anesthesia, PAION plans to submit an extension of the marketing authorization for remimazolam for general anesthesia. The review process for an extension is generally faster than for an MAA. The complete data from the EU Phase III study in general anesthesia, which are required for the submission of an extension of marketing authorization, are expected to be available at the time of the regulatory decision on the MAA in procedural sedation.

Licensee activities in other territories

Japanese licensee Mundipharma submitted a market approval dossier for remimazolam for general anesthesia in December 2018, which was approved by the Japanese Pharmaceuticals and Medical Devices Agency (PMDA) in January 2020. Mundipharma currently plans to launch remimazolam mid-2020.

Chinese licensee Yichang Humanwell submitted a market approval dossier for remimazolam for procedural sedation to the Chinese National Medical Products Administration (NMPA) in November 2018. Market approval is currently expected in 2020.

PAION's South Korean licensee Hana Pharm submitted a market approval dossier for remimazolam in general anesthesia in South Korea in December 2019. Market approval is currently expected in the second half of 2020.

Russian licensee R-Pharm announced the successful completion of a Phase III trial with remimazolam in general anesthesia in November 2018. R-Pharm is currently preparing first market approval dossiers for the licensed territories.

In Canada, PAION expects its licensee Pharmascience to use the U.S. market approval dossier as the basis for filing for market approval of remimazolam.

The following table provides an overview of the regulatory progress of remimazolam in the different territories:

Overview of remimazolam approval processes			
Applicant, Country	Indication	Date of NDA/MAA submission	Market approval
Mundipharma, Japan	General anesthesia	12/2018	Granted in 01/2020
Yichang Humanwell, China	Procedural sedation	11/2018	Expected in 2020
Cosmo, U.S.	Procedural sedation	04/2019	PDUFA date 05 July 2020
PAION, EU	Procedural sedation	11/2019	Expected beginning of 2021 the earliest
Hana Pharm, S. Korea	General anesthesia	12/2019	Expected in H2 2020

The following table gives an overview of received and potential future upfront and milestone payments as well as potential royalties:

Upfront and milestone payments			
	Total received	Maximum outstanding amount	Royalty rate
Ono, Japan (2007) (terminated in 2015)	USD 8 m	None	None
Yichang Humanwell, China (2012)	EUR 3.5 m ⁵	EUR 0.5 m ⁵	10% ⁵
Hana Pharm, S. Korea (2013)	EUR 2.0 m ⁶	EUR 1.0 m	10%
Hana Pharm, Southeast Asia (2020)	EUR 1.5 m ⁶	EUR 3.2 m	Low double-digit
R-Pharm, CIS (2013)	EUR 1 m	EUR 3 m	Low double-digit
R-Pharm, Turkey (2013)	EUR 1.5 m ⁶	EUR 2.5 m	Low double-digit
R-Pharm, MENA (2014)	EUR 1.5 m	EUR 5.5 m	Low double-digit
Pharmascience, Canada (2014)	EUR 0.4 m ¹	~ EUR 3.9 m	Tiered (starting at 15%)
Cosmo, U.S. (2016)	EUR 27.5m ²	EUR 35 m	20–25% ³
Mundipharma, Japan (2017)	EUR 4 m ⁶	EUR 22 m	Up to over 20% ⁴
Total	EUR 48.8 m	~ EUR 76.6 m	

¹⁾ This amount relates to the premium received in the course of the private placement in the amount of EUR 4 million in 2014 which was disclosed as revenues in 2014.

²⁾ Comprising EUR 10 million received via private placement in 2016 and via capital increase with subscription rights conducted in 2017, the upfront payment of EUR 10 million received in 2016 as well as the milestone payment of EUR 7.5 million received in 2019

³⁾ Subject to adjustments under specific circumstances, but not below 15% of net sales.

⁴⁾ Tiered royalties starting in the low double-digits to over 20%

⁵⁾ In case of commercialization of a competing remimazolam product in China, PAION is obliged to pay back 50% of the milestone payments already received (partially to be set off against royalties); potential future milestone payments would be halved. Moreover, royalties would drop to 5%.

⁶⁾ (Partially) received/receivable after the balance sheet date

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). It is available for two years and can be drawn down in a total of three tranches based on certain conditions as e.g. the achievement of operational milestones. Each tranche has a term of five years and will be repaid beginning in the fourth year after drawdown. The interest rate corresponds to the market conditions for risky debt financing of innovative companies (venture debt); it consists of a cash interest component, a deferred interest component due at maturity and a performance-related interest component. The first tranche of the loan is already available and the two further tranches could become available in 2020. PAION has not drawn down the loan yet.

Moreover, 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 EUR 5 million was issued to Yorkville under exclusion of pre-emptive rights on 12 September 2019. The minimum conversion price is EUR 1.91 per share. Until the balance sheet date, convertible notes with a nominal amount of KEUR 800 were converted into 407,443 PAION shares. A further utilization of the financing agreement with Yorkville by issuing additional tranches of convertible notes is not planned.

3. Net assets, financial position and results of operations

a. Results of operations

	2019 KEUR	2018 KEUR	Change in result KEUR
Revenues	8,000	2,766	5,234
Gross profit	8,000	2,766	5,234
Research and development	-13,099	-12,167	-932
General administrative and selling	-5,023	-3,408	-1,615
Other income (expenses)	796	354	442
Operating expenses	-17,326	-15,221	-2,105
Operating result	-9,326	-12,455	3,129
Financial result	-122	6	-128
Income taxes	2,432	2,510	-78
Net result	-7,016	-9,939	2,923

Revenues recognized in the reporting period amount to KEUR 8,000 and relate to the remimazolam license agreement with Cosmo in connection with the filing of the market approval dossier in the U.S. in the amount of KEUR 7,500 and to the remimazolam license agreement with R-Pharm in connection with the transfer of the Japanese filing dossier in the amount of KEUR 500. Revenues in the previous year mainly resulted from the remimazolam license agreements with Mundipharma, Hana Pharm and Yichang Humanwell.

Research and development expenses amounted to KEUR 13,099 and mainly relate to expenses in connection with the ongoing EU Phase III trial in general anesthesia and the validation of commercial scale production. The increase of KEUR 932 compared to the prior year is mainly due to higher expenses for the EU Phase III study.

General administrative and selling expenses amounted to KEUR 5,023 and increased by KEUR 1,615 compared to the previous year. Administrative expenses increased by KEUR 392 to KEUR 3,432 and selling expenses increased by KEUR 1,223 to KEUR 1,591. The increase of administrative expenses is mainly in connection with the conclusion of the loan agreement with the EIB and the issue of convertible notes in the reporting period. The increase of selling expenses

mainly results from pre-commercial activities and the start of the build-up of a supply chain for remimazolam.

Other income (expenses) mainly results from recharges to licensees.

The **financial result** amounts to KEUR -122 and decreased by KEUR 128 compared to the previous year. This is mainly attributable to the issue of convertible notes in the reporting period.

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 slight decrease in comparison to the prior year despite increased research and development expenses is mainly due to a cap of the claim based on the net result of PAION UK Ltd.

PAION closes fiscal year 2019 with a **net loss** of KEUR 7,016 after a net loss of KEUR 9,939 in the previous year.

b. Net assets

	31 Dec. 2019 KEUR	31 Dec. 2018 KEUR	Change KEUR
Non-current assets	2,262	2,286	-24
Current assets	22,650	22,037	613
Assets	24,912	24,323	589
Equity	14,732	20,822	-6,090
Non-current liabilities	26	0	26
Current liabilities	10,154	3,501	6,653
Equity and liabilities	24,912	24,323	589

Non-current assets mainly comprise the book value of the development project remimazolam (KEUR 2,096; 31 December 2018: KEUR 2,159) resulting from the purchase price allocation in the course of the CeNeS acquisition in 2008 reduced by scheduled amortization.

Compared to 31 December 2018, **current assets** increased by KEUR 613 to KEUR 22,650 and comprised cash and cash equivalents, prepaid expenses and other assets as well as trade receivables as of 31 December 2019. Cash and cash equivalents increased by KEUR 1,560 in the reporting period from KEUR 17,227 as of 31 December 2018 to KEUR 18,787 as of 31 December 2019. Prepaid expenses and other assets slightly increased from KEUR 3,311 as of 31 December 2018 by KEUR 52 to KEUR 3,363 as of 31 December 2019. Trade receivables amounted to KEUR 500 as of 31 December 2019 and decreased by KEUR 1,000 as compared to 31 December 2018. Trade receivables as of 31 December 2019 result from a milestone payment from licensee

R-Pharm received after the balance sheet date for the transfer of the Japanese market approval dossier.

The decrease in **equity** by KEUR 6,090 compared to 31 December 2018 mainly results from the net loss of the year and the issue of a total of 407,443 new shares from the partial conversion of convertible notes issued in the reporting period. The equity ratio amounts to 59.1% as of 31 December 2019 (31 December 2018: 85.6%).

Non-current liabilities entirely result from lease liabilities.

As of 31 December 2019, **current liabilities** comprise trade payables, financial debt, provisions, lease liabilities and other liabilities. The increase of KEUR 6,653 to KEUR 10,154 mainly results from the increase of trade payables by KEUR 2,625 and the issue of convertible notes in the reporting period. Mostly in the course of the conduct of the EU Phase III study in general anaesthesia, trade payables increased again as planned in the reporting period, after they had decreased in the previous year due to the completion of certain development activities and corresponding payments. Convertible notes with a total nominal value of KEUR 5,000 were issued in the reporting period. As of 31 December 2019, KEUR 800 of the total nominal value were converted into shares of the company. Carrying amount and fair value of the financial debt recognized on the balance sheet amount to KEUR 4,354 as of the balance sheet date. Moreover, provisions decreased by KEUR 360 compared to the previous year mainly due to lower premiums and management bonuses.

c. Financial position

Compared to 31 December 2018, **cash and cash equivalents** increased by KEUR 1,560 to KEUR 18,787. The change in cash and cash equivalents stems from the following areas:

	2019 KEUR	2018 KEUR	Change KEUR
Cash flow from operating activities	-2,847	-12,813	9,966
Cash flow from investing activities	-14	-13	-1
Cash flow from financing activities	4,414	5,214	-800
Effect of exchange rate changes	7	0	7
Change in cash and cash equivalents	1,560	-7,612	9,172

The **cash flow from operating activities** primarily results from the net loss of the year in the amount of KEUR 7,016 and changes in the working capital, particularly the increase of trade payables by KEUR 2,625 and the decrease of trade receivables by KEUR 1,000.

The **cash flow from financing activities** mainly results from the gross proceeds of convertible notes issued in the reporting period with a discount of 5% of KEUR 4,750 (nominal amount:

KEUR 5,000), transaction costs incurred in this context (KEUR 278) and the principal portion of lease payments (KEUR 52).

d. Overall appraisal

The net loss of EUR 7.0 million is at the lower end of the forecast range of approx. EUR 7 million to approx. EUR 10 million projected for fiscal year 2019 in the previous year.

Recognized revenues of EUR 8.0 million meet the amount of approx. EUR 8 million forecasted per prior year for 2019 since underlying milestones were achieved.

General administrative and selling expenses of EUR 5.0 million are at the upper end of the range of approx. EUR 4 million to approx. EUR 5 million forecasted per prior year for 2019 as pre-commercial activities and the build-up of a supply chain for remimazolam could be initiated as planned.

With EUR 13.1 million, research and development expenses are within the forecast range of approx. EUR 13 million to approx. EUR 15 million projected for fiscal year 2019 in the previous year.

Tax income of EUR 2.4 million is slightly above the prior-year forecast for 2019 of approx. EUR 2 million since the cap of the claim based on the net result of PAION UK Ltd was less restricting than expected.

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

Since remimazolam is not yet marketed and therefore no sustainable revenue is generated, PAION continues to incur losses.

Headcount

In fiscal year 2019, PAION had an average of 44 employees (previous year: 39 employees). Of these 44 employees, 35 worked in development and nine in administration and sales. PAION UK Group had an average headcount of ten employees. As of 31 December 2019, the headcount was 45 (31 December 2018: 40).

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 2.01 per stock option and is based on the average price of the shares in a certain time period before the allocation in accordance with the terms of the stock option plan. As of 31 December 2019, the exercise hurdle was EUR 2.60.

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, EUR 2.30 or EUR 2.60 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 in accordance with the terms of the stock option plan. As of 31 December 2019, the exercise hurdle was EUR 2.34, EUR 2.87 or EUR 2.85, depending on the grant date.

From the Stock Option Plan 2016 approved by the Annual General Meeting on 25 May 2016, a total of 244,500 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 2.25 or EUR 2.60 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 in accordance with the terms of the stock option plan. As of 31 December 2019, the exercise hurdle was EUR 2.42 or EUR 2.85, depending on the grant date.

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 2019 can be gathered from the following tables (according to German Corporate Governance Code):

Benefits granted in EUR	Dr. James Phillips CEO since 16 October 2019				Dr. Wolfgang Söhngen CEO (until 15 October 2019) Management Board member (until 22 November 2019)			
	2018	2019	2019 (Min)	2019 (Max)	2018	2019	2019 (Min)	2019 (Max)
Fixed compensation	0	128,952*	128,952	128,952	275,000	245,972	245,972	245,972
Other remuneration	0	4,977	4,977	4,977	45,301	39,045	39,045	39,045
Total	0	133,928	133,928	133,928	320,301	285,017	285,017	285,017
One-year variable compensation	0	0	0	0	175,000	156,528	0	242,618
Multi-year variable compensation								
Stock Option Plan 2014 - Grant 2018 (Waiting period 2018 to 2022) **	0	0	-	-	0	0	-	-
Stock Option Plan 2016 - Grant 2018 (Waiting period 2018 to 2022) **	0	0	-	-	102,000	0	-	-
Total	0	133,928	133,928	133,928	597,301	441,545	285,017	527,635
Service cost	0	0	0	0	0	0	0	0
Total remuneration	0	133,928	133,928	133,928	597,301	441,545	285,017	527,635

*) Dr. Phillips' fixed compensation includes a signing bonus for lost compensation from his previous employment and 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

Allocation in EUR	Dr. James Phillips CEO since 16 October 2019		Dr. Wolfgang Söhngen CEO (until 15 October 2019) Management Board member (until 22 November 2019)	
	2018	2019	2018	2019
Fixed compensation	0	128,952*	275,000	245,972
Other remuneration	0	4,977	45,301	39,045
Total	0	133,928	320,301	285,017
One-year variable compensation	0	0	114,100	62,611
Multi-year variable compensation				
Stock Option Plan 2008 - Grant 2008 (Waiting period 2008 to 2010)	0	0	50,028**	0
Total	0	133,928	484,429	347,629
Service cost	0	0	0	0
Total remuneration	0	133,928	484,429	347,629

*) Dr. Phillips' fixed compensation includes a signing bonus for lost compensation from his previous employment and a yearly bonus which was not variable for 2019 and is therefore disclosed as part of the fixed compensation.

**) Dr. Söhngen exercised 41,517 stock options in fiscal year 2018

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

	Abdelghani Omari CFO				Dr. Jürgen Beck CDO			
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	2018	2019	2019 (Min)	2019 (Max)	2018	2019	2019 (Min)	2019 (Max)
	180,000	180,000	180,000	180,000	200,000	200,000	200,000	200,000
	15,127	15,127	15,127	15,127	15,127	15,127	15,127	15,127
	195,127	195,127	195,127	195,127	215,127	215,127	215,127	215,127
	90,000	90,000	0	139,500	70,000	70,000	0	108,500
	0	0	-	-	76,035	0	-	-
	102,000	0	-	-	60,965	0	-	-
	387,127	285,127	195,127	334,627	422,127	285,127	215,127	323,627
	0	0	0	0	0	0	0	0
	387,127	285,127	195,127	334,627	422,127	285,127	215,127	323,627

	Abdelghani Omari CFO		Dr. Jürgen Beck CDO	
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	2018	2019	2018	2019
	180,000	180,000	200,000	200,000
	15,127	15,127	15,127	15,127
	195,127	195,127	215,127	215,127
	58,680	36,000	45,640	28,000
	0	0	0	0
	253,807	231,127	260,767	243,127
	0	0	0	0
	253,807	231,127	260,767	243,127

Management Board remuneration in fiscal year 2019 amounted to KEUR 956 in total (previous year: KEUR 1,290) and is composed as follows:

in EUR	2019	2018
Fixed remuneration	754,924	655,000
Other remuneration	74,277	75,556
Total non-performance based remuneration	829,201	730,555
Short-term variable remuneration	126,611	218,420
Total short-term remuneration	955,812	948,975
Long-term variable remuneration	0	341,000
Total long-term remuneration	0	341,000
Total remuneration	955,812	1,289,975

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

The Management Board members held the following stock options as of 31 December 2019:

Status of non-exercised stock options as of 31 December 2019:		Dr. James Phillips	Abdelghani Omari	Dr. Jürgen Beck
Stock options 2010	No.	0	80,000	0
Stock options 2010 - fair value *	EUR	-	133,600	-
Stock options 2014	No.	0	111,000	55,500
Stock options 2014 - fair value *	EUR	-	119,325	76,035
Stock options 2016	No.	0	100,000	44,500
Stock options 2016 – fair value *	EUR	-	102,000	60,965

*) 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 and Dr. Beck, 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 and 2016, 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 2019 can be gathered from the following table:

	Basic remuneration EUR	Per-meeting fees EUR	Total EUR
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	12,167	2,000	14,167
John Dawson	7,889	2,000	9,889

Supervisory Board remuneration in fiscal year 2019 amounted to KEUR 162. In the previous year the remuneration also amounted to KEUR 162.

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

Composition of subscribed capital

As of 31 December 2019, PAION AG had a subscribed capital of EUR 64,265,586.00, divided into 64,265,586 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 2019 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 21 May 2024, with the consent of the Supervisory Board, on one or more occasions, by up to EUR 31,929,071.00 in total by issuing up to 31,929,071 new no-par value bearer shares in return for cash contributions or contributions in kind (Authorized Capital 2019). 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 22 May 2019 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.

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 407,443.00 by conversion of convertible notes issued under exclusion of pre-emptive rights in the reporting period and amounts to EUR 25,792,557.00 as of 31 December 2019. Conditional Capital 2019 can be used under exclusion of pre-emptive rights in an amount of EUR 5,978,371.00 as of 31 December 2019. Accordingly, Authorized Capital 2019 can be used under exclusion of pre-emptive rights in an amount of EUR 5,978,371.00 as of 31 December 2019 as well. Furthermore, the company is authorized to issue 281,093 shares (Conditional Capital 2008 I), 720,000 shares (Conditional Capital 2010 I), 740,000 shares (Conditional Capital 2014), 840,000 shares (Conditional Capital 2016) and 900,000 shares (Conditional Capital 2018 II) in connection with the Stock Option Plans 2008, 2010, 2014, 2016 and 2018.

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 and 2018 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 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. 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 are 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:

		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 remimazolam

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

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.¹⁶

In order to ensure timely filings for market approval of remimazolam, PAION cooperates with renowned 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 is currently conducting an EU Phase III study in general anesthesia. There is a risk that patients cannot be recruited fast enough or at all. The resulting delay, necessary amendment or discontinuation of the 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 have been taken into account for the study design 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. This is a moderate risk. The risk classification decreased by two categories compared to the previous year.

¹⁶ 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 an increased risk. In case of occurrence, the potential damage level could pose a threat to the continued existence of the group. 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 start or 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 actively 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. The risk classification increased by one category compared to the previous year.

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. 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. Based on the properties of remimazolam shown so far, PAION aims for a remimazolam label in the U.S. comparable to midazolam which is allowed to be applied by adequately trained proceduralists and nurses conditional on a certain safety set-up and continuous monitoring of relevant cardiac and respiratory parameters. There is a risk that remimazolam will not be granted this target label significantly reducing or entirely eliminating commercial usability in the U.S. In order to reduce this risk, PAION has addressed this aspect with the FDA under consideration of existing study data at that time and used according feedback for the design of the U.S. Phase III program. PAION has implemented a system to continuously monitor the relevant parameters in this regard. 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 is currently analyzing market access in different markets in the EU. 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 the EU, 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 continues to work on the preparation of the relevant markets, including bringing in external consultants for communication with the scientific community and establishing a network of key opinion leaders. Moreover, there is regular information exchange with the U.S. licensee Cosmo and the licensees in the other regions. A direct exchange with Cosmo's sublicensee Acacia is planned to ensure support in the preparation of commercialization in the U.S. in the best possible way. PAION is also evaluating the possibility of initially launching remimazolam in a different indication than planned as main indication in single countries in the EU in order to support later commercialization in the main indication in these markets. 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 a potential own commercialization in parts of the EU) 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 finalized 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 preparing implementation also under consultation of external experts. Moreover, there is a regular information exchange with the U.S. licensee Cosmo and the licensees in the other regions. Cosmo's sublicensee Acacia plans the start of commercialization of an own product with the same distribution structure also intended to be used for remimazolam already before the planned start of commercialization 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. The risk classification increased by one category compared to the previous year.

For commercial supply of remimazolam, certain regulatory permissions and licenses need to be acquired. There is a risk that potentially required changes of processes or in the documentation at PAION cannot be implemented fast enough or that extensive inspections are undertaken

by the authorities prior to the grant of such permissions leading to a delay in the supply of the commercially usable medicine for the licensees as well as for PAION itself. In order to avoid this risk, requirements and potentially necessary changes at PAION are being analyzed and implemented well in advance. This is an increased risk.

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 on the one hand and to detect and address potential weaknesses in the processes at an early stage on the other hand. 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 risk classification increased by one category compared to the previous year.

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. In case of occurrence, the potential damage level could pose a threat to the continued existence of the group. The risk classification decreased by one category compared to the previous year.

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 completed the implementation of a supply chain. Moreover, commercial production orders have not yet been submitted to the contractual manufacturers. If the complete build-up of the supply chain should not be completed in time or commercial production orders cannot be submitted early enough, 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 contractual manufacturers and on the planning of production orders under involvement of the licensees. This is a moderate risk. The risk classification decreased by two categories compared to the previous year.

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 a moderate risk.

For the Chinese market, a competing remimazolam product is being developed by Hengrui Medicine, a competitor of PAION's Chinese licensee Yichang Humanwell, for which market approval was granted end of 2019. Should commercialization of this product be possible within a certain timeframe without infringement of Yichang Humanwell's and PAION's existing patents, Yichang Humanwell's revenues from sales could be reduced significantly. Moreover, PAION would be obliged to pay an amount of EUR 1.75 million (partially to be set off against royalties) to Yichang Humanwell, potential future milestone payments would be halved and the royalty rate would be reduced from 10% to 5%. PAION is cooperating with Yichang Humanwell to prevent commercialization of the competing remimazolam product. This is a high risk.

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 a high risk and the potential damage level could pose a threat to the continued existence of the group in case of occurrence.

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.

Since PAION neither owns distribution structures nor aims at implementing these globally, potential commercialization of remimazolam can only be carried out by licensees in certain or all regions. Should license agreements not be concluded in time, a potential commercialization could only start delayed in spite of the potential availability of market approval. PAION has partnering discussions with potential further licensees in order to allow for swift commercialization of remimazolam after potential market approval. This is an increased risk.

b. Finance risks

aa) Financing risks

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

PAION's future ability to secure additional funding will depend on the success of its development, licensee and partnering activities, the situation on the capital markets and other factors. If PAION is unable to raise financing at favorable terms or unable to raise financing at all, it could be forced to reduce its operating expenses by delaying, reducing or discontinuing the development and commercialization of remimazolam.

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 contact to investors as well as (potential) pharma partners and licensees. PAION has entered into a loan agreement with the EIB which is already available partially. This is a high risk. In case of occurrence, the potential damage level could pose a threat to the continued existence of the group.

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 the development and market preparation 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 successfully. Dependent on the actual structure, the consequences of the Brexit could also lead to tax payments on potential earnings expected in the future, e.g. due to controlled foreign corporation rules. These tax payments would correspondingly reduce liquidity.

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 2020 onwards.

PAION continuously monitors the relevant tax legislation and jurisdiction and consults external tax consultants for all material issues. Usability of tax losses carried forward is an increased risk. In case of occurrence, the potential damage level could pose a threat to the continued existence of the group. The reduction or cessation of tax credits from British tax authorities is a moderate risk.

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, if expected payments from subsidiaries, e.g. loan repayments, are not made, this could lead to the insolvency of PAION.

For the purpose of monitoring the financial position, results of operations and cash flows of 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. 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. This is a moderate risk.

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.

e. Risks in relation to the “Brexit”

The exit of the United Kingdom from the European Union (so-called “Brexit”) realized end of January 2020 bears a variety of potential risks which can neither be comprehensively captured or specified in more detail qualitatively nor be defined quantitatively in regard to potential damage levels based on the current state of negotiations between the United Kingdom and the EU with respect to the future economic relations after the interim term which is supposed to end on 31 December 2020. Basically, potential risks for PAION could stem from the following areas nevertheless. This overview is however not necessarily exhaustive due to the given uncertainties. Also, potential risks cannot be reasonably categorized due to this fact.

Regulatory requirements for market approval of new drugs could potentially 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 drug candidate 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.

Moreover, also apart from intragroup services, tax risks in particular could result from the Brexit, e.g. due to controlled foreign corporation rules.

f. Risks in relation to the Coronavirus (SARS-CoV-2)

A new form of the Coronavirus (SARS-CoV-2) is spreading internationally since the beginning of 2020 leading to regionally different, partly massive limitations of public life and significant decreases of economic activity. On 11 March 2020, the World Health Organization (WHO) classified the spread of the virus as a pandemic.¹⁷ In the beginning of March 2020, the OECD already corrected the forecast for growth of the world economy downwards; in Germany, the government assured support of the economy.

Limitations of public life (as e.g. in regard to travel restrictions) owed to the spread of the virus and the economic consequences of the spread could directly affect PAION's business activity and its results of operations, net assets and financial position. Among others, development and manufacture of remimazolam, 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 spread as well as the (potential) impact of the virus on public life and the global economy, this risk cannot be classified currently.

4. Market opportunities

PAION is focusing on the clinical development of drug candidates in anesthesia for which there is a substantial unmet medical need with the vision to participate in the commercialization.

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, anesthetists often express the desire for a short-acting, safe and well controllable agent. PAION is responding to this medical need with the development of remimazolam.

Procedural sedation

Clinical development of remimazolam in procedural sedation for minor medical interventions in the U.S. has already been completed. PAION's U.S. licensee Cosmo filed for market approval in April 2019. The start of commercialization of remimazolam in the U.S. can be expected in 2020 in case of a positive FDA decision. PAION's Chinese licensee Yichang Humanwell filed for market approval in procedural sedation in China in November 2018; market approval is expected in 2020. In Europe, PAION submitted an MAA in procedural sedation to the EMA in November 2019. Market approval is

¹⁷ World Health Organization: WHO Director-General's opening remarks at the media briefing on COVID-19 - 11 March 2020; <https://www.who.int/dg/speeches/detail/who-director-general-s-opening-remarks-at-the-media-briefing-on-covid-19---11-march-2020>; accessed on 12 March 2020.

expected beginning of 2021 at the earliest. Based on its own projections, PAION currently estimates an annual peak sales potential of approx. EUR 50 million to approx. EUR 75 million for procedural sedation in the EU.

General anesthesia

Development in general anesthesia in Japan is completed. The Japanese licensee Mundipharma filed for market approval of remimazolam in general anesthesia in Japan in December 2018 and received market approval in January 2020. PAION's Russian licensee R-Pharm is currently preparing first market approval dossiers for the licensed territories based on the Phase III trial in general anesthesia successfully completed in November 2018. PAION's South Korean licensee Hana Pharm submitted a market approval dossier for remimazolam in general anesthesia in South Korea in December 2019. Market approval is currently expected in the second half of 2020. Assuming approval in procedural sedation and positive results in the Phase III trial in general anesthesia, PAION plans to submit an extension of the marketing authorization for remimazolam for general anesthesia. The review process for an extension 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 150 million to approx. EUR 200 million for general anesthesia in the EU.

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. In total, potential future milestone payments from existing license agreements add up to nearly EUR 77 million. In addition, all license agreements in place bear royalties upon commercialization ranging from 10% up to over 20% of net sales based on the respective territory. For selected European markets, an own commercialization is being evaluated. 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 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.

Overall evaluation of opportunities and risks

The filings for market approval in the U.S, the EU and South Korea in the reporting period were further important milestones on the way to market approval for remimazolam in even more than one region and indication. The progress of the development of remimazolam worldwide is illustrated by the fact that there were a total of five approval dossiers in review by the respective regional authorities at the end of the reporting period submitted by PAION and its licensees. Shortly after the end of the reporting period, market approval in general anesthesia was granted in Japan. Thus, the risk of failure of the development of remimazolam has further decreased.

The financing agreement signed with the EIB and the convertible notes issued in the reporting period have further decreased potential additional financing requirement depending on the respective scenario. Thus, the risk situation has improved compared to the previous year.

With a regular course of the approval process, market approval and subsequent start of commercialization of remimazolam in the U.S. can be expected in 2020. In Japan, remimazolam could be launched by licensee Mundipharma mid-2020. Market approvals in China and South Korea are currently also expected in 2020. Moreover, market approval could be granted in procedural sedation in the EU beginning of 2021 at the earliest. Taking these factors into account, the opportunity situation has improved in comparison to the previous year. Since remimazolam is not yet marketed and therefore no sustainable revenue is generated, PAION continues to incur losses.

Report on post-balance sheet date events

On 08 January 2020, PAION and licensee Hana Pharm extended the existing remimazolam license agreement for South Korea to include six additional countries in Southeast Asia.

On 23 January 2020, licensee Mundipharma received market approval for remimazolam in general anesthesia in Japan.

On 12 March 2020, licensee Cosmo announced the postponement of the target date for completion of the review (PDUFA date) of the NDA for remimazolam by the FDA by up to three months from 05 April 2020 to 05 July 2020.

There were no further significant events in the period between the reporting date, 31 December 2019, and the preparation of this report.

Report on expected developments

Outlook on development and commercialization

PAION's focus for 2020 is on the completion of the ongoing Phase III study in general anesthesia in Europe, market approval processes in the U.S., Europe and other regions, the build-up of the supply chain and commercial manufacture of remimazolam as well as the market preparation and start of commercialization of remimazolam in different territories.

Europe

For the EU, PAION is working on the advancement of the clinical development program of remimazolam. Focus are the conduct and completion of the ongoing Phase III study in general anesthesia as well as first development work to address the pediatric development plan stretching over several years. Due to the Coronavirus pandemic, completion of patient recruitment of the Phase III study previously planned in the first half of 2020 will be delayed until hospitals which are currently increasingly working to capacity with the treatment of patients infected with the Coronavirus will have capacities for the recruitment of patients for planned interventions available again. EMA's decision on the market approval dossier in procedural sedation is expected beginning of 2021 at the earliest. Following this, PAION plans to file for market approval in general anesthesia. Moreover, PAION continues to conduct pre-commercial activities. The build-up of an own distribution structure in Europe is dependent on the possibility of extending the portfolio by additional products. Therefore, PAION also considers the option to outlicense remimazolam for Europe as an alternative to building up an own distribution structure.

U.S.

For the U.S., the FDA's decision on the approval dossier in procedural sedation is prominent. PDUFA date is 05 July 2020, and in case of approval, Acacia, sublicensee of U.S. licensee Cosmo, expects start of commercialization of remimazolam in the U.S. in the second half of 2020.

Rest of the World

In Japan, market approval for remimazolam in general anesthesia was granted in January 2020. Start of commercialization by licensee Mundipharma could happen mid-2020.

In China, licensee Yichang Humanwell filed for market approval for remimazolam in procedural sedation in November 2018 and expects a decision still this year.

PAION's South Korean licensee Hana Pharm submitted a market approval dossier for remimazolam in general anesthesia in South Korea in December 2019. Market approval is currently expected in the second half of 2020.

Licensee R-Pharm is preparing first market approval dossiers for the licensed territories.

In Canada, PAION expects its licensee Pharmascience to use the U.S. market approval dossier as the basis for filing for market approval of remimazolam.

Further activities

PAION is working on setting up the supply chain in order to be able to provide remimazolam product to the licensees timely for commercial use as well as having it available early enough for PAION's potential own commercialization. The planned development of the structures, establishment of the processes and obtaining all pharmaceutical permits are planned to be implemented in the second half of 2020 to an extent that allows for regular supply of the licensees with remimazolam.

Financial outlook 2020

PAION expects revenues of about EUR 20 million in 2020, thereof EUR 15 million from Cosmo for market approval of remimazolam in the U.S. Further revenues relate to the market approval of remimazolam in Japan, the license extension signed with Hana Pharm in January 2020 to include six additional countries in Southeast Asia as well as milestones in connection with possible market approvals in further regions. Royalties from the commercialization of remimazolam in the U.S. and Japan are expected in a small amount of less than EUR 1 million in total in 2020.

Research and development expenses will amount to between approx. EUR 10 million and approx. EUR 12 million, depending on the progress of development. General administrative and selling expenses will amount to between approx. EUR 7 million and approx. EUR 9 million depending on the progress of the build-up of the supply chain and the volume of pre-commercial activities. Net result is expected to amount to between approx. EUR -1 million and approx. EUR 3 million in 2020.

Income from tax credits on parts of research and development expenses from British tax authorities are not expected or only expected in a small amount of up to EUR 0.5 million and therefore not included in the outlook due to a change in calculation and capping rules and the amount of expected revenues.

This outlook assumes that PAION and licensee activities progress as expected. In case of delays, essential cost blocks and/or revenues would shift into 2021 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 Coronavirus pandemic on our business and the business of our partners could lead to delays and a shift of revenues and/or costs.

Based on current planning, cash and cash equivalents at hand and expected payments from milestones and royalties secure a liquidity runway into the second half of 2021.

Additional funds could be required for a potential own commercialization of remimazolam in selected European markets, the execution of the multi-year pediatric development plan as well as for potential portfolio extensions. The total magnitude of potentially required funds will be dependent on PAION's decision on building up an own distribution and what an actual setup would look like, as well as on the magnitude and timing of incoming milestone and royalty payments from licensees. A final decision on building up an own distribution has not been made yet. The financing

agreement of up to EUR 20 million concluded with the EIB and milestone and royalty payments expected in the next years could partially or completely cover a potential financing requirement depending on the decision on an own commercialization. The first tranche of EUR 5 million from the financing agreement with the EIB, which is already available, has not been drawn down yet. Availability of the further two tranches is dependent on certain conditions as e.g. the achievement of operational milestones. The loan can be accessed until mid-2021. A further utilization of the financing agreement on convertible notes with Yorkville in addition to the first tranche already issued is not planned. The magnitude of royalties from licensees will depend on the success of commercialization in the U.S., Japan and the other territories and on remimazolam's price level and pace of market penetration. However, this can only be evaluated with sufficient certainty after the launch phase.

Aachen, Germany, 25 March 2020

PAION AG



Dr. James Phillips Dr. Jürgen Beck Abdelghani Omar

Consolidated Financial Statements

PAION AG

Consolidated Balance Sheet as of 31 December 2019

ASSETS	Note	31 Dec. 2019 EUR	31 Dec. 2018 EUR
Non-current assets			
Intangible assets	1.	2,137,302.29	2,212,476.80
Equipment	2.	45,860.19	73,569.84
Right-of-use assets	10.	79,075.61	0.00
Other assets		14.05	13.93
		2,262,252.14	2,286,060.57
Current assets			
Trade receivables	3.	500,000.00	1,500,000.00
Prepaid expenses and other assets	4.	3,362,893.03	3,310,694.39
Cash and cash equivalents	5.	18,786,680.89	17,226,658.20
		22,649,573.92	22,037,352.59
Total assets		24,911,826.06	24,323,413.16

EQUITY AND LIABILITIES	Note	31 Dec. 2019 EUR	31 Dec. 2018 EUR
Equity	6.		
Share capital		64,265,586.00	63,858,143.00
Capital reserve		139,421,819.80	138,730,764.25
Translation reserve		-884,259.03	-712,030.72
Loss carryforward		-181,054,833.90	-171,115,423.14
Result for the period		-7,015,815.07	-9,939,410.76
		14,732,497.80	20,822,042.63
Non-current liabilities			
Lease liabilities	10.	25,632.41	0.00
Current liabilities			
Trade payables	8.	4,843,429.10	2,217,979.06
Financial debt	11.	4,354,136.41	0.00
Provisions	7.	270,042.03	629,506.26
Lease liabilities	10.	54,579.74	0.00
Other current liabilities	9.	631,508.57	653,885.21
		10,153,695.85	3,501,370.53
Total equity and liabilities		24,911,826.06	24,323,413.16

Consolidated Statement of Comprehensive Income for Fiscal Year 2019

	Note	2019 EUR	2018 EUR
Revenues	12.	8,000,000.00	2,765,900.33
Gross profit		8,000,000.00	2,765,900.33
Research and development expenses		-13,099,393.66	-12,167,169.44
General administrative and selling expenses		-5,022,729.37	-3,407,785.10
Other income (expenses), net	13.	796,271.78	353,802.76
Operating expenses		-17,325,851.25	-15,221,151.78
Operating result		-9,325,851.25	-12,455,251.45
Financial income		975.69	6,183.15
Financial expenses		-123,391.51	0.00
Financial result	14.	-122,415.82	6,183.15
Result for the period before taxes		-9,448,267.07	-12,449,068.30
Income taxes	15.	2,432,452.00	2,509,657.54
Result for the period		-7,015,815.07	-9,939,410.76
of which attributable to other shareholders		0.00	0.00
of which attributable to shareholders of PAION AG		-7,015,815.07	-9,939,410.76
Foreign currency translation of subsidiaries		-172,228.31	-81,838.12
Total income and expense recognized directly in equity that will be reclassified to profit or loss when specific conditions are met		-172,228.31	-81,838.12
Other comprehensive income		-172,228.31	-81,838.12
Total comprehensive income		-7,188,043.38	-10,021,248.88
of which attributable to other shareholders		0.00	0.00
of which attributable to shareholders of PAION AG		-7,188,043.38	-10,021,248.88
Earnings per share (basic)	16.	-0.11	-0.16
Earnings per share (diluted)	16.	-0.11	-0.16

Consolidated Cash Flow Statement for Fiscal Year 2019

	2019	2018
	EUR	EUR
Cash flows from operating activities:		
Net result for the year	-7,015,815.07	-9,939,410.76
Reconciliation of net profit (loss) for the period to cash flows from operating activities:		
Income taxes	-2,432,452.00	-2,509,657.54
Amortization/depreciation and non-cash changes of fixed assets	118,148.48	255,574.27
Loss/Profits from the disposal of non-current assets	-1,023.51	0.00
Interest expenses and interest income	122,415.82	-6,183.15
Release of deferred income	0.00	-982,405.73
Expenses from stock option plans	334,972.25	399,691.16
Transaction costs and fair value adjustments in connection with financing activities	210,923.80	0.00
Changes in assets and liabilities which are not attributable to investing or financing activities:		
Trade receivables	1,000,000.00	-1,462,566.85
Prepaid expenses and other assets	272,517.31	-48,372.59
Trade payables	2,625,450.04	-3,702,989.93
Provisions	-359,464.23	238,650.32
Other current liabilities	-22,900.16	328,431.42
Deferred income	0.00	963,491.07
Non-cash exchange losses/gains	-126,523.35	-81,364.70
	-5,273,750.62	-16,547,113.01
Tax payments received	2,435,055.74	3,729,251.01
Interest paid	-9,187.25	0.00
Interest received	954.17	4,983.92
Net cash used in operating activities	-2,846,927.96	-12,812,878.08
Cash flows from investing activities:		
Cash paid for investments in intangible assets and equipment	-15,264.44	-13,068.33
Proceeds from Sale of Property, Plant and Equipment	1,023.51	0.00
Net cash used in investing activities	-14,240.93	-13,068.33
Cash flows from financing activities:		
Proceeds from the issue of convertible bonds	4,750,000.00	0.00
Transaction costs in connection with the issue of convertible bonds	-277,840.00	0.00
Principal portion of lease payments	-52,076.05	0.00
Payments in connection with raising capital	-6,400.00	-159,576.44
Capital increase	0.00	2,738,097.00
Contributions to the capital reserve	0.00	2,635,905.22
Net cash provided from financing activities	4,413,683.95	5,214,425.78
Change in cash and cash equivalents	1,552,515.06	-7,611,520.63
Effect of exchange rate changes on cash	7,507.63	-473.41
Cash and cash equivalents at beginning of the period	17,226,658.20	24,838,652.24
Cash and cash equivalents at end of the period	18,786,680.89	17,226,658.20
Composition of cash and cash equivalents at the end of the period:		
Cash and cash equivalents	18,786,680.89	17,226,658.20

Consolidated Statement of Changes in Equity for Fiscal Year 2019

EUR	Share capital	Capital reserve	Translation reserve	Loss carryforward	Equity
31 December 2017	61,120,046.00	135,854,744.31	-630,192.60	-171,115,423.14	25,229,174.57
Total comprehensive income	0.00	0.00	-81,838.12	-9,939,410.76	-10,021,248.88
Issue of shares	2,738,097.00	0.00	0.00	0.00	2,738,097.00
Contribution to the capital reserve	0.00	2,635,905.22	0.00	0.00	2,635,905.22
Cost of raising capital	0.00	-159,576.44	0.00	0.00	-159,576.44
Additional contribution to the capital reserve due to the issue of options	0.00	399,691.16	0.00	0.00	399,691.16
31 December 2018	63,858,143.00	138,730,764.25	-712,030.72	-181,054,833.90	20,822,042.63
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
31 December 2019	64,265,586.00	139,421,819.80	-884,259.03	-188,070,648.97	14,732,497.80

Consolidated Notes

PAION AG

Notes to the consolidated financial statements for fiscal year 2019

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/Netherlands
- TheraSci Limited, Cambridge/UK

PAION Netherlands B.V. was founded in July 2019 and is being accounted for using the full consolidation.

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 2019 are scheduled for authorization and approval for publication by the Supervisory Board in its meeting on 25 March 2020.

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 2019, 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 2019 according to IAS 1.

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

- IFRS 16 “Leases”
- IFRIC 23 “Uncertainty over Income Tax Treatments”
- IFRSs 2015–2017 Cycle “Annual Improvements to IFRSs 2015–2017” implemented changes to following standards:
 - IFRS 3 “Business Combinations”
 - IFRS 11 “Joint Arrangements”
 - IAS 12 “Income Taxes”
 - IAS 23 “Borrowing Costs”
- Amendments to IFRS 9 “Financial Instruments”
- Amendments to IAS 19 “Employee Benefits”
- Amendments to IAS 28 “Investments in Associates and Joint Ventures”

The application of IFRS 16 had minor effects on the Group’s net assets, financial position and results of operations. In this context, IFRS 16.C5 b), IFRS 16.C8 a) and b) ii) and the practical expedients according to IFRS 16.C10 a) and c) were applied; there was no cumulative effect to be recognized in equity. The initial recognition of lease liabilities and corresponding capitalization of right-of-use assets of leases previously not recognized on the balance sheet led to a balance sheet extension of EUR 0.1 million at the time of first-time adoption of IFRS 16. Lease liabilities were measured at the present value of the remaining lease payments, discounted with the incremental borrowing rate. The weighted average incremental borrowing rate applied for the lease liabilities as of 1 January 2019 was 3.74%. Rent and lease expenses previously entirely recognized in the operating expenses are now mostly recognized as depreciation of tangibles and as financial expenses to a small degree. Financial expenses are initially higher and decrease over the respective lease term due to application of the effective interest method. Overall, this has led to a slightly earlier recognition of expenses and to a shift of a small part of expenses previously recognized as general administrative and selling as well as research and development costs to the financial expenses. Due

to disclosure of the principal portion of lease payments in the cash flows from financing activities, cash flows from financing activities have decreased and cash flows from operating activities have increased. Moreover, the application of IFRS 16 has led to additional notes disclosures.

The application of the other 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”: This standard is effective for fiscal years beginning on or after 1 January 2021. Earlier adoption is allowed. The adoption by the EU is still pending.
- Amendments to References to the Conceptual Framework in IFRS Standards: The amendments are effective for fiscal years beginning on or after 1 January 2020. Earlier adoption is allowed.
- Amendments to IFRS 3 “Business Combinations”: The amendments are effective for fiscal years beginning on or after 1 January 2020. 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 2022. 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): The amendments are effective for fiscal years beginning on or after 1 January 2020. Earlier adoption is allowed.
- Amendments to IAS 1 and IAS 8 (Definition of Material): The amendments are effective for fiscal years beginning on or after 1 January 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 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. Except for IFRS 16, 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 2019: 0.8500 GBP/EUR; exchange rate as of 31 December 2018: 0.8969 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 2019 from 0.8476 GBP/EUR to 0.9153 GBP/EUR; bandwidth in 2018 from 0.8720 GBP/EUR to 0.8978 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.

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 not selling products at the market yet, revenues are essentially realized by means of selling or out-licensing substances or drug candidates. Processually, the sale or out-licensing 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.

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:

EUR	Industrial rights and similar rights and assets
Acquisition Cost	
1 Jan. 2018	12,690,723.15
Additions	12,164.83
Disposals	0.00
Reclassifications	0.00
Exchange rate differences	-113,494.43
31 Dec. 2018	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
Accumulated amortization, depreciation and impairment losses	
1 Jan. 2018	10,275,852.60
Additions	195,428.46
Disposals	0.00
Exchange rate differences	-94,364.31
31 Dec. 2018	10,376,916.75
Additions	203,424.28
Disposals	0.00
Exchange rate differences	559,062.65
31 Dec. 2019	11,139,403.68
Carrying amounts as of 31 Dec. 2018	2,212,476.80
Carrying amounts as of 31 Dec. 2019	2,137,302.29

The intangible assets mainly comprise the development project remimazolam (KEUR 2,096; 31 December 2018: KEUR 2,159). This development project 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:

EUR	Plant and machinery	Other plant, factory and office equipment	Total
Acquisition Cost			
1 Jan. 2018	172,585.59	791,083.90	963,669.49
Additions	0.00	903.50	903.50
Disposals	0.00	0.00	0.00
Reclassifications	0.00	0.00	0.00
Exchange rate differences	0.00	-2,213.32	-2,213.32
31 Dec. 2018	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
Accumulated amortization, depreciation and impairment losses			
1 Jan. 2018	158,920.74	691,066.74	849,987.48
Additions	5,090.06	35,504.37	40,594.43
Disposals	0.00	0.00	0.00
Exchange rate differences	0.00	-1,792.08	-1,792.08
31 Dec. 2018	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
Carrying amounts as of 31 Dec. 2018	8,574.79	64,995.05	73,569.84
Carrying amounts as of 31 Dec. 2019	8,965.53	36,894.66	45,860.19

(3) Trade receivables

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

(4) 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 2,567; previous year: KEUR 2,481), VAT refund claims (KEUR 196; previous year: KEUR 81), prepaid expenses relating to insurance contributions, rents and other prepayments (KEUR 159; previous year: KEUR 155) as well as claims for reimbursement from recharges to licensees (KEUR 55; previous year: KEUR 304). Moreover, prepaid expenses and other assets include a so-called day-one loss in connection with the issue of convertible notes in the reporting period that was capitalized as the difference between transaction price and fair value of the financial debt in accordance with IFRS 9.B5.1.2A b) and amounts to KEUR 327 as of the balance sheet date.

(5) Cash and cash equivalents

Cash and cash equivalents are comprised of the following:

	31 Dec. 2019 KEUR	31 Dec. 2018 KEUR
Current deposits	7,870	0
Bank balance and cash in hand	10,917	17,227
	18,787	17,227

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.

(6) Equity

As of 31 December 2019, the share capital amounts to EUR 64,265,586.00 (previous year: EUR 63,858,143.00); it is divided into 64,265,586 no-par value shares (previous year: 63,858,143 shares). The increase of the share capital in the total amount of EUR 407,443.00 results from the conversion of convertible notes issued in the reporting period. Registration in the Commercial Register took place after the balance sheet date on 27 February 2020.

The capital reserve amounts to EUR 139,421,819.80 as of 31 December 2019 (previous year: EUR 138,730,764.25) 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 22 May 2019, the Management Board was authorized to increase the share capital on or prior to 21 May 2024, with the consent of the Supervisory Board, on one or more occasions, by up to EUR 31,929,071.00 in total by issuing up to 31,929,071 new no-par value bearer shares in return for cash contributions or contributions in kind (Authorized Capital 2019). Furthermore, the Management Board was authorized to use up to EUR 6,385,814.00 of the Authorized Capital 2019 to issue new shares for cash by excluding pre-emptive rights. The still available Authorized Capital 2018 in the amount of EUR 27,960,023.00 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. Conditional Capital 2018 I in the amount of EUR 26,200,000.00 was revoked. Conditional Capital 2019 was utilized in an amount of EUR 407,443.00 by conversion of convertible notes issued under exclusion of pre-emptive rights in the reporting period and amounts to EUR 25,792,557.00 as of 31 December 2019. Conditional Capital 2019 can be used under exclusion of pre-emptive rights in an amount of EUR 5,978,371.00 as of 31 December 2019. Accordingly, Authorized Capital 2019 can be used under exclusion of pre-emptive rights in an amount of EUR 5,978,371.00 as of 31 December 2019 as well.

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, 205,250 stock options were issued to former Management Board members and current and former employees of the PAION Group as of 31 December 2019. To date, 479,142 stock options from the Stock Option Plan 2008 have been exercised. As of 31 December 2019, 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, 696,626 stock options were issued to current and former Management Board members and employees of the PAION Group as of 31 December 2019. No stock options have been exercised yet.

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 2019. 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, 610,772 stock options were issued to former and current Management Board members and employees of the PAION Group as of 31 December 2019. 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, 248,720 stock options were issued to employees of the PAION Group as of 31 December 2019. No stock options have been exercised yet.

The currency translation reserve amounts to KEUR -884 as of 31 December 2019 (previous year: KEUR -712). Of these, KEUR 6,301 concern cumulative exchange rate gains (as of 31 December 2018 cumulative exchange rate gains of KEUR 7,523) 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 2018 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 -866 concern cumulative exchange rate losses (as of 31 December 2018 cumulative exchange rate losses of KEUR -1,916) incurred on the loan from PAION AG to the British subsidiary PAION UK Ltd. As of 31 December 2019, the loan granted to PAION UK Ltd amounts to KEUR 23,142 (31 December 2018: KEUR 22,434).

(7) Provisions

Provisions developed as follows:

in KEUR	Premiums/ Management Bonuses	Other	Total
31 Dec. 2017	295	96	391
Utilization	252	0	252
Addition	497	0	497
Release	6	0	6
31 Dec. 2018	534	96	630
Utilization	533	0	533
Addition	173	0	173
Release	3	0	3
Exchange rate differences	2	1	3
31 Dec. 2019	173	97	270

(8) Trade payables

Trade payables amount to KEUR 4,843 as of 31 December 2019 (previous year: KEUR 2,218). 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.

(9) Other current liabilities

Other current liabilities comprise the following:

	31 Dec. 2019 KEUR	31 Dec. 2018 KEUR
Refund liability	250	250
Wage taxes	217	220
Holiday allowances	110	93
Supervisory Board remuneration	35	55
Others	20	36
	632	654

(10) 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 five years 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.

Until 2018, leases were either classified as operating leases or finance leases in line with IAS 17. Based on this categorization, there were no finance leases as of 31 December 2018 and no lease liabilities or corresponding right-of-use assets were recognized on the balance sheet. Since 1 January 2019, leases are accounted for initially recognizing a right-of-use asset and corresponding lease liability. For leases existing as of 1 January 2019 that were previously classified as operating leases, lease liabilities and corresponding right-of-use assets were recognized on the balance sheet as of 1 January 2019 in the amount of the present value of remaining lease payments of KEUR 108.

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. 2019 KEUR	31 Dec. 2018 KEUR
Right-of-use assets		
Land, land rights and buildings	42	0
Other plant, factory and office equipment	37	0
Total	79	0
Lease liabilities		
Short-term	26	0
Long-term	54	0
Total	80	0

The additions of right-of-use assets amounted to KEUR 24 in the reporting period.

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

	2019 KEUR	2018 KEUR
Depreciation of right-of-use assets		
Land, land rights and buildings	48	0
Other plant, factory and office equipment	7	0
Total	55	0
Interest expenses	3	0
Expenses for short-term leases according to IFRS 16.6	240	0

Total payments for leases amounted to KEUR 295 in fiscal year 2019. Future minimum lease payments from untermi-

short-term leases and leases of low value amount to KEUR 230 as of 31 December 2019.

(II) 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 is 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 are 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 is partially amortized by direct offset of these costs of raising capital from the capital reserve according to IAS 32.35.

Moreover, it is amortized as financial expenses based on the change of the time factor.

In the course of the issue of the convertible notes, transaction costs amounting to KEUR 278 were recognized in the income statement.

Until the balance sheet date, convertible notes with a nominal amount of KEUR 800 were converted into 407,443 PAION shares. As of 31 December 2019, both fair value and carrying amount of the financial debt amount to KEUR 4,354; the outstanding nominal amount is KEUR 4,200.

Consolidated statement of comprehensive income disclosures

(12) Revenues

Revenues in the reporting period amount to KEUR 8,000 and relate to the remimazolam license agreement with Cosmo Pharmaceuticals (Cosmo) in connection with the filing of the market approval dossier in the U.S. in the amount of KEUR 7,500 and to the remimazolam license agreement with R-Pharm in connection with the transfer of the Japanese filing dossier in the amount of KEUR 500. Revenues in the previous year mainly resulted from the remimazolam license agreements with Mundi-pharma, Hana Pharm and Yichang Humanwell.

Disaggregation of revenue

Revenues in the reporting period entirely result from consideration from remimazolam licensees for data and know-how transfers as well as the achievement of (development) milestones whose licenses each grant rights (e.g. for development and commercialization) in certain geographical regions. 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 7,500

Others/worldwide: KEUR 500

Contract balances and performance obligations

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

	01 Jan. 2019 KEUR	31 Dec. 2019 KEUR
Trade receivables	1,500	500
Refund liabilities	250	250

In the reporting period, no revenues were realized from (parts of) consideration recognized on the balance sheet as of 31 December 2018. Revenues amounting to KEUR 7,500 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 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 currently only product candidate remimazolam which has not been granted market approval yet until the balance sheet date, PAION does not generate sustainable revenues in the form of royalties yet. Before the potential (future) recognition of royalties upon commercialization of remimazolam, there are mostly upfront payments at the beginning of the contract regularly compensating an extensive data, technology, process and/or know-how transfer as the typically first performance obligation in the course of entering into license agreements. 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 repayment obligation in the amount of KEUR 1,500 from the license contract with Yichang Humanwell (also see the notes to contingent liabilities). In this context, there is also a potential refund liability in the amount of KEUR 250 which can be (potentially partially) set off against future 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 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 2019. Performance obligations existing as of 31 December 2019 entirely relate to variable consideration which is constrained according to IFRS 15.56 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 decrease of trade receivables. As of 31 December 2019, these result from the transfer of the Japanese filing dossier to licensee R-Pharm.

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 and royalties not being 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 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.

(13) Other income (expenses), net

Other income (expenses) in the fiscal year includes income from recharges to licensees in the amount of KEUR 503 (previous year: KEUR 417).

(14) Financial result

Financial income of KEUR 1 (previous year: KEUR 6) entirely results from interest income based on amortized costs for bank balances and current deposits as in the previous year.

Financial expenses of KEUR 123 (previous year: KEUR 0) relate to the amortization (change of the time factor) of a part of the day-one loss capitalized in the reporting period in the course of the issue of convertible bonds based on IFRS 9.B5.1.2A b) in an amount of KEUR 114, to negative interest on bank balances and current deposits in an amount of KEUR 6 and to the compounding of lease liabilities in an amount of KEUR 3.

(15) Income taxes / Deferred taxes

As of 31 December 2019, the tax losses carried forward by PAION Germany group (PAION AG and PAION Deutschland GmbH) amounted to about EUR 80 million (previous year: EUR 79 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 2019 (equivalent to EUR 130 million if translated at the exchange rate applicable on the reporting date). In the previous year, these amounted to GBP 111 million or EUR 124 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 founded in the reporting period amounts to less than EUR 1 million as of 31 December 2019. 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 211 million (previous year: EUR 202 million). No deferred tax assets were recognized regarding a partial amount of EUR 209 million (previous year: EUR 200 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% and will be reduced to 17% starting 1 April 2020. The corporate income tax in the Netherlands is 19% or 25% respectively for taxable earnings above KEUR 200 for calendar year 2019. Corporate income tax in the Netherlands will be 16.5% or 25% respectively in 2020 and 15% or 21.7% respectively 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 356 (previous year: KEUR 367) 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 2019, the resulting deferred tax assets would amount to EUR 26 million (previous year: EUR 26 million). Based on the income tax rate of 17% that will be applicable in Great Britain in the future, the losses carried forward in Great Britain as of 31 December 2019 would produce deferred tax assets in an amount of GBP 19 million (equivalent to EUR 22 million if translated at the rate applicable on the reporting date). In the previous year, these amounted to GBP 19 million or EUR 21 million, respectively. In the Netherlands, only immaterial deferred tax assets of less than KEUR 100 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 2019 of deferred tax assets in an amount of KEUR 254 (previous year: KEUR 240), of which Germany accounts for KEUR 5 (previous year: KEUR 0), Great Britain for KEUR 249 (previous year: KEUR 240) and the Netherlands for KEUR 0. The depicted differences in carrying amounts relate mainly to fixed assets and provisions. Total deferred tax assets would amount to EUR 48 million (previous year: EUR 47 million).

In the fiscal year, PAION Deutschland GmbH reported a (low) profit; 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. 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	2019	2018
Result for the period before taxes	-9,448	-12,449
Anticipated tax expense (+)/income (-)	-2,834	-3,735
Non-recognition of deferred taxes on tax losses	725	826
Difference between anticipated Group tax rate and actual local tax rates	664	1,413
Effects from currency translation	257	136
Expenses in connection with stock options	102	119
Non-deductible expenses	31	40
Effect of tax rate changes	7	0
Revaluation of tax losses due to tax rate changes	0	2,473
Correction of non-recognition of deferred taxes on temporary differences in prior years	0	112
Correction of non-recognition of deferred taxes on tax losses in prior years	0	-112
Adjustment non-recognition of deferred taxes on tax losses due to tax rate changes	0	-2,473
Cost in connection with capital increases	-2	-52
Non-recognition of deferred taxes on temporary differences	-5	139
Tax losses used	-78	-315
Effects from tax credits	-1,300	-1,082
Other	1	1
Actual tax expense (+) / income (-)	-2,432	-2,510

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.

(I6) 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:

	2019	2018
Shares outstanding as of 1 January	63,858,143	61,120,046
Weighted average number of shares issued	60,609	1,392,329
Weighted average number of ordinary shares	63,918,752	62,512,375

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

	2019	2018
Net result for the year (in EUR)	-7,015,815.07	-9,939,410.76
Weighted average number of ordinary shares for basic earnings per share	63,918,752	62,512,375
Weighted average number of ordinary shares for diluted earnings per share	64,035,132	62,754,424
Earnings per share (in EUR):		
Basic	-0.11	-0.16
Diluted	-0.11	-0.16

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 result per share. Under consideration of the current result of the PAION group, potential new ordinary shares do therefore not induce a dilutive effect.

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 (10) 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. Details of the individual plans can be found in the following table:

	Stock Option Plan 2008 Approved 5 May 2008	Stock Option Plan 2010 Approved 19 May 2010
Underlying Capital	Conditional Capital 2008 I	Conditional Capital 2010 I
Term of the options	10 years	10 years
Vesting period	2–4 years	2 years
Waiting period	2–4 years	4 years
Number of outstanding options for which the waiting period has expired as of 31 December 2019	205,250	696,626
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 1.84 to EUR 2.69	EUR 2.01
Weighted average exercise price *	EUR 1.89	EUR 2.01
Exercise hurdle as of 31 Dec. 2019 *	EUR 2.75 to EUR 4.01	EUR 2.60
Weighted average remaining term as of 31 Dec. 2019	0.4 years	4.1 years
Further grants possible? (as of 31 Dec. 2019)	No	No
Number of totally granted options until 31 Dec. 2019	817,550	720,000
Number of outstanding options as of 31 Dec. 2019 **	205,250	696,626
granted to employees	91,000	392,876
granted to Management Board members	114,250	303,750
Number of totally lapsed options as of 31 Dec. 2019	133,158	23,374
thereof lapsed in the reporting period	0	0
Number of totally exercised options until 31 Dec. 2019	479,142	0
thereof exercised in the reporting period	0	0
Personnel expenses in the reporting period	EUR 0	EUR 0
Fair value per option at the time of the grant ***	EUR 0.57 to EUR 2.48	EUR 1.67
Elements of calculation		
Valuation model	Black/Scholes	Black/Scholes
Risk-free rate	2.5% to 4.47%	0.7%
Volatility	83.31% to 88.44%	73.75%
Staff turnover ****	0% to 5% per year	10% per year
<p>*) in relation to outstanding options as of 31 Dec. 2019 **) in relation to employee/Management Board member status at the time of the grant ***) in relation to totally granted options ****) turnover last used for update of the quantity structure conducted until the end of the respective vesting period</p>		

Stock Option Plan 2014
Approved 21 May 2014

Stock Option Plan 2016
Approved 25 May 2016

Stock Option Plan 2018
Approved 25 May 2018

Conditional Capital 2014	Conditional Capital 2016	Conditional Capital 2018 II
10 years	10 years	10 years
2-4 years	2-4 years	2-4 years
4 years	4 years	4 years
257,385	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	Cumulative stock price increase of 5% per year since grant in relation to exercise price
EUR 1.99 to EUR 2.60	EUR 2.25 to EUR 2.60	EUR 2.31
EUR 2.21	EUR 2.34	EUR 2.31
EUR 2.34 to EUR 2.96	EUR 2.42 to EUR 2.85	EUR 2.33
6.0 years	8.2 years	9.8 years
No	Yes	Yes
740,000	706,500	248,720
530,010	610,772	248,720
231,697	395,438	248,720
298,313	215,334	0
209,990	95,728	0
3,875	90,413	0
0	0	0
0	0	0
KEUR 40	KEUR 276	KEUR 19
EUR 1.02 to EUR 1.39	EUR 1.02 to EUR 1.70	EUR 0.79
Black/Scholes	Black/Scholes	Black/Scholes
-0.26% to 0.08%	-0.25% to -0.14%	-0.44%
72.34% to 83.76%	67.62% to 81.61%	56.15%
9% per year	9% per year	9% per year

Other financial obligations/Contingent liabilities

PAION has rented office space and leased parts of its factory and office equipment.

Since 1 January 2019, PAION capitalizes right-of-use assets for these leases (except for short-term leases and leases of low value) (see note (10) under the consolidated balance sheet disclosures).

The minimum future rental and lease payments arising from these contracts were as follows in the previous year:

	31 Dec. 2018 KEUR
Due within one year	283
Due after more than one year	64
Total	347

Rental and lease expenses amounted to KEUR 295 in fiscal year 2018.

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 5.1 million. The underlying contracts have variable notice periods of several months at the maximum. If contracts were terminated, the depicted financial obligations would decrease.

PAION has an obligation to pay Mr. Greg Papaz, former CEO of the former subsidiary PAION, Inc., 0.5% of income from milestone payments from Cosmo.

PAION is obliged to pay the Chinese licensee Yichang Humanwell an amount of EUR 1.5 million if a competing remimazolam product is commercialized by a competitor within a certain timeframe. Moreover, KEUR 250 from the milestone payment received in 2018 in connection with the filing of the market approval dossier in China have been recognized as a refund liability and would become repayable in above-mentioned case

but would be set off against future royalties. Potential future milestone payments would be halved. Also, future royalties would be reduced in the above-mentioned case. A competitor of Yichang Humanwell, Hengrui Medicine, received market approval for a competing remimazolam product in China end of 2019. PAION is cooperating with Yichang Humanwell to prevent commercialization of this product.

Headcount and personnel expenses

In fiscal year 2019, PAION had an average of 44 employees (previous year: 39 employees). Of these 44 employees, 35 worked in development and nine in administration and sales. PAION UK Group had an average headcount of ten employees. As of 31 December 2019, the headcount was 45 (31 December 2018: 40).

The following personnel expenses were incurred in fiscal years 2019 and 2018:

	2019 KEUR	2018 KEUR
Wages and salaries	4,772	4,598
Social security contributions	602	482
Total	5,374	5,080

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 335 (previous year: KEUR 400). The figures also include contributions to the German and British social insurance schemes in an amount of KEUR 536 (previous year: KEUR 448) and expenses for defined contribution plans in the amount of 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 clinical development, the production development and to a minor extent preclinical development of remimazolam. Moreover, PAION is working on building up a supply chain and conducting pre-commercial activities for remimazolam. Since these activities are not yet generating any revenues from the sale of launched products, losses are still scheduled. PAION aims at bringing remimazolam through the clinical development and regulatory approval phases either itself or through partners 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 potentially 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 or receive technology access and further milestone payments from cooperation partners will depend to a large extent on the positive clinical development progress and the regulatory process, mainly in the U.S., as well as the success of the licensee Cosmo in regard to a potential market approval and subsequent commercialization of remimazolam. 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, financial debt 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 1,050 in fiscal year 2019 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 1,121 compared to the change in the currency component actually recognized in equity in 2019. 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 1,121 compared to the change in the currency component actually recognized in equity in 2019.

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 3 in fiscal year 2019.

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 2019 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. 2019	31 Dec. 2018	31 Dec. 2019	31 Dec. 2018	
Financial assets:					
Cash and cash equivalents	(1)	18,787	17,227	18,787	17,227
Trade receivables	(1)	500	1,500	500	1,500
Other assets	(1)	101	369	101	369
Financial liabilities:					
Trade payables	(1)	4,843	2,218	4,843	2,218
Financial debt	(2)	4,354	0	4,354	0
Provisions	(1)	270	630	270	630
Lease liabilities		80	0	80	0
Other liabilities	(1)	415	434	415	434

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, provisions, trade payables 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 2019, 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 (since 16 October 2019)
Other supervisory board memberships or similar positions:
 - Herantis Pharma plc, Espoo/Finland, Member of the Board of Directors
- Abdelghani Omari, CFO
- Dr. Jürgen Beck, CDO
- Dr. Wolfgang Söhngen, CEO, Chairman (Chairman until 15 October 2019, Member of the Management Board until 22 November 2019)

Management Board remuneration totalled KEUR 956 in fiscal year 2019. As of 31 December 2019, a total of 391,000 stock options (fair value at time of granting: EUR 491,925) had been issued to active Management Board members as of 31 December 2019. 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 and PAION Holdings UK Ltd and its subsidiaries. Dr. Jürgen Beck and Mr. Abdelghani Omari are also Managing Directors of the subsidiary PAION Netherlands B.V., which was founded in the reporting period. All Management Board members work full-time for the company and its subsidiaries.

As of 31 December 2019, Dr. Jürgen Beck owned 0.02% (10,000 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
Other supervisory board memberships or similar positions:
 - Dr. Loges + Co. GmbH, Winsen (Luhe)/Germany, Chairman of the Board

- 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
Other supervisory board memberships or similar positions:
 - Gerresheimer AG, Dusseldorf/Germany, Member of the Supervisory Board
 - Almirall S.A., Barcelona/Spain, Member of the Board of Directors
 - Triton Beteiligungsberatung GmbH, Frankfurt/Germany, Member of the Triton Industry Board
 - Kerry Group plc, Tralee/Ireland, Non-executive director
 - Humedics GmbH, Berlin/Germany, Chairman of the Board (until 15 November 2019)
 - Julius Clinical Research BV, Zeist/The Netherlands, Member of the Supervisory Board
- John Dawson (until 22 May 2019), Fetcham/England, Chairman of the Audit Committee; CEO of Oxford BioMedica plc, Oxford/England
- Dr. Dr. Irina Antonijevic, Boston, MA/U.S., Chairman of the Research and Development Committee; Senior Vice President Development at Triplet Therapeutics, Inc., Cambridge, MA/U.S.
Other supervisory board memberships or similar positions:
 - 4SC AG, Planegg-Martinsried (Munich)/Germany, Member of the Supervisory Board
- Dr. Hans Christoph Tanner, Zurich/Switzerland, Chairman of the Audit Committee, Head of Transactions of Cosmo Pharmaceuticals N.V., Amsterdam/The Netherlands, Chief Financial Officer & Head of Investor Relations of Cassiopea SpA, Milan/Italy
Other supervisory board memberships or similar positions:
 - Cosmo Pharmaceuticals N.V., Amsterdam/The Netherlands, Member of the Board of Directors
 - DKSH Holding AG, Zurich/Switzerland, Member of the Board of Directors and Chairman of the Audit Committee
 - CureVac AG, Tübingen/Germany, Member of the Supervisory Board and Chairman of the Audit Committee

- Joimax GmbH, Karlsruhe/Germany, Member of the Advisory Board
 - Qvanteq AG, Zurich/Switzerland, Member of the Board of Directors
 - Wyss Zurich (ETH Zürich), Zurich/Switzerland, Member of the Evaluation Board
- Dr. Markus Leyck Dieken (since 22 May 2019), 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 162 in fiscal year 2019. For more information on Supervisory Board remuneration, please see the disclosures in the remuneration report of the group management report.

As of 31 December 2019, none of the members of the Supervisory Board owned shares in PAION AG.

Financial statements auditor

The Annual General Meeting on 22 May 2019 appointed Ernst & Young GmbH Wirtschaftsprüfungsgesellschaft, Cologne office, Germany, as auditor of the annual and consolidated financial statements for fiscal year 2019. The auditor has received or will invoice the following fees for services rendered to PAION AG and its subsidiaries in fiscal year 2019:

	2019 KEUR	2018 KEUR
Audits of financial statements	96	96
	96	96

The fees for audits of financial statements include remuneration for reviewing the interim financial statements in the amount of KEUR 11 (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 2019, the Supervisory Board and the Management Board issued the declaration of compliance with the Corporate Governance Code pursuant to Section 161 AktG. The company complies with all recommendations set forth in the version of the German Corporate Governance Code dated 7 February 2017 applicable at the time. This declaration of compliance 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 08 January 2020, PAION and licensee Hana Pharm extended the existing remimazolam license agreement for South Korea to include six additional countries in Southeast Asia.


On 23 January 2020, licensee Mundipharma received market approval for remimazolam in general anesthesia in Japan.


On 12 March 2020, licensee Cosmo announced the postponement of the target date for completion of the review (PDUFA date) of the NDA for remimazolam by the FDA by up to three months from 05 April 2020 to 05 July 2020.

There were no further significant events in the period between the reporting date, 31 December 2019, and the preparation of this report.

Aachen, Germany, 25 March 2020

PAION AG


Dr. James Phillips


Abdelghani Omari

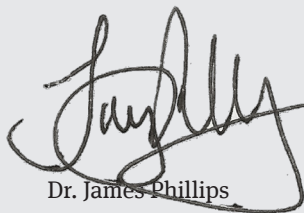

Dr. Jürgen Beck

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)

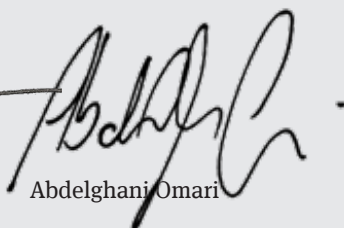
“To the best of our knowledge, and in accordance with the applicable reporting principles, the consolidated financial statements give a true and fair view of the assets, liabilities, financial position and profit or loss of the group, and the group management report includes a fair review of the development 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, 25 March 2020

PAION AG



Dr. James Phillips



Abdelghani Omari



Dr. Jürgen Beck

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 2019, 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 2019 to 31 December 2019, 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 2019 to 31 December 2019. 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 the 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 2019 and of its financial performance for the fiscal year from 1 January 2019 to 31 December 2019, 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 the 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 2019 to 31 December 2019. 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

Due to the ongoing development activities performed by PAION UK Ltd. pertaining to remimazolam, 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 2019 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 2019 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 the section Accounting policies, paragraph: Income taxes/deferred taxes and the section Consolidated balance sheet disclosures, (4) Prepaid expenses and other assets in the notes to the Company's consolidated financial statements.

2. Recognition and measurement of the convertible bond issued in the fiscal year

2.1 Reasons why the matter was determined to be a key audit matter

With effect from 30 August 2019, PAION AG entered into an agreement with the US institutional investor Yorkville Advisors, to issue convertible debt of up to EUR 15.0 million in up to three

tranches. The first tranche had been issued as of 12 September 2019 with a nominal amount of EUR 5.0 million. The convertible bond is recognised at fair value in accordance with IAS 32. In light of the complexity and use of judgement involved, the recognition and measurement of the convertible bond was a key audit matter.

2.2 Auditor's response

As part of our audit procedures, we examined the process established by the Company for recognising and measuring the convertible bond. We also examined the adequacy of the controls implemented in the process for identifying relevant risks of material misstatement. We engaged specialists to verify, based on IAS 32, that both the equity and debt components had been correctly identified. We examined the converted portion of the convertible bond by comparing the shares with the confirmations received from Yorkville. We also verified the respective conversion price by checking the average prices of the PAION share on which the calculation was based. In addition, we checked the clerical accuracy of the measurement and disclosure of the components as of the reporting date.

Our procedures did not lead to any reservations relating to the recognition and measurement of the convertible bond.

2.3 Reference to related disclosures

With regard to the accounting bases applied for the convertible bond as well as other disclosures, refer to the section Accounting policies, paragraph: Financial Debt and the section Consolidated balance sheet disclosures, (11) Financial Debt in the Company's notes to the 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 the 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

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

We were elected as group auditor by the Annual General Meeting on 22 May 2019. We were engaged by the Supervisory Board on 22 May 2019. 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, 25 March 2020

Ernst & Young GmbH
Wirtschaftsprüfungsgesellschaft

Zwirner
Wirtschaftsprüfer
[German Public Auditor]

Conrad
Wirtschaftsprüfer
[German Public Auditor]

PAION AG

Martinstrasse 10-12

52062 Aachen Germany

Phone +49 241 4453-0

Fax +49 241 4453-100

info@paion.com www.paion.com

PAION AG, Aachen

Financial Statements

as of 31 December 2019

Management Report

for Fiscal Year 2019

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Management report for fiscal year 2019

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 developing and aiming to commercialize innovative drugs to be used in out-patient and 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, while the Group companies provide each other with development-related services. The activities of the PAION Group (hereinafter also referred to as PAION) are mainly determined by the development operations of the subsidiaries, particularly PAION UK Ltd, which are presented below.

PAION's portfolio exclusively comprises the drug candidate remimazolam. In January 2020, the first marketing approval was granted in Japan (after the balance sheet date).

For remimazolam, PAION has licensees in the U.S., China, South Korea, Southeast Asia, Canada, Russia/CIS, Turkey, the MENA region and Japan. For the use of remimazolam for procedural sedation, clinical development is completed; market approval dossiers have been filed in the U.S., EU and China. For the indication general anesthesia, remimazolam is in the final stage of clinical development and has already been completed for Japan and South Korea; market approval dossiers have been filed in both markets. The different indications for application of remimazolam will be described in detail in the following chapters.

Fiscal year 2019 was marked by the continuation of the development of remimazolam, regulatory as well as supply chain and pre-commercial activities, in particular the conduct of a Phase III study in general anesthesia in the EU and preparations and support for the market approval dossiers in the U.S., the EU and Japan.

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 subsequent commercialization of remimazolam. The progress of these activities is being documented and discussed continuously. PAION has already signed several regional license agreements. 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 is driven mainly by the research and development activities 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

German economy has continued its growth in the previous years also in 2019. Driver in particular was consumption. Private consumption increased by 1.6%, state expenditure on consumption increased by 2.6% compared to the prior year. With an increase of the gross domestic product (GDP) of 0.6% (2018: 1.5%), growth has lost momentum the second year in a row however.¹

A decrease in economic growth has also manifested in the Euro area: The GDP in the Euro zone only increased by 1.2% in 2019 after 1.9% growth in 2018. A further slowdown to 0.9% is expected for 2020. While in 2018, an increase in growth of the U.S. economy to 2.9% mainly borne by the U.S. tax reform had a soothing impact on the decrease of the world GDP, this trend did not

¹ Federal Statistical Office: Volkswirtschaftliche Gesamtrechnungen 2019: Wichtige Zusammenhänge im Überblick; 26 February 2020.

continue in 2019. U.S. GDP only increased by 2.3% in 2019 and a further slowdown to 1.7% is expected in 2020.² In terms of the world GDP, growth slowed down from 3.6% in 2018 to 2.9% in 2019. However, an increase of 3.3% is expected for 2020. While for the developed countries overall, a slightly lower growth of 1.6% in 2020 compared to 1.7% in 2019 is expected, the expected increase is mainly driven by stronger growth in the developing and emerging countries.³

There is major uncertainty in regard to international trade restrictions and tariffs, particularly with regard to the relations between the U.S. and China as well as in terms of economic relations between the EU and the United Kingdom after the transition period following the Brexit. Moreover, the short- and mid-term outlook is tarnished by geopolitical tensions.⁴ In addition, the Organisation for Economic Co-operation and Development (OECD) cautions against the impact of the Coronavirus spreading worldwide since the beginning of 2020 on the world economy and only expects a growth of 2.4% for the world GDP in 2020 under these conditions.⁵

On the stock markets however, an acceleration of stock price growth could be observed: The DAX registered an increase of 25.5% in 2019 in comparison to the prior year's end closing value; the EUROSTOXX 50 also closed 2019 with a considerable plus of 24.8% as compared to the previous year. The Dow Jones strongly increased, too, and closed 2019 with a plus of 22.3% in comparison to the prior year's end closing value.

b. Development of the pharmaceutical and biotechnology industry

The pharmaceutical and biotechnology industry continues 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 (gene) therapies which in turn are faced by increasingly lower income particularly due to higher competition, patent expiry of formerly high-selling products and price pressure from governmental regulation.⁶ Average development costs of a new drug increased by approx. 82% from 2010 to 2018 on average for big pharma companies while peak sales potential approximately halved.⁷

The consolidation pressure resulting from these trends has significantly materialized in the worldwide transaction volume in the pharmaceutical industry in 2019 that reached a new all-time high with USD 357 billion.⁸

The financing environment for the pharmaceutical and biotechnology industry was also good in 2019 but lagged behind the record year 2018. In 2019, USD 7.6 billion were raised through IPOs compared to USD 8.3 billion in 2018. However, the volume in 2019 was still approx.

² Commerzbank Research: Economic and Market Monitor – Chart Book February 2020.

³ International Monetary Fund: World Economic Outlook Update, January 2020.

⁴ International Monetary Fund: World Economic Outlook Update, January 2020.

⁵ OECD Interim Economic Assessment: Coronavirus: The world economy at risk, 02 March 2020.

⁶ 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.

⁷ Deloitte Centre for Health Solutions: Unlocking R&D productivity: Measuring the return from pharmaceutical innovation 2018, 2018.

⁸ Ernst & Young: 2020 EY M&A Firepower report: How will deals done now deliver what the health ecosystem needs next?, 2019.

20% above the previous all-time high from 2014.⁹ With EUR 858 million of funds raised in total in 2019, German biotech companies also did not reach the all-time high of financing volume of EUR 1.3 billion from 2018, but the sum was still about 27% above the figure from 2017.¹⁰ The positive climate in the industry is also reflected in the valuation of pharma companies: The DAXsubsector Biotechnology Index increased by 29.7% in 2019 in comparison to the prior year's end closing value; the NASDAQ Biotechnology Index closed the year 2019 with a plus of 24.4%.

The significant competitive drivers in the pharmaceutical and biotechnology industry are likely to also persist in 2020 and to maintain consolidation pressure. In addition to intensifying competition and continuously increasing challenges for the industry, mainly in regard to digitalization, individualization of therapies and regulatory requirements, companies with a clear therapeutic focus are often more successful than their less focused competitors.¹¹ Under consideration of the availability of significant amounts of funds, an increasing concentration on therapeutic focus, a recently increased market volatility and a lower valuation of many small- and mid-sized biotech companies as compared to the 12-month average¹² as well as the central banks' continuing (and increasing) loose monetary policy, a high acquisition and transaction volume worldwide can be expected in the pharmaceutical industry also in 2020. However, it remains to be seen to what extent particularly the development of international trade restrictions and protective tendencies, political uncertainty mainly in the important U.S. market¹³ and last but not least the impact of the spread of the Coronavirus on the world economy have a damping effect on acquisition and transaction volumes.

2. Presentation of the course of business and development activities

The development portfolio of PAION Group essentially comprises remimazolam with its three indications procedural sedation, general anesthesia and ICU sedation.

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. In clinical studies, remimazolam demonstrated efficacy and safety in around 2,500 volunteers and

⁹ Morrison, C. (2019): Boom: 2018's biotech IPOs, in: Nature Reviews Drug Discovery, Vol. 18, January 2019; Morrison, C. (2020): 2019 biotech IPOs: party on, in: Nature Reviews Drug Discovery, Vol. 19, January 2020.

¹⁰ BIO Deutschland: Biotech-Branche: erneut gute Finanzierungszahlen; press release from 13 January 2020.

¹¹ 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.

¹² Ernst & Young: 2020 EY M&A Firepower report: How will deals done now deliver what the health ecosystem needs next?, 2019.

¹³ PwC Health Research Institute: Top health industry issues of 2020: Will digital start to show an ROI?, 2019; Evaluate: Vantage 2020 Preview, 2019.

patients. Data so far indicate that remimazolam has a rapid onset and offset of action combined with a favorable cardio-respiratory safety profile.

In Japan, licensee Mundipharma received market approval in general anesthesia in January 2020. In the U.S., licensee Cosmo Pharmaceuticals (Cosmo) submitted a New Drug Application (NDA) for procedural sedation in April 2019 for which the U.S. Food and Drug Administration (FDA) set 05 July 2020 (previously 05 April 2020) as target date for completion of the review under the Prescription Drug User Fee Act (PDUFA date) after announcement of an extension of the review period of up to three months for the evaluation of additional data. In China, licensee Yichang Humanwell filed for market approval in procedural sedation in November 2018. In South Korea, licensee Hana Pharm filed for market approval in general anesthesia in December 2019. In Europe, PAION submitted a Marketing Authorization Application (MAA) to the European Medicines Agency (EMA) in procedural sedation in November 2019 and a Phase III trial in general anesthesia is ongoing.

In addition to procedural sedation and general anesthesia, based on positive Phase II study results, ICU sedation is another possible indication.

Remimazolam is partnered in the U.S. (Cosmo Pharmaceuticals, sublicensed to Acacia Pharma), Japan (Mundipharma), China (Yichang Humanwell), Canada (Pharmascience), Russia/CIS, Turkey and the MENA region (R-Pharm) as well as South Korea and Southeast Asia (Hana Pharm). For all other markets including parts of the EU, remimazolam is available for licensing.

Procedural Sedation Market

Based on external sources (Symphony Health Solutions, Centers for Disease Control and Prevention) and own projections, PAION estimates that more than 40 million procedures using procedural sedation are currently taking place in the U.S. per year, predominantly outside the hospital setting.

The growth of the procedural sedation market in the U.S. has been driven for many years by the increase in medical interventions requiring procedural sedation, such as colonoscopies, as well as an increase in general demand for preventive screenings. According to iData Research, which examines historical trends and creates procedure forecasts in the U.S. drawing from an extensive collection of national- and state-level procedure databases, 26.7 million colonoscopy and endoscopy claims were reported in the U.S. in 2015. PAION estimates that 75% of the colonoscopies and endoscopies are conducted in an out-patient setting.

Regular colonoscopy screening for people aged 50 or older is recommended and covered by all major health insurance plans, including those under the Centers for Medicare and Medicaid Services (“CMS”), a U.S. federal agency that administers Medicare (the national social insurance program), since effective prevention is considered to reduce the likelihood of incidence of illnesses such as cancer, thereby reducing the suffering of patients and related financial burden to be borne by the payors. Statistics show that the rate at which people are diagnosed with colon cancer in the U.S. has dropped by approximately 30% in the recent years for those aged 50 years and older, partly due to more people getting recommended screening tests. Colorectal cancer is the third most diagnosed cancer and the third leading cause of cancer death in the U.S. Despite the decrease of

colorectal cancer death rates as a result of early screening and detection, it was reported in 2010 that only 59% of people aged 50 or older, for whom screening is recommended, reported having received colorectal cancer testing consistent with current guidelines. The market for endoscopies in gastroenterology represents the most important market segment for remimazolam in procedural sedation with approximately 20 million procedures per year in the U.S.

Currently, the most widely used products in procedural sedation are propofol and midazolam – both generic. PAION estimates that these two drugs each have a market share of approximately 50% in terms of volume of procedures performed in the out-patient market for colonoscopies in the U.S. The propofol label mandates the presence of an anesthesia professional throughout the procedure due to propofol's potential for respiratory- and cardio-depressive effects, which results in additional costs and higher risks, since there is no reversal agent available for propofol in order to be able to quickly stop sedation if required. For midazolam, these side effects are less pronounced and have a different relevance, since an undesirably deep sedation can be reversed with flumazenil. Midazolam has a slower onset and a longer duration of action which can impact patient throughput and overall efficiency.

In the U.S. increased enrollment and screenings are expected to result in a performance-based payment system that will seek to better align payments with high quality of care measures. This would imply that cost-efficient medicines with clinical value will be used more extensively and that continued premium prices will be paid for innovative medicines with strong clinical profile. Thus, PAION believes that concerns related to the overall cost of procedures, driven by the need for the presence of anesthesia professionals during procedures using agents such as propofol, will impact the choice of drug products for procedural sedation. Costs related to anesthesia services in gastrointestinal endoscopy procedures alone were estimated at USD 1.3 billion in 2009.¹⁴ Accordingly, PAION expects reimbursement regimes under national and commercial healthcare systems, such as Medicare, which differentiate the amounts reimbursed to physicians and/or patients depending on whether an anesthesia professional's service is used, may also positively impact the demand for products that do not require monitoring by an anesthesia professional.

PAION expects that remimazolam, subject to FDA approval with a safety labeling comparable to that of midazolam, would be able to offer a competitive alternative to midazolam. This is based on its enhanced efficiency profile compared to midazolam.

PAION submitted an MAA for procedural sedation to the EMA in November 2019 after it had been discussed in the course of a pre-submission meeting with the EMA held in February 2019 that the existing data package from the U.S. Phase III clinical development program will be sufficient for submitting an MAA in procedural sedation. An essential task to be completed prior to the MAA submission was EMA approval of the Pediatric Investigation Plan (PIP), which was granted in November 2019.

¹⁴ Liu, H. et al. (2012): Utilization of Anesthesia Services During Outpatient Endoscopies and Colonoscopies and Associated Spending in 2003-2009, *The Journal of the American Medical Association*, 2012 307(11):1178-1184; Al-Awabdy, B. and Wilcox, C.M. (2013): Use of anesthesia on the rise in gastrointestinal endoscopy, *World Journal of Gastrointestinal Endoscopy*, January 2013 5(1): 1-5.

In the EU, based on its own projections for procedural sedation, PAION currently estimates an annual peak sales potential of approx. EUR 50 million to approx. EUR 75 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. This entails a high potential for synergies with the planned commercialization of remimazolam for use in general anesthesia.

General Anesthesia Market

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. 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 the EU, the current standard-of-care drugs for general anesthesia are propofol (especially for induction) and narcotic gases; mostly used in conjunction with intravenous opioids.

Patient demographics in the EU will presumably continue to evolve driven by the aging population. PAION anticipates an increasing number and complexity of medical interventions requiring induction and maintenance of anesthesia in the EU in the future also driven by an ongoing aging of the population. 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 the EU 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. PAION also expects similar developments for the U.S. and other important international markets, subject to further market research. In the EU, based on its own projections, PAION currently estimates an annual peak sales potential of approx. EUR 150 million to approx. EUR 200 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.¹⁵ 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 the number of total adult beds in various countries in the EU, PAION estimates that there are approximately 14 million ICU patient days requiring ICU sedation in the U.S. and EU combined per year. PAION expects this number to increase in the years to come, driven by demand from the aging population in both regions. 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.

PAION is currently evaluating the risk-benefit ratio of developing remimazolam for ICU sedation.

¹⁵ 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.

Clinical Development

Overview of the studies conducted with remimazolam to date	
Phase II and III studies	Phase I studies
Procedural Sedation (U.S.) - completed	
Phase IIa Single bolus in upper GI endoscopy (100)	Phase I Single bolus in healthy volunteers (81)
Phase IIb Multiple bolus in colonoscopy (161)	Phase Ib Multiple bolus in volunteers undergoing colonoscopy (51)
Phase III in colonoscopy (461)	Phase I Renal Impairment (22)
Phase III ASA III/IV in colonoscopy (79)	Phase I Thorough QT (54)
Phase III in bronchoscopy (446)	Phase I Abuse Liability
	• Intravenous administration (40)
	• Oral bioavailability (14)
	• Oral administration with alcohol (20)
	• Intranasal administration (12)
General Anesthesia (Japan) - completed	
Phase II Induction and maintenance of anesthesia in general surgery (85)	Phase I Bolus in healthy volunteers (42)
Phase II/III Induction and maintenance of anesthesia in general surgery (375)	Phase Ib Infusion in healthy volunteers (10)
Phase III in ASA III or higher surgical patients (62)	Phase I Hepatic impairment (U.S.) (20)
General Anesthesia (EU)	
Phase II in cardiac surgery patients (90)	Phase I PK/PD modeling study (EEG) in healthy volunteers (20)
Phase III in cardiac surgery patients (23)*	
Phase III in general surgery (approx. 500)**	
ICU Sedation (Japan)	
Phase II in ICU patients (49)*	
Studies in other territories	
Phase III in general anesthesia - Russia (150)	Phase I single ascending dose in China (62)
Phase III in general anesthesia - South Korea (198)	Phase I continuous infusion in China (12)
Phase II in procedural sedation - China (150)	
Phase III in procedural sedation - China (480)	
Phase IIa dose finding study - China (24)	

Patient/volunteer numbers in brackets

*) Discontinued studies, no safety concerns

***) Ongoing study

Procedural sedation (U.S. + China)

With a total of eight Phase I, two Phase II and three Phase III trials, PAION deems the clinical development program for remimazolam in procedural sedation in the U.S. completed. In China, one Phase II and one Phase III trial have also been successfully conducted.

The first in-human trial explored a broad range of doses from no effect to loss of consciousness (not wanted for procedural sedation but indicative for induction of general anesthesia). Based on this trial, the next set of trials covered a colonoscopy study in healthy volunteers and a Phase IIa study in upper GI endoscopy. These studies confirmed the need for an approximately 50% dose reduction in combination with opioids (colonoscopy) and were the basis for the Phase IIb study in colonoscopy patients. In this study, a fixed dose regime consisting of starting dose and top-ups was tested with the lowest of the starting doses which was selected for use in the Phase III program.

The first U.S. Phase III study 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 study had an open-label midazolam arm.

The primary outcome measure was a composite endpoint defined as: no need for rescue medication, completion of the procedure and no more than 5 doses within any 15-minute window. The primary endpoint was reached in 91.3% of the patients in the remimazolam arm and 1.7% in the placebo (including midazolam rescue) arm.

Important secondary endpoints in the remimazolam arm showed a median time from start of medication to start of procedure of 4.0 minutes (placebo 19.5 minutes) and a mean time from end of procedure to return to full alertness of 7.2 minutes (placebo 21.3 minutes). Additionally, time from last dose to “back to normal” as reported by patients on remimazolam was 331 minutes (placebo 572 minutes).

There were no treatment-emergent serious adverse events in the trial. Hypotension was 44.3% with remimazolam and 47.5% with placebo and accounted for most of the adverse events in all study arms. Hypoxia occurred in 1.0% of patients given remimazolam, 3.4% in the placebo arm.

On the Hopkins Verbal Learning Test administered five minutes after reaching the fully alert status, the total raw score, delayed recall, memory retention, and recognition discrimination scores were all better with remimazolam compared to placebo.

Patient satisfaction was similar in all arms of the study.

The open-label midazolam patients showed a median time from start of medication to start of procedure of 19.0 minutes and a mean time from end of procedure to return to full alertness of 15.7 minutes. Midazolam patients took 553 minutes to be back to normal.

In addition to the above study, the U.S. Phase III program includes a second confirmatory, prospective, double-blind, randomized, placebo-controlled multi-center trial with an open-label midazolam arm in 446 patients undergoing bronchoscopies.

The study was successfully completed in 2017, and the primary efficacy endpoint was achieved. The Phase III trial enrolled 446 patients at 15 U.S. sites and was designed to evaluate the

efficacy and safety of remimazolam compared to placebo (with midazolam rescue medication) in procedural sedation in patients undergoing bronchoscopy.

The primary outcome measure was a composite endpoint defined as: no need for rescue medication, completion of the procedure and no more than 5 doses within any 15-minute window for remimazolam/placebo and no more than 3 doses within any 12-minute window for midazolam. The primary endpoint was reached in 82.5% of the patients treated in the remimazolam arm and 3.4% in the placebo arm (p-value of <0.0001). Important secondary endpoints included median time from start of medication to start of procedure (5.0 minutes in the remimazolam arm versus 17.0 minutes for placebo) and median time from end of procedure to return to full alertness (remimazolam 6.0 minutes versus placebo 14.0 minutes). Additionally, the patients' subjective impression of time from last dose to "back to normal" was a median of 404 minutes for remimazolam versus 935 minutes for placebo.

In the open-label midazolam arm, procedural success was achieved in 34.8% of patients. Midazolam patients showed a median time from start of medication to start of procedure of 16.0 minutes and a median time from end of procedure to return to full alertness of 12.0 minutes. Additionally, time from last dose to "back to normal" as reported by patients on midazolam was a median of 479 minutes.

As part of the U.S. development program, also a safety study 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 efficacy and safety of remimazolam compared to placebo (with midazolam 'rescue' sedation) in patients undergoing proceduralist-supervised sedation for colonoscopy. This study also included an open-label arm in which midazolam was dosed according to U.S. label. The trial confirmed remimazolam's safety profile and tolerability shown in all previous studies in a more vulnerable patient population. Overall, remimazolam demonstrated good respiratory and cardiovascular stability as compared to placebo with midazolam rescue. No adverse events of concern were observed in either group. In addition, the efficacy and efficiency improvements were comparable to the two positive pivotal U.S. Phase III trials in colonoscopy and bronchoscopy patients. Success of the procedure (including no requirement for rescue medication and the application of not more than five doses in any 15-minute interval) was achieved in 84.4% of patients in the remimazolam arm and 0% in the placebo arm. Other relevant endpoints showed a median time from start of medication to start of procedure of 5.0 minutes for remimazolam (placebo: 18.5 minutes) and a median time from end of procedure to return to full alertness of 3.0 minutes (placebo: 5.0 minutes). By comparison, procedural success was achieved in 12.9% of the midazolam patients. Midazolam patients showed a median time from start of medication to start of procedure of 19.0 minutes and a median time from end of procedure to return to full alertness of 7.0 minutes.

Summary of headline data of the three Phase III studies:

	Remimazolam	Placebo	Midazolam (Open Label)*
Primary endpoint achieved	82.5–91.3%	0.0–3.4%	12.9–34.8%
Time from start of medication to start of procedure	4.0–5.0 min	17–19.5 min	16.0–19.0 min
Time from end of procedure to fully alert	3.0–7.2 min	5.0–21.3 min	7.0–15.7 min
Time to back to normal	331–404 min	572–935 min	478.5–553 min

*) not part of label claim

Based on the results of preclinical and Phase I studies and in consultation with the FDA, PAION conducted additional Phase I studies to further assess the abuse potential of remimazolam. Two aspects were being studied: if remimazolam could inappropriately be used as a knock-out cocktail in combination with alcohol and if it could be abused intranasally. PAION deems the clinical development program for remimazolam in procedural sedation in the U.S. completed, and Cosmo filed for market approval in April 2019.

General anesthesia (Japan, EU, Russia, China + South Korea)

A total of six Phase I, three Phase II and four Phase III trials have been completed for use of remimazolam in 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 Japanese program started with a comparative Phase I study building on PAION's first human trial and showed an identical pharmacokinetic and pharmacodynamic profile. The next step was a continuous infusion Phase I study to define induction and maintenance doses for anesthesia. The doses for induction and maintenance identified as safe and effective in the Phase II study subsequently conducted were then used in the Japanese Phase III studies, which confirmed remimazolam's efficacy and safety as a general anesthetic and its favorable hemodynamic profile compared to propofol.

In order to allow using the Japanese data for filing in the EU, the same induction and maintenance doses were used in the Phase II trial performed in Germany in 2014 as part of the European development program, delivering further evidence for a potentially beneficial hemodynamic profile of remimazolam. The primary efficacy endpoint for general anesthesia was achieved in 98% of patients in the remimazolam dose groups and 96% in the propofol/sevoflurane group demonstrating an excellent efficacy rate across all treatment groups. As expected, the onset and offset of action profile was comparable between all treatment groups, showing that remimazolam indeed shares the fast-acting sedative profile of propofol.

One of the key targets of this trial was to assess the hemodynamic stability during cardiac surgery with remimazolam when compared to propofol/sevoflurane, both of which are known to

cause cardiac depression. The study evaluated a substantial number of parameters to analyse these effects. Remimazolam confirmed the improved hemodynamic stability that had already been shown in the Ono Phase III study.

Based on these positive data, a multi-national, multi-center, randomized, single-blind, propofol-controlled, confirmatory Phase III study in patients undergoing major cardiac surgery was started in the EU in August 2015. Due to the complex study design in cardiac surgery, the trial faced recruitment challenges. Despite intensive efforts to enhance patient recruitment, the trial proved to be difficult to implement in practice. Therefore, in February 2016, PAION decided to discontinue the trial in order to avoid a long and expensive study with the existing design. No drug-related serious adverse events were observed.

Subsequently, PAION evaluated how to resume the clinical development of remimazolam in the EU. In consultation with key opinion leaders in general anesthesia, PAION has successfully conducted a Phase I trial which served as a means to define key elements and sample size calculation for the planned Phase III trial. Based on the results of this study, subsequent simulations and scientific advice obtained from the European authority EMA for defining the new European Phase III program, PAION has started an EU Phase III clinical trial with remimazolam for the induction and maintenance of general anesthesia in July 2018.

The randomized, single-blind, propofol-controlled, confirmatory Phase III trial is expected to enroll approx. 500 ASA III/IV patients (American Society of Anesthesiologists classification III to IV) undergoing planned surgery. The primary objective of the trial is to demonstrate the non-inferiority of remimazolam compared to propofol for the induction and maintenance of general anesthesia during elective surgery. The key secondary objective is to show improved hemodynamic stability (avoidance of intraoperative drop of blood pressure and vasopressor usage) compared to propofol. Currently, 424 patients have been enrolled in the study. Due to the Coronavirus pandemic, completion of patient recruitment previously planned in the first half of 2020 will be delayed until hospitals which are currently increasingly working to capacity with the treatment of patients infected with the Coronavirus will have capacities for the recruitment of patients for planned interventions available again.

Based on Scientific Advice obtained from the EMA in January 2018, PAION expects that a positive Phase III trial in combination with previously completed clinical studies in Europe and Japan should be sufficient for market approval in the indication of general anesthesia in the EU.

In November 2018, PAION's licensee R-Pharm announced the successful completion of a Phase III trial in general anesthesia and PAION's licensee Hana Pharm also successfully completed a Phase III trial in general anesthesia in October 2018.

ICU sedation

PAION's former licensee in Japan, Ono, independently initiated a Phase II trial for sedation in intensive care units (ICUs). Higher than by Ono expected plasma concentrations 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 being evaluated.

Pediatric development

Another field of high clinical need is pediatric use.

The aims of sedation and general anesthesia are the same in both adults and children: to enable diagnostic, surgical or dental procedures to be carried out safely and successfully while minimizing distress and discomfort to the patient. Advances in the diagnostics and treatment of pediatric diseases has led to an increase in the number of painful or distressing procedures for which many children need effective sedation or general anesthesia. While in adults many procedures can be undertaken with local anesthesia and verbal reassurance, this is often not possible with children and teenagers. Particularly for children, procedures are often too frightening, too painful, or need to be performed in children who are uncooperative, ill or in pain. In 2018, PAION submitted a PIP 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, followed by general anesthesia and finally ICU sedation. The clinical trials will initially be conducted with adolescents and further studies will be performed with increasingly younger children. At the same time, while at the beginning less serious diseases are included in the trials, increasingly severe diseases will be included in the trials in the later course of the development program.

Partnerships, regulatory and commercial activities

Development and commercialization collaborations with partners with local expertise or with a specific therapeutic focus with respect to remimazolam are an effective way of funding and advancing remimazolam's development and of assisting PAION with its commercialization in international markets where PAION does not intend to directly conduct sales and marketing activities. The local further development of remimazolam leads to additional data and potential milestone payments for PAION. PAION has partnering discussions with potential further licensees in order to allow for swift commercialization of remimazolam after potential market approval. In order to exploit remimazolam's full potential, PAION is evaluating commercializing remimazolam on its own in selected European markets after a potential market approval.

PAION is starting to build up a supply chain for remimazolam. Process validation of the manufacture of remimazolam at commercial scale has been completed successfully and commercial production contracts have been signed with the contract manufacturers. On this basis, the planned development of the structures, establishment of the processes and obtaining all pharmaceutical permits should be implemented in the second half of 2020 to an extent that allows for regular supply of the licensees with remimazolam.

In the U.S., the NDA in procedural sedation was prepared together with licensee Cosmo and submitted to the FDA by Cosmo in April 2019. The FDA informed Cosmo in June 2019 that the filing had been accepted. After announcement of an extension of the review period of up to three months for the evaluation of additional data, the FDA set 05 July 2020 (previously 05 April 2020) as PDUFA date. Under this timeline, market approval and subsequent launch of remimazolam in the U.S. can be expected in 2020 assuming a regular approval process.

In January 2020, Cosmo announced that its remimazolam (ByFavo) U.S. rights were sub-licensed to Acacia Pharma (Acacia). Going forward, Acacia will be responsible for the marketing of remimazolam in the U.S. In 2016, PAION entered into a U.S. license agreement for remimazolam (ByFavo) with Cosmo which remains unchanged.

Also in January 2020, PAION and Hana Pharma extended their license agreement for remimazolam to include Southeast Asia (Indonesia, Malaysia, Philippines, Singapore, Thailand, Vietnam), and Hana Pharm will be responsible for the development and marketing approval process in these markets. PAION and Hana Pharm entered into an exclusive remimazolam license agreement for South Korea in 2013.

In Europe, PAION is seeking approval for remimazolam in general anesthesia and in procedural sedation.

Procedural sedation: PAION submitted an MAA for procedural sedation to the EMA in November 2019 after it had been discussed in the course of a pre-submission meeting with the EMA held in February 2019 that the existing data package from the U.S. Phase III clinical development program will be sufficient for submitting an MAA in procedural sedation. Market approval is currently expected in the beginning of 2021 at the earliest.

General anesthesia: Assuming approval in procedural sedation and positive results in the Phase III trial in general anesthesia, PAION plans to submit an extension of the marketing authorization for remimazolam for general anesthesia. The review process for an extension is generally faster than for an MAA. The complete data from the EU Phase III study in general anesthesia, which are required for the submission of an extension of marketing authorization, are expected to be available at the time of the regulatory decision on the MAA in procedural sedation.

Licensee activities in other territories

Japanese licensee Mundipharma submitted a market approval dossier for remimazolam for general anesthesia in December 2018, which was approved by the Japanese Pharmaceuticals and Medical Devices Agency (PMDA) in January 2020. Mundipharma currently plans to launch remimazolam mid-2020.

Chinese licensee Yichang Humanwell submitted a market approval dossier for remimazolam for procedural sedation to the Chinese National Medical Products Administration (NMPA) in November 2018. Market approval is currently expected in 2020.

PAION's South Korean licensee Hana Pharm submitted a market approval dossier for remimazolam in general anesthesia in South Korea in December 2019. Market approval is currently expected in the second half of 2020.

Russian licensee R-Pharm announced the successful completion of a Phase III trial with remimazolam in general anesthesia in November 2018. R-Pharm is currently preparing first market approval dossiers for the licensed territories.

In Canada, PAION expects its licensee Pharmascience to use the U.S. market approval dossier as the basis for filing for market approval of remimazolam.

The following table provides an overview of the regulatory progress of remimazolam in the different territories:

Overview of remimazolam approval processes			
Applicant, Country	Indication	Date of NDA/MAA submission	Market approval
Mundipharma, Japan	General anesthesia	12/2018	Granted in 01/2020
Yichang Humanwell, China	Procedural sedation	11/2018	Expected in 2020
Cosmo, U.S.	Procedural sedation	04/2019	PDUFA date 05 July 2020
PAION, EU	Procedural sedation	11/2019	Expected beginning of 2021 the earliest
Hana Pharm, S. Korea	General anesthesia	12/2019	Expected in H2 2020

The following table gives an overview of received and potential future upfront and milestone payments as well as potential royalties:

Upfront and milestone payments (Group)			
	Total received	Maximum outstanding amount	Royalty rate
Ono, Japan (2007) (terminated in 2015)	USD 8 m	None	None
Yichang Humanwell, China (2012)	EUR 3.5 m ⁵	EUR 0.5 m ⁵	10% ⁵
Hana Pharm, S. Korea (2013)	EUR 2.0 m ⁶	EUR 1.0 m	10%
Hana Pharm, Southeast Asia (2020)	EUR 1.5 m ⁶	EUR 3.2 m	Low double-digit
R-Pharm, CIS (2013)	EUR 1 m	EUR 3 m	Low double-digit
R-Pharm, Turkey (2013)	EUR 1.5 m ⁶	EUR 2.5 m	Low double-digit
R-Pharm, MENA (2014)	EUR 1.5 m	EUR 5.5 m	Low double-digit
Pharmascience, Canada (2014)	EUR 0.4 m ¹	~ EUR 3.9 m	Tiered (starting at 15%)
Cosmo, U.S. (2016)	EUR 27.5m ²	EUR 35 m	20–25% ³
Mundipharma, Japan (2017)	EUR 4 m ⁶	EUR 22 m	Up to over 20% ⁴
Total	EUR 48.8 m	~ EUR 76.6 m	

¹⁾ This amount relates to the premium received in the course of the private placement in the amount of EUR 4 million in 2014.

²⁾ Comprising EUR 10 million received via private placement in 2016 and via capital increase with subscription rights conducted in 2017, the upfront payment of EUR 10 million received in 2016 as well as the milestone payment of EUR 7.5 million received in 2019

³⁾ Subject to adjustments under specific circumstances, but not below 15% of net sales.

⁴⁾ Tiered royalties starting in the low double-digits to over 20%

⁵⁾ In case of commercialization of a competing remimazolam product in China, PAION is obliged to pay back 50% of the milestone payments already received (partially to be set off against royalties); potential future milestone payments would be halved. Moreover, royalties would drop to 5%.

⁶⁾ (Partially) received/receivable after the balance sheet date

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). It is available for two years and can be drawn down in a total of three tranches based on certain conditions as e.g. the achievement of operational milestones. Each tranche has a term of five years and will be repaid beginning in the fourth year after drawdown. The interest rate corresponds to the market conditions for risky debt financing of innovative companies (venture debt); it consists of a cash interest component, a deferred interest component due at maturity and a performance-related interest component. The first tranche of the loan is already available and the two further tranches could become available in 2020. PAION has not drawn down the loan yet.

Moreover, 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 EUR 5 million was issued to Yorkville under exclusion of pre-emptive rights on 12 September 2019. The minimum conversion price is EUR 1.91 per share. Until the balance sheet date, convertible notes with a nominal amount of KEUR 800 were converted into 407,443 PAION shares. A further utilization of the financing agreement with Yorkville by issuing additional tranches of convertible notes is not planned.

3. Net assets, financial position and results of operations of PAION AG

a. Results of operations

The net result decreased by KEUR 2,667 compared to the prior year to a net loss of KEUR 2,013 in fiscal year 2019. This decrease is particularly attributable to lower interest income from affiliated companies due to a lower loan amount on average during the year as well as higher other operating expenses which were incurred in the reporting period in connection with the issue of convertible notes and the conclusion of a financing agreement with the EIB that has not been utilized yet.

The net result is within the previous year's forecast range for 2019.

	2019 KEUR	2018 KEUR	Change in result KEUR
Revenues	1,359	1,026	333
Other operating income	266	264	2
Personnel expenses	-1,907	-1,785	-122
Other operating expenses	-2,399	-1,861	-538
Operating result	-2,681	-2,356	-325
Financial result	668	3,010	-2,342
Net result	-2,013	654	-2,667

Revenues increased by KEUR 333 in the reporting period compared to the previous year and result entirely from the provision of management and other services to the subsidiaries, of which PAION UK Ltd accounted for KEUR 1,217 (previous year: KEUR 895) and PAION Deutschland GmbH for KEUR 142 (previous year: KEUR 131).

Other operating income increased by KEUR 2 in the reporting period compared to the previous year and includes recharges to the subsidiaries amounting to KEUR 155 (previous year: KEUR 145), of which PAION Deutschland GmbH accounted for KEUR 79 (previous year: KEUR 75) and PAION UK Ltd for KEUR 76 (previous year: KEUR 70). Exchange rate gains were recognized in an amount of KEUR 51 (previous year: KEUR 86).

Personnel expenses increased by KEUR 122 to KEUR 1,907.

Year on year, **other operating expenses** increased by KEUR 538 to KEUR 2,399 and mainly include legal and consulting fees (KEUR 1,116; previous year: KEUR 763), insurance, contributions and fees (KEUR 221; previous year: KEUR 233), expenses in connection with Supervisory Board remuneration (KEUR 162; previous year: KEUR 162), services rendered by PAION Deutschland GmbH (KEUR 158; previous year: KEUR 150), travel expenses (KEUR 150; previous year: KEUR 161), expenses for IT hosting (KEUR 111; previous year: KEUR 104) as well as audit costs and costs for the annual report (KEUR 70; previous year: KEUR 64). In the reporting period, foreign exchange losses in the amount of KEUR 21 (previous year: KEUR 68) have been recognized. Moreover, other operating expenses include a fee amounting to KEUR 150 in connection with the issue of convertible notes to an institutional investor. The increase of other operating expenses in comparison to the previous year mainly results from higher expenses for legal and consulting fees particularly in connection with the conclusion of a financing agreement with the EIB that has not been utilized yet as well as the issue of the convertible notes.

Compared to the previous year, the **financial result** decreased by KEUR 2,342 to KEUR 668. The decrease mainly stems from lower interest income from affiliated companies (KEUR 734; previous year: KEUR 3,004) due to a significantly lower amount of the loans granted to the PAION UK group on yearly average. Moreover, the financial result includes expenses amounting to KEUR 60 from the pro-rated release of the discount recognized on the balance sheet in connection with the issue of convertible notes as well as negative interest on bank deposits in an amount of KEUR 6.

b. Net assets and financial position

The balance sheet total as of 31 December 2019 amounts to KEUR 135,435 and has increased by KEUR 2,990 compared to the previous year. The equity ratio is 96.3% at the current balance sheet date (previous year: 99.4%). As of 31 December 2019, cash and cash equivalents amounted to KEUR 16,864 and increased by KEUR 1,816 compared to the previous year.

	31 Dec. 2019 KEUR	31 Dec. 2018 KEUR	Change KEUR
Fixed assets	94,780	94,761	19
Current assets and prepaid expenses	40,655	37,684	2,971
Assets	135,435	132,445	2,990
Equity	130,394	131,607	-1,213
Current liabilities	5,041	838	4,203
Shareholders' equity and liabilities	135,435	132,445	2,990

Fixed assets increased by KEUR 19 in the reporting period in the course of the founding of wholly-owned subsidiary PAION Netherlands B.V. and the purchase of licenses. As of the balance sheet date, fixed assets mainly relate to the shares in PAION Holdings UK Ltd (KEUR 94,311), the shares in PAION Deutschland GmbH (KEUR 450) and the shares in PAION Netherlands B.V. (KEUR 10).

Current assets (including prepaid expenses) have increased by KEUR 2,971 to KEUR 40,655 in fiscal year 2019. The loan granted to PAION UK Ltd has increased by (net) KEUR 708 to KEUR 23,142 as of 31 December 2019. Cash and cash equivalents have increased by KEUR 1,816 from KEUR 15,048 to KEUR 16,864 as of 31 December 2019.

The increase of **current liabilities** by KEUR 4,203 to KEUR 5,041 mainly results from the issue of convertible notes with a nominal amount of KEUR 5,000 in the reporting period. Until the balance sheet date, convertible notes with a nominal amount of KEUR 800 were converted into shares of the company resulting in a carrying amount of KEUR 4,200 as of 31 December 2019.

The change in cash and cash equivalents over the fiscal year is attributable to the following areas:

	2019 KEUR	2018 KEUR
Cash flow from operating activities	-1,917	1,183
Cash flow from investing activities	-727	-14,966
Cash flow from financing activities	4,460	5,214
Change in cash and cash equivalents	1,816	-8,569

The **cash flow from operating activities** mainly results from the net result of the year, corrected for transactions costs incurred in connection with the issue of convertible notes as well as working capital changes.

The **cash flow from investing activities** primarily results from the (net) grant of a loan to PAION UK Ltd. In the previous year, the cash flow from investing activities also mainly resulted from the (net) grant of loans to the British subsidiaries.

The **cash flow from financing activities** mainly results from the gross proceeds of convertible notes issued in the reporting period with a discount of 5% of KEUR 4,750 (nominal amount: KEUR 5,000) as well as transaction costs incurred in this context (KEUR 284). In the previous year, the cash flow from financing activities resulted from gross proceeds from the capital increase under exclusion of subscription rights conducted in June 2018 (KEUR 5,200), the cost of funds for this transaction (KEUR 160) as well as the exercise of stock options (KEUR 174).

4. Net assets, financial position and results of operations of PAION Group

The Group generated a consolidated net loss of KEUR 7,016 in fiscal year 2019 (previous year: net loss of KEUR 9,939). The key items in the consolidated balance sheet as of 31 December 2019 were cash and cash equivalents (KEUR 18,787; previous year: KEUR 17,227), equity (KEUR 14,732; previous year: KEUR 20,822), trade payables (KEUR 4,843; previous year: KEUR 2,218) as well as financial debt (KEUR 4,354; previous year: KEUR 0).

Headcount

As of 31 December 2019, the total headcount of PAION Group was 45 employees, of whom eleven worked for PAION UK Group. By comparison, the headcount as of 31 December 2018 amounted to 40 employees. As of 31 December 2019, the headcount at PAION AG totalled nine employees (previous year: seven employees).

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 2.01 per stock option and is based on the

average price of the shares in a certain time period before the allocation in accordance with the terms of the stock option plan. As of 31 December 2019, the exercise hurdle was EUR 2.60.

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, EUR 2.30 or EUR 2.60 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 in accordance with the terms of the stock option plan. As of 31 December 2019, the exercise hurdle was EUR 2.34, EUR 2.87 or EUR 2.85, depending on the grant date.

From the Stock Option Plan 2016 approved by the Annual General Meeting on 25 May 2016, a total of 244,500 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 2.25 or EUR 2.60 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 in accordance with the terms of the stock option plan. As of 31 December 2019, the exercise hurdle was EUR 2.42 or EUR 2.85, depending on the grant date.

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 2019 can be gathered from the following tables (according to German Corporate Governance Code):

Benefits granted in EUR	Dr. James Phillips CEO since 16 October 2019				Dr. Wolfgang Söhngen CEO (until 15 October 2019) Management Board member (until 22 November 2019)			
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	2018	2019	2019 (Min)	2019 (Max)	2018	2019	2019 (Min)	2019 (Max)
Fixed compensation	0	128,952*	128,952	128,952	275,000	245,972	245,972	245,972
Other remuneration	0	4,977	4,977	4,977	45,301	39,045	39,045	39,045
Total	0	133,928	133,928	133,928	320,301	285,017	285,017	285,017
One-year variable compensation	0	0	0	0	175,000	156,528	0	242,618
Multi-year variable compensation								
Stock Option Plan 2014 - Grant 2018 (Waiting period 2018 to 2022) **	0	0	-	-	0	0	-	-
Stock Option Plan 2016 - Grant 2018 (Waiting period 2018 to 2022) **	0	0	-	-	102,000	0	-	-
Total	0	133,928	133,928	133,928	597,301	441,545	285,017	527,635
Service cost	0	0	0	0	0	0	0	0
Total remuneration	0	133,928	133,928	133,928	597,301	441,545	285,017	527,635

* Dr. Phillips' fixed compensation includes a signing bonus for lost compensation from his previous employment and 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

Allocation in EUR	Dr. James Phillips CEO since 16 October 2019		Dr. Wolfgang Söhngen CEO (until 15 October 2019) Management Board member (until 22 November 2019)	
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	2018	2019	2018	2019
Fixed compensation	0	128,952*	275,000	245,972
Other remuneration	0	4,977	45,301	39,045
Total	0	133,928	320,301	285,017
One-year variable compensation	0	0	114,100	62,611
Multi-year variable compensation				
Stock Option Plan 2008 - Grant 2008 (Waiting period 2008 to 2010)	0	0	50,028**	0
Total	0	133,928	484,429	347,629
Service cost	0	0	0	0
Total remuneration	0	133,928	484,429	347,629

* Dr. Phillips' fixed compensation includes a signing bonus for lost compensation from his previous employment and a yearly bonus which was not variable for 2019 and is therefore disclosed as part of the fixed compensation.

** Dr. Söhngen exercised 41,517 stock options in fiscal year 2018

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

	Abdelghani Omari CFO				Dr. Jürgen Beck CDO			
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	2018	2019	2019 (Min)	2019 (Max)	2018	2019	2019 (Min)	2019 (Max)
	180,000	180,000	180,000	180,000	200,000	200,000	200,000	200,000
	15,127	15,127	15,127	15,127	15,127	15,127	15,127	15,127
	195,127	195,127	195,127	195,127	215,127	215,127	215,127	215,127
	90,000	90,000	0	139,500	70,000	70,000	0	108,500
	0	0	-	-	76,035	0	-	-
	102,000	0	-	-	60,965	0	-	-
	387,127	285,127	195,127	334,627	422,127	285,127	215,127	323,627
	0	0	0	0	0	0	0	0
	387,127	285,127	195,127	334,627	422,127	285,127	215,127	323,627

	Abdelghani Omari CFO		Dr. Jürgen Beck CDO	
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	2018	2019	2018	2019
	180,000	180,000	200,000	200,000
	15,127	15,127	15,127	15,127
	195,127	195,127	215,127	215,127
	58,680	36,000	45,640	28,000
	0	0	0	0
	253,807	231,127	260,767	243,127
	0	0	0	0
	253,807	231,127	260,767	243,127

Management Board remuneration in fiscal year 2019 amounted to KEUR 956 in total (previous year: KEUR 1,290) and is composed as follows:

in EUR	2019	2018
Fixed remuneration	754,924	655,000
Other remuneration	74,277	75,556
Total non-performance based remuneration	829,201	730,555
Short-term variable remuneration	126,611	218,420
Total short-term remuneration	955,812	948,975
Long-term variable remuneration	0	341,000
Total long-term remuneration	0	341,000
Total remuneration	955,812	1,289,975

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

The Management Board members held the following stock options as of 31 December 2019:

Status of non-exercised stock options as of 31 December 2019:		Dr. James Phillips	Abdelghani Omari	Dr. Jürgen Beck
Stock options 2010	No.	0	80,000	0
Stock options 2010 - fair value *	EUR	-	133,600	-
Stock options 2014	No.	0	111,000	55,500
Stock options 2014 - fair value *	EUR	-	119,325	76,035
Stock options 2016	No.	0	100,000	44,500
Stock options 2016 – fair value *	EUR	-	102,000	60,965

*) 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 and Dr. Beck, 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 and 2016, 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 2019 can be gathered from the following table:

	Basic remuneration EUR	Per-meeting fees EUR	Total EUR
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	12,167	2,000	14,167
John Dawson	7,889	2,000	9,889

Supervisory Board remuneration in fiscal year 2019 amounted to KEUR 162. In the previous year the remuneration also amounted to KEUR 162.

Disclosures pursuant to section 289a (1) HGB and explanatory report

Composition of subscribed capital

As of 31 December 2019, PAION AG had a subscribed capital of EUR 64,265,586.00, divided into 64,265,586 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 2019 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 21 May 2024, with the consent of the Supervisory Board, on one or more occasions, by up to EUR 31,929,071.00 in total by issuing up to 31,929,071 new no-par value bearer shares in return for cash contributions or contributions in kind (Authorized Capital 2019). 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 22 May 2019 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.

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 407,443.00 by conversion of convertible notes issued under exclusion of pre-emptive rights in the reporting period and amounts to EUR 25,792,557.00 as of 31 December 2019. Conditional Capital 2019 can be used under exclusion of pre-emptive rights in an amount of EUR 5,978,371.00 as of 31 December 2019. Accordingly, Authorized Capital 2019 can be used under exclusion of pre-emptive rights in an amount of EUR 5,978,371.00 as of 31 December 2019 as well. Furthermore, the company is authorized to issue 281,093 shares (Conditional Capital 2008 I), 720,000 shares (Conditional Capital 2010 I), 740,000 shares (Conditional Capital 2014), 840,000 shares (Conditional Capital 2016) and 900,000 shares (Conditional Capital 2018 II) in connection with the Stock Option Plans 2008, 2010, 2014, 2016 and 2018.

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 and 2018 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 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. 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 are 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:

		Damage Level				
Likelihood of occurrence		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 remimazolam

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

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.¹⁶

In order to ensure timely filings for market approval of remimazolam, PAION cooperates with renowned 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 is currently conducting an EU Phase III study in general anesthesia. There is a risk that patients cannot be recruited fast enough or at all. The resulting delay, necessary amendment or discontinuation of the 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 have been taken into account for the study design 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. This is a moderate risk. The risk classification decreased by two categories compared to the previous year.

¹⁶ 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 an increased risk. In case of occurrence, the potential damage level could pose a threat to the continued existence of the group. 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 start or 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 actively 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. The risk classification increased by one category compared to the previous year.

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. 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. Based on the properties of remimazolam shown so far, PAION aims for a remimazolam label in the U.S. comparable to midazolam which is allowed to be applied by adequately trained proceduralists and nurses conditional on a certain safety set-up and continuous monitoring of relevant cardiac and respiratory parameters. There is a risk that remimazolam will not be granted this target label significantly reducing or entirely eliminating commercial usability in the U.S. In order to reduce this risk, PAION has addressed this aspect with the FDA under consideration of existing study data at that time and used according feedback for the design of the U.S. Phase III program. PAION has implemented a system to continuously monitor the relevant parameters in this regard. 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 is currently analyzing market access in different markets in the EU. 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 the EU, 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 continues to work on the preparation of the relevant markets, including bringing in external consultants for communication with the scientific community and establishing a network of key opinion leaders. Moreover, there is regular information exchange with the U.S. licensee Cosmo and the licensees in the other regions. A direct exchange with Cosmo's sublicensee Acacia is planned to ensure support in the preparation of commercialization in the U.S. in the best possible way. PAION is also evaluating the possibility of initially launching remimazolam in a different indication than planned as main indication in single countries in the EU in order to support later commercialization in the main indication in these markets. 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 a potential own commercialization in parts of the EU) 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 finalized 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 preparing implementation also under consultation of external experts. Moreover, there is a regular information exchange with the U.S. licensee Cosmo and the licensees in the other regions. Cosmo's sublicensee Acacia plans the start of commercialization of an own product with the same distribution structure also intended to be used for remimazolam already before the planned start of commercialization 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. The risk classification increased by one category compared to the previous year.

For commercial supply of remimazolam, certain regulatory permissions and licenses need to be acquired. There is a risk that potentially required changes of processes or in the documentation at PAION cannot be implemented fast enough or that extensive inspections are undertaken by

the authorities prior to the grant of such permissions leading to a delay in the supply of the commercially usable medicine for the licensees as well as for PAION itself. In order to avoid this risk, requirements and potentially necessary changes at PAION are being analyzed and implemented well in advance. This is an increased risk.

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 on the one hand and to detect and address potential weaknesses in the processes at an early stage on the other hand. 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 risk classification increased by one category compared to the previous year.

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. In case of occurrence, the potential damage level could pose a threat to the continued existence of the group. The risk classification decreased by one category compared to the previous year.

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 completed the implementation of a supply chain. Moreover, commercial production orders have not yet been submitted to the contractual manufacturers. If the complete build-up of the supply chain should not be completed in time or commercial production orders cannot be submitted early enough, 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 contractual manufacturers and on the planning of production orders under involvement of the licensees. This is a moderate risk. The risk classification decreased by two categories compared to the previous year.

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 a moderate risk.

For the Chinese market, a competing remimazolam product is being developed by Hengrui Medicine, a competitor of PAION's Chinese licensee Yichang Humanwell, for which market approval was granted end of 2019. Should commercialization of this product be possible within a certain timeframe without infringement of Yichang Humanwell's and PAION's existing patents, Yichang Humanwell's revenues from sales could be reduced significantly. Moreover, PAION would be obliged to pay an amount of EUR 1.75 million (partially to be set off against royalties) to Yichang Humanwell, potential future milestone payments would be halved and the royalty rate would be reduced from 10% to 5%. PAION is cooperating with Yichang Humanwell to prevent commercialization of the competing remimazolam product. This is a high risk.

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 a high risk and the potential damage level could pose a threat to the continued existence of the group in case of occurrence.

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.

Since PAION neither owns distribution structures nor aims at implementing these globally, potential commercialization of remimazolam can only be carried out by licensees in certain or all regions. Should license agreements not be concluded in time, a potential commercialization could only start delayed in spite of the potential availability of market approval. PAION has partnering discussions with potential further licensees in order to allow for swift commercialization of remimazolam after potential market approval. This is an increased risk.

b. Finance risks

aa) Financing risks

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

PAION's future ability to secure additional funding will depend on the success of its development, licensee and partnering activities, the situation on the capital markets and other factors. If PAION is unable to raise financing at favorable terms or unable to raise financing at all, it could be forced to reduce its operating expenses by delaying, reducing or discontinuing the development and commercialization of remimazolam.

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 contact to investors as well as (potential) pharma partners and licensees. PAION has entered into a loan agreement with the EIB which is already available partially. This is a high risk. In case of occurrence, the potential damage level could pose a threat to the continued existence of the group.

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 the development and market preparation 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 successfully. Dependent on the actual structure, the consequences of the Brexit could also lead to tax payments on potential earnings expected in the future, e.g. due to controlled foreign corporation rules. These tax payments would correspondingly reduce liquidity.

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 2020 onwards.

PAION continuously monitors the relevant tax legislation and jurisdiction and consults external tax consultants for all material issues. Usability of tax losses carried forward is an increased risk. In case of occurrence, the potential damage level could pose a threat to the continued existence of the group. The reduction or cessation of tax credits from British tax authorities is a moderate risk.

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, if expected payments from subsidiaries, e.g. loan repayments, are not made, this could lead to the insolvency of PAION.

For the purpose of monitoring the financial position, results of operations and cash flows of 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. 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. This is a moderate risk.

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.

e. Risks in relation to the “Brexit”

The exit of the United Kingdom from the European Union (so-called “Brexit”) realized end of January 2020 bears a variety of potential risks which can neither be comprehensively captured or specified in more detail qualitatively nor be defined quantitatively in regard to potential damage levels based on the current state of negotiations between the United Kingdom and the EU with respect to the future economic relations after the interim term which is supposed to end on 31 December 2020. Basically, potential risks for PAION could stem from the following areas nevertheless. This overview is however not necessarily exhaustive due to the given uncertainties. Also, potential risks cannot be reasonably categorized due to this fact.

Regulatory requirements for market approval of new drugs could potentially 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 drug candidate 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.

Moreover, also apart from intragroup services, tax risks in particular could result from the Brexit, e.g. due to controlled foreign corporation rules.

f. Risks in relation to the Coronavirus (SARS-CoV-2)

A new form of the Coronavirus (SARS-CoV-2) is spreading internationally since the beginning of 2020 leading to regionally different, partly massive limitations of public life and significant decreases of economic activity. On 11 March 2020, the World Health Organization (WHO) classified the spread of the virus as a pandemic.¹⁷ In the beginning of March 2020, the OECD already corrected the forecast for growth of the world economy downwards; in Germany, the government assured support of the economy.

Limitations of public life (as e.g. in regard to travel restrictions) owed to the spread of the virus and the economic consequences of the spread could directly affect PAION's business activity and its results of operations, net assets and financial position. Among others, development and manufacture of remimazolam, 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 spread as well as the (potential) impact of the virus on public life and the global economy, this risk cannot be classified currently.

4. Market opportunities

PAION is focusing on the clinical development of drug candidates in anesthesia for which there is a substantial unmet medical need with the vision to participate in the commercialization.

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, anesthetists often express the desire for a short-acting, safe and well controllable agent. PAION is responding to this medical need with the development of remimazolam.

Procedural sedation

Clinical development of remimazolam in procedural sedation for minor medical interventions in the U.S. has already been completed. PAION's U.S. licensee Cosmo filed for market approval in April 2019. The start of commercialization of remimazolam in the U.S. can be expected in 2020 in case of a positive FDA decision. PAION's Chinese licensee Yichang Humanwell filed for market approval in

¹⁷ World Health Organization: WHO Director-General's opening remarks at the media briefing on COVID-19 - 11 March 2020; <https://www.who.int/dg/speeches/detail/who-director-general-s-opening-remarks-at-the-media-briefing-on-covid-19---11-march-2020>; accessed on 12 March 2020.

procedural sedation in China in November 2018; market approval is expected in 2020. In Europe, PAION submitted an MAA in procedural sedation to the EMA in November 2019. Market approval is expected beginning of 2021 at the earliest. Based on its own projections, PAION currently estimates an annual peak sales potential of approx. EUR 50 million to approx. EUR 75 million for procedural sedation in the EU.

General anesthesia

Development in general anesthesia in Japan is completed. The Japanese licensee Mundipharma filed for market approval of remimazolam in general anesthesia in Japan in December 2018 and received market approval in January 2020. PAION's Russian licensee R-Pharm is currently preparing first market approval dossiers for the licensed territories based on the Phase III trial in general anesthesia successfully completed in November 2018. PAION's South Korean licensee Hana Pharm submitted a market approval dossier for remimazolam in general anesthesia in South Korea in December 2019. Market approval is currently expected in the second half of 2020. Assuming approval in procedural sedation and positive results in the Phase III trial in general anesthesia, PAION plans to submit an extension of the marketing authorization for remimazolam for general anesthesia. The review process for an extension 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 150 million to approx. EUR 200 million for general anesthesia in the EU.

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. In total, potential future milestone payments from existing license agreements add up to nearly EUR 77 million. In addition, all license agreements in place bear royalties upon commercialization ranging from 10% up to over 20% of net sales based on the respective territory. For selected European markets, an own commercialization is being evaluated. 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 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.

Overall evaluation of opportunities and risks

The filings for market approval in the U.S, the EU and South Korea in the reporting period were further important milestones on the way to market approval for remimazolam in even more than one region and indication. The progress of the development of remimazolam worldwide is illustrated by the fact that there were a total of five approval dossiers in review by the respective regional authorities at the end of the reporting period submitted by PAION and its licensees. Shortly after the end of the reporting period, market approval in general anesthesia was granted in Japan. Thus, the risk of failure of the development of remimazolam has further decreased.

The financing agreement signed with the EIB and the convertible notes issued in the reporting period have further decreased potential additional financing requirement depending on the respective scenario. Thus, the risk situation has improved compared to the previous year.

With a regular course of the approval process, market approval and subsequent start of commercialization of remimazolam in the U.S. can be expected in 2020. In Japan, remimazolam could be launched by licensee Mundipharma mid-2020. Market approvals in China and South Korea are currently also expected in 2020. Moreover, market approval could be granted in procedural sedation in the EU beginning of 2021 at the earliest. Taking these factors into account, the opportunity situation has improved in comparison to the previous year. Since remimazolam is not yet marketed and therefore no sustainable revenue is generated, PAION continues to incur losses.

Report on post-balance sheet date events

On 08 January 2020, the subsidiary PAION UK Ltd and licensee Hana Pharm extended the existing remimazolam license agreement for South Korea to include six additional countries in Southeast Asia.

On 23 January 2020, Mundipharma, licensee of the subsidiary PAION UK Ltd, received market approval for remimazolam in general anesthesia in Japan.

On 12 March 2020, Cosmo, licensee of the subsidiary PAION UK Ltd, announced the postponement of the target date for completion of the review (PDUFA date) of the NDA for remimazolam by the FDA by up to three months from 05 April 2020 to 05 July 2020.

There were no further significant events in the period between the reporting date, 31 December 2019, and the preparation of this report.

Report on expected developments

Outlook on development and commercialization (PAION group)

PAION's focus for 2020 is on the completion of the ongoing Phase III study in general anesthesia in Europe, market approval processes in the U.S., Europe and other regions, the build-up of the supply chain and commercial manufacture of remimazolam as well as the market preparation and start of commercialization of remimazolam in different territories.

Europe

For the EU, PAION is working on the advancement of the clinical development program of remimazolam. Focus are the conduct and completion of the ongoing Phase III study in general anesthesia as well as first development work to address the pediatric development plan stretching over several years. Due to the Coronavirus pandemic, completion of patient recruitment of the Phase III study previously planned in the first half of 2020 will be delayed until hospitals which are currently increasingly working to capacity with the treatment of patients infected with the Coronavirus will have capacities for the recruitment of patients for planned interventions available again. EMA's decision on the market approval dossier in procedural sedation is expected beginning of 2021 at the earliest. Following this, PAION plans to file for market approval in general anesthesia. Moreover, PAION continues to conduct pre-commercial activities. The build-up of an own distribution structure in Europe is dependent on the possibility of extending the portfolio by additional products. Therefore, PAION also considers the option to outlicense remimazolam for Europe as an alternative to building up an own distribution structure.

U.S.

For the U.S., the FDA's decision on the approval dossier in procedural sedation is prominent. PDUFA date is 05 July 2020, and in case of approval, Acacia, sublicensee of U.S. licensee Cosmo, expects start of commercialization of remimazolam in the U.S. in the second half of 2020.

Rest of the World

In Japan, market approval for remimazolam in general anesthesia was granted in January 2020. Start of commercialization by licensee Mundipharma could happen mid-2020.

In China, licensee Yichang Humanwell filed for market approval for remimazolam in procedural sedation in November 2018 and expects a decision still this year.

PAION's South Korean licensee Hana Pharm submitted a market approval dossier for remimazolam in general anesthesia in South Korea in December 2019. Market approval is currently expected in the second half of 2020.

Licensee R-Pharm is preparing first market approval dossiers for the licensed territories.

In Canada, PAION expects its licensee Pharmascience to use the U.S. market approval dossier as the basis for filing for market approval of remimazolam.

Further activities

PAION is working on setting up the supply chain in order to be able to provide remimazolam product to the licensees timely for commercial use as well as having it available early enough for PAION's potential own commercialization. The planned development of the structures, establishment of the processes and obtaining all pharmaceutical permits are planned to be implemented in the second half of 2020 to an extent that allows for regular supply of the licensees with remimazolam.

Financial outlook 2020 (PAION group)

PAION expects revenues of about EUR 20 million in 2020, thereof EUR 15 million from Cosmo for market approval of remimazolam in the U.S. Further revenues relate to the market approval of remimazolam in Japan, the license extension signed with Hana Pharm in January 2020 to include six additional countries in Southeast Asia as well as milestones in connection with possible market approvals in further regions. Royalties from the commercialization of remimazolam in the U.S. and Japan are expected in a small amount of less than EUR 1 million in total in 2020.

Research and development expenses will amount to between approx. EUR 10 million and approx. EUR 12 million, depending on the progress of development. General administrative and selling expenses will amount to between approx. EUR 7 million and approx. EUR 9 million depending on the progress of the build-up of the supply chain and the volume of pre-commercial activities. Net result is expected to amount to between approx. EUR -1 million and approx. EUR 3 million in 2020.

Income from tax credits on parts of research and development expenses from British tax authorities are not expected or only expected in a small amount of up to EUR 0.5 million and therefore not included in the outlook due to a change in calculation and capping rules and the amount of expected revenues.

This outlook assumes that PAION and licensee activities progress as expected. In case of delays, essential cost blocks and/or revenues would shift into 2021 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 Coronavirus pandemic on our business and the business of our partners could lead to delays and a shift of revenues and/or costs.

Based on current planning, cash and cash equivalents at hand and expected payments from milestones and royalties secure a liquidity runway into the second half of 2021.

Additional funds could be required for a potential own commercialization of remimazolam in selected European markets, the execution of the multi-year pediatric development plan as well as for potential portfolio extensions. The total magnitude of potentially required funds will be dependent on PAION's decision on building up an own distribution and what an actual setup would look like, as well as on the magnitude and timing of incoming milestone and royalty payments from licensees. A final decision on building up an own distribution has not been made yet. The financing

agreement of up to EUR 20 million concluded with the EIB and milestone and royalty payments expected in the next years could partially or completely cover a potential financing requirement depending on the decision on an own commercialization. The first tranche of EUR 5 million from the financing agreement with the EIB, which is already available, has not been drawn down yet. Availability of the further two tranches is dependent on certain conditions as e.g. the achievement of operational milestones. The loan can be accessed until mid-2021. A further utilization of the financing agreement on convertible notes with Yorkville in addition to the first tranche already issued is not planned. The magnitude of royalties from licensees will depend on the success of commercialization in the U.S., Japan and the other territories and on remimazolam's price level and pace of market penetration. However, this can only be evaluated with sufficient certainty after the launch phase.

Under consideration of the current cost structures, a net loss of approx. EUR 0.5 million to approx. EUR 1.5 million is expected for PAION AG in fiscal year 2020.

Aachen, Germany, 25 March 2020

PAION AG


Dr. James Phillips


Dr. Jürgen Beck


Abdelghani Omar

Financial Statements

PAION AG

Balance Sheet as of 31 December 2019

ASSETS	31 Dec. 2019 EUR	31 Dec. 2018 EUR
Fixed assets		
Intangible assets		
Franchises, trademarks, patents, licenses and similar rights	8,481.00	0.00
Financial assets		
Shares in affiliated companies	94,771,015.15	94,761,015.15
Securities	11.70	11.70
	94,771,026.85	94,761,026.85
	94,779,507.85	94,761,026.85
Current assets		
Receivables and other assets		
Receivables from affiliated companies	23,436,834.24	22,549,566.47
Other assets	72,719.42	32,013.96
	23,509,553.66	22,581,580.43
Cash on hand and bank balances	16,864,427.61	15,047,836.95
	40,373,981.27	37,629,417.38
Prepaid expenses	281,180.34	54,740.41
	135,434,669.46	132,445,184.64

EQUITY AND LIABILITIES	31 Dec. 2019 EUR	31 Dec. 2018 EUR
Equity		
Subscribed capital	64,265,586.00	63,858,143.00
thereof: 64,265,586 no-par value shares (prior year: 63,858,143 no-par value shares)		
Conditional capital: EUR 29,273,650.00 (prior year: EUR 29,681,093.00)		
Capital reserve	149,688,030.46	149,295,473.46
Accumulated loss	-83,559,690.53	-81,546,376.56
	130,393,925.93	131,607,239.90
Accruals		
Other accruals	481,538.27	545,697.38
Liabilities		
Bonds	4,200,000.00	0.00
thereof due in up to one year: EUR 4,200,000.00 (prior year: EUR 0.00)		
thereof convertible: EUR 4,200,000.00		
Trade payables	213,662.10	130,103.49
thereof due in up to one year: EUR 213,662.10 (prior year: EUR 130,103.49)		
Liabilities to affiliated companies	17,562.75	9,478.64
thereof due in up to one year: EUR 17,562.75 (prior year: EUR 9,478.64)		
Other liabilities	127,980.41	152,665.23
thereof due in up to one year: EUR 127,980.41 (prior year: EUR 152,665.23)		
thereof for taxes: EUR 86,918.73 (prior year: EUR 92,525.89)		
thereof relating to social security: EUR 5,904.66 (prior year: EUR 0.00)		
	4,559,205.26	292,247.36
	135,434,669.46	132,445,184.64

Income Statement for Fiscal Year 2019

	2019 EUR	2018 EUR
Revenues	1,359,421.33	1,026,159.35
Other operating income	265,928.38	263,851.16
Personnel expenses		
Wages and salaries	-1,774,936.83	-1,676,315.69
Social security	-132,151.07	-108,376.50
	-1,907,087.90	-1,784,692.19
Depreciation of intangible assets	-144.00	0.00
Other operating expenses	-2,398,998.27	-1,860,828.10
Other interest and similar income	733,995.69	3,009,796.54
thereof from affiliated companies: EUR 733,020.00 (prior year: EUR 3,003,640.97)		
Other interest and similar expenses	-66,429.20	0.00
Result before tax	-2,013,313.97	654,286.76
Net result for the year	-2,013,313.97	654,286.76
Loss carryforward	-81,546,376.56	-82,200,663.32
Accumulated loss	-83,559,690.53	-81,546,376.56

Notes

PAION AG

Notes to the financial statements for fiscal year 2019

Preliminary remarks

The financial statements of PAION AG, Martinstr. 10–12, 52062 Aachen, Germany, HRB 12528, register court Aachen, for the fiscal year from 1 January 2019 to 31 December 2019 were prepared in accordance with the applicable provisions of the German Commercial Code (Handelsgesetzbuch, HGB) and the German Stock Corporation Act (Aktiengesetz, AktG), as amended. The balance sheet and income statement have been classified according to the provisions of Sections 266 and 275 HGB. The notes to the financial statements were prepared in accordance with the requirements of Sections 284 to 288 HGB.

PAION AG shares are admitted to trading on the Frankfurt Stock Exchange and are listed in the Prime Standard of the Regulated Market. Pursuant to Section 267 paragraph 3 sentence 2 HGB PAION AG is a large corporation, as shares issued by it are traded on an organized market within the meaning of Section 2 paragraph 11 of the German Securities Trading Act claim (Wertpapierhandels-gesetz, WpHG).

than one year the realization principle (Section 252 (1) No. 4 Sentence 2 HGB) and the acquisition cost principle (Section 253 (1) Sentence 1 HGB) are considered.

4. Prudent business judgement is applied to the estimation of accruals; these are recognized at an amount deemed necessary and adequate. Accruals with a remaining term of more than one year are discounted with the weighted market interest rate of the last seven years.
5. Liabilities (including bonds and those denominated in foreign currencies) are carried at the amount repayable. Liabilities denominated in a foreign currency are generally converted with the average spot exchange rate at the balance sheet date. In case of a remaining term of more than one year the realization principle (Section 252 (1) No. 4 Sentence 2 HGB) and the acquisition cost principle (Section 253 (1) Sentence 1 HGB) are considered.
6. The income statement is prepared using the cost-summary method in accordance with Section 275 (2) HGB.

Accounting and valuation methods

1. Fixed assets are measured at acquisition cost and are subject to scheduled linear amortization. Low-value assets costing less than EUR 800 are written off in full in the year of acquisition. The lower applicable value is subject to unscheduled depreciation if required. If the reason for the unscheduled depreciation ceases to exist, the assets are written up in accordance with Section 253 (5) HGB.
2. Financial assets are recognized at the lower of acquisition cost or market value.
3. Receivables and other assets are always stated at nominal value. Receivables denominated in a foreign currency are generally converted with the average spot exchange rate at the balance sheet date. In case of a remaining term of more

Notes to the items of the balance sheet and the income statement

(I) Financial assets

The shareholdings in affiliated companies as of 31 December 2019 refer to PAION Holdings UK Ltd (KEUR 94,311), PAION Deutschland GmbH (KEUR 450) and the wholly-owned subsidiary PAION Netherlands B.V. (KEUR 10) founded in 2019. The composition and performance of the fixed assets is as follows:

	Historic Costs			31 Dec. 2019 EUR
	1 Jan. 2019 EUR	Additions EUR	Disposals EUR	
Intangible assets				
Franchises, trademarks, patents, licenses and similar rights	60,075.05	8,625.00	0.00	68,700.05
	60,075.05	8,625.00	0.00	68,700.05
Financial assets				
Shares in affiliated companies	141,959,512.25	10,000.00	0.00	141,969,512.25
Securities	11.70	0.00	0.00	11.70
	141,959,523.95	10,000.00	0.00	141,969,523.95
	142,019,599.00	18,625.00	0.00	142,038,224.00

1 Jan. 2019	Depreciation		31 Dec. 2019	Net Book Values	
	Additions	Disposals		31 Dec. 2019	31 Dec. 2018
EUR	EUR	EUR	EUR	EUR	EUR
60,075.05	144.00	0.00	60,219.05	8,481.00	0.00
60,075.05	144.00	0.00	60,219.05	8,481.00	0.00
47,198,497.10	0.00	0.00	47,198,497.10	94,771,015.15	94,761,015.15
0.00	0.00	0.00	0.00	11.70	11.70
47,198,497.10	0.00	0.00	47,198,497.10	94,771,026.85	94,761,026.85
47,258,572.15	144.00	0.00	47,258,716.15	94,779,507.85	94,761,026.85

(2) Receivables from affiliated companies

The receivables from affiliated companies are comprised as follows as of 31 December 2019:

EUR	Total	of which: loans	of which: services and interest
PAION UK Ltd	23,427,944.70	23,142,000.00	285,944.70
PAION Deutschland GmbH	8,889.54	0.00	8,889.54
	23,436,834.24	23,142,000.00	294,834.24

Receivables from affiliated companies have a term of less than 12 months.

(3) Other assets

As of 31 December 2019, other assets are comprised substantially of VAT receivables (KEUR 60; previous year: KEUR 31).

(4) Prepaid expenses

As of 31 December 2019, prepaid expenses comprise a discount amounting to KEUR 190 resulting from the issue of convertible notes with a nominal value of KEUR 5,000 at an issue amount of KEUR 4,750 in September 2019 which is expensed linearly over the term of 15 months.

(5) Equity

As of 31 December 2019, the share capital amounts to EUR 64,265,586.00 (previous year: EUR 63,858,143.00); it is divided into 64,265,586 no-par value shares (previous year: 63,858,143 shares). The increase of the share capital in the total amount of EUR 407,443.00 in the reporting period results from the conversion of convertible notes issued in 2019 (see details in section (7) Bonds). Registration in the

Commercial Register took place after the balance sheet date on 27 February 2020.

By virtue of a resolution adopted by the Annual General Meeting on 22 May 2019, the Management Board was authorized to increase the share capital on or prior to 21 May 2024, with the consent of the Supervisory Board, on one or more occasions, by up to EUR 31,929,071.00 in total by issuing up to 31,929,071 new no-par value bearer shares in return for

cash contributions or contributions in kind (Authorized Capital 2019). Furthermore, the Management Board was authorized to use up to EUR 6,385,814.00 of the Authorized Capital 2019 to issue new shares for cash by excluding pre-emptive rights. The still available Authorized Capital 2018 in the amount of EUR 27,960,023.00 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. Conditional Capital 2018 I in the amount of EUR 26,200,000.00 was revoked. Conditional Capital 2019 was utilized in an amount of EUR 407,443.00 by conversion of convertible notes issued under exclusion of pre-emptive rights in the reporting period and amounts to EUR 25,792,557.00 as of 31 December 2019. Conditional Capital 2019 can be used under exclusion of pre-emptive rights in an amount of EUR 5,978,371.00 as of 31 December 2019. Accordingly, Authorized Capital 2019 can be used under exclusion of pre-emptive rights in an amount of EUR 5,978,371.00 as of 31 December 2019 as well.

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, 205,250 stock options were issued to former Management Board members and current and former employees of the PAION Group as of 31 December 2019. To date, 479,142 stock options from the Stock Option Plan 2008 have been exercised. As of 31 December 2019, 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, 696,626 stock options were issued to current and former Management Board members and employees of the PAION Group as of 31 December 2019. No stock options have been exercised yet.

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 2019. 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, 610,772 stock options were issued to former

and current Management Board members and employees of the PAION Group as of 31 December 2019. 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, 248,720 stock options were issued to employees of the PAION Group as of 31 December 2019. No stock options have been exercised yet.

The capital reserve amounts to EUR 149,688,030.46 as of 31 December 2019 and has increased by EUR 392,557.00 in the reporting period. This amount entirely relates to the premium from capital increases in the course of the conversion of convertible notes issued in the reporting period.

(6) Accruals

The accruals break down as follows:

	31 Dec. 2019 EUR	31 Dec. 2018 EUR
Bonuses	164,958.33	302,350.00
Legal advice	108,815.00	26,491.00
Outstanding invoices	84,443.44	95,362.23
Financial statements and audit	76,531.00	74,194.53
Others	46,790.50	47,299.62
	481,538.27	545,697.38

(7) Bonds

Convertible notes with a nominal amount of KEUR 5,000 and a term of 15 months were issued to an institutional investor under exclusion of pre-emptive rights with an issue amount

of KEUR 4,750 on 12 September 2019. The issued convertible notes grant the right of conversion into a variable number of shares dependent on the share price of PAION AG. The minimum conversion price is EUR 1.91 per share. The convertible notes do not include a coupon. Until 31 December 2019, convertible notes with a nominal amount of KEUR 800 were converted into a total of 407,443 shares of PAION AG. As of 31 December 2019, the nominal amount of remaining convertible notes amounts of KEUR 4,200. The remaining term is less than 12 months as of the balance sheet date.

(8) Liabilities to affiliated companies

The liabilities to affiliated companies refer completely to PAION Deutschland GmbH as a result of VAT affiliation. The liabilities to affiliated companies have a term of less than 12 months.

(9) Revenues

Revenues resulted entirely from the provision of management and other services to the subsidiaries, of which PAION UK Ltd accounted for KEUR 1,217 (previous year: KEUR 895) and PAION Deutschland GmbH for KEUR 142 (previous year: KEUR 131).

(10) Other operating income

Other operating income includes recharges to the subsidiaries amounting to KEUR 155 (previous year: KEUR 145), of which PAION Deutschland GmbH accounted for KEUR 79 (previous year: KEUR 75) and PAION UK Ltd for KEUR 76 (previous year: KEUR 70). Exchange rate gains were recognized in an amount of KEUR 51 (previous year: KEUR 86).

(II) Other operating expenses

Other operating expenses mainly include legal and consulting fees (KEUR 1,116; previous year: KEUR 763), insurance, contributions and fees (KEUR 221; previous year: KEUR 233), expenses in connection with Supervisory Board remuneration (KEUR 162; previous year: KEUR 162), services

rendered by PAION Deutschland GmbH (KEUR 158; previous year: KEUR 150), travel expenses (KEUR 150; previous year: KEUR 161), expenses for IT hosting (KEUR 111; previous year: KEUR 104) as well as audit costs and costs for the annual report (KEUR 70; previous year: KEUR 64). In the reporting period, foreign exchange losses in the amount of KEUR 21 (previous year: KEUR 68) have been recognized. Moreover, other operating expenses include a fee amounting to KEUR 150 in connection with the issue of convertible notes (see section (7) Bonds). The increase of other operating expenses in comparison to the previous year mainly results from higher expenses for legal and consulting fees particularly in connection with the conclusion of a financing agreement with the European Investment Bank that has not been utilized yet as well as the issue of the convertible notes.

(12) Other interest and similar expenses

Other interest and similar expenses include expenses amounting to KEUR 60 from the pro-rated release of the discount recognized on the balance sheet in connection with the issue of convertible notes as well as negative interest on bank deposits in an amount of KEUR 6.

(13) Income attributable to other periods

In fiscal year 2019, income that is attributable to other periods amounts to KEUR 57 and results from the reimbursement of contributions in an amount of KEUR 44 and from the reversal of accruals in an amount of KEUR 13.

(14) Taxes

As of 31 December 2019, the company's tax losses carried forward relating to corporate income tax amounted to about EUR 34.5 million (previous year: EUR 32.5 million) and relating to trade tax to about EUR 33.2 million (previous year: EUR 31.3 million). Based on the 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 combined German 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%.

If the current compound income tax rate was applied to the tax losses carried forward as of 31 December 2019, the resulting deferred tax assets would amount to KEUR 10,977 (previous year: KEUR 10,351).

Temporary differences between the tax base and the HGB carrying amount do not exist as of 31 December 2019 and did not exist as of the previous year's reporting date.

Other compulsory disclosures

(1) Average number of employees

In fiscal year 2019, the company had an average of eight employees (previous year: seven employees).

(2) Other financial obligations

The loan facility granted to the subsidiary PAION UK Ltd of up to KEUR 40,000 as of the balance sheet date will be granted until further notice. As of 31 December 2019, the utilization amounts to KEUR 23,142.

(3) 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. 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. Details of the individual plans can be found in the following table:

	Stock Option Plan 2008 Approved 5 May 2008	Stock Option Plan 2010 Approved 19 May 2010
Underlying Capital	Conditional Capital 2008 I	Conditional Capital 2010 I
Term of the options	10 years	10 years
Vesting period	2–4 years	2 years
Waiting period	2–4 years	4 years
Number of outstanding options for which the waiting period has expired as of 31 December 2019	205,250	696,626
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 1.84 to EUR 2.69	EUR 2.01
Weighted average exercise price *	EUR 1.89	EUR 2.01
Exercise hurdle as of 31 Dec. 2019 *	EUR 2.75 to EUR 4.01	EUR 2.60
Weighted average remaining term as of 31 Dec. 2019	0.4 years	4.1 years
Further grants possible? (as of 31 Dec. 2019)	No	No
Number of totally granted options until 31 Dec. 2019	817,550	720,000
Number of outstanding options as of 31 Dec. 2019 **	205,250	696,626
granted to employees	91,000	392,876
granted to Management Board members	114,250	303,750
Number of totally lapsed options as of 31 Dec. 2019	133,158	23,374
thereof lapsed in the reporting period	0	0
Number of totally exercised options until 31 Dec. 2019	479,142	0
thereof exercised in the reporting period	0	0
<p>*) in relation to outstanding options as of 31 Dec. 2019 **) in relation to employee/Management Board member status at the time of the grant</p>		

Stock Option Plan 2014
Approved 21 May 2014

Stock Option Plan 2016
Approved 25 May 2016

Stock Option Plan 2018
Approved 25 May 2018

Conditional Capital 2014	Conditional Capital 2016	Conditional Capital 2018 II
10 years	10 years	10 years
2–4 years	2–4 years	2–4 years
4 years	4 years	4 years
257,385	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	Cumulative stock price increase of 5% per year since grant in relation to exercise price
EUR 1.99 to EUR 2.60	EUR 2.25 to EUR 2.60	EUR 2.31
EUR 2.21	EUR 2.34	EUR 2.31
EUR 2.34 to EUR 2.96	EUR 2.42 to EUR 2.85	EUR 2.33
6.0 years	8.2 years	9.8 years
No	Yes	Yes
740,000	706,500	248,720
530,010	610,772	248,720
231,697	395,438	248,720
298,313	215,334	0
209,990	95,728	0
3,875	90,413	0
0	0	0
0	0	0

(4) Management Board and Supervisory Board

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

- Dr. James Phillips, CEO, Chairman (since 16 October 2019)
Other supervisory board memberships or similar positions:
 - Herantis Pharma plc, Espoo/Finland, Member of the Board of Directors
- Abdelghani Omari, CFO
- Dr. Jürgen Beck, CDO
- Dr. Wolfgang Söhngen, CEO, Chairman (Chairman until 15 October 2019, Member of the Management Board until 22 November 2019)

Management Board remuneration totalled KEUR 956 in fiscal year 2019. As of 31 December 2019, a total of 391,000 stock options (fair value at time of granting: EUR 491,925) had been issued to active Management Board members as of 31 December 2019. For more information on Management Board remuneration, please see the disclosures in the remuneration report, which is part of the management report.

All Management Board members are also Managing Directors of PAION Deutschland GmbH and PAION Holdings UK Ltd and its subsidiaries. Dr. Jürgen Beck and Mr. Abdelghani Omari are also Managing Directors of the subsidiary PAION Netherlands B.V., which was founded in the reporting period. All Management Board members work full-time for the company and its subsidiaries.

As of 31 December 2019, Dr. Jürgen Beck owned 0.02% (10,000 voting rights) of the shares in PAION AG.

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
Other supervisory board memberships or similar positions:
 - Dr. Loges + Co. GmbH, Winsen (Luhe)/Germany, Chairman of the Board

- 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
Other supervisory board memberships or similar positions:
 - Gerresheimer AG, Dusseldorf/Germany, Member of the Supervisory Board
 - Almirall S.A., Barcelona/Spain, Member of the Board of Directors
 - Triton Beteiligungsberatung GmbH, Frankfurt/Germany, Member of the Triton Industry Board
 - Kerry Group plc, Tralee/Ireland, Non-executive director
 - Humedics GmbH, Berlin/Germany, Chairman of the Board (until 15 November 2019)
 - Julius Clinical Research BV, Zeist/The Netherlands, Member of the Supervisory Board
- John Dawson (until 22 May 2019), Fetcham/England, Chairman of the Audit Committee; CEO of Oxford BioMedica plc, Oxford/England
- Dr. Dr. Irina Antonijevic, Boston, MA/U.S., Chairman of the Research and Development Committee; Senior Vice President Development at Triplet Therapeutics, Inc., Cambridge, MA/U.S.
Other supervisory board memberships or similar positions:
 - 4SC AG, Planegg-Martinsried (Munich)/Germany, Member of the Supervisory Board
- Dr. Hans Christoph Tanner, Zurich/Switzerland, Chairman of the Audit Committee, Head of Transactions of Cosmo Pharmaceuticals N.V., Amsterdam/The Netherlands, Chief Financial Officer & Head of Investor Relations of Cassiopea SpA, Milan/Italy
Other supervisory board memberships or similar positions:
 - Cosmo Pharmaceuticals N.V., Amsterdam/The Netherlands, Member of the Board of Directors
 - DKSH Holding AG, Zurich/Switzerland, Member of the Board of Directors and Chairman of the Audit Committee
 - CureVac AG, Tübingen/Germany, Member of the Supervisory Board and Chairman of the Audit Committee

- Joimax GmbH, Karlsruhe/Germany, Member of the Advisory Board
 - Qvanteq AG, Zurich/Switzerland, Member of the Board of Directors
 - Wyss Zurich (ETH Zürich), Zurich/Switzerland, Member of the Evaluation Board
- Dr. Markus Leyck Dieken (since 22 May 2019), 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 162 in fiscal year 2019. For more information on Supervisory Board remuneration, please see the disclosures in the remuneration report of the management report.

As of 31 December 2019, none of the members of the Supervisory Board owned shares in PAION AG.

(5) Shareholdings

The company owns the following direct and indirect shareholdings:

	Shares in in %	Currency	Equity as of 31 Dec. 2019 *	Result 2019 *
PAION Deutschland GmbH, Aachen	100	EUR	1,808,439.27	238,659.38
PAION Holdings UK Ltd, Cambridge/UK	100	GBP	75,966,442.40	-801.56
PAION UK Ltd, Cambridge/UK	100	GBP	-20,757,049.89	-3,074,708.26
TheraSci Limited, Cambridge/UK	100	GBP	0.00	0.00
PAION Netherlands B.V., Heerlen/Netherlands	100	EUR	-377,030.82	-387,030.82
*) Reporting according to local reporting standards				

(6) Reportable equity investments in PAION AG pursuant to section 33 WpHG

The following notifications in respect of reportable equity investments pursuant to Section 33 (1) and (2) WpHG, which were published in accordance with the stipulations of Section 40 (1) WpHG, are relevant for assessing which shareholders held more than 3% of the shares as of 31 December 2019:

- On July 10, 2014, the College Retirement Equities Fund, New York, New York, USA has informed us according to Article 21, Section 1 of the WpHG that its voting rights in PAION AG, Aachen, Germany, have exceeded the 3% threshold of the voting rights on June 23, 2014 and on that day amounted to 3.001% (this corresponds to 925,543 voting rights).

On July 10, 2014, TIAA-CREF Investment Management, LLC, New York, New York, USA has informed us according to Article 21, Section 1 of the WpHG that its voting rights in PAION AG, Aachen, Germany have exceeded the 3% threshold of the voting rights on June 23, 2014 and on that day amounted to 3.001% (this corresponds to 925,543 voting rights). According to Article 22, Section 1, Sentence 1, No. 6 of the WpHG, 3.001% of the voting rights (this corresponds to 925,543 voting rights) are to be attributed to TIAA-CREF Investment Management, LLC from the College Retirement Equities Fund.

• **1. Details of issuer**

PAION AG
 Martinstr. 10-12
 52062 Aachen
 Germany

2. Reason for notification

X Acquisition/disposal of shares with voting rights
 Acquisition/disposal of instruments
 Change of breakdown of voting rights
 Other reason:

3. Details of person subject to the notification obligation

Name: Cosmo Pharmaceuticals N.V. City and country of registered office: Amsterdam, Netherlands

4. Names of shareholder(s)

holding directly 3% or more voting rights, if different from 3.
 Granell Strategic Investment Fund Limited

5. Date on which threshold was crossed or reached

29 Jun 2016

6. Total positions

	% of voting rights attached to shares (total of 7.a.)	% of voting rights through instruments (total of 7.b.1 + 7.b.2)	total of both in % (7.a. + 7.b.)	total number of voting rights of issuer
Resulting situation	9.09 %	0 %	9.09 %	55736594
Previous notification	n/a %	n/a %	n/a %	/

7. Notified details of the resulting situation

a. Voting rights attached to shares (Sec.s 21, 22 WpHG)

ISIN	absolute	in %		
	direct (Sec. 21 WpHG)	indirect (Sec. 22 WpHG)	direct (Sec. 21 WpHG)	indirect (Sec. 22 WpHG)
DE000A0B65S3		5064194	%	9.09 %
Total	5064194	9.09 %		

b.1. Instruments according to Sec. 25 para. 1 No. 1 WpHG

Type of instrument	Expiration or maturity date	Exercise or conversion period	Voting rights absolute	Voting rights in %
				%
		Total		%

b.2. Instruments according to Sec. 25 para. 1 No. 2 WpHG

Type of instrument	Expiration or maturity date	Exercise or conversion period	Cash or physical settlement	Voting rights absolute	Voting rights in %
					%
			Total		%

8. Information in relation to the person subject to the notification obligation

Person subject to the notification obligation is not controlled and does itself not control any other undertaking(s) holding directly or indirectly an interest in the (underlying) issuer (1.).

X Full chain of controlled undertakings starting with the ultimate controlling natural person or legal entity:

Name	% of voting rights (if at least held 3% or more)	% of voting rights through instruments (if at least held 5% or more)	Total of both (if at least held 5% or more)
Cosmo Pharmaceuticals N.V.	%	%	%
Granell Strategic Investment Fund Limited	9.09 %	0 %	9.09 %

9. In case of proxy voting according to Sec. 22 para. 3 WpHG

Date of general meeting:

Holding position after general meeting: % (equals voting rights)

According to the notifications we have received pursuant to Section 33 WpHG, the following companies or individuals held shares of more than 3% in the voting rights of PAION AG as of 31 December 2019:

- College Retirement Equities Fund (TIAA-CREF)
- Cosmo Pharmaceuticals N.V. (via Granell Strategic Investment Fund Limited)

(7) Financial statements auditor

The fees of the financial statements auditor for fiscal year 2019 are disclosed in the consolidated financial statements of PAION AG.

(8) 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 2019, the Supervisory Board and the Management Board issued the declaration of compliance with the Corporate Governance Code pursuant to Section 161 AktG. The company complies with all recommendations set forth in the version of the German Corporate Governance Code dated 7 February 2017 applicable at the time. This declaration of compliance is published on PAION AG's website (<http://www.paion.com/media-and-investors/corporate-governance/declaration-of-conformity/>).

(9) Report on post-balance sheet date events

On 08 January 2020, the subsidiary PAION UK Ltd and licensee Hana Pharm extended the existing remimazolam license agreement for South Korea to include six additional countries in Southeast Asia.

On 23 January 2020, Mundipharma, licensee of the subsidiary PAION UK Ltd, received market approval for remimazolam in general anesthesia in Japan.

On 12 March 2020, Cosmo Pharmaceuticals, licensee of the subsidiary PAION UK Ltd, announced the postponement of the target date for completion of the review (PDUFA date) of the NDA for remimazolam by the FDA by up to three months from 05 April 2020 to 05 July 2020.

There were no further significant events in the period between the reporting date, 31 December 2019, and the preparation of this report.

Aachen, Germany, 25 March 2020

PAION AG



Dr. James Phillips Abdelghani Omar



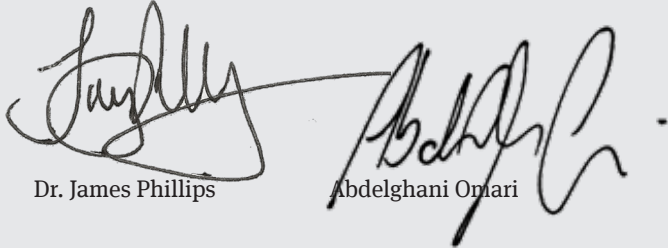
Dr. Jürgen Beck

Responsibility Statement (Bilanzaid) in accordance with section 114(1) and (2) of the Wertpapierhandelsgesetz (WpHG – German Securities Trading Act) in conjunction with sections 264(2) sentence 3 and 289(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 financial statements give a true and fair view of the assets, liabilities, financial position and profit or loss of PAION AG, and the management report includes a fair review of the development and performance of the business and the position of PAION AG, together with a description of the principal opportunities and risks associated with the expected development of PAION AG.”

Aachen, Germany, 25 March 2020

PAION AG

Two handwritten signatures in black ink. The first signature is on the left, and the second is on the right. Both are written in a cursive style.

Dr. James Phillips

Abdelghani Omari

A handwritten signature in black ink, written in a cursive style.

Dr. Jürgen Beck

Reproduction of the auditor's report

“Independent auditor's report

To PAION AG,

Report on the audit of the annual financial statements and of the management report

Opinions

We have audited the annual financial statements of PAION AG, Aachen, which comprise the balance sheet as at 31 December 2019, and the income statement for the fiscal year from 1 January 2019 to 31 December 2019, and notes to the financial statements, including the recognition and measurement policies presented therein. In addition, we have audited the management report of PAION AG for the fiscal year from 1 January 2019 to 31 December 2019. In accordance with the German legal requirements, we have not audited the content of the statement on corporate governance that is part of the management report and was published on the website cited in the management report. Furthermore, we have not audited the content of subsection “Clinical development” of the section “Economic report” of the management report which relates to extraneous information. This relates to any information whose disclosure in the management report is not required pursuant to Secs. 315, 315a HGB or Secs. 315b to 315d HGB [“Handelsgesetzbuch”: German Commercial Code].

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

- the accompanying annual financial statements comply, in all material respects, with the requirements of German commercial law applicable to business corporations and give a true and fair view of the assets, liabilities and financial position of the Company as at 31 December 2019 and of its financial performance for the fiscal year from 1 January 2019 to 31 December 2019 in compliance with German legally required accounting principles, and
- the accompanying management report as a whole provides an appropriate view of the Company's position. In all material respects, this management report is consistent with the annual financial statements, complies with German

legal requirements and appropriately presents the opportunities and risks of future development. Our opinion on the management report does not cover the content of the statement on corporate governance referred to above or the subsection “Clinical development” in the section “Economic report” of the 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 annual financial statements and of the management report.

Basis for the opinions

We conducted our audit of the annual financial statements and of the 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). Our responsibilities under those requirements and principles are further described in the “Auditor's responsibilities for the audit of the annual financial statements and of the management report” section of our auditor's report. We are independent of the Company 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 annual financial statements and on the management report.

Key audit matters in the audit of the annual financial statements

Key audit matters are those matters that, in our professional judgement, were of most significance in our audit of the annual financial statements for the fiscal year from 1 January 2019 to 31 December 2019. These matters were addressed in the context of our audit of the annual 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. Valuation of equity investments and valuation of loans to affiliates

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

Because the lead compound remimazolam had not yet been approved until the balance sheet date, the subsidiary of PAION UK Holdings Ltd., PAION UK Ltd., recorded a net loss for the year. The financing of PAION UK Ltd. is provided indirectly via PAION AG. Due to the expectation of negative results in the future, a risk exists that the loans issued to PAION UK Ltd. and the carrying value of the equity investment in this company could be impaired and that such impairment could be permanent.

The Management Board performs an annual test of the impairment of loans issued to affiliates and of the carrying value of equity investments based on an annually updated development and marketing plan for remimazolam. Furthermore, the Management Board tests for impairment of the equity investments and loans to affiliates on an ad hoc basis whenever appropriate.

The inherent uncertainties concerning the estimation and discounting of future cash flows expected from royalties for remimazolam pose a significant risk to the presentation of a true and fair view of the assets, liabilities, financial position and financial performance of the Company. In light of this and the related use of judgement, the valuation of the equity investments and of the loans issued to affiliates was a key audit matter.

1.2 Auditor's response:

We assessed the Company's process for drawing up the development and marketing plan for remimazolam as well as the principles and completeness of the Company's discounted cash flow model with a view to its adequacy for the purposes of valuing the future cash flows of PAION UK Ltd. to PAION AG. In this connection, we discussed the significant planning assumptions with the Management Board, focusing on the assessment of the expected future cash flows in the medium-term plan as well as the discount rates and growth rates used. For this purpose, we analysed the assumptions underlying the impairment test to determine whether they are in line with industry-specific market expectations.

In order to assess the cash flows, we evaluated the reliability of the planning process in the past. For this purpose, we compared the past assumptions concerning future cash flows with the actual figures. Additionally, we examined the forecast figures for future cash flows using information about the pharmaceutical market for agents for short-term sedation as well as publicly accessible information about the future industry development with the aim of determining whether they are in line with market expectations and our expectations.

With regard to the discount rate, we compared the assumptions made by the Company with data from external sources (such as bond yields and inflation rates). Another audit procedure that we performed to examine and scrutinise the recoverable amounts for remimazolam was a sensitivity analysis of the significant assumptions in order to assess any potential impairment risk in the event of a change in valuation assumptions. Furthermore, we compared the discounted present value of the future cash flows with the Group's market capitalisation.

Our audit procedures did not lead to any reservations regarding the valuation of the equity investments in and loans to affiliates.

1.3 Reference to related disclosures

With regard to the accounting bases applied to the equity investments and the valuation of loans to affiliates, refer to section

Accounting and valuation methods (note 2) and to section Notes to the items of the balance sheet and the income statement, (1) Financial assets in the notes to the Company's financial statements.

Other information

The executive directors are responsible for the other information. The other information comprises the statement on corporate governance referred to above and the subsection "Clinical development" in the section "Economic report" of the management report referred to above.

Our opinions on the annual financial statements and on the 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 annual financial statements, with the 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 annual financial statements and the management report

The executive directors are responsible for the preparation of the annual financial statements that comply, in all material respects, with the requirements of German commercial law applicable to business corporations, and that the annual financial statements give a true and fair view of the assets, liabilities, financial position and financial performance of the Company in compliance with German legally required accounting principles. In addition, the executive directors are responsible for such internal control as they, in accordance with German legally required accounting principles, have determined necessary to enable the preparation of annual financial statements that are free from material misstatement, whether due to fraud or error.

In preparing the annual financial statements, the executive directors are responsible for assessing the Company'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, provided no actual or legal circumstances conflict therewith.

Furthermore, the executive directors are responsible for the preparation of the management report that, as a whole, provides an appropriate view of the Company's position and is, in all material respects, consistent with the annual 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 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 management report.

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

Auditor's responsibilities for the audit of the annual financial statements and of the management report

Our objectives are to obtain reasonable assurance about whether the annual financial statements as a whole are free from material misstatement, whether due to fraud or error, and whether the management report as a whole provides an appropriate view of the Company's position and, in all material respects, is consistent with the annual 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 annual financial statements and on the 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) 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 annual financial statements and this 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 annual financial statements and of the 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 annual financial statements and of arrangements and measures (systems) relevant to the audit of the 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 of the Company.
- 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 Company'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 annual financial statements and in the 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 Company to cease to be able to continue as a going concern.

- Evaluate the overall presentation, structure and content of the annual financial statements, including the disclosures, and whether the annual financial statements present the underlying transactions and events in a manner that the annual financial statements give a true and fair view of the assets, liabilities, financial position and financial performance of the Company in compliance with German legally required accounting principles.
- Evaluate the consistency of the management report with the annual financial statements, its conformity with [German] law, and the view of the Company's position it provides.
- Perform audit procedures on the prospective information presented by the executive directors in the 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 annual 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

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

We were elected as auditor by the Annual General Meeting on 22 May 2019. We were engaged by the Supervisory Board on 22 May 2019. We have been the auditor of PAION AG 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, 25 March 2020

Ernst & Young GmbH
Wirtschaftsprüfungsgesellschaft

Zwirner
Wirtschaftsprüfer
[German Public Auditor]

Conrad
Wirtschaftsprüfer
[German Public Auditor]

PAION AG

Martinstrasse 10-12

52062 Aachen Germany

Phone +49 241 4453-0

Fax +49 241 4453-100

info@paion.com www.paion.com