

PAION AG, Aachen

Annual Financial Report

for the Fiscal Year 2016



PAION AG, Aachen

Consolidated Financial Statements

as of 31 December 2016 and

Group Management Report

for the Fiscal Year 2016

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Group management report for fiscal year 2016

Fundamental information of PAION AG and the PAION Group

I. Business model of PAION AG and PAION Group

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. The product candidates M6G and GGF2 are not in active development and therefore no significant value drivers in the portfolio of PAION group. M6G is licensed to Yichang Humanwell for the Chinese market. GGF2 is being developed by Acorda Therapeutics, Inc. (Acorda).

For remimazolam which currently is in clinical Phase III development, PAION has license partners in the U.S., China, South Korea, Canada, Russia/CIS, Turkey and the MENA region.

Fiscal year 2016 was marked by the concentration of PAION on the further development of remimazolam, in particular the U.S. Phase III development, as well as the conclusion of an exclusive license agreement for the development and commercialization of remimazolam in the U.S. with Cosmo Pharmaceuticals (Cosmo).

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 development activity both clinically and non-clinically and in terms of production technology is 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 an aimed approval 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.

Licensing activities aim at the subsequent commercialization of remimazolam by partners. The progress of these activities is being documented and discussed continuously. PAION has already signed several regional licensing agreements. The cooperation partners operate independently in their respective license territory. However, the cooperation agreements require the partners to exchange relevant information. Development in the U.S. is being conducted by PAION and will be handed over to U.S. license partner Cosmo after the development program agreed with the FDA including subsequent reports and necessary analyses has been completed. Cosmo will then be responsible for all further activities in the U.S.

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

3. Research and Development

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 with an increase of the gross domestic product of 1.9% in 2016 which was equally pushed by the manufacturing industry as well as the service sector. With an increase of 2.5% compared to the prior year, consumption in particular was an important driver of growth of the German economy, while investments also slightly increased by 0.8%.¹

Growth is expected to develop on a comparable level in 2017² and will primarily stem from private consumption. Although exports proved to be robust in spite of the Brexit vote and the U.S. presidential election outcome, international protective tendencies are likely to hit the export-oriented German economy prominently in the mid-term.³ Also, economic growth decreased in

¹ Federal Statistical Office: WISTA 1/2017 – Bruttoinlandsprodukt 2016.

² Commerzbank Research: Konjunktur und Finanzmärkte – Januar 2017.

³ German Institute for Economic Research: DIW Konjunkturbarometer Januar 2017: Deutsche Wirtschaft durchläuft kräftiges Winterhalbjahr, press release dated 31 January 2017.

the EU as well as the U.S. and other major economies; in the U.S. it dropped to 1.6% in 2016 after a growth of 2.6% in the prior year. After an estimated growth of 3.1% in 2016, the International Monetary Fund expects the world gross domestic product to grow by 3.4% in 2017 driven by developed economies as well as emerging markets and developing countries. The outlook for the growth of the world economy is curbed by internationally observable protective tendencies and geopolitical tensions.⁴

Stock markets in the U.S. and Germany showed a positive development in 2016. The Dow Jones increased by 13.4% in comparison to the prior year's end closing value, and the DAX increased by 6.9%. EUROSTOXX 50 on the other hand closed 2016 only with a slight increase of 0.7% in comparison to the prior year's end closing value.

b. Development of the pharmaceutical and biotechnology industry

In 2016, the pharmaceutical and biotechnology industry continued to be marked by increasing costs for pharmaceutical development, lower income from formerly high-selling products due to the expiry of patent protection during the last years and persisting price pressure on established drugs as well as new therapies.⁵ Development costs for new drugs increased by nearly 30% from 2010 to 2016 only.⁶ The resulting consolidation pressure has led to an increase of the worldwide transaction volume in the pharmaceutical industry by 14% compared to the prior year to USD 201 billion in 2016.⁷

The financing environment for the pharmaceutical and biotechnology industry was more difficult in 2016 than in prior years. In the U.S., the number of biotechnology IPOs decreased by over 50 % compared to the prior year and the average gross proceeds were lower than in 2015.⁸ In Europe, the financing volume also declined significantly with EUR 3.3 billion in 2016 compared to EUR 6.2 billion in the prior year.⁹ Investors obviously assess the potential of companies in need of financing significantly more critical than in the prior year, while particularly products generating value for patients as well as for payers promise most success.¹⁰ The increased hesitance especially in the U.S. is also reflected in the valuation of pharmaceutical companies. The NASDAQ Biotechnology Index showed a decline by 21.7% in 2016. In contrast, the DAXsubsector Biotechnology Index increased by a total of 7.6% in 2016 in comparison to the prior year's end closing value after an initial drop in the beginning of the year.

⁴ International Monetary Fund: World Economic Outlook Update, 16 January 2017.

⁵ Ernst & Young: EY M&A Outlook and Firepower Report 2017 – Will payer leverage and post-election optimism shift dealmaking into a higher gear?.

⁶ Deloitte: 2017 global life sciences outlook – Thriving in today's uncertain market.

⁷ Ernst & Young: Trübe Umsatzaussichten und anhaltender Preisdruck: Anstieg der Fusionen und Übernahmen in der Pharma-Branche erwartet, 24 January 2017.

⁸ Scrip Pharma Intelligence: US IPOs In Review: Relatively Muted Market In 2016 To Continue In 2017, 30 December 2016.

⁹ Börsen-Zeitung: Biotech-Unternehmen sammeln 500 Mill. Euro ein, No. 9 dated 13 January 2017.

¹⁰ Scrip Pharma Intelligence: J.P. Morgan Executive Roundtable, Part 3: Financing Is Difficult, But Available For Drugs That Provide Value, 26 January 2017.

It is expected that the significant competitive drivers and consolidation pressure will also persist in 2017. In particular, tax legislation changes announced by the new U.S. government could make significant amounts of funds available for U.S. companies by means of repatriation of income in the U.S. and could thus increase the acquisition and transaction volumes in the pharmaceutical industry worldwide.¹¹ The development of the financing environment especially in the U.S. will significantly depend upon the design of legislation amendments announced by the new U.S. administration in regard to the regulation of drug prices, the reversion of the Affordable Care Act as well as the reform of Medicare and the U.S. authority FDA.¹² Moreover, future monetary policy in the U.S. and the EU will influence the financing environment.

Altogether, in 2017 PAION expects the financing environment to improve over 2016 while investors will continue to be very selective in choosing their investments.

2. Presentation of the course of business and development activities

The development portfolio of PAION Group essentially comprises the lead compound 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 not metabolized by cytochrome-dependent hepatic pathways. Like other benzodiazepines, remimazolam can be reversed with flumazenil to rapidly terminate sedation and anesthesia if necessary.

In clinical studies, remimazolam demonstrated efficacy and safety in far over 1,000 patients. Data so far indicate that remimazolam has a rapid onset and offset of action combined with a favorable cardio-respiratory safety profile.

Remimazolam is currently in clinical Phase III development for procedural sedation in the U.S. After completion of the ongoing development, the implementation of a pediatric development plan already agreed with the FDA is planned. A full clinical development program for general anesthesia was completed in Japan, and a Phase II study in general anesthesia was completed in the EU. Based on the positive results of a Phase II study, development for ICU sedation beyond 24 hours is another attractive indication.

Procedural Sedation (U.S. lead indication)

Based on external sources (Symphony Health Solutions, Centers for Disease Control and Prevention) and own projections, PAION estimates that approximately 43 million procedures using procedural sedation took place in the U.S. in 2013, predominantly outside the hospital setting.

¹¹ Ernst & Young: EY M&A Outlook and Firepower Report 2017 – Will payer leverage and post-election optimism shift dealmaking into a higher gear?.

¹² PwC Health Research Institute: Top health industry issues of 2017 – A year of uncertainty and opportunity, December 2016; Scrip Pharma Intelligence: Expect Industry To Step Up Drug Pricing Self-Regulation In 2017 – PwC, 15 December 2016.

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 colorectal cancer screening using colonoscopy, and an increase in demand for preventive screenings. According to iData Research, which draws from an extensive collection of national- and state-level procedure databases to examine historical trends and create procedure forecasts in the U.S., 26.7 million colonoscopy and endoscopy claims were reported in 2015 in the U.S., and the number is expected to grow at an average rate of 2.6% annually through 2020. PAION estimates that 75% of the colonoscopies and endoscopies claimed were conducted in an out-patient setting due to the higher reimbursement fees compared to hospitals.

Regular endoscopic 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 cancer victims and payors. Statistics show that the rate at which people are diagnosed with colon cancer in the U.S. has dropped by 30% in the last 10 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 both men and women 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 lucrative market segment for remimazolam in procedural sedation with approximately 20 million procedures per year.

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. 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 cost. 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 will be placed on innovative medicines with strong clinical profile. Thus, PAION believes that concerns related to the overall cost of procedures, driven by the need for anesthesia professionals monitoring 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. 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 believes that remimazolam, subject to FDA approval with a safety labeling comparable to that of midazolam, could benefit from the pending changes in payment policies. Provided that it could be administered under the supervision of a proceduralist, remimazolam would be able to offer a competitive alternative to midazolam. This is based on its enhanced efficiency profile compared to midazolam.

General Anesthesia (Japan + EU lead indication)

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 ageing 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.

Another potential and attractive indication could be intensive care unit (ICU) sedation, which is currently not in focus for PAION. Another field of great clinical need is pediatric use, which is a development requirement for both the EU and U.S. after the respective first approval.

Clinical development

Plan to have tested remimazolam on more than 1,500 volunteers/patients at FDA filing	
Phase II and III studies	Phase I studies
Procedural Sedation (U.S.)	
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 (420)*	Phase I Abuse Liability
	• Intravenous administration (40)
	• Oral bioavailability (14)
	Phase I Abuse Liability*
	• Oral administration in combination with alcohol (approx. 50–60)
	• Intranasal administration part 1 (approx. 10–15)
	• Intranasal administration part 2 (approx. 10–15)
General Anesthesia (Japan)	
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 III in cardiac surgery patients (23)**	
ICU Sedation (Japan)	
Phase II in ICU patients (49)**	

Patient/volunteer numbers in brackets

*) Studies not yet completed

***) Discontinued studies, no safety concerns

Procedural sedation (Lead indication U.S.)

A total of six Phase I, two Phase II and two Phase III trials have been completed in procedural sedation. 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 being selected for use in the ongoing Phase III program.

In March 2015, the first U.S. Phase III study was started, the patient recruitment was completed in April 2016, and in June 2016, PAION announced that remimazolam met its primary efficacy endpoint. 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.

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.

Further data on the clinical results of remimazolam's U.S. Phase III colonoscopy trial were presented at the 2016 American College of Gastroenterology (ACG) Annual Scientific Meeting in Las Vegas in October 2016:

	Remimazolam	Placebo	Midazolam (Open Label)*
Success of procedure	91.3%	1.7%	25.2%
Use of rescue sedation	3.4%	95.0%	64.7%
Average fentanyl dose	88.6 mcg	121.3 mcg	106.9 mcg
Time from start of medication to start of procedure (median)	4.0 minutes	19.5 minutes	19.0 minutes
Time from end of procedure to fully alert (mean)	7.2 minutes	21.3 minutes	15.7 minutes
Time to back to normal	331 minutes	572 minutes	553 minutes

*) not part of label claim

Patient satisfaction was similar in all arms of the study.

In addition to the above study, the U.S. Phase III program includes a second confirmatory, prospective, double-blind placebo-controlled, randomized, multi-center open label vs. midazolam trial in 420 patients undergoing bronchoscopies. Patient recruitment was initially moderate.

However, continuous measures to accelerate patient recruitment, such as improvements in the feasibility of the study protocol, opening additional study centers and intensified support of existing study centers have significantly increased the recruitment rate and completion of patient recruitment is expected shortly.

As part of the U.S. development program, also a safety study in ASA III/IV patients undergoing colonoscopy (American Society of Anesthesiologists classification) was performed. In December 2016, successful completion of patient recruitment was announced, and headline data are planned to be presented shortly. This prospective, double-blind, randomized, placebo- and active controlled, multicenter, parallel group study enrolled 79 high-risk patients (i.e. ASA III/IV) undergoing a colonoscopy into a remimazolam, midazolam or placebo (including midazolam 'rescue' sedation) treatment group.

Four Phase I studies were performed in the course of the U.S. Phase III development program. Based on the results of preclinical and Phase I studies and in consultation with the FDA, PAION will now start additional Phase I studies to further assess the abuse potential of remimazolam. One aspect is if remimazolam could inappropriately be used as a knock-out cocktail in combination with alcohol and another aspect is if it could be abused intranasally.

General anesthesia (Lead indication in Japan + EU)

A total of three Phase I (Japan), two Phase II (Japan and EU) and two Phase III (Japan) trials in general anesthesia have been completed. In the clinical program, specific attention was paid to hemodynamic stability, which addresses a current need in general anesthesia. Preclinical data had suggested that remimazolam may lead to a hemodynamic stability; this has been clinically confirmed.

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.

Based upon the successful completion of Phase III in Japan, a pre-NDA meeting (NDA = New Drug Application) with the Japanese Pharmaceuticals and Medical Devices Agency ("PMDA") took place in January 2016. During the meeting, all open questions raised for discussion following the preliminary assessment of the PMDA were clarified. The PMDA stated that the non-clinical and clinical data package were regarded as complete for filing in the indication "Induction and maintenance of general anesthesia". The clinical development program fully carried out in Japan by PAION's former partner Ono in general anesthesia was complemented by PAION's growing data sets in all aspects from CMC (chemistry, manufacturing, control) to clinical and pre-clinical data generated outside of Japan. In October 2015, PAION already reported that the PMDA had confirmed

that both the raw materials produced by PAION in Europe as well as the finished formulation of remimazolam fulfill the requirements for filing in Japan. PAION now plans the preparation and submission of an application for market approval of remimazolam in Japan. This includes, among other things, the necessary validation of commercial-scale production for the Japanese market. The required approval dossier will be prepared by an experienced contract research organization (CRO) in close consultation with PAION. Such a dossier could serve as a reference dossier in certain other markets. This would significantly reduce the necessary additional investment for partners in the respective markets depending on the specific regulatory environment.

In order to allow using the Japanese data for filing in the EU, the same induction and maintenance doses were used in the European Phase II trial performed in 2014, delivering further evidence for a potentially beneficial hemodynamic profile of remimazolam.

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.

In the meantime, PAION evaluated how to resume the clinical development of remimazolam in the EU. Based on the findings, PAION considers a study design analogous to the successfully completed Phase III program in general anesthesia in Japan to be useful. Such a Phase III study would thus be conducted with procedures in general surgery. Therefore and based on consultation with key opinion leaders in general anesthesia, a Phase I study is currently being prepared aiming at determining required patient numbers for the new Phase III study with a different patient population as precisely as possible. In this Phase I study it is planned to measure the depth of sedation of remimazolam particularly accurately on the basis of the subjects' brain activity, since sedation depth needs to be measured objectively in addition to the subjective measurement by an anesthetist as an approval prerequisite in the EU. In particular, it is supposed to be demonstrated that patients are sufficiently narcotized during the surgery compared to the reference medication.

For a Phase III program in the EU, PAION currently expects funding needs of approx. EUR 20 million to EUR 25 million until filing for market approval subject to further coordination with the regulatory authority. Secured funding, the conduct of the preparatory Phase I study and the necessary scientific consultations with the relevant European regulatory authority EMA to specify the new European Phase III program are a prerequisite for a study start in 2018.

ICU sedation

PAION's former partner in Japan, Ono, independently initiated a Phase II trial for sedation in intensive care units (ICUs). Higher than expected plasma concentrations of remimazolam were observed in isolated cases after long-term treatment 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 the patient presenting on the ICU. Further development of the program "ICU sedation" is part of the future remimazolam development plan which could be addressed after availability of required funds.

Partnering

Remimazolam is partnered in the U.S., Canada, China, Russia (CIS), Turkey, the MENA region, and South Korea with Cosmo, Pharmascience (Pendopharm), Yichang Humanwell, R-Pharm, TR-Pharm, and Hana Pharm, respectively. For all other markets, remimazolam is available for licensing.

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 m	EUR 4 m	10%
Hana Pharm, S. Korea (2013)	EUR 1 m	EUR 2 m	10%
R-Pharm, CIS (2013)	EUR 1 m	EUR 3 m	Low double-digit
(T)R-Pharm, Turkey (2013)	EUR 1 m	EUR 3 m	Low double-digit
(T)R-Pharm, MENA (2014)	EUR 1.5 m	EUR 5.5 m	Low double-digit
Pendopharm, Canada (2014)	EUR 0.4 m*	~ EUR 4.0 m	Tiered (starting at 15%)
Cosmo, U.S. (2016)	EUR 20 m**	EUR 42.5 m	20–25%***
Total	EUR 33.8 m	~ EUR 64 m	

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

**) Comprising EUR 10 million received via private placement in June 2016 and via capital increase with subscription rights conducted in February 2017 as well as the received upfront payment in the amount of EUR 10 million.

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

In June 2016, PAION entered into an investment and a license agreement with Cosmo. In the course of the investment agreement, Cosmo has committed to invest an amount of EUR 10 million in PAION shares. Cosmo invested an amount of EUR 9.6 million in the course of a capital increase under exclusion of shareholders' subscription rights ("private placement") in June 2016 and the remaining EUR 0.4 million in the course of a capital increase with subscription rights in February 2017.

In the course of the license agreement, Cosmo has received an exclusive license for the development and commercialization of remimazolam in the U.S and is responsible for the market authorization as well as sales and distribution of remimazolam. PAION remains responsible for and bears the cost associated with the completion of the ongoing U.S. clinical development program in procedural sedation. In addition to an upfront payment in the amount of EUR 10 million already received, PAION in return is entitled to receive further payments of up to EUR 42.5 million depending on the achievement of certain regulatory milestones in total for all of the three indications in the U.S., as well as tiered royalties upon commercialization ranging from 20% to 25% of the net sales (which may be adjusted under certain conditions but not to below 15%). EUR 4.3 million of the received upfront payment were recognized as revenues in the reporting period, and EUR 5.7 million will presumably be recognized as revenues in fiscal year 2017.

PAION has selectively formed, and seeks to enter into, development and marketing collaborations with partners with local expertise or with a specific therapeutic focus with respect to remimazolam. Such collaborations are an effective way of funding and advancing remimazolam's late-stage development and of assisting PAION with its commercialization in international markets where PAION does not intend to directly conduct sales and marketing activities. PAION expects that the existing collaboration partners will continue the development of remimazolam on the basis of data generated from our U.S., Japanese and European clinical development programs, and subsequently PAION may receive additional data and payments under the existing agreements in the medium to long term. PAION's ultimate goal is to participate in the worldwide commercialization of remimazolam and is well positioned to also find further collaboration partners. 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.

3. Net assets, financial position and results of operations

a. Results of operations

	2016 KEUR	2015 KEUR	Change in result KEUR
Revenues	4,262	72	4,190
Cost of revenues	0	-11	11
Gross profit	4,262	61	4,201
Research and development	-23,408	-29,385	5,977
General administrative and selling	-5,129	-5,729	600
Other income (expenses)	-807	965	-1,772
Operating expenses	-29,344	-34,149	4,805
Operating result	-25,082	-34,088	9,006
Financial result	21	42	-21
Income taxes	4,943	5,834	-891
Net result	-20,118	-28,212	8,094

Revenues of KEUR 4,262 recognized in the reporting period resulted from the upfront payment of EUR 10 million received from Cosmo in the course of the license agreement concluded in 2016 in the amount of KEUR 4,251 and increased by KEUR 4,190 compared to the previous year. Revenue recognition of the received upfront payment is dependent on the progress of certain development components.

Research and development costs amounted to KEUR 23,408 and particularly resulted from the U.S. Phase III development program in procedural sedation. The decrease of KEUR 5,977 compared to the prior year is mainly attributable to lower expenses for Phase I studies, production development and preparations of the market approval dossier in the course of the U.S. development program, while expenses for Phase III development have increased compared to the previous year in particular as a result of successful acceleration measures and corresponding progress of the U.S. bronchoscopy study.

General administrative and selling costs amounted to KEUR 5,129 and decreased by KEUR 600 compared to the previous year. Administrative costs increased by KEUR 352 to KEUR 3,813 while selling costs decreased by KEUR 952 to KEUR 1,316. The increase of administrative costs mainly results from the preparation of potential capital measures, which were ultimately not conducted in light of the agreements entered into with Cosmo. Selling costs mainly comprise costs related to the initiation and preparation of license agreements in the reporting period, while higher selling costs in the previous year primarily resulted from market research, pre-marketing and market access activities.

The **other income (expenses)** in the fiscal year mainly comprises foreign exchange losses (KEUR 1,064; previous year: foreign exchange gains of KEUR 907).

The **financial result** amounted to KEUR 21, a decrease of KEUR 21 compared to the previous year. This is mainly due to lower interest on sight and short-term deposits.

Income taxes of the fiscal year essentially relate to tax claims for reimbursement of parts of the research and development costs from the British tax authorities. The change in comparison to the prior year is mainly associated with the decrease of the development costs for remimazolam.

PAION closes fiscal year 2016 with a **net loss** of KEUR 20,118 after a net loss of KEUR 28,212 in the previous year.

b. Net Assets

	31 Dec. 2016 KEUR	31 Dec. 2015 KEUR	Change KEUR
Non-current assets	2,855	3,417	-562
Current assets	35,128	40,051	-4,923
Assets	37,983	43,468	-5,485
Equity	24,943	35,562	-10,619
Non-current liabilities	0	6	-6
Current liabilities	13,040	7,900	5,140
Equity and liabilities	37,983	43,468	-5,485

The **non-current assets** mainly comprise the book value of the development project remimazolam (KEUR 2,626; 31 December 2015: KEUR 3,347) resulting from the value allocated per purchase price allocation in the course of the CeNeS acquisition in 2008 reduced by scheduled amortization.

Compared to 31 December 2015, **current assets** decreased by KEUR 4,923 to KEUR 35,128 and comprised cash and cash equivalents as well as prepaid expenses and other assets as of 31 December 2016. Cash and cash equivalents decreased by KEUR 2,569 in the reporting period from KEUR 32,680 as of 31 December 2015 to KEUR 30,111 as of 31 December 2016. Prepaid expenses and other assets decreased from KEUR 7,371 as of prior year's balance sheet date by KEUR 2,354 to KEUR 5,017 per year-end. The decrease is substantially due to a by KEUR 1,118 lower tax claim for reimbursement of parts of the research and development costs from the British tax authorities as compared to 31 December 2015 amounting to KEUR 4,737 per year-end, as well as lower prepayments for development services compared to prior year's balance sheet date.

The decrease in **equity** by KEUR 10,619 compared to 31 December 2015 mainly results from the net loss of the year and the private placement conducted with Cosmo in June 2016. The equity ratio amounts to 65.7% as of 31 December 2016 (31 December 2015: 81.8%).

The rise of **current liabilities** by KEUR 5,140 to KEUR 13,040 is mainly due to the increase of current deferred income from KEUR 39 as of prior year's balance sheet date to KEUR 5,774 as of 31 December 2016, which mainly comprises the portion of the upfront payment of KEUR 10,000 received from Cosmo in the reporting period that has not been recognized as revenue yet. Compared to 31 December 2015, trade payables decreased by KEUR 980 to KEUR 6,353 as of 31 December 2016.

c. Financial Position

Compared to 31 December 2015, **cash and cash equivalents** decreased by KEUR 2,569 to KEUR 30,111. The change in cash and cash equivalents stems from the following areas:

	2016 KEUR	2015 KEUR	Change KEUR
Cash flow from operating activities	-11,586	-26,287	14,701
Cash flow from investing activities	-192	-33	-159
Cash flow from financing activities	9,212	22	9,190
Effect of exchange rate changes	-3	66	-69
Change in cash and cash equivalents	-2,569	-26,232	23,663

The **cash flow from operating activities** primarily results from the net loss of the year in the amount of KEUR 20,118 and the upfront payment of KEUR 10,000 received from Cosmo.

The **cash flow from financing activities** results from the private placement conducted with Cosmo in June 2016 with gross proceeds of KEUR 9,643, cost of funds of KEUR 475 incurred in this regard and the exercise of stock options in the amount of KEUR 44.

d. Overall appraisal

The net loss of EUR 20.1 million is below the forecast range of EUR 24.5 million to EUR 27.5 million projected for fiscal year 2016 in the previous year. This is mainly due to the revenues recognized in connection with the cooperation entered into with Cosmo in June 2016 which had not been forecasted for 2016 in the previous year.

In the reporting period, revenues of EUR 4.3 million were recognized in connection with the concluded license agreement, which had not been planned in the forecast for fiscal year 2016. With EUR 23.4 million, research and development expenses were also slightly below the forecasted range of EUR 24 million to EUR 27 million for fiscal year 2016. This is in particular due to lower than planned expenses for production development and preparations for the market approval dossier in the course of the U.S. development program.

General administrative and selling expenses slightly exceeded the range of EUR 4.5 million to EUR 5 million anticipated for 2016 per prior year with EUR 5.1 million.

Tax income in the amount of EUR 4.9 million was above the forecast of EUR 4 million to EUR 4.5 million, as a higher proportion of the total research and development expenses than expected was subject to tax credits from the British tax authorities.

Under consideration of the upfront payment received and private placement conducted in the course of entering into the cooperation with Cosmo, net assets and the financial position have also evolved better than expected.

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

Headcount

As of 31 December 2016, the total headcount of the PAION Group was 34 employees. By comparison, the headcount as of 31 December 2015 was 35 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 2008 approved by the Annual General Meeting on 5 May 2008, a total of 391,650 stock options were granted to acting Management Board members at the time of the respective grant. The Supervisory Board determined the number of stock options to be allocated to the Management Board. The two- to 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 members of the Management Board is EUR 1.26 or EUR 1.84 per stock option depending on the grant date 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 2016, the exercise hurdle was EUR 1.78 or EUR 2.48 depending on the grant date.

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 2016, the exercise hurdle was EUR 2.30.

From the Stock Option Plan 2014 approved by the Annual General Meeting on 21 May 2014, a total of 277,500 stock options were granted to acting Management Board members at the time of the grant, thereof 111,000 in fiscal year 2016. The Supervisory Board determined the number of stock options to be allocated to the Management Board. The four-year waiting period before stock options can be exercised acts as a long-term incentive to increase the company's value. The exercise price of stock options granted to current Management Board members is EUR 1.99 or EUR 2.30 per stock option, depending on the date of issue of the stock options, and is based on the average price of the shares in a certain time period before the allocation in accordance with the terms of the stock option plan. As of 31 December 2016, the exercise hurdle was EUR 2.04 or EUR 2.52, 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 2016 (according to German Corporate Governance Code) can be gathered from the following tables:

Benefits granted in EUR	Dr. Wolfgang Söhngen CEO			
	2015	2016	2016 (Min)	2016 (Max)
Fixed compensation	262,500	275,000	275,000	275,000
Other remuneration	47,974	48,471	48,471	48,471
Total	310,474	323,471	323,471	323,471
One-year variable compensation	120,000	175,000	0	175,000
Multi-year variable compensation				
Stock Option Plan 2014 - Grant 2015 (Waiting period 2015 to 2019)**	62,715	0	-	-
Stock Option Plan 2014 - Grant 2016 (Waiting period 2016 to 2020)**	0	56,610	-	-
Total	493,189	555,081	323,471	498,471
Service cost	0	0	0	0
Total remuneration	493,189	555,081	323,471	498,471

*) Prior year remuneration for Dr. Raths relates to the time period since joining the Management Board
**) Applicable fair value at the time of issuance, calculated using the Black/Scholes option pricing model

Allocation in EUR	Dr. Wolfgang Söhngen CEO	
	2015	2016
Fixed compensation	262,500	275,000
Other remuneration	47,974	48,471
Total	310,474	323,471
One-year variable compensation	48,000	124,600
Multi-year variable compensation	0	0
Total	358,474	448,071
Service cost	0	0
Total remuneration	358,474	448,071

*) Prior year remuneration for Dr. Raths relates to the time period since joining the Management Board

	Abdelghani Omari CFO				Dr. Jürgen Raths* COO since 1 September 2015			
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	2015	2016	2016 (Min)	2016 (Max)	2015	2016	2016 (Min)	2016 (Max)
	150,000	165,000	165,000	165,000	105,000	315,000	315,000	315,000
	15,127	15,127	15,127	15,127	42	127	127	127
	165,127	180,127	180,127	180,127	105,042	315,127	315,127	315,127
	60,000	70,000	0	70,000	0	50,000	0	50,000
	62,715	0	-	-	0	0	-	-
	0	56,610	-	-	0	0	-	-
	287,842	306,737	180,127	250,127	105,042	365,127	315,127	365,127
	0	0	0	0	0	0	0	0
	287,842	306,737	180,127	250,127	105,042	365,127	315,127	365,127

	Abdelghani Omari CFO		Dr. Jürgen Raths* COO since 1 September 2015	
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	2015	2016	2015	2016
	150,000	165,000	105,000	315,000
	15,127	15,127	42	127
	165,127	180,127	105,042	315,127
	24,000	53,690	0	41,100
	0	0	0	0
	189,127	233,817	105,042	356,227
	0	0	0	0
	189,127	233,817	105,042	356,227

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

Management Board remuneration in fiscal year 2016 amounted to KEUR 1,151 in total (previous year: KEUR 1,160) and is composed as follows:

in EUR	2016	2015
Fixed remuneration	755,000	709,167
Other remuneration	63,725	98,997
Total non-performance based remuneration	818,725	808,163
Short-term variable remuneration	219,390	163,667
Total short-term remuneration	1,038,115	971,830
Long-term variable remuneration	113,220	188,145
Total long-term remuneration	113,220	188,145
Total remuneration	1,151,335	1,159,975

The Management Board members held the following stock options as of 31 December 2016:

Status of non-exercised stock options as of 31 December 2016:		Dr. Wolfgang Söhngen	Dr. Jürgen Raths	Abdelghani Omari
Stock options 2008	No.	98,067	0	0
Stock options 2008 - fair value*	EUR	163,909	-	-
Stock options 2010	No.	162,000	0	80,000
Stock options 2010 - fair value*	EUR	270,540	-	133,600
Stock options 2014	No.	111,000	0	111,000
Stock options 2014 - fair value*	EUR	119,325	-	119,325

*) 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 200% of their annual fixed basic remuneration. For Dr. Jürgen Raths, a claim to termination benefits in connection with a change of control could only have been exerted

if the change of control had also entailed 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 2008, 2010 and 2014, 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 currently 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. Members of the Supervisory Board who are resident in a country outside Europe receive double the regular per-meeting fee for each Supervisory Board meeting they physically attend. The per-meeting fee is paid for a maximum of six meetings per year. The members of the Supervisory Board received the following remuneration for their activities in fiscal year 2016:

	Basic remuneration EUR	Per-meeting fees EUR	Total EUR
Dr. Jörg Spiekerkötter	40,000	15,000	55,000
Dr. Karin Dorrepaal	30,000	11,250	41,250
John Dawson	20,000	6,000	26,000

Supervisory Board remuneration in fiscal year 2016 amounted to KEUR 122. In the previous year the remuneration amounted to KEUR 131.

Disclosures pursuant to section 315 (4) HGB and explanatory report

Composition of subscribed capital

As of 31 December 2016, PAION AG had a subscribed capital of EUR 55,757,094.00, divided into 55,757,094 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 2016 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 19 May 2020, with the consent of the Supervisory Board, on one or more occasions, by up to EUR 25,320,970.00 in total by issuing up to 25,320,970 new no-par value bearer shares in return for cash contributions or contributions in kind (Authorized Capital 2015). 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 20 May 2015 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. By resolution from 24 June 2016, the Authorized Capital 2015 was used in the amount of EUR 5,064,194.00 and amounts to EUR 20,256,776.00 as of 31 December 2016.

Furthermore, subject to the consent of the Supervisory Board, the Management Board is authorized to issue on or before 19 May 2020, 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 22,433,285.00 in total (Conditional Capital 2015). Conditional Capital 2015 has not yet been used. Furthermore, the company is authorized to issue 34,847 shares (Conditional Capital 2004 II), 518,604 shares (Conditional Capital 2008 I), 720,000 shares (Conditional Capital 2010 I), 740,000 shares (Conditional Capital 2014) and 840,000 shares (Conditional Capital 2016) in connection with the Stock Option Plans 2005, 2008, 2010, 2014 and 2016.

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

The company has not concluded material arrangements which are dependent on a change in control in the event of a takeover bid.

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 and 2016 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 a HGB

The Statement on Corporate Governance pursuant to Section 289 a 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 and future opportunities. 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 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 interim 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 interim and annual financial statements are published and are discussed with 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.
Likelihood of occurrence						
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 to drug candidate 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, the conduct of clinical studies in the respective study centers is monitored by independent third parties and an independent data monitoring committee. 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 according to Tufts Center for the Study of Drug Development.¹³

In order to ensure a timely filing for approval of remimazolam in the U.S. after completion of the clinical studies, 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 are not met sufficiently leading to a delay of market approval. This is an industry-specific high risk. In case of occurrence, the potential damage level could pose a threat to the continued existence of the group.

PAION conducts various clinical studies with different requirements in terms of patient and volunteer profiles and thus patient and volunteer populations. There is a risk that patients cannot be recruited fast enough or at all for individual studies. The resulting delay/necessary amendment or discontinuation of studies would usually (e. g. in case of the initiation of a new study) lead to higher costs and delayed market approval. 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 high risk. In case of occurrence, the potential damage level could pose a threat to the continued existence of the group.

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. 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

¹³ Tufts Center for the Study of Drug Development (2014): Briefing – Cost of Developing a New 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, potential dosage modifications and amendments to clinical trial protocols 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 moderate risk. The risk classification of insufficient study outcomes decreased 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. 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 has obtained official scientific advice from the respective authorities in the EU and the U.S. Moreover, PAION consults regulatory experts. This is a high risk.

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 the studies. 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. 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 increased by one category compared to the previous year.

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 or PAION's contractual manufacturers 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 regularly conducts own audits in order to ensure a constantly high quality of the manufacturing. 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 of remimazolam, potential commercialization is closing in as well and imposes several risks.

PAION has conducted comprehensive market research as a basis for assessing different market potentials. However, there is a risk 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 cannot be influenced. 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 license partners will not be able to sufficiently prepare the market for launch by means of pre-marketing and market access activities as for example communication 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. This is a high risk.

In order to be able to successfully commercialize remimazolam upon market approval, the distribution set-up needs to be fully established. There is a risk that this process will not have been finalized until market approval. In order to reduce this risk to the highest possible degree, PAION has analyzed potential distribution set-ups and there is a regular information exchange with the U.S. cooperation partner Cosmo. 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 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

So far, relatively low quantities of remimazolam have been produced in course of the clinical trials. Up until commercialization, a further so-called scale-up process needs to be finalized. There is a risk that as a result of this process, remimazolam cannot be produced in sufficient quantities or at competitive costs for the market. This is a typical development risk that can only be influenced to a minor extent. However, in order to reduce this risk, PAION cooperates with established manufacturers and conducts a process validation before beginning commercialization in order to guarantee

technical feasibility. This is an increased risk. In case of occurrence, the potential damage level could pose a threat to the continued existence of the group.

Moreover, (additional) requirements of the authorities or problems relating to process validation might delay production development and 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. 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 has increased by one category compared to the previous year.

Due to the currently limited availability of stability data for remimazolam, there is a risk that for potential new or further studies, additional batches of the drug product need to be manufactured unless process validation has been finalized until then. This could lead to a delay of studies and incur additional costs. PAION is therefore working on a timely process validation in cooperation with experienced and renowned Contract Manufacturing Organizations (CMOs). This is a moderate risk.

Based on the production risks depicted, there is a risk that (potential) supply obligations towards license partners cannot be fulfilled if production development has not been completed. In cooperation with its contractual manufacturers, PAION would initiate the acceleration of validation procedures if a shortage in that regard should become foreseeable. This is an increased risk.

Medical ingredients are combined with certain other substances in order to have a sufficient shelf life, to be well applicable and to be specifically operative in the human organism among other things. In spite of a variety of tests, there is a risk that such a so-called pharmaceutical formulation does not remain stable in the long term and can thus not or only be used with reduced shelf life for products sold at the market. In order to reduce this risk to the highest possible extent, PAION continuously conducts tests and long-term stability studies before commercialization. This is a moderate risk.

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

Although PAION already cooperates with experienced and established contractual manufacturers, commercial supply agreements have not been finalized yet. There is a risk that a timely agreement cannot be reached leading to a delay of commercialization or higher costs. This is a high risk that PAION addresses by means of industry-typical precautions. In case of occurrence, the potential damage level could pose a threat to the continued existence of the group.

dd) Risks in relation to patents and other intellectual property

PAION's business operations are largely dependent on its ability to secure extensive patent protection and other intellectual property protection for the individual substances and to defend these against third parties without violating their rights. There can be no assurance that current or future patent applications will be granted or that any patents issued or licensed to PAION will be valid and sufficiently extensive to provide PAION and its license partners with adequate legal protection or any commercial advantage.

PAION continuously collaborates with an experienced patent law firm to secure the protection of PAION's intellectual property and to identify and address potential threats at an early stage as well as to make sure to not infringe any other third parties' patents itself. This is an increased risk.

ee) Partnering risks

In light of the progress of the development activities for remimazolam, important regulatory coordinations and meetings with the respective regulatory authorities are increasingly coming into focus for PAION's license partners. There is a risk that results from discussions with the authorities render the further development of remimazolam unattractive for existing license partner 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 license partners and engages in the evaluation of development plans in order to make sure meeting the respective regional regulatory requirements. 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.

Since PAION neither owns distribution structures nor aims at implementing these globally, potential commercialization of remimazolam can only be carried out by license partners in certain 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 regularly has partnering discussions with potential licensees in order to allow for an immediate 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 needs additional funding for further development in the EU or 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 license partners are not met.

PAION's future ability to secure additional funding will depend on the success of its development and licensing 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 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 and (potential) pharma partners. 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, in particular on the U.S. dollar and the pound sterling to a lower degree. These primarily relate to the development of remimazolam in the U.S. A strong rise of the U.S. dollar 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. Currency risks also arise from translating the foreign subsidiaries' separate financial statements from pound sterling or U.S. dollar into euros because the pound sterling/U.S. dollar is the functional currency of the UK subsidiaries/U.S. subsidiary.

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 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, British and U.S.-American 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, income tax payments would become due on the expected earnings if remimazolam is developed successfully. Dependent on the actual structure which has neither been decided nor can be anticipated yet, the consequences of a potential Brexit could also lead to tax payments on potential earnings expected in the future. 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 legislation change or 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.

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. 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.

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.

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.

Remimazolam is currently in Phase III development in the U.S. in procedural sedation for minor medical interventions; an extensive Phase III study in patients undergoing colonoscopies and a smaller Phase III safety study in severely sick patients undergoing colonoscopies were already successfully completed. The development for general anesthesia in Japan is completed, and PAION expects that only one Phase III trial will be required for market approval in the EU. For Japan, PAION plans to start work on a market approval dossier and to look for a partner for commercialization. Approval in Japan could give access to specific other markets (e. g. Latin America,

Asia-Pacific region). After completion of the development in the U.S. and the EU, it is intended to use the respective approval dossiers in the course of filing for market approval in other regions as well. The third indication is ICU sedation, and a respective Phase II study was already started in Japan, but not completed. PAION deems each of these three indications to have attractive sales potentials based on the respective regional conditions.

PAION benefits from the progress of the development of remimazolam in the U.S. and the development partners in China, South Korea, Canada, Russia/CIS, Turkey, and the MENA region financially in the form of milestone payments and royalties from launch onwards as well as in the form of additional development data. For the EU, an own commercialization is targeted, but partnering options are being evaluated as well. For all other regions, it is targeted to find license or distribution partners. In 2017, focus is on the completion of the U.S. Phase III program in order to allow handing over to Cosmo completely and enable Cosmo to subsequently file for market approval for procedural sedation in the U.S. as soon as possible. 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 successfully completed Phase III studies with remimazolam in the U.S. were an important milestone on the pathway to market approval. In particular, positive results from the comprehensive colonoscopy study in 461 patients have substantially contributed to finding a strong license partner for the U.S. market with Cosmo who are featuring a range of products that perfectly match remimazolam. Since further development of remimazolam in the indication general anesthesia in the EU requires additional funds, PAION's success is currently nearly entirely dependent on the successful completion of the development in the U.S. Even though the risk remains that this development is not successful in the end, the risk situation has improved in comparison to the previous year in light of the development progress and the partnering of the U.S. market.

It is anticipated that the imminent completion of recruitment of the last Phase III study in the U.S. in bronchoscopy patients in the indication procedural sedation and the resulting data will be another important milestone on the way to filing for market approval in the indication procedural sedation in the U.S. In addition, PAION expects that potential additional positive study data will further improve the opportunity situation. It is expected that the preparation of a market approval dossier for Japan will bring new dynamics to discussions with potential Japanese partners. Taking into account the above-mentioned factors, the opportunity situation has improved in comparison to the previous year.

Report on post-balance sheet date events

In February 2017, a capital increase with subscription rights and gross proceeds of EUR 4.99 million was successfully completed. By utilization of the Authorized Capital 2015 in the amount of EUR 2,439,023.00, the share capital of PAION AG was increased from EUR 55,757,094.00 to EUR 58,196,117.00 by issuing 2.439.023 new shares. The remaining Authorized Capital 2015 amounts to EUR 17,817,753.00 after this transaction.

Dr. Jürgen Raths resigned from his office as Chief Operating Officer of PAION AG as of the end of 14 March 2017.

There were no further significant events in the period between the reporting date, 31 December 2016, and the preparation of this report.

Report on expected developments

Outlook on development and commercialization

PAION's major goals for 2017 are the completion of the ongoing clinical development program in the U.S. and the handover of the completed work to Cosmo. In addition, PAION continues to work on production development for remimazolam. Furthermore, PAION will commence work on a filing dossier for the Japanese market in general anesthesia. In preparation for the EU Phase III development program in general anesthesia, a Phase I study and necessary consultations with the regulatory authority are planned to be conducted. PAION expects its other regional partners to continue their remimazolam development activities.

In the U.S., PAION is allocating significant resources to achieve the planned completion of the Phase III program, especially on patient enrolment in the Phase III bronchoscopy study and the subsequent evaluation of the study data. In addition, PAION is working on the data analysis of the remimazolam safety trial in ASA III/IV colonoscopy patients completed in December 2016. The development program is being completed by further smaller (preclinical and Phase I) studies. Regular interactions with the FDA in this regard are being maintained in order to ensure that all data relevant for the regulatory authority have been collected. This will be followed by an integrated "overall" analysis of all clinical studies with remimazolam. Subject to the successful completion of the clinical development program, including the completion of all analyses and reports, filing for approval in the U.S. could take place subsequently after finalization of a market approval dossier. Before filing, usually a pre-NDA meeting with the U.S. regulatory authority FDA is held, which is currently planned to take place in the end of 2017. The necessary coordination and preparatory work are currently being conducted with Cosmo, U.S. key opinion leaders and regulatory experts. Filing for market approval will then take place under Cosmo's responsibility depending on the outcome of the pre-NDA meeting. Conditional on successful study results and dependent on interactions with the FDA, PAION and Cosmo currently expect filing for approval mid of 2018.

For the EU, PAION is currently planning to continue the clinical development program for remimazolam with a study design analogous to the successfully completed Phase III program in general anesthesia in Japan. Secured funding, the conduct of the preparatory Phase I study and the necessary scientific consultations with the relevant European regulatory authority EMA to specify the new European Phase III program are a prerequisite for a study start in 2018.

Based on the positive pre-NDA meeting with the Japanese authority in the beginning of 2016 and the financing in February 2017, PAION will now prepare an application for market approval of remimazolam in Japan. This creates important prerequisites to further continuing partnering discussions with potential licensees in parallel with the aim to partner the Japanese market during the process of dossier preparation or subsequently. The preparation includes, among other things, the necessary validation of commercial-scale production for the Japanese market. Such a dossier could serve as a reference dossier for market approval in certain other markets. This would significantly reduce the necessary additional investment volume for partners in the respective markets depending on the specific regulatory environment. Subject to further coordination with the regulatory authority, filing for market approval in Japan is expected by mid-2018.

Financial outlook

In 2017, PAION expects revenues of approximately EUR 5.8 million. These mainly result from the upfront payment of EUR 10 million received from Cosmo in connection with the U.S. license agreement for remimazolam in July 2016, of which EUR 4.3 million were already realized as revenues in the reporting period. Depending on the progress of certain development components, the remaining EUR 5.7 million of the upfront payment will presumably be recognized as revenues in 2017. No further license agreements or milestone payments from existing license agreements are included in the financial planning for fiscal year 2017 which is the basis for the financial outlook.

Due to the ongoing investment in the development of remimazolam, PAION expects research and development expenses to be between approximately EUR 18 million and EUR 20 million, depending on the progress of development. Income from tax credits on parts of the research and development expenses from British tax authorities is expected to be between EUR 3.5 million and EUR 4 million. General administrative and selling expenses are expected to amount to approximately EUR 3.5 million to EUR 4 million. Net loss is expected to be between approx. EUR 12 million and approx. EUR 14 million, a decrease compared to the reporting period (2016: EUR 20.1 million).

This outlook assumes that development activities for remimazolam in the U.S. will progress as expected. Otherwise, cost blocks would shift into 2018. Expense forecasts are also based on the current status of discussions with the FDA. Costs could be higher than planned and lead to a delay in approval should the FDA impose additional requirements for filing for market approval.

Based on current plans, PAION believes that cash and cash equivalents of EUR 30.1 million as of 31 December 2016 enable PAION to complete all remaining development activities in the U.S. Thereafter, PAION expects to receive further payments from Cosmo subject to the achievement of

certain regulatory milestones in the U.S., and, once remimazolam is approved, royalties on net sales. Should development, filing and approval go according to plan, PAION will not need additional funding to bring remimazolam to the U.S. market. For the further development in the EU, PAION is currently planning to continue the clinical development program for remimazolam. In order to carry out a development program in the EU, additional funding of approximately EUR 20 million to EUR 25 million is required until filing for approval, subject to further coordination with the regulatory authority. Cash and cash equivalents including expected tax credits from the British tax authorities on parts of the research and development expenses secure a cash reach at least until the end of 2018 without consideration of potential milestone payments and without consideration of potential costs incurred by the targeted continuation of the Phase III development program in the EU.

Aachen, Germany, 15 March 2017

PAION AG



Dr. Wolfgang Söhngen



Abdelghani Omari

Consolidated Financial Statements

PAION AG

Consolidated Balance Sheet as of 31 December 2016

ASSETS	Note	31 Dec. 2016 EUR	31 Dec. 2015 EUR
Non-current assets			
Intangible assets	1.	2,687,855.47	3,361,501.93
Equipment	2.	167,210.31	55,590.77
Other assets		14.04	14.42
		2,855,079.82	3,417,107.12
Current assets			
Prepaid expenses and other assets	3.	5,017,115.86	7,371,001.85
Cash and cash equivalents	4.	30,111,355.87	32,679,797.20
		35,128,471.73	40,050,799.05
Total assets		37,983,551.55	43,467,906.17

EQUITY AND LIABILITIES	Note	31 Dec. 2016 EUR	31 Dec. 2015 EUR
Equity	5.		
Share capital		55,757,094.00	50,659,440.00
Capital reserve		128,548,802.57	124,236,225.22
Translation reserve		-340,777.37	-429,475.43
Loss carryforward		-138,904,359.04	-110,691,994.16
Result for the period		-20,117,636.81	-28,212,364.88
		24,943,123.35	35,561,830.75
Non-current liabilities			
Deferred income	9.	0.00	5,555.48
		0.00	5,555.48
Current liabilities			
Trade payables	7.	6,352,616.12	7,332,458.12
Provisions	6.	554,962.54	224,365.06
Other current liabilities	8.	358,814.11	304,774.95
Current portion of deferred income	9.	5,774,035.43	38,921.81
		13,040,428.20	7,900,519.94
Total equity and liabilities		37,983,551.55	43,467,906.17

Consolidated Statement of Comprehensive Income for Fiscal Year 2016

	Note	2016 EUR	2015 EUR
Revenues	10.	4,261,774.17	71,614.71
Cost of revenues		0.00	-10,940.75
Gross profit		4,261,774.17	60,673.96
Research and development expenses		-23,408,395.77	-29,384,797.19
General administrative and selling expenses		-5,128,622.06	-5,728,973.92
Other income (expenses), net	11.	-806,887.33	965,091.67
Operating expenses		-29,343,905.16	-34,148,679.44
Operating result		-25,082,130.99	-34,088,005.48
Financial income	12.	20,882.18	41,689.08
Financial result		20,882.18	41,689.08
Result for the period before taxes		-25,061,248.81	-34,046,316.40
Income taxes	13.	4,943,612.00	5,833,951.52
Result for the period		-20,117,636.81	-28,212,364.88
of which attributable to other shareholders		0.00	0.00
of which attributable to shareholders of PAION AG		-20,117,636.81	-28,212,364.88
Foreign currency translation of subsidiaries		88,698.06	354,476.61
Total income and expense recognized directly in equity that will be reclassified to profit or loss when specific conditions are met		88,698.06	354,476.61
Other comprehensive income		88,698.06	354,476.61
Total comprehensive income		-20,028,938.75	-27,857,888.27
of which attributable to other shareholders		0.00	0.00
of which attributable to shareholders of PAION AG		-20,028,938.75	-27,857,888.27
Earnings per share (basic)	14.	-0.38	-0.56
Earnings per share (diluted)	14.	-0.38	-0.56

Consolidated Cash Flow Statement for Fiscal Year 2016

	2016 EUR	2015 EUR
Cash flows from operating activities:		
Net result for the period	-20,117,636.81	-28,212,364.88
Reconciliation of net profit (loss) for the period to cash flows from operating activities:		
Income taxes	-4,943,612.00	-5,833,951.53
Amortization/depreciation and non-cash changes of fixed assets	758,914.35	124,823.24
Loss/Profits from the disposal of non-current assets	-4,745.39	7,715.21
Interest expenses and interest income	-20,882.18	-41,689.08
Release of deferred income	-4,135,952.68	-27,633.43
Expenses from stock option plans	198,365.47	790,485.82
Changes in assets and liabilities which are not attributable to investing or financing activities:		
Trade receivables	0.00	467,040.00
Prepaid expenses and other assets	1,788,336.56	-460,976.13
Trade payables	-979,842.00	3,994,051.48
Provisions	274,221.29	-81,984.93
Other current liabilities	54,039.16	50,853.20
Deferred income	9,865,510.81	29,818.95
Non-cash exchange losses/gains	128,405.38	288,498.80
	-17,134,878.04	-28,905,313.28
Tax payments received	5,529,216.50	2,575,181.54
Interest received	19,324.50	43,494.51
Net cash used in operating activities	-11,586,337.04	-26,286,637.23
Cash flows from investing activities:		
Cash paid for investments in intangible assets and equipment	-198,864.35	-33,476.91
Proceeds from Sale of Property, Plant and Equipment	6,722.69	0.00
Net cash used in investing activities	-192,141.66	-33,476.91
Cash flows from financing activities:		
Capital increase	5,097,654.00	17,500.00
Contributions to the capital reserve	4,589,483.82	4,550.00
Payments in connection with raising capital	-475,271.94	0.00
Net cash provided from financing activities	9,211,865.88	22,050.00
Change in cash and cash equivalents	-2,566,612.82	-26,298,064.14
Effect of exchange rate changes on cash	-1,828.51	65,977.78
Cash and cash equivalents at beginning of the period	32,679,797.20	58,911,883.56
Cash and cash equivalents at end of the period	30,111,355.87	32,679,797.20
Composition of cash and cash equivalents at the end of the period:		
Cash and cash equivalents	30,111,355.87	32,679,797.20

Consolidated Statement of Changes in Equity for Fiscal Year 2016

EUR	Share capital	Capital reserve	Translation reserve	Loss carryforward	Equity
31 December 2014	50,641,940.00	123,441,189.40	-783,952.04	-110,691,994.16	62,607,183.20
Total comprehensive income	0.00	0.00	354,476.61	-28,212,364.88	-27,857,888.27
Issue of shares	17,500.00	0.00	0.00	0.00	17,500.00
Contribution to the capital reserve	0.00	4,550.00	0.00	0.00	4,550.00
Additional contribution to the capital reserve due to the issue of options	0.00	790,485.82	0.00	0.00	790,485.82
31 December 2015	50,659,440.00	124,236,225.22	-429,475.43	-138,904,359.04	35,561,830.75
Total comprehensive income	0.00	0.00	88,698.06	-20,117,636.81	-20,028,938.75
Issue of shares	5,097,654.00	0.00	0.00	0.00	5,097,654.00
Contribution to the capital reserve	0.00	4,589,483.82	0.00	0.00	4,589,483.82
Cost of raising capital	0.00	-475,271.94	0.00	0.00	-475,271.94
Additional contribution to the capital reserve due to the issue of options	0.00	198,365.47	0.00	0.00	198,365.47
31 December 2016	55,757,094.00	128,548,802.57	-340,777.37	-159,021,995.85	24,943,123.35

Consolidated Notes

PAION AG

Notes to the consolidated financial statements for fiscal year 2016

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, Inc., Delaware/U.S.
- TheraSci Limited, Cambridge/UK

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

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

It is planned to dissolve PAION, Inc. during fiscal year 2017.

The consolidated financial statements as of 31 December 2016 and the group management report for fiscal year 2016 are scheduled for adoption and approval for publication by the Supervisory Board in its meeting on 15 March 2017.

Basis of accounting

The consolidated financial statements have been prepared according to Section 315a 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 2016, 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 2016 according to IAS 1.

The following new and/or revised standards, amendments and interpretations were applied for the first time in the fiscal year. The application of these standards and interpretations did not necessitate the provision of additional disclosures and did not influence the net assets, financial position and results of the group's operations in any way.

- Amendments to IAS 1 “Presentation of Financial Statements”
- Amendments to IAS 16 “Property, Plant and Equipment” and IAS 38 “Intangible Assets”
- Amendments to IFRS 11 “Joint Arrangements”
- IFRSs 2010–2012 Cycle “Annual Improvements to IFRSs 2010–2012” implements changes to the following standards:
 - IFRS 2 “Share-based payment”
 - IFRS 3 “Business Combinations”
 - IFRS 8 “Operating Segments”
 - IFRS 13 “Fair Value Measurement”
 - IAS 16 “Property, Plant and Equipment”/IAS 38 “Intangible Assets”
 - IAS 24 “Related Party Disclosures”
- IFRSs 2012–2014 Cycle “Annual Improvements to IFRSs 2012–2014” implements changes to the following standards:
 - IFRS 5 “Non-current Assets Held for Sale and Discontinued Operations”
 - IFRS 7 „Financial Instruments: Disclosures“
 - IAS 19 „Employee Benefits“
 - IAS 34 „Interim Financial Reporting“
- Amendments to IAS 27 “Separate Financial Statements”
- Amendments to IFRS 10 “Consolidated Financial Statements”, to IFRS 12 “Disclosure of Interests in Other Entities”, and to IAS 28 “Investments in Associates and Joint Ventures”

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:

- IFRSs 2014–2016 Cycle “Annual Improvements to IFRSs 2014–2016” implements changes to the following standards:

- IFRS 1 “First-time Adoption of International Financial Reporting Standards”
- IFRS 12 “Disclosure of Interests in Other Entities”
- IAS 28 “Investments in Associates and Joint Ventures”

The amendments to IFRS 1 and IAS 28 are effective for annual periods beginning on or after 1 January 2018, the amendment to IFRS 12 for annual periods beginning on or after 1 January 2017. Earlier adoption is allowed. The adoption by the EU is still pending.

- IFRIC 22 “Foreign Currency Transactions and Advance Consideration”: The interpretation is effective for annual periods beginning on or after 1 January 2018. Earlier adoption is allowed. The adoption by the EU is still pending.
- Amendments to IAS 40 “Investment Property”: The amendments are effective for annual periods beginning on or after 1 January 2018. Earlier adoption is allowed. The adoption by the EU is still pending.
- IFRS 9 “Financial Instruments”: The new guidelines are effective for fiscal years beginning on or after 1 January 2018. Earlier adoption is allowed.
- Amendments to IAS 12 “Income Taxes”: The amendments are effective for fiscal years beginning on or after 1 January 2017. Earlier adoption is allowed. The adoption by the EU is still pending.
- Amendments to IAS 7 “Statement of Cash Flows”: The amendments are effective for fiscal years beginning on or after 1 January 2017. Earlier adoption is allowed. The adoption by the EU is still pending.
- Amendments to IFRS 2 “Share-based payment”: The amendments are effective for fiscal years beginning on or after 1 January 2018. Earlier adoption is allowed. The adoption by the EU is still pending.
- IFRS 15 “Revenue from contracts with customers”: This standard is effective for fiscal years beginning on or after 1 January 2018. Earlier adoption is allowed.
- Clarifications to IFRS 15 “Revenues from contracts with customers”: The clarifications are effective for fiscal years beginning on or after 1 January 2018. Earlier adoption is allowed. The adoption by the EU is still pending.

- IFRS 16 “Leases”: This standard is effective for fiscal years beginning on or after 1 January 2019. Earlier adoption is allowed. The adoption by the EU is still pending.

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, except for IFRS 15 and IFRS 16, will presumably not have any effects on the Group’s net assets, financial position and results of operations.

The application of IFRS 15 may have effects on the Group’s net assets, financial position and results of operations in the future. PAION recognizes essential parts of its revenues from license agreements. According to IFRS 15, the analysis of revenue recognition is based on a process consisting of five steps. The application of IFRS 15 could particularly result in a different timing of the realization of revenues in regard to the achievement of contractually defined development milestones. The magnitude of these effects depends on the respective individual contractual agreement; particularly additional disclosure requirements might apply in the future. Existing contracts are currently being evaluated based on the five-step process with particular attention on differentiation between rights to access and rights to use as well as the distinction of sales-based royalties upon commercialization. As it stands, no further performance obligations have been identified in comparison to current accounting treatment. Therefore, application of IFRS 15 will presumably have no effects on revenue recognition of existing contracts. Future contracts will be subject to the same evaluation methodology. In terms of transition to IFRS 15, the cumulative effect method will be applied presumably.

The application of IFRS 16 may have effects on the Group’s net assets, financial position and results of operations in the future if leases existing at that time which are/would currently be treated off balance sheet would then need to be reflected in the balance sheet according to IFRS 16.

The consolidated financial statements have been prepared in Euros. Amounts were 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 business or geographical segments 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.

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

Consolidation principles

The consolidated financial statements include PAION AG, its subsidiaries PAION Deutschland GmbH, PAION, Inc. 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 and the U.S. dollar for the U.S.-american company PAION, Inc. 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 rates as of 31 December 2016: 0.8553 GBP/EUR; 1.0553 USD/EUR; exchange rate as of 31 December 2015: 0.7350 GBP/EUR; 1.0892 USD/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 2016 from 0.7539 GBP/EUR to 0.8927 GBP/EUR and from 1.0537 USD/EUR to 1.1346 USD/EUR; bandwidth in 2015 from 0.7060 GBP/EUR to 0.7810 GBP/EUR and from 1.0720 USD/EUR to 1.1634 USD/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.

Leased equipment that meets certain requirements defined in IAS 17 "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 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 liabilities

Financial liabilities are recognized at amortized cost using the effective interest method.

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. Income is realized upon performance of the service owed and

transfer of the risk, when the amount of anticipated consideration can be reliably estimated, when it is probable that the economic benefits will flow to the entity and when the cost incurred and to be potentially incurred in respect of the transaction can be measured reliably.

Since PAION is not selling products at the market yet, revenues are essentially realized by means of selling or outlicensing substances or drug candidates. Processually, the sale or outlicensing of substances or technological knowledge regularly starts with an extensive technology and know-how access by the buyer or licensee. Depending on the strategy of the licensee, subsequent services like the (support in regard to the) implementation of a production process, the completion of clinical trials in other regions or e. g. providing dossiers for market approvals from other regions are contractually agreed. Revenues in the context of services 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 the context of quantifiable services for which PAION does not know a success, are recognized based on the stage of completion in the respective 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.

Cost of revenues

Development costs that are charged on to third parties are reported as costs of revenues.

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 obligations arising from stock appreciation rights and further agreements are recognized as a provision once the respective requirements are met and measured at fair value on the balance sheet date. The costs are recognized as personnel expenses over the vesting period. The fair value of both the stock options and the stock appreciation rights 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. 2015	14,306,705.12
Additions	3,013.15
Disposals	0.00
Reclassifications	0.00
Exchange rate differences	898,528.31
31 Dec. 2015	15,208,246.58
Additions	57,073.05
Disposals	0.00
Reclassifications	0.00
Exchange rate differences	-2,111,121.09
31 Dec. 2016	13,154,198.54
Accumulated amortization, depreciation and impairment losses	
1 Jan. 2015	10,866,857.97
Additions	302,185.17
Disposals	0.00
Exchange rate differences	677,701.51
31 Dec. 2015	11,846,744.65
Additions	271,078.37
Disposals	0.00
Exchange rate differences	-1,651,479.95
31 Dec. 2016	10,466,343.07
Carrying amounts as of 31 Dec. 2015	3,361,501.93
Carrying amounts as of 31 Dec. 2016	2,687,855.47

The intangible assets mainly comprise the development project remimazolam (KEUR 2,626; 31 December 2015; KEUR 3,347). This development project was being written off over the expected useful life until mid-2027 based on forward-looking assumptions

in respect of the expected time at which regulatory approval is obtained, and of patent protection. From 2017 onwards, the expected useful life of the development project remimazolam will be until mid-2031.

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. 2015	207,767.35	678,485.14	886,252.49
Additions	18,830.42	11,632.48	30,462.90
Disposals	54,893.98	2,006.78	56,900.76
Reclassifications	0.00	0.00	0.00
Exchange rate differences	81.41	6,236.28	6,317.69
31 Dec. 2015	171,785.20	694,347.12	866,132.32
Additions	3,132.14	169,177.74	172,309.88
Disposals	0.00	28,501.30	28,501.30
Reclassifications	0.00	0.00	0.00
Exchange rate differences	171.45	-21,813.17	-21,641.72
31 Dec. 2016	175,088.79	813,210.39	988,299.18
Accumulated amortization, depreciation and impairment losses			
1 Jan. 2015	166,904.17	643,041.07	809,945.24
Additions	18,224.77	25,322.77	43,547.54
Disposals	47,178.77	2,006.78	49,185.55
Exchange rate differences	5.96	6,228.36	6,234.32
31 Dec. 2015	137,956.13	672,585.42	810,541.55
Additions	13,147.48	39,772.73	52,920.21
Disposals	0.00	26,524.00	26,524.00
Exchange rate differences	55.34	-15,904.23	-15,848.89
31 Dec. 2016	151,158.95	669,929.92	821,088.87
Carrying amounts as of 31 Dec. 2015	33,829.07	21,761.70	55,590.77
Carrying amounts as of 31 Dec. 2016	23,929.84	143,280.47	167,210.31

(3) 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 4,737; previous year: KEUR 5,855), VAT refund claims (KEUR 122; previous year: KEUR 418) and prepaid expenses relating to insurance contributions, rents and other prepayments (KEUR 113; previous year: KEUR 186).

(4) Cash and cash equivalents

Cash and cash equivalents are comprised of the following:

	31 Dec. 2016 KEUR	31 Dec. 2015 KEUR
Current deposits	13,049	5,307
Bank balance and cash in hand	17,062	27,373
	30,111	32,680

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.

(5) Equity

As of 31 December 2016, the share capital amounts to EUR 55,757,094.00 (previous year: EUR 50,659,440.00); it is divided into 55,757,094 no-par value shares (previous year: 50,659,440 shares).

The capital reserve amounts to EUR 128,548,802.57 as of 31 December 2016 (previous year: EUR 124,236,225.22) 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.

By virtue of a resolution adopted by the Annual General Meeting on 20 May 2015, the Management Board was authorized to increase the share capital on or prior to 19 May 2020, with the consent of the Supervisory Board, on one or more occasions, by up to EUR 25,320,970.00 in total by issuing up to 25,320,970 new no-par value bearer shares in return for cash contributions or contributions in kind (Authorized Capital 2015). Furthermore, the Management Board was authorized to use up to EUR 5,064,194.00 of the Authorized Capital 2015 to issue new shares for cash by excluding pre-emptive rights.

On 24 June 2016, the Management Board decided with the approval of the Supervisory Board and based on the authorization of the General Meeting to issue 5,064,194 no-par value bearer shares in return for cash contribution by excluding pre-emptive rights for the existing shareholders to Granell Strategic Investment Fund Limited, an affiliated company of the U.S. license partner Cosmo Pharmaceuticals (Cosmo). The new shares were issued at a price of EUR 1.9042. The capital increase led to a gross cash inflow of EUR 9.6 million. As a result, the share capital of the company was increased from EUR 50,672,400.00 by EUR 5,064,194.00 to EUR 55,736,594.00 through the issuing of 5,064,194 new shares. The capital increase was registered in the Commercial Register on 28 June 2016. The Authorized Capital 2015 was reduced by EUR 5,064,194.00 in the course of this capital measure and amounts to EUR 20,256,776.00 as of 31 December 2016.

Furthermore, by virtue of another resolution adopted by the Annual General Meeting on 20 May 2015, subject to the consent of the Supervisory Board, the Management Board was authorized to issue on or before 19 May 2020, 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 22,433,285.00 in total (Conditional Capital 2015). Furthermore, the Management Board was authorized to use up to EUR 5,064,194.00 of the Conditional Capital 2015

for Bonds against cash by excluding pre-emptive rights. Under consideration of the decision of the Management Board from 24 June 2016 to issue 5,064,194 no-par value bearer shares in return for cash contribution by excluding pre-emptive rights for the existing shareholders, the Conditional Capital 2015 can be no longer used excluding pre-emptive rights.

The Annual General Meeting of 25 May 2016 adopted a resolution to reduce Conditional Capital 2004 II to EUR 34,847.00. 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 2005 exercise their options. Under the Stock Option Plan 2005, 34,847 stock options were issued to (former) employees of the PAION Group as of 31 December 2016. No stock options have been exercised yet.

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, 475,161 stock options were issued to current and former Management Board members and employees of the PAION Group as of 31 December 2016. To date, 241,631 stock options from the Stock Option Plan 2008 have been exercised, thereof 33,460 in fiscal year 2016. The exercises led to cash inflows of EUR 43,899.60 in the fiscal year. As of 31 December 2016, Conditional Capital 2008 I amounts to EUR 518,604.00.

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 2016. 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, 537,225 stock options were issued to current and former Management Board members and employees of the PAION Group as of 31 December 2016. 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, no stock options were issued as of 31 December 2016.

The currency translation reserve amounted to EUR -340,777.37 as of 31 December 2016 (previous year: EUR -429,475.43). Of these, KEUR 5,205 concern cumulative exchange rate gains (as of 31 December 2015 cumulative exchange rate losses of KEUR -4,557) arising from the translation of the financial statements of the British subsidiaries from GBP into EUR and of the U.S. subsidiary from USD into EUR whereas KEUR -5,546 concern cumulative exchange rate losses (as of 31 December 2015 KEUR 4,127 cumulative exchange rate gains) incurred on loans from PAION AG to the British subsidiaries and the U.S. subsidiary. As of 31 December 2016, these loans amount to KEUR 72,435 (previous year: KEUR 60,180).

(6) Provisions

Provisions developed as follows:

in KEUR	Premiums/ Management Bonuses	Taxes	Other	Total
31 Dec. 2014	244	0	62	306
Utilization	236	0	0	236
Addition	153	0	0	153
Exchange rate differences	1	0	0	1
31 Dec. 2015	162	0	62	224
Utilization	72	0	0	72
Addition	310	18	173	501
Release	88	0	0	88
Exchange rate differences	-3	0	-7	-10
31 Dec. 2016	309	18	228	555

The tax provision results from a tax audit of the corporate income, trade and value-added tax of PAION Deutschland GmbH for the years 2010 to 2013, which was completed after the balance sheet date, and relates to a tax payment for fiscal year 2012. The addition to other provisions mainly includes a potential payment obligation towards a development service provider.

(7) Trade payables

Trade payables amounted to KEUR 6,353 as of 31 December 2016 (previous year: KEUR 7,332). These liabilities do not bear interest and are generally due for payment within 30 days. In case of accrued liabilities as of the balance sheet date, the maturity may be later than 30 days after balance sheet date, depending on the respective invoice date.

(8) Other current liabilities

Other current liabilities comprise the following:

	31 Dec. 2016 KEUR	31 Dec. 2015 KEUR
Wage taxes	194	176
Holiday allowances	82	79
Supervisory Board remuneration	27	33
Others	56	17
	359	305

(9) Deferred income

Deferred income is current in the full amount as of 31 December 2016, amounts to KEUR 5,774 (current amount as of 31 December 2015: KEUR 39) and contains the portion of the upfront payment of KEUR 10,000 received in the reporting period that has not been recognized as revenue yet (KEUR 5,749).

Consolidated statement of comprehensive income disclosures

(10) Revenues

Revenue recognized in the reporting period amounted to KEUR 4,262 and mainly resulted from the upfront payment of KEUR 10,000 received in the course of the U.S. license agreement for remimazolam entered into with Cosmo in June 2016. Revenue recognition of the upfront payment is dependent on the progress of certain development components.

(11) Other income (expenses), net

Other income (expenses) in the fiscal year mainly comprises foreign exchange losses (KEUR 1,064; previous year: foreign exchange gains of KEUR 907).

(12) Financial income

Financial income consists of the following:

	2016 KEUR	2015 KEUR
Interest income based on amortized costs (bank balances and current deposits)	21	42
	21	42

(13) Income taxes / Deferred taxes

As of 31 December 2016, the tax losses carried forward by PAION Germany group (PAION AG and PAION Deutschland GmbH) amounted to about EUR 80 million (previous year: EUR 77 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 100 million per 31 December 2016 (equivalent to EUR 117 million if translated at the exchange rate applicable on the reporting date). In the previous year, these amounted to GBP 86 million or EUR 116 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.

The losses carried forward by the U.S. subsidiary amount to KUSD 341 as of 31 December 2016 (previous year: KUSD 335). According to current tax legislation, these can be carried forward indefinitely.

Overall, the losses carried forward within the Group amount to EUR 198 million (previous year: EUR 193 million). No deferred tax assets were recognized regarding a partial amount of EUR 195 million (previous year: EUR 190 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 income tax rate in Great Britain is 20%. The income tax rate in the United States of America is 34%. 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 525 (previous year: KEUR 669) 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 2016, the resulting deferred tax assets would amount to EUR 26 million (previous year: EUR 25 million). Based on the income tax rate of 20% that is currently applicable in Great Britain, the losses

carried forward in Great Britain as of 31 December 2016 would produce deferred tax assets in an amount of GBP 20 million (equivalent to EUR 23 million if translated at the rate applicable on the reporting date). In the previous year, these amounted to GBP 17 million or EUR 23 million, respectively. The temporary differences between the tax base and the IFRS carrying amount would produce a net balance as of 31 December 2016 of deferred tax assets in an amount of KEUR 26 (previous year: KEUR 44), of which Germany accounts for KEUR 2 (previous year: KEUR 5) and Great Britain for KEUR 24 (previous year: KEUR 39). Deferred taxes from PAION, Inc. only result in an immaterial amount as of 31 December 2016 and are therefore not considered. The depicted differences in carrying amounts relate mainly to fixed assets, provisions and deferred income. Total deferred tax assets would amount to EUR 49 million (previous year: EUR 48 million).

In the fiscal year, PAION Deutschland GmbH and PAION, Inc. reported a low profit; all 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 market approval 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	2016	2015
Result for the period before taxes	-25,061	-34,046
Anticipated tax expense (+) / income (-)	-7,518	-10,214
Non-recognition of deferred taxes on tax losses	4,074	3,000
Deferred taxes on additional tax losses from previous years	-689	0
Difference between anticipated Group tax rate and actual local tax rates	3,318	3,139
Effects from currency translation	-2,724	573
Expenses in connection with stock options	69	219
Non-deductible expenses	29	27
Non-recognition of deferred taxes on temporary differences	-10	-6
Tax losses used	-67	-378
Correction of prior years' tax expenses	18	0
Non-recognition of deferred taxes on additional tax losses from previous years	689	0
Effects from tax credits	-1,980	-2,195
Cost in connection with capital increases	-154	0
Other	1	1
Actual tax expense (+) / income (-)	-4,944	-5,834

The actual tax income results in an amount of KEUR 4,962 from the expected reimbursement of research and development costs through British tax authorities. The expected tax credits reduced the tax losses carried forward accordingly. The actual tax income also includes a tax expense of KEUR 18, resulting from a tax audit of the corporate income, trade and value-added tax of PAION Deutschland GmbH for the years 2010 to 2013 completed after the balance sheet date and relating to a tax payment for fiscal year 2012.

(14) 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:

	2016	2015
Shares outstanding as of 1 January	50,659,440	50,641,940
Weighted average number of shares issued	2,586,192	10,623
Weighted average number of ordinary shares	53,245,632	50,652,563

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

	2016	2015
Net result for the year (in EUR)	-20,117,636.81	-28,212,364.50
Weighted average number of ordinary shares for basic earnings per share	53,245,632	50,652,563
Weighted average number of ordinary shares for diluted earnings per share	53,491,803	50,895,530
Earnings per share (in EUR):		
Basic	-0.38	-0.56
Diluted	-0.38	-0.56

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.

Other disclosures

Stock Option Plans

PAION has implemented a total of five stock option plans in the course of which stock options can be/have been granted to Management Board members in accordance with the provisions of IFRS 2. All stock option plans include vesting periods, waiting periods and exercise hurdles. The respective exercise programs can be found in the following table (the presentation of the Stock Option Plan 2016, from which no stock options have been issued yet, is omitted).

	Stock Option Plan 2005 Approved 30 December 2004	Stock Option Plan 2016 Approved 5 March 2016
Underlying Capital	Conditional Capital 2004 II	Conditional Capital 2016 I
Term of the options	10 years	10 years
Vesting period	2–4 years	2–4 years
Waiting period	2–4 years	2–4 years
Number of outstanding options for which the waiting period has expired as of 31 December 2016	34,847	34,847
Exercise condition	Cumulative stock price increase of 5% per year since grant in relation to stock price at grant date	Cumulative stock price increase of 5% per year since grant in relation to stock price at grant date
Exercise price *	EUR 8.00	EUR 8.00
Weighted average exercise price *	EUR 8.00	EUR 8.00
Exercise hurdle as of 31 Dec. 2016 *	EUR 11.87	EUR 11.87
Weighted average remaining term as of 31 Dec. 2016	0.3 years	0.3 years
Further grants possible?	No	No
Number of totally granted options	1,055,767	1,055,767
Number of outstanding options as of 31 Dec. 2016 **	34,847	34,847
granted to employees	34,847	34,847
granted to Management Board members	0	0
Number of totally lapsed options as of 31 Dec. 2016	1,020,920	1,020,920
thereof lapsed in the reporting period	11,615	11,615
Number of totally exercised options until 31 Dec. 2016	0	0
thereof exercised in the reporting period	0	0
Personnel expenses in the reporting period	0	0
Fair value per option at the time of the grant ***	EUR 2.41 to EUR 4.08	EUR 2.41 to EUR 4.08
Elements of calculation		
Valuation model	Black/Scholes	Black/Scholes
Risk-free rate	3–4.5%	3–4.5%
Volatility	27.81–47.77%	27.81–47.77%
Staff turnover	6.5% per year	6.5% per year
<p>*) in relation to outstanding options as of 31 Dec. 2016 **) in relation to employee/Management Board member status at the time of the grant ***) in relation to totally granted options</p>		

members and employees of PAION AG and its subsidiaries at the time of the grant. The stock options are accounted for in exercise price is based on the average stock price during a certain period of time before the grant. Details of the individual pro- omitted):

an 2008 y 2008	Stock Option Plan 2010 Approved 19 May 2010	Stock Option Plan 2014 Approved 21 May 2014
Conditional Capital 2008 I	Conditional Capital 2010 I	Conditional Capital 2014
10 years	10 years	10 years
2–4 years	2–4 years	2–4 years
2–4 years	4 years	4 years
475,161	0	0
se of 5% per year since lation 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 1.11 to EUR 2.69	EUR 2.01	EUR 1.99 to EUR 2.40
EUR 1.58	EUR 2.01	EUR 2.14
EUR 1.55 to EUR 3.61	EUR 2.30	EUR 2.04 to EUR 2.61
2.4 years	7.1 years	8.8 years
No	No	Yes
817,550	720,000	684,500
475,161	696,626	537,225
259,580	392,876	294,412
215,581	303,750	242,813
100,758	23,374	147,275
1,625	3,124	106,088
241,631	0	0
33,460	0	0
0	KEUR 21	KEUR 177
EUR 0.57 to EUR 2.48	EUR 1.67	EUR 1.02 to EUR 1.39
Black/Scholes	Black/Scholes	Black/Scholes
2.5–4.47%	0.70%	-0.26–0.08%
83.31–88.44%	73.75%	82.64–83.76%
0–5% per year	10% per year	10–14.5% per year

Employee Participation Plan 2006

With the consent of the Supervisory Board, the Management Board of PAION AG had launched an employee participation plan granting stock appreciation rights. A stock appreciation right entitled the holder to receive a sum of money based on the PAION AG share price. The maximum amount payable on a stock appreciation right was limited to 100% of the exercise price. The stock appreciation rights had a term of ten years and could only be exercised after a two-year waiting period. In addition, they could only be exercised when the stock price on the exercise date had increased by a cumulative 5% each year since issuance. As of 31 December 2016, all previously issued stock appreciation rights from the Employee Participation Plan 2006 had expired, thereof 134,000 stock appreciation rights in fiscal year 2016.

No more stock appreciation rights can be issued from the Employee Participation Plan 2006.

The obligations arising from these stock appreciation rights were recognized at fair value on the balance sheet date in accordance with the provisions of IFRS 2 "Share-Based Payment". As a result of the expiration of the last stock appreciation rights from the Employee Participation Plan 2006 in the reporting period, a payment obligation no longer exists as of 31 December 2016 and no expenses or income from the Employee Participation Plan 2006 were recognized in the reporting period.

Other financial obligations/Contingent liabilities

PAION has rented office space and leased parts of its factory and office equipment. The rental contracts for the office spaces in some cases include an automatic extension of the respective contract unless it is terminated by one of the two contract parties at a certain point in time prior to its expiry. The minimum future rental and lease obligations arising from these contracts are as follows:

	31 Dec. 2016 KEUR	31 Dec. 2015 KEUR
Due within one year	327	332
Due after more than one year	82	156
Total	409	488

Rental and lease expenses amounted to KEUR 322 in fiscal year 2016 (previous year: KEUR 345). The long-term rental and lease obligations in the amount of KEUR 82 exist for the years 2018 to 2019.

Based on assigning the conduct of clinical studies to Clinical Research Organizations (CROs) and having contractual manufacturers perform the production development and manufacture the study medication, PAION has contractually committed financial obligations in the amount of approx. EUR 6 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, CEO of the subsidiary PAION, Inc., 0.5% of income from milestone payments from Cosmo.

Headcount and personnel expenses

In fiscal year 2016, PAION employed an average of 36 persons (previous year: 29 employees). Of these 36 employees, 26 worked in development and ten in administration and sales. PAION UK Group had an average headcount of nine employees, and PAION, Inc. of three employees. As of 31 December 2016, the headcount was 34 (31 December 2015: 35).

The following personnel expenses were incurred in fiscal years 2016 and 2015:

	2016 KEUR	2015 KEUR
Wages and salaries	4,905	4,633
Social security contributions	470	363
Total	5,375	4,996

The personnel expenses stated above include (net) expenses from the granting of stock options in connection with the Stock Option Plan 2010 and the Stock Option Plan 2014 in an amount of KEUR 198 (previous year: KEUR 783). The figures also include contributions to the German, British and U.S. social insurance schemes in an amount of KEUR 414 (previous year: KEUR 343).

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.

Dr. Mariola Söhnngen has been a consultant for the company since her retirement from the Management Board of PAION AG and qualifies as related party as wife of Dr. Wolfgang Söhnngen, acting Chief Executive Officer of PAION AG as of 31 December 2016. In fiscal year 2016, expenses in the amount of KEUR 19 have been incurred for consulting services provided by Dr. Mariola Söhnngen. As of 31 December 2016, trade payables to Dr. Mariola Söhnngen amount to KEUR 5.

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. Since these development activities are not yet generating any revenues from the sale of launched products, the scheduled expenses are correspondingly high. 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 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 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, especially in the U.S., as well as the success of the license partner 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 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.

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 its trade payables, in particular in connection with the Phase III development of remimazolam in the U.S. and from the loans

granted to its foreign subsidiary companies. Liquid assets are mainly invested in euros, but also funds in U.S. dollar and Pound Sterling are held.

Based on current planning, the expected U.S. dollar share of cash outflows for the development of remimazolam in the U.S. amounts to approximately USD 7.0 million. Under consideration of the fact that approximately 20% of the development expenses incurred at PAION are subsidized in the form of tax credits according to the current legislation in Great Britain, the U.S. dollar exposure is reduced to about USD 5.6 million. In order to partly hedge the risk of a stronger U.S. dollar in relation to the euro, PAION holds funds in U.S. dollar. As of 31 December 2016, PAION held an amount of USD 3.1 million. This way, per year-end, about 55% of the current U.S. dollar risk in connection with the development of remimazolam in the U.S. were hedged taking into account the expected tax credits. Taking into account further U.S. dollar purchases after the balance sheet date, the U.S. dollar risk in connection with the development of remimazolam in the U.S. is hedged nearly entirely for 2017.

The loans granted by PAION AG to its foreign subsidiaries produced exchange rate losses of KEUR 9,673 in 2016, which were recognized in equity. These mainly relate to the British subsidiaries and to a minor degree to the U.S. subsidiary. If the EUR/GBP and the EUR/USD 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 3,779 compared to the change in the currency component actually recognized in equity in 2016. If the EUR/GBP and the EUR/USD exchange rate had been 5% lower on the balance sheet date, the currency component recognized in equity in the reporting period would have decreased by KEUR 3,779 less compared to the change in the currency component actually recognized in equity in 2016.

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 would have reduced consolidated result by KEUR 31 in fiscal year 2016 (previous year: KEUR 46).

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 2016 by the British tax authorities has however not taken place as of the balance sheet date. A review of the tax credit for 2015 received in 2016 is currently being undertaken by the British tax authorities.

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. 2016	31 Dec. 2015	31 Dec. 2016	31 Dec. 2015
Financial assets:					
Cash and cash equivalents	(1)	30,111	32,680	30,111	32,680
Other assets	(1)	3	313	3	313
Financial liabilities:					
Provisions	(2) (3)	537	224	537	224
Trade payables	(2) (3)	6,353	7,332	6,353	7,332
Other liabilities	(2) (3)	165	129	165	129

Measurement category according to IAS 39:

- (1) Loans and receivables
- (2) Liabilities recognized at amortized cost
- (3) lead to cash outflows

In light of the short residual terms of the cash and cash equivalents, other assets, provisions, trade payables and other liabilities, their carrying amounts are equivalent to the fair values as of the balance sheet date. Thus, the determination of the fair values of these financial instruments was based on unobservable input factors (input factors of level 3 according to IFRS 13). In fiscal year 2016, there were no movements between the hierarchy levels.

Members of the Management Board

The members of the company's Management Board are:

- Dr. Wolfgang Söhnngen, CEO, Chairman
- Abdelghani Omari, CFO
- Dr. Jürgen Raths, COO (until 14 March 2017)

Other positions:

- Vesselon, Inc., Norwalk (Connecticut)/U.S., Member of the Board of Directors
- MSPI Medical Specialty Partners International AG, Zug/Switzerland, Member of the Supervisory Board

Management Board remuneration totalled KEUR 1,151 in fiscal year 2016. As of 31 December 2016, a total of 562,067 stock options (fair value at time of granting: EUR 806,699) had been issued to active Management Board members as of 31 December 2016. For more information on Management Board remuneration, please see the disclosures in the remuneration report, which is part of the management report.

Dr. Wolfgang Söhnngen and Mr. Abdelghani Omari are also Managing Directors of PAION Deutschland GmbH and

non-executive directors of PAION, Inc. Mr. Abdelghani Omari is also Managing Director of PAION Holdings UK Ltd and its subsidiaries. All Management Board members work full-time for the company and its subsidiaries.

As of 31 December 2016, Dr. Wolfgang Söhnngen owned 1.12% (621,791 voting rights) of the shares in PAION AG. This equity interest includes 0.01% (6,425 voting rights) of the shares in PAION AG that are held by Dres. Söhnngen Beteiligungs GmbH, in which Dr. Wolfgang Söhnngen holds 50%.

Members of the Supervisory Board

The members of the Supervisory Board are:

- Dr. Jörg Spiekerkötter, Kleinmachnow/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 (since 1 August 2016)

- Dr. Karin Louise Dorrepaal, Amsterdam/The Netherlands, Vice Chairman; former Member of the Management Board of Schering AG
Other supervisory board memberships or similar positions:
 - Gerresheimer AG, Düsseldorf/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
 - Julius Clinical Research BV, Bunnik/The Netherlands, Member of the Supervisory Board (since 1 October 2016)

- John Dawson, Fetcham/England, Chairman of the Audit Committee; CEO of Oxford BioMedica plc, Oxford/England

Remuneration to the members of the Supervisory Board totalled KEUR 122 in fiscal year 2016. For more information on

Supervisory Board remuneration, please see the disclosures in the remuneration report of the group management report.

As of 31 December 2016, none of the members of the Supervisory Board owned shares in PAION AG.

Financial statements auditor

The Annual General Meeting on 25 May 2016 appointed Ernst & Young GmbH Wirtschaftsprüfungsgesellschaft, Cologne office, Germany, as auditor of the annual and consolidated financial statements for fiscal year 2016. The auditor has received or will invoice the following fees for services rendered to PAION AG and its subsidiaries in fiscal year 2016:

	2016 KEUR	2015 KEUR
Audits of financial statements	105	99
Other assurance services	23	40
Other services	203	45
	331	184

The other assurance services relate to fees for reviewing the interim financial statements. The other services comprise the preparation of a comfort letter in the context of the preparation of a potential capital increase, which was ultimately not conducted due to the cooperation with Cosmo.

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.

The company complies with the recommendations set forth in the most recent version of the German Corporate Governance Code dated 5 May 2015 with one exception. In December 2016, the Supervisory Board and the Management Board issued the declaration of compliance with the Corporate Governance Code pursuant to Section 161 AktG. 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

In February 2017, a capital increase with subscription rights and gross proceeds of EUR 4.99 million was successfully completed. By utilization of the Authorized Capital 2015 in the amount of EUR 2,439,023.00, the share capital of PAION AG was increased from EUR 55,757,094.00 to EUR 58,196,117.00 by issuing 2.439.023 new shares. The remaining Authorized Capital 2015 amounts to EUR 17,817,753.00 after this transaction.

Dr. Jürgen Raths resigned from his office as Chief Operating Officer of PAION AG as of the end of 14 March 2017.

There were no further significant events in the period between the reporting date, 31 December 2016, and the preparation of this report.

Aachen, Germany, 15 March 2017

PAION AG

The image shows two handwritten signatures in black ink. The signature on the left is for Dr. Wolfgang Söhngen, and the signature on the right is for Abdelghani Omani. Both signatures are written in a cursive, flowing style.

Dr. Wolfgang Söhngen

Abdelghani Omani

Responsibility Statement (Bilanzzeit) in accordance with section 37y no.1 of the Wertpapierhandelsgesetz (WpHG – German Securities Trading Act) in conjunction with sections 297(2) sentence 4 and 315(1) sentence 6 of the Handelsgesetzbuch (HGB – German Commercial Code)

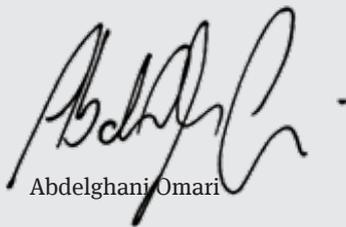
“To the best of our knowledge, and in accordance with the applicable reporting principles, the consolidated financial statements give a true and fair view of the assets, liabilities, financial position and profit or loss of the group, and the group management report includes a fair review of the development 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, 15 March 2017

PAION AG



Dr. Wolfgang Söhngen



Abdelghani Omari

Audit Opinion

We issued the following opinion on the consolidated financial statements and the group management report:

“We have audited the consolidated financial statements prepared by PAION AG, Aachen, comprising the balance sheet, the statement of comprehensive income, the cash flow statement, the statement of changes in equity and the notes to the consolidated financial statements, together with the group management report for the fiscal year from 1 January 2016 to 31 December 2016. The preparation of the consolidated financial statements and the group management report in accordance with IFRSs [International Financial Reporting Standards] as adopted by the EU and the additional requirements of German commercial law pursuant to Sec. 315a (1) HGB [“Handelsgesetzbuch”: German Commercial Code] is the responsibility of the Company’s management. Our responsibility is to express an opinion on the consolidated financial statements and on the group management report based on our audit.

We conducted our audit of the consolidated financial statements in accordance with Sec. 317 HGB [“Handelsgesetzbuch”: German Commercial Code] and German generally accepted standards for the audit of financial statements promulgated by the Institut der Wirtschaftsprüfer [Institute of Public Auditors in Germany] (IDW). Those standards require that we plan and perform the audit such that misstatements materially affecting the presentation of the net assets, financial position and results of operations in the consolidated financial statements in accordance with the applicable financial reporting framework and in the group management report are detected with reasonable assurance. Knowledge of the business activities and the economic and legal environment of the Group and expectations as to possible misstatements are taken into account in the determination of audit procedures. The effectiveness of the accounting-related internal control system and the evidence supporting the disclosures in the consolidated financial statements and the group management report are examined primarily on a test basis within the framework of the audit. The audit includes assessing the annual financial statements of those entities included in consolidation, the determination of entities to be included in consolidation, the accounting and consolidation principles used and significant estimates made

by management, as well as evaluating the overall presentation of the consolidated financial statements and the group management report. We believe that our audit provides a reasonable basis for our opinion.

Our audit has not led to any reservations.

In our opinion, based on the findings of our audit, the consolidated financial statements comply with IFRSs as adopted by the EU and the additional requirements of German commercial law pursuant to Sec. 315a (1) HGB and give a true and fair view of the net assets, financial position and results of operations of the Group in accordance with these requirements. The group management report is consistent with the consolidated financial statements, complies with the legal requirements and as a whole provides a suitable view of the Group’s position and suitably presents the opportunities and risks of future development.”

Cologne, 15 March 2017

Ernst & Young GmbH
Wirtschaftsprüfungsgesellschaft

(s) Ueberschär
Wirtschaftsprüfer
[German Public Auditor]

(s) Galden
Wirtschaftsprüfer
[German Public Auditors]

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 2016

Management Report

for Fiscal Year 2016

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Management report for fiscal year 2016

Fundamental information of PAION AG and the PAION Group

I. Business model of PAION AG and PAION Group

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. The product candidates M6G and GGF2 are not in active development and are therefore no significant value drivers in the portfolio of PAION group. M6G is licensed to Yichang Humanwell for the Chinese market. GGF2 is being developed by Acorda Therapeutics, Inc. (Acorda).

For remimazolam which currently is in clinical Phase III development, PAION has license partners in the U.S., China, South Korea, Canada, Russia/CIS, Turkey and the MENA region.

Fiscal year 2016 was marked by the concentration of PAION on the further development of remimazolam, in particular the U.S. Phase III development, as well as the conclusion of an exclusive license agreement for the development and commercialization of remimazolam in the U.S. with Cosmo Pharmaceuticals (Cosmo).

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 development activity both clinically and non-clinically and in terms of production technology is 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 an aimed approval 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.

Licensing activities aim at the subsequent commercialization of remimazolam by partners. The progress of these activities is being documented and discussed continuously. PAION has already signed several regional licensing agreements. The cooperation partners operate independently in their respective license territory. However, the cooperation agreements require the partners to exchange relevant information. Development in the U.S. is being conducted by PAION and will be handed over to U.S. license partner Cosmo after the development program agreed with the FDA including subsequent reports and necessary analyses has been completed. Cosmo will then be responsible for all further activities in the U.S.

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

3. Research and Development

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 with an increase of the gross domestic product of 1.9% in 2016 which was equally pushed by the manufacturing industry as well as the service sector. With an increase of 2.5% compared to the prior year, consumption in particular was an important driver of growth of the German economy, while investments also slightly increased by 0.8%.¹

Growth is expected to develop on a comparable level in 2017² and will primarily stem from private consumption. Although exports proved to be robust in spite of the Brexit vote and the U.S. presidential election outcome, international protective tendencies are likely to hit the export-oriented German economy prominently in the mid-term.³ Also, economic growth decreased in the EU as well as the U.S. and other major economies; in the U.S. it dropped to 1.6% in 2016 after

¹ Federal Statistical Office: WISTA 1/2017 – Bruttoinlandsprodukt 2016.

² Commerzbank Research: Konjunktur und Finanzmärkte – Januar 2017.

³ German Institute for Economic Research: DIW Konjunkturbarometer Januar 2017: Deutsche Wirtschaft durchläuft kräftiges Winterhalbjahr, press release dated 31 January 2017.

a growth of 2.6% in the prior year. After an estimated growth of 3.1% in 2016, the International Monetary Fund expects the world gross domestic product to grow by 3.4% in 2017 driven by developed economies as well as emerging markets and developing countries. The outlook for the growth of the world economy is curbed by internationally observable protective tendencies and geopolitical tensions.⁴

Stock markets in the U.S. and Germany showed a positive development in 2016. The Dow Jones increased by 13.4% in comparison to the prior year's end closing value, and the DAX increased by 6.9%. EUROSTOXX 50 on the other hand closed 2016 only with a slight increase of 0.7% in comparison to the prior year's end closing value.

b. Development of the pharmaceutical and biotechnology industry

In 2016, the pharmaceutical and biotechnology industry continued to be marked by increasing costs for pharmaceutical development, lower income from formerly high-selling products due to the expiry of patent protection during the last years and persisting price pressure on established drugs as well as new therapies.⁵ Development costs for new drugs increased by nearly 30% from 2010 to 2016 only.⁶ The resulting consolidation pressure has led to an increase of the worldwide transaction volume in the pharmaceutical industry by 14% compared to the prior year to USD 201 billion in 2016.⁷

The financing environment for the pharmaceutical and biotechnology industry was more difficult in 2016 than in prior years. In the U.S., the number of biotechnology IPOs decreased by over 50% compared to the prior year and the average gross proceeds were lower than in 2015.⁸ In Europe, the financing volume also declined significantly with EUR 3.3 billion in 2016 compared to EUR 6.2 billion in the prior year.⁹ Investors obviously assess the potential of companies in need of financing significantly more critical than in the prior year, while particularly products generating value for patients as well as for payers promise most success.¹⁰ The increased hesitance especially in the U.S. is also reflected in the valuation of pharmaceutical companies. The NASDAQ Biotechnology Index showed a decline by 21.7% in 2016. In contrast, the DAXsubsector Biotechnology Index increased by a total of 7.6% in 2016 in comparison to the prior year's end closing value after an initial drop in the beginning of the year.

⁴ International Monetary Fund: World Economic Outlook Update, 16 January 2017.

⁵ Ernst & Young: EY M&A Outlook and Firepower Report 2017 – Will payer leverage and post-election optimism shift dealmaking into a higher gear?.

⁶ Deloitte: 2017 global life sciences outlook – Thriving in today's uncertain market.

⁷ Ernst & Young: Trübe Umsatzaussichten und anhaltender Preisdruck: Anstieg der Fusionen und Übernahmen in der Pharma-Branche erwartet, 24 January 2017.

⁸ Scrip Pharma Intelligence: US IPOs In Review: Relatively Muted Market In 2016 To Continue In 2017, 30 December 2016.

⁹ Börsen-Zeitung: Biotech-Unternehmen sammeln 500 Mill. Euro ein, No. 9 dated 13 January 2017.

¹⁰ Scrip Pharma Intelligence: J.P. Morgan Executive Roundtable, Part 3: Financing Is Difficult, But Available For Drugs That Provide Value, 26 January 2017.

It is expected that the significant competitive drivers and consolidation pressure will also persist in 2017. In particular, tax legislation changes announced by the new U.S. government could make significant amounts of funds available for U.S. companies by means of repatriation of income in the U.S. and could thus increase the acquisition and transaction volumes in the pharmaceutical industry worldwide.¹¹ The development of the financing environment especially in the U.S. will significantly depend upon the design of legislation amendments announced by the new U.S. administration in regard to the regulation of drug prices, the reconvocation of the Affordable Care Act as well as the reform of Medicare and the U.S. authority FDA.¹² Moreover, future monetary policy in the U.S. and the EU will influence the financing environment.

Altogether, in 2017 PAION expects the financing environment to improve over 2016 while investors will continue to be very selective in choosing their investments.

2. Presentation of the course of business and development activities

The development portfolio of PAION Group essentially comprises the lead compound 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 not metabolized by cytochrome-dependent hepatic pathways. Like other benzodiazepines, remimazolam can be reversed with flumazenil to rapidly terminate sedation and anesthesia if necessary.

In clinical studies, remimazolam demonstrated efficacy and safety in far over 1,000 patients. Data so far indicate that remimazolam has a rapid onset and offset of action combined with a favorable cardio-respiratory safety profile.

Remimazolam is currently in clinical Phase III development for procedural sedation in the U.S. After completion of the ongoing development, the implementation of a pediatric development plan already agreed with the FDA is planned. A full clinical development program for general anesthesia was completed in Japan, and a Phase II study in general anesthesia was completed in the EU. Based on the positive results of a Phase II study, development for ICU sedation beyond 24 hours is another attractive indication.

¹¹ Ernst & Young: EY M&A Outlook and Firepower Report 2017 – Will payer leverage and post-election optimism shift dealmaking into a higher gear?.

¹² PwC Health Research Institute: Top health industry issues of 2017 – A year of uncertainty and opportunity, December 2016; Scrip Pharma Intelligence: Expect Industry To Step Up Drug Pricing Self-Regulation In 2017 – PwC, 15 December 2016.

Procedural Sedation (U.S. lead indication)

Based on external sources (Symphony Health Solutions, Centers for Disease Control and Prevention) and own projections, PAION estimates that approximately 43 million procedures using procedural sedation took place in the U.S. in 2013, 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 colorectal cancer screening using colonoscopy, and an increase in demand for preventive screenings. According to iData Research, which draws from an extensive collection of national- and state-level procedure databases to examine historical trends and create procedure forecasts in the U.S., 26.7 million colonoscopy and endoscopy claims were reported in 2015 in the U.S., and the number is expected to grow at an average rate of 2.6% annually through 2020. PAION estimates that 75% of the colonoscopies and endoscopies claimed were conducted in an out-patient setting due to the higher reimbursement fees compared to hospitals.

Regular endoscopic 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 cancer victims and payors. Statistics show that the rate at which people are diagnosed with colon cancer in the U.S. has dropped by 30% in the last 10 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 both men and women 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 lucrative market segment for remimazolam in procedural sedation with approximately 20 million procedures per year.

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. 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 cost. 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 will be placed on innovative medicines with strong clinical profile.

Thus, PAION believes that concerns related to the overall cost of procedures, driven by the need for anesthesia professionals monitoring 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. 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 believes that remimazolam, subject to FDA approval with a safety labeling comparable to that of midazolam, could benefit from the pending changes in payment policies. Provided that it could be administered under the supervision of a proceduralist, remimazolam would be able to offer a competitive alternative to midazolam. This is based on its enhanced efficiency profile compared to midazolam.

General Anesthesia (Japan + EU lead indication)

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 ageing 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.

Another potential and attractive indication could be intensive care unit (ICU) sedation, which is currently not in focus for PAION. Another field of great clinical need is pediatric use, which is a development requirement for both the EU and U.S. after the respective first approval.

Clinical development

Plan to have tested remimazolam on more than 1,500 volunteers/patients at FDA filing	
Phase II and III studies	Phase I studies
Procedural Sedation (U.S.)	
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 (420)*	Phase I Abuse Liability
	• Intravenous administration (40)
	• Oral bioavailability (14)
	Phase I Abuse Liability*
	• Oral administration in combination with alcohol (approx. 50–60)
	• Intranasal administration part 1 (approx. 10–15)
	• Intranasal administration part 2 (approx. 10–15)
General Anesthesia (Japan)	
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 III in cardiac surgery patients (23)**	
ICU Sedation (Japan)	
Phase II in ICU patients (49)**	

Patient/volunteer numbers in bracketed

*) Studies not yet completed

***) Discontinued studies, no safety concerns

Procedural sedation (Lead indication U.S.)

A total of six Phase I, two Phase II and two Phase III trials have been completed in procedural sedation. 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 being selected for use in the ongoing Phase III program.

In March 2015, the first U.S. Phase III study was started, the patient recruitment was completed in April 2016, and in June 2016, PAION announced that remimazolam met its primary efficacy endpoint. 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.

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.

Further data on the clinical results of remimazolam's U.S. Phase III colonoscopy trial were presented at the 2016 American College of Gastroenterology (ACG) Annual Scientific Meeting in Las Vegas in October 2016:

	Remimazolam	Placebo	Midazolam (Open Label)*
Success of procedure	91.3%	1.7%	25.2%
Use of rescue sedation	3.4%	95.0%	64.7%
Average fentanyl dose	88.6 mcg	121.3 mcg	106.9 mcg
Time from start of medication to start of procedure (median)	4.0 minutes	19.5 minutes	19.0 minutes
Time from end of procedure to fully alert (mean)	7.2 minutes	21.3 minutes	15.7 minutes
Time to back to normal	331 minutes	572 minutes	553 minutes

*) not part of label claim

Patient satisfaction was similar in all arms of the study.

In addition to the above study, the U.S. Phase III program includes a second confirmatory, prospective, double-blind placebo-controlled, randomized, multi-center open label vs. midazolam trial in 420 patients undergoing bronchoscopies. Patient recruitment was initially moderate. However, continuous measures to accelerate patient recruitment, such as improvements in the feasibility of the study protocol, opening additional study centers and intensified support of existing study

centers have significantly increased the recruitment rate and completion of patient recruitment is expected shortly.

As part of the U.S. development program, also a safety study in ASA III/IV patients undergoing colonoscopy (American Society of Anesthesiologists classification) was performed. In December 2016, successful completion of patient recruitment was announced, and headline data are planned to be presented shortly. This prospective, double-blind, randomized, placebo- and active controlled, multicenter, parallel group study enrolled 79 high-risk patients (i.e. ASA III/IV) undergoing a colonoscopy into a remimazolam, midazolam or placebo (including midazolam 'rescue' sedation) treatment group.

Four Phase I studies were performed in the course of the U.S. Phase III development program. Based on the results of preclinical and Phase I studies and in consultation with the FDA, PAION will now start additional Phase I studies to further assess the abuse potential of remimazolam. One aspect is if remimazolam could inappropriately be used as a knock-out cocktail in combination with alcohol and another aspect is if it could be abused intranasally.

General anesthesia (Lead indication in Japan + EU)

A total of three Phase I (Japan), two Phase II (Japan and EU) and two Phase III (Japan) trials in general anesthesia have been completed. In the clinical program, specific attention was paid to hemodynamic stability, which addresses a current need in general anesthesia. Preclinical data had suggested that remimazolam may lead to a hemodynamic stability; this has been clinically confirmed.

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.

Based upon the successful completion of Phase III in Japan, a pre-NDA meeting (NDA = New Drug Application) with the Japanese Pharmaceuticals and Medical Devices Agency ("PMDA") took place in January 2016. During the meeting, all open questions raised for discussion following the preliminary assessment of the PMDA were clarified. The PMDA stated that the non-clinical and clinical data package were regarded as complete for filing in the indication "Induction and maintenance of general anesthesia". The clinical development program fully carried out in Japan by PAION's former partner Ono in general anesthesia was complemented by PAION's growing data sets in all aspects from CMC (chemistry, manufacturing, control) to clinical and pre-clinical data generated outside of Japan. In October 2015, PAION already reported that the PMDA had confirmed that both the raw materials produced by PAION in Europe as well as the finished formulation of remimazolam fulfill the requirements for filing in Japan. PAION now plans the preparation and submission of an application for market approval of remimazolam in Japan. This includes, among

other things, the necessary validation of commercial-scale production for the Japanese market. The required approval dossier will be prepared by an experienced contract research organization (CRO) in close consultation with PAION. Such a dossier could serve as a reference dossier in certain other markets. This would significantly reduce the necessary additional investment for partners in the respective markets depending on the specific regulatory environment.

In order to allow using the Japanese data for filing in the EU, the same induction and maintenance doses were used in the European Phase II trial performed in 2014, delivering further evidence for a potentially beneficial hemodynamic profile of remimazolam.

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.

In the meantime, PAION evaluated how to resume the clinical development of remimazolam in the EU. Based on the findings, PAION considers a study design analogous to the successfully completed Phase III program in general anesthesia in Japan to be useful. Such a Phase III study would thus be conducted with procedures in general surgery. Therefore and based on consultation with key opinion leaders in general anesthesia, a Phase I study is currently being prepared aiming at determining required patient numbers for the new Phase III study with a different patient population as precisely as possible. In this Phase I study it is planned to measure the depth of sedation of remimazolam particularly accurately on the basis of the subjects' brain activity, since sedation depth needs to be measured objectively in addition to the subjective measurement by an anesthetist as an approval prerequisite in the EU. In particular, it is supposed to be demonstrated that patients are sufficiently narcotized during the surgery compared to the reference medication.

For a Phase III program in the EU, PAION currently expects funding needs of approx. EUR 20 million to EUR 25 million until filing for market approval subject to further coordination with the regulatory authority. Secured funding, the conduct of the preparatory Phase I study and the necessary scientific consultations with the relevant European regulatory authority EMA to specify the new European Phase III program are a prerequisite for a study start in 2018.

ICU sedation

PAION's former partner in Japan, Ono, independently initiated a Phase II trial for sedation in intensive care units (ICUs). Higher than expected plasma concentrations of remimazolam were observed in isolated cases after long-term treatment 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 the patient presenting on the ICU. Further development of the program "ICU sedation" is part of the future remimazolam development plan which could be addressed after availability of required funds.

Partnering

Remimazolam is partnered in the U.S., Canada, China, Russia (CIS), Turkey, the MENA region, and South Korea with Cosmo, Pharmascience (Pendopharm), Yichang Humanwell, R-Pharm, TR-Pharm, and Hana Pharm, respectively. For all other markets, remimazolam is available for licensing.

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 m	EUR 4 m	10%
Hana Pharm, S. Korea (2013)	EUR 1 m	EUR 2 m	10%
R-Pharm, CIS (2013)	EUR 1 m	EUR 3 m	Low double-digit
(T)R-Pharm, Turkey (2013)	EUR 1 m	EUR 3 m	Low double-digit
(T)R-Pharm, MENA (2014)	EUR 1.5 m	EUR 5.5 m	Low double-digit
Pendopharm, Canada (2014)	EUR 0.4 m*	~ EUR 4.0 m	Tiered (starting at 15%)
Cosmo, U.S. (2016)	EUR 20 m**	EUR 42.5 m	20–25%***
Total	EUR 33.8 m	~ EUR 64 m	

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

**) Comprising EUR 10 million received via private placement in June 2016 and via capital increase with subscription rights conducted in February 2017 as well as the received upfront payment in the amount of EUR 10 million.

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

In June 2016, PAION entered into an investment and a license agreement with Cosmo. In the course of the investment agreement, Cosmo has committed to invest an amount of EUR 10 million in PAION shares. Cosmo invested an amount of EUR 9.6 million in the course of a capital increase under exclusion of shareholders' subscription rights ("private placement") in June 2016 and the remaining EUR 0.4 million in the course of a capital increase with subscription rights in February 2017.

In the course of the license agreement, Cosmo has received an exclusive license for the development and commercialization of remimazolam in the U.S and is responsible for the market authorization as well as sales and distribution of remimazolam. PAION remains responsible for and bears the cost associated with the completion of the ongoing U.S. clinical development program in procedural sedation. In addition to an upfront payment in the amount of EUR 10 million already received, PAION in return is entitled to receive further payments of up to EUR 42.5 million depending on the achievement of certain regulatory milestones in total for all of the three indications in the U.S., as well as tiered royalties upon commercialization ranging from 20% to 25% of the net sales (which may be adjusted under certain conditions but not to below 15%). EUR 4.3 million of the received upfront payment were recognized as revenues on group level in the reporting period and EUR 5.7 million will presumably be recognized as revenues on group level in fiscal year 2017.

PAION has selectively formed, and seeks to enter into, development and marketing collaborations with partners with local expertise or with a specific therapeutic focus with respect to remimazolam. Such collaborations are an effective way of funding and advancing remimazolam's late-stage development and of assisting PAION with its commercialization in international markets where PAION does not intend to directly conduct sales and marketing activities. PAION expects that the existing collaboration partners will continue the development of remimazolam on the basis of data generated from our U.S., Japanese and European clinical development programs, and subsequently PAION may receive additional data and payments under the existing agreements in the medium to long term. PAION's ultimate goal is to participate in the worldwide commercialization of remimazolam and is well positioned to also find further collaboration partners. 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.

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

a. Results of operations

The net result decreased by KEUR 2,120 from a net income of KEUR 538 in the prior year to a net loss of KEUR 1,582 in fiscal year 2016. This change compared to the previous year mainly resulted from multiple factors. On the one hand, in the course of the ongoing intensive development activities of the subsidiary PAION UK Ltd for remimazolam, higher interest income from the loan granted to the subsidiary was realized in the reporting period. On the other hand, the result was mainly strained by higher expenses and lower income from exchange rate differences as well as expenses arising from the preparation of potential capital measures that were ultimately not conducted and expenses in connection with the private placement carried out with Cosmo in June 2016.

The net result is slightly below the previous year's forecast range for 2016.

	2016 KEUR	2015 KEUR	Change in result KEUR
Revenues	1,146	0	1,146
Other operating income	1,251	3,327	-2,076
Personnel expenses	-1,793	-1,517	-276
Depreciation and amortization	-5	-5	0
Other operating expenses	-4,767	-3,190	-1,577
Operating result	-4,168	-1,385	-2,783
Financial result	2,586	1,923	663
Net result	-1,582	538	-2,120

Revenues increased by KEUR 1,146 in the reporting period compared to the previous year and resulted entirely from the provision of management and other services to the subsidiaries, of which PAION UK Ltd accounted for KEUR 978 (previous year: KEUR 0) and PAION Deutschland GmbH for KEUR 168 (previous year: KEUR 0). The increase compared to previous year is the result of the first-time application of the German Accounting Directive Implementation Act (Bilanzrichtlinie-Umsetzungsgesetz, BilRUG) leading to disclosure of services as revenues from 2016 onward which were previously recognized as other operating income.

Other operating income decreased by KEUR 2,076 in the reporting period compared to the previous year and mainly comprises foreign exchange gains in the amount of KEUR 789 (previous year: KEUR 2,005). Moreover, other operating income includes recharges to the subsidiaries (KEUR 389; previous year: KEUR 1,305), of which PAION UK Ltd accounted for KEUR 341 (previous year: KEUR 1,120) and PAION Deutschland GmbH for KEUR 48 (previous year: KEUR 186). The decrease in income from recharges within the PAION Group compared to the previous year is the result of the first-time application of the BilRUG leading to disclosure of services as revenues from 2016 onward which were previously recognized as other operating income.

Personnel expenses increased by KEUR 276 to KEUR 1,793. This development is mainly due to the higher average number of employees compared to 2015 in the reporting period.

Year on year, **other operating expenses** increased by KEUR 1,577 to KEUR 4,767 and mainly include legal and consulting fees (KEUR 2,067; previous year: KEUR 919), insurance, contributions and fees (KEUR 243; previous year: KEUR 276), travel expenses (KEUR 217; previous year: KEUR 249), services rendered by PAION Deutschland GmbH (KEUR 190; previous year: KEUR 184), expenses in connection with Supervisory Board remuneration (KEUR 122; previous year: KEUR 131) as well as audit costs and costs for the annual report (KEUR 73; previous year: KEUR 120). In the reporting period, an impairment on trade receivables from PAION, Inc. in the amount of KEUR 350 (previous year: KEUR 0) is included in other operating expenses and foreign exchange losses in the amount of KEUR 1,220 (previous year: KEUR 1,064) have been recognized. Compared to the previous year, the significant increase of the other operating expenses is mainly due to the preparation of potential capital measures, which were ultimately not conducted due to the conclusion of a license agreement and an investment agreement with the U.S. license partner Cosmo, as well as expenses incurred in connection with the private placement conducted with Cosmo in June 2016.

Compared to the previous year, the **financial result** has improved by KEUR 663 to KEUR 2,586. The increase of the financial result mainly stems from higher interest income from affiliated companies which was generated from the loans granted to the PAION UK Group companies and PAION, Inc. (KEUR 2,565; previous year: KEUR 1,881).

b. Net assets and financial position

The balance sheet total as of 31 December 2016 amounts to KEUR 113,145 and has increased by KEUR 8,223 compared to the previous year. The equity ratio, as in the previous year, is 99.5% at the current balance sheet date. As of 31 December 2016, cash and cash equivalents amounted to KEUR 27,828 and decreased by KEUR 3,647 compared to the previous year.

	31 Dec. 2016 KEUR	31 Dec. 2015 KEUR	Change KEUR
Fixed assets	12,781	12,786	-5
Current assets and prepaid expenses	100,364	92,136	8,228
Assets	113,145	104,922	8,223
Equity	112,543	104,438	8,105
Current liabilities	602	484	118
Shareholders' equity and liabilities	113,145	104,922	8,223

Fixed assets mainly relate to the shares in PAION Holdings UK Ltd (KEUR 12,318), the shares in PAION Deutschland GmbH (KEUR 450) and the shares in PAION, Inc. (KEUR 8).

The **current assets** (including prepaid expenses) have increased by KEUR 8,228 in fiscal year 2016. On the one hand, loans granted to the subsidiaries have increased by KEUR 11,905 to KEUR 72,085. On the other hand, cash and cash equivalents have decreased from KEUR 31,475 to KEUR 27,828.

The increase of **current liabilities** by KEUR 118 to KEUR 602 mainly results from higher provisions in the reporting period.

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

	2016 KEUR	2015 KEUR
Cash flow from operating activities	-604	319
Cash flow from investing activities	0	0
Cash flow from financing activities	-3,043	-26,458
Change in cash and cash equivalents	-3,647	-26,139

The **cash flow from operating activities** mainly resulted from the net result of the year, corrected by cost of funds (KEUR 475) incurred in connection with the private placement conducted with Cosmo in June 2016, as well as working capital changes.

The **cash flow from financing activities** mainly resulted from the (net) grant of loans to subsidiaries (KEUR 12,255), gross proceeds from the private placement conducted with Cosmo in June 2016 (KEUR 9,643) as well the cost of funds in this regard (KEUR 475). In the previous year, the cash flow from financing activities primarily resulted from the (net) grant of loans to subsidiaries (KEUR 26,480).

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

The Group generated a consolidated net loss of KEUR 20,118 in fiscal year 2016 (previous year: net loss of KEUR 28,212). The key items in the consolidated balance sheet as of 31 December 2016 were cash and cash equivalents (KEUR 30,111; previous year: KEUR 32,680) and equity (KEUR 24,943; previous year: KEUR 35,562).

Headcount

As of 31 December 2016, the total headcount of the PAION Group was 34 employees, of whom six worked for PAION UK Group and three worked for PAION, Inc. By comparison, the headcount as of 31 December 2015 amounted to 35 employees. As of 31 December 2016, the headcount at PAION AG totalled eight employees (previous year: eight 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 2008 approved by the Annual General Meeting on 5 May 2008, a total of 391,650 stock options were granted to acting Management Board members at the time of the respective grant. The Supervisory Board determined the number of stock options to be allocated to the Management Board. The two- to 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 members of the Management Board is EUR 1.26 or EUR 1.84 per stock option depending on the grant date 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 2016, the exercise hurdle was EUR 1.78 or EUR 2.48 depending on the grant date.

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 2016, the exercise hurdle was EUR 2.30.

From the Stock Option Plan 2014 approved by the Annual General Meeting on 21 May 2014, a total of 277,500 stock options were granted to acting Management Board members at the time of the grant, thereof 111,000 in fiscal year 2016. The Supervisory Board determined the number of stock options to be allocated to the Management Board. The four-year waiting period before stock options can be exercised acts as a long-term incentive to increase the company's value. The exercise price of stock options granted to current Management Board members is EUR 1.99 or EUR 2.30 per stock option, depending on the date of issue of the stock options, and is based on the average price of the shares in a certain time period before the allocation in accordance with the terms of the stock option plan. As of 31 December 2016, the exercise hurdle was EUR 2.04 or EUR 2.52, 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 2016 (according to German Corporate Governance Code) can be gathered from the following tables:

Benefits granted in EUR	Dr. Wolfgang Söhngen CEO			
	2015	2016	2016 (Min)	2016 (Max)
Fixed compensation	262,500	275,000	275,000	275,000
Other remuneration	47,974	48,471	48,471	48,471
Total	310,474	323,471	323,471	323,471
One-year variable compensation	120,000	175,000	0	175,000
Multi-year variable compensation				
Stock Option Plan 2014 - Grant 2015 (Waiting period 2015 to 2019)**	62,715	0	-	-
Stock Option Plan 2014 - Grant 2016 (Waiting period 2016 to 2020)**	0	56,610	-	-
Total	493,189	555,081	323,471	498,471
Service cost	0	0	0	0
Total remuneration	493,189	555,081	323,471	498,471
*) Prior year remuneration for Dr. Raths relates to the time period since joining the Management Board				
**) Applicable fair value at the time of issuance, calculated using the Black/Scholes option pricing model				

Allocation in EUR	Dr. Wolfgang Söhngen CEO	
	2015	2016
Fixed compensation	262,500	275,000
Other remuneration	47,974	48,471
Total	310,474	323,471
One-year variable compensation	48,000	124,600
Multi-year variable compensation	0	0
Total	358,474	448,071
Service cost	0	0
Total remuneration	358,474	448,071
*) Prior year remuneration for Dr. Raths relates to the time period since joining the Management Board		

	Abdelghani Omari CFO				Dr. Jürgen Raths* COO since 1 September 2015			
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	2015	2016	2016 (Min)	2016 (Max)	2015	2016	2016 (Min)	2016 (Max)
	150,000	165,000	165,000	165,000	105,000	315,000	315,000	315,000
	15,127	15,127	15,127	15,127	42	127	127	127
	165,127	180,127	180,127	180,127	105,042	315,127	315,127	315,127
	60,000	70,000	0	70,000	0	50,000	0	50,000
	62,715	0	-	-	0	0	-	-
	0	56,610	-	-	0	0	-	-
	287,842	306,737	180,127	250,127	105,042	365,127	315,127	365,127
	0	0	0	0	0	0	0	0
	287,842	306,737	180,127	250,127	105,042	365,127	315,127	365,127

	Abdelghani Omari CFO		Dr. Jürgen Raths* COO since 1 September 2015	
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	2015	2016	2015	2016
	150,000	165,000	105,000	315,000
	15,127	15,127	42	127
	165,127	180,127	105,042	315,127
	24,000	53,690	0	41,100
	0	0	0	0
	189,127	233,817	105,042	356,227
	0	0	0	0
	189,127	233,817	105,042	356,227

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

Management Board remuneration in fiscal year 2016 amounted to KEUR 1,151 in total (previous year: KEUR 1,160) and is composed as follows:

in EUR	2016	2015
Fixed remuneration	755,000	709,167
Other remuneration	63,725	98,997
Total non-performance based remuneration	818,725	808,163
Short-term variable remuneration	219,390	163,667
Total short-term remuneration	1,038,115	971,830
Long-term variable remuneration	113,220	188,145
Total long-term remuneration	113,220	188,145
Total remuneration	1,151,335	1,159,975

The Management Board members held the following stock options as of 31 December 2016:

Status of non-exercised stock options as of 31 December 2016:		Dr. Wolfgang Söhngen	Dr. Jürgen Raths	Abdelghani Omari
Stock options 2008	No.	98,067	0	0
Stock options 2008 - fair value*	EUR	163,909	-	-
Stock options 2010	No.	162,000	0	80,000
Stock options 2010 - fair value*	EUR	270,540	-	133,600
Stock options 2014	No.	111,000	0	111,000
Stock options 2014 - fair value*	EUR	119,325	-	119,325

*) 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 200% of their annual fixed basic remuneration. For Dr. Jürgen Raths, a claim to termination benefits in connection with a change of control could only have been exerted if the change of control had also entailed 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 2008, 2010 and 2014, 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 currently 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. Members of the Supervisory Board who are resident in a country outside Europe receive double the regular per-meeting fee for each Supervisory Board meeting they physically attend. The per-meeting fee is paid for a maximum of six meetings per year. The members of the Supervisory Board received the following remuneration for their activities in fiscal year 2016:

	Basic remuneration EUR	Per-meeting fees EUR	Total EUR
Dr. Jörg Spiekerkötter	40,000	15,000	55,000
Dr. Karin Dorrepaal	30,000	11,250	41,250
John Dawson	20,000	6,000	26,000

Supervisory Board remuneration in fiscal year 2016 amounted to KEUR 122. In the previous year the remuneration amounted to KEUR 131.

Disclosures pursuant to section 289 (4) HGB and explanatory report

Composition of subscribed capital

As of 31 December 2016, PAION AG had a subscribed capital of EUR 55,757,094.00, divided into 55,757,094 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 2016 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 19 May 2020, with the consent of the Supervisory Board, on one or more occasions, by up to EUR 25,320,970.00 in total by issuing up to 25,320,970 new no-par value bearer shares in return for cash contributions or contributions in kind (Authorized Capital 2015). 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 20 May 2015 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. By resolution from 24 June 2016, the Authorized Capital 2015 was used in the amount of EUR 5,064,194.00 and amounts to EUR 20,256,776.00 as of 31 December 2016.

Furthermore, subject to the consent of the Supervisory Board, the Management Board is authorized to issue on or before 19 May 2020, 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 22,433,285.00 in total (Conditional Capital 2015). Conditional Capital 2015 has not yet been used. Furthermore, the company is authorized to issue 34,847 shares (Conditional Capital 2004 II), 518,604 shares (Conditional Capital 2008 I), 720,000 shares (Conditional Capital 2010 I), 740,000 shares (Conditional Capital 2014) and 840,000 shares (Conditional Capital 2016) in connection with the Stock Option Plans 2005, 2008, 2010, 2014 and 2016.

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

The company has not concluded material arrangements which are dependent on a change in control in the event of a takeover bid.

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 and 2016 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 a HGB

The Statement on Corporate Governance pursuant to Section 289 a 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 and future opportunities. 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 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 interim 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 interim and annual financial statements are published and are discussed with 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 to drug candidate 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, the conduct of clinical studies in the respective study centers is monitored by independent third parties and an independent data monitoring committee. 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 according to Tufts Center for the Study of Drug Development.¹³

In order to ensure a timely filing for approval of remimazolam in the U.S. after completion of the clinical studies, 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 are not met sufficiently leading to a delay of market approval. This is an industry-specific high risk. In case of occurrence, the potential damage level could pose a threat to the continued existence of the group.

PAION conducts various clinical studies with different requirements in terms of patient and volunteer profiles and thus patient and volunteer populations. There is a risk that patients cannot be recruited fast enough or at all for individual studies. The resulting delay/necessary amendment or discontinuation of studies would usually (e. g. in case of the initiation of a new study) lead to higher costs and delayed market approval. 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 high risk. In case of occurrence, the potential damage level could pose a threat to the continued existence of the group.

¹² Tufts Center for the Study of Drug Development (2014): Briefing – Cost of Developing a New Drug.

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. 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, potential dosage modifications and amendments to clinical trial protocols 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 moderate risk. The risk classification of insufficient study outcomes decreased 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. 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 has obtained official scientific advice from the respective authorities in the EU and the U.S. Moreover, PAION consults regulatory experts. This is a high risk.

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 the studies. 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. 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 increased by one category compared to the previous year.

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 or PAION's contractual manufacturers 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 regularly conducts own audits in order to ensure a constantly high quality of the manufacturing. 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 of remimazolam, potential commercialization is closing in as well and imposes several risks.

PAION has conducted comprehensive market research as a basis for assessing different market potentials. However, there is a risk 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 cannot be influenced. 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 license partners will not be able to sufficiently prepare the market for launch by means of pre-marketing and market access activities as for example communication 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. This is a high risk.

In order to be able to successfully commercialize remimazolam upon market approval, the distribution set-up needs to be fully established. There is a risk that this process will not have been finalized until market approval. In order to reduce this risk to the highest possible degree, PAION has analyzed potential distribution set-ups and there is a regular information exchange with the U.S. cooperation partner Cosmo. 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 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

So far, relatively low quantities of remimazolam have been produced in course of the clinical trials. Up until commercialization, a further so-called scale-up process needs to be finalized. There is a risk that as a result of this process, remimazolam cannot be produced in sufficient quantities or at competitive costs for the market. This is a typical development risk that can only be influenced to a minor extent. However, in order to reduce this risk, PAION cooperates with established manufacturers and conducts a process validation before beginning commercialization in order to guarantee technical feasibility. This is an increased risk. In case of occurrence, the potential damage level could pose a threat to the continued existence of the group.

Moreover, (additional) requirements of the authorities or problems relating to process validation might delay production development and 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. 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 has increased by one category compared to the previous year.

Due to the currently limited availability of stability data for remimazolam, there is a risk that for potential new or further studies, additional batches of the drug product need to be manufactured unless process validation has been finalized until then. This could lead to a delay of studies and incur additional costs. PAION is therefore working on a timely process validation in cooperation with experienced and renowned Contract Manufacturing Organizations (CMOs). This is a moderate risk.

Based on the production risks depicted, there is a risk that (potential) supply obligations towards license partners cannot be fulfilled if production development has not been completed. In cooperation with its contractual manufacturers, PAION would initiate the acceleration of validation procedures if a shortage in that regard should become foreseeable. This is an increased risk.

Medical ingredients are combined with certain other substances in order to have a sufficient shelf life, to be well applicable and to be specifically operative in the human organism among other things. In spite of a variety of tests, there is a risk that such a so-called pharmaceutical formulation does not remain stable in the long term and can thus not or only be used with reduced shelf life for products sold at the market. In order to reduce this risk to the highest possible extent, PAION continuously conducts tests and long-term stability studies before commercialization. This is a moderate risk.

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

Although PAION already cooperates with experienced and established contractual manufacturers, commercial supply agreements have not been finalized yet. There is a risk that a timely

agreement cannot be reached leading to a delay of commercialization or higher costs. This is a high risk that PAION addresses by means of industry-typical precautions. In case of occurrence, the potential damage level could pose a threat to the continued existence of the group.

dd) Risks in relation to patents and other intellectual property

PAION's business operations are largely dependent on its ability to secure extensive patent protection and other intellectual property protection for the individual substances and to defend these against third parties without violating their rights. There can be no assurance that current or future patent applications will be granted or that any patents issued or licensed to PAION will be valid and sufficiently extensive to provide PAION and its license partners with adequate legal protection or any commercial advantage.

PAION continuously collaborates with an experienced patent law firm to secure the protection of PAION's intellectual property and to identify and address potential threats at an early stage as well as to make sure to not infringe any other third parties' patents itself. This is an increased risk.

ee) Partnering risks

In light of the progress of the development activities for remimazolam, important regulatory coordinations and meetings with the respective regulatory authorities are increasingly coming into focus for PAION's license partners. There is a risk that results from discussions with the authorities render the further development of remimazolam unattractive for existing license partner 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 license partners and engages in the evaluation of development plans in order to make sure meeting the respective regional regulatory requirements. 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.

Since PAION neither owns distribution structures nor aims at implementing these globally, potential commercialization of remimazolam can only be carried out by license partners in certain 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 regularly has partnering discussions with potential licensees in order to allow for an immediate 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 needs additional funding for further development in the EU or 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 license partners are not met.

PAION's future ability to secure additional funding will depend on the success of its development and licensing 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 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 and (potential) pharma partners. 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, in particular on the U.S. dollar and the pound sterling to a lower degree. These primarily relate to the development of remimazolam in the U.S. A strong rise of the U.S. dollar 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. Currency risks also arise from translating the foreign subsidiaries' separate financial statements from pound sterling or U.S. dollar into euros because the pound sterling/U.S. dollar is the functional currency of the UK subsidiaries/U.S. subsidiary.

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 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, British and U.S.-American 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, income tax payments would become due on the expected earnings if remimazolam is developed successfully. Dependent on the actual structure which has neither been decided nor can be anticipated yet, the consequences of a potential Brexit could also lead to tax payments on potential earnings expected in the future. 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 legislation change or 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.

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. 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.

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.

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.

Remimazolam is currently in Phase III development in the U.S. in procedural sedation for minor medical interventions; an extensive Phase III study in patients undergoing colonoscopies and a smaller Phase III safety study in severely sick patients undergoing colonoscopies were already successfully completed. The development for general anesthesia in Japan is completed, and PAION expects that only one Phase III trial will be required for market approval in the EU. For Japan, PAION plans to start work on a market approval dossier and to look for a partner for commercialization. Approval in Japan could give access to specific other markets (e. g. Latin America, Asia-Pacific region). After completion of the development in the U.S. and the EU, it is intended to use the respective approval dossiers in the course of filing for market approval in other regions as well. The third indication is ICU sedation, and a respective Phase II study was already started in Japan, but not completed. PAION deems each of these three indications to have attractive sales potentials based on the respective regional conditions.

PAION benefits from the progress of the development of remimazolam in the U.S. and the development partners in China, South Korea, Canada, Russia/CIS, Turkey, and the MENA region financially in the form of milestone payments and royalties from launch onwards as well as in the form of additional development data. For the EU, an own commercialization is targeted, but partnering options are being evaluated as well. For all other regions, it is targeted to find license or distribution partners. In 2017, focus is on the completion of the U.S. Phase III program in order to allow handing over to Cosmo completely and enable Cosmo to subsequently file for market approval for procedural sedation in the U.S as soon as possible. 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 successfully completed Phase III studies with remimazolam in the U.S. were an important milestone on the pathway to market approval. In particular, positive results from the comprehensive colonoscopy study in 461 patients have substantially contributed to finding a strong license partner for the U.S. market with Cosmo who are featuring a range of products that perfectly match remimazolam. Since further development of remimazolam in the indication general anesthesia in the EU requires additional funds, PAION's success is currently nearly entirely dependent on the successful completion of the development in the U.S. Even though the risk remains that this development is not successful in the end, the risk situation has improved in comparison to the previous year in light of the development progress and the partnering of the U.S. market.

It is anticipated that the imminent completion of recruitment of the last Phase III study in the U.S. in bronchoscopy patients in the indication procedural sedation and the resulting data will be another important milestone on the way to filing for market approval in the indication procedural sedation in the U.S. In addition, PAION expects that potential additional positive study data will further improve the opportunity situation. It is expected that the preparation of a market approval dossier for Japan will bring new dynamics to discussions with potential Japanese partners. Taking into account the above-mentioned factors, the opportunity situation has improved in comparison to the previous year.

Report on post-balance sheet date events

In February 2017, a capital increase with subscription rights and gross proceeds of EUR 4.99 million was successfully completed. By utilization of the Authorized Capital 2015 in the amount of EUR 2,439,023.00, the share capital of PAION AG was increased from EUR 55,757,094.00 to EUR 58,196,117.00 by issuing 2.439.023 new shares. The remaining Authorized Capital 2015 amounts to EUR 17,817,753.00 after this transaction.

Dr. Jürgen Raths resigned from his office as Chief Operating Officer of PAION AG as of the end of 14 March 2017.

There were no further significant events in the period between the reporting date, 31 December 2016, and the preparation of this report.

Report on expected developments

Outlook on development and commercialization (PAION group)

PAION's major goals for 2017 are the completion of the ongoing clinical development program in the U.S. and the handover of the completed work to Cosmo. In addition, PAION continues to work on production development for remimazolam. Furthermore, PAION will commence work on a filing dossier for the Japanese market in general anesthesia. In preparation for the EU Phase III development program in general anesthesia, a Phase I study and necessary consultations with the regulatory authority are planned to be conducted. PAION expects its other regional partners to continue their remimazolam development activities.

In the U.S., PAION is allocating significant resources to achieve the planned completion of the Phase III program, especially on patient enrolment in the Phase III bronchoscopy study and the subsequent evaluation of the study data. In addition, PAION is working on the data analysis of the remimazolam safety trial in ASA III/IV colonoscopy patients completed in December 2016. The development program is being completed by further smaller (preclinical and Phase I) studies. Regular interactions with the FDA in this regard are being maintained in order to ensure that all data relevant for the regulatory authority have been collected. This will be followed by an integrated

“overall” analysis of all clinical studies with remimazolam. Subject to the successful completion of the clinical development program, including the completion of all analyses and reports, filing for approval in the U.S. could take place subsequently after finalization of a market approval dossier. Before filing, usually a pre-NDA meeting with the U.S. regulatory authority FDA is held, which is currently planned to take place in the end of 2017. The necessary coordination and preparatory work are currently being conducted with Cosmo, U.S. key opinion leaders and regulatory experts. Filing for market approval will then take place under Cosmo’s responsibility depending on the outcome of the pre-NDA meeting. Conditional on successful study results and dependent on interactions with the FDA, PAION and Cosmo currently expect filing for approval mid of 2018.

For the EU, PAION is currently planning to continue the clinical development program for remimazolam with a study design analogous to the successfully completed Phase III program in general anesthesia in Japan. Secured funding, the conduct of the preparatory Phase I study and the necessary scientific consultations with the relevant European regulatory authority EMA to specify the new European Phase III program are a prerequisite for a study start in 2018.

Based on the positive pre-NDA meeting with the Japanese authority in the beginning of 2016 and the financing in February 2017, PAION will now prepare an application for market approval of remimazolam in Japan. This creates important prerequisites to further continuing partnering discussions with potential licensees in parallel with the aim to partner the Japanese market during the process of dossier preparation or subsequently. The preparation includes, among other things, the necessary validation of commercial-scale production for the Japanese market. Such a dossier could serve as a reference dossier for market approval in certain other markets. This would significantly reduce the necessary additional investment volume for partners in the respective markets depending on the specific regulatory environment. Subject to further coordination with the regulatory authority, filing for market approval in Japan is expected by mid-2018.

Financial outlook (PAION group)

In 2017, PAION expects revenues of approximately EUR 5.8 million. These mainly result from the upfront payment of EUR 10 million received from Cosmo in connection with the U.S. license agreement for remimazolam in July 2016, of which EUR 4.3 million were already realized as revenues in the reporting period. Depending on the progress of certain development components, the remaining EUR 5.7 million of the upfront payment will presumably be recognized as revenues in 2017. No further license agreements or milestone payments from existing license agreements are included in the financial planning for fiscal year 2017 which is the basis for the financial outlook.

Due to the ongoing investment in the development of remimazolam, PAION expects research and development expenses to be between approximately EUR 18 million and EUR 20 million, depending on the progress of development. Income from tax credits on parts of the research and development expenses from British tax authorities is expected to be between EUR 3.5 million and EUR 4 million. General administrative and selling expenses are expected to amount to approximately EUR 3.5 million to EUR 4 million. Net loss is expected to be between approx.

EUR 12 million and approx. EUR 14 million, a decrease compared to the reporting period (2016: EUR 20.1 million).

This outlook assumes that development activities for remimazolam in the U.S. will progress as expected. Otherwise, cost blocks would shift into 2018. Expense forecasts are also based on the current status of discussions with the FDA. Costs could be higher than planned and lead to a delay in approval should the FDA impose additional requirements for filing for market approval.

Based on current plans, PAION believes that cash and cash equivalents of EUR 30.1 million as of 31 December 2016 enable PAION to complete all remaining development activities in the U.S. Thereafter, PAION expects to receive further payments from Cosmo subject to the achievement of certain regulatory milestones in the U.S., and, once remimazolam is approved, royalties on net sales. Should development, filing and approval go according to plan, PAION will not need additional funding to bring remimazolam to the U.S. market. For the further development in the EU, PAION is currently planning to continue the clinical development program for remimazolam. In order to carry out a development program in the EU, additional funding of approximately EUR 20 million to EUR 25 million is required until filing for approval, subject to further coordination with the regulatory authority. Cash and cash equivalents including expected tax credits from the British tax authorities on parts of the research and development expenses secure a cash reach at least until the end of 2018 without consideration of potential milestone payments and without consideration of potential costs incurred by the targeted continuation of the Phase III development program in the EU.

Under consideration of the current cost structures, a net result of approximately EUR 0.5 million to EUR -1.0 million is expected for PAION AG in fiscal year 2017.

Aachen, Germany, 15 March 2017

PAION AG



Dr. Wolfgang Söhnge



Abdelghani Omari

Financial Statements

PAION AG

Balance Sheet as of 31 December 2016

ASSETS	31 Dec. 2016 EUR	31 Dec. 2015 EUR
Fixed assets		
Intangible assets		
Franchises, trademarks, patents, licenses and similar rights	5,258.00	10,316.00
Financial assets		
Shares in affiliated companies	12,775,929.67	12,775,929.67
Securities	11.70	11.70
	12,775,941.37	12,775,941.37
	12,781,199.37	12,786,257.37
Current assets		
Receivables and other assets		
Receivables from affiliated companies	72,431,309.32	60,492,032.59
Other assets	34,747.33	93,927.49
	72,466,056.65	60,585,960.08
Cash on hand and bank balances	27,828,305.26	31,474,947.56
	100,294,361.91	92,060,907.64
Prepaid expenses	70,032.52	75,274.27
	113,145,593.80	104,922,439.28

EQUITY AND LIABILITIES	31 Dec. 2016 EUR	31 Dec. 2015 EUR
Equity		
Subscribed capital	55,757,094.00	50,659,440.00
thereof: 55,757,094 no-par value shares (prior year: 50,659,440 no-par value shares)		
Conditional capital: EUR 25,286,736.00 (prior year: EUR 25,303,470.00)		
Capital reserve	138,841,024.08	134,251,540.26
Accumulated loss	-82,054,854.44	-80,472,839.18
	112,543,263.64	104,438,141.08
Accruals		
Other accruals	447,455.92	311,558.77
Liabilities		
Trade payables	34,144.13	60,068.53
thereof due in up to one year: EUR 34,144.13 (prior year: EUR 60,068.53)		
Liabilities to affiliated companies	17,565.94	15,577.02
thereof due in up to one year: EUR 17,565.94 (prior year: EUR 15,577.02)		
Other liabilities	103,164.17	97,093.88
thereof due in up to one year: EUR 103,164.17 (prior year: EUR 97,093.88)		
thereof for taxes: EUR 73,107.16 (prior year: EUR 64,383.88)		
	154,874.24	172,739.43
	113,145,593.80	104,922,439.28

Income Statement for Fiscal Year 2016

	2016 EUR	2015 EUR
Revenues	1,146,384.80	0.00
Other operating income	1,250,678.18	3,327,100.00
Personnel expenses		
Wages and salaries	-1,701,572.59	-1,444,200.73
Social security	-91,289.87	-72,479.75
	-1,792,862.46	-1,516,680.48
Depreciation of intangible assets	-5,538.00	-5,382.00
Other operating expenses	-4,766,841.73	-3,189,987.71
Other interest and similar income	2,586,321.95	1,922,847.24
thereof from affiliated companies:		
EUR 2,565,461.25 (previous year: EUR 1,881,142.00)		
Result before tax	-1,581,857.26	537,897.05
Other taxes	-158.00	4.65
Net result for the year	-1,582,015.26	537,901.70
Loss carryforward	-80,472,839.18	-81,010,740.88
Accumulated loss	-82,054,854.44	-80,472,839.18

Notes

PAION AG

Notes to the financial statements for fiscal year 2016

Preliminary remarks

The financial statements of PAION AG, HRB 12528, for the fiscal year from 1 January 2016 to 31 December 2016 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 5 of the German Securities Trading Act claim (Wertpapierhandelsgesetz, WpHG).

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 150 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 280 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 were 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) were 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 those denominated in foreign currencies) are carried at the amount repayable. Liabilities denominated in a foreign currency were 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) were considered.
6. The income statement is prepared using the cost-summary method in accordance with Section 275 (2) HGB.

The accounting and valuation methods were maintained unchanged compared to the previous year, unless new findings required a different valuation or resulted from the new HGB regulations according to the German Accounting Directive Implementation Act (Bilanzrichtlinie-Umsetzungsgesetz, BilRUG).

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

(I) Financial assets

The shareholdings in affiliated companies as of 31 December 2016 refer to PAION Holdings UK Ltd (KEUR 12,318), PAION Deutschland GmbH (KEUR 450) and PAION, Inc. (KEUR 8).

The composition and performance of the fixed assets is as follows:

	1 Jan. 2016	Historic Costs		31 Dec. 2016
		Additions	Disposals	
	EUR	EUR	EUR	EUR
Intangible assets				
Franchises, trademarks, patents, licenses and similar rights	59,595.05	480.00	0.00	60,075.05
	59,595.05	480.00	0.00	60,075.05
Financial assets				
Shares in affiliated companies	59,974,426.77	0.00	0.00	59,974,426.77
Securities	11.70	0.00	0.00	11.70
	59,974,438.47	0.00	0.00	59,974,438.47
	60,034,033.52	480.00	0.00	60,034,513.52

Depreciation				Net Book Values	
1 Jan. 2016	Additions	Disposals	31 Dec. 2016	31 Dec. 2016	31 Dec. 2015
EUR	EUR	EUR	EUR	EUR	EUR
49,279.05	5,538.00	0.00	54,817.05	5,258.00	10,316.00
49,279.05	5,538.00	0.00	54,817.05	5,258.00	10,316.00
47,198,497.10	0.00	0.00	47,198,497.10	12,775,929.67	12,775,929.67
0.00	0.00	0.00	0.00	11.70	11.70
47,198,497.10	0.00	0.00	47,198,497.10	12,775,941.37	12,775,941.37
47,247,776.15	5,538.00	0.00	47,253,314.15	12,781,199.37	12,786,257.37

(2) Receivables from affiliated companies

The receivables from affiliated companies are comprised as follows:

EUR	Total	of which: loans	of which: services and interest
PAION UK Ltd	67,784,359.68	67,465,000.00	319,359.68
PAION Holdings UK Ltd	4,484,117.20	4,470,000.00	14,117.20
PAION, Inc.	151,614.53	150,000.00	1,614.53
PAION Deutschland GmbH	11,217.91	0.00	11,217.91
	72,431,309.32	72,085,000.00	346,309.32

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

(3) Other assets

As of 31 December 2016, other assets are comprised substantially of VAT receivables (KEUR 30; previous year: KEUR 71).

(4) Equity

As of 31 December 2016, the share capital amounts to EUR 55,757,094.00 (previous year: EUR 50,659,440.00); it is divided into 55,757,094 no-par value shares (previous year: 50,659,440 shares).

By virtue of a resolution adopted by the Annual General Meeting on 20 May 2015, the Management Board was authorized to increase the share capital on or prior to 19 May 2020, with the consent of the Supervisory Board, on one or more occasions, by up to EUR 25,320,970.00 in total by issuing up to 25,320,970 new no-par value bearer shares in return for cash contributions or contributions in kind (Authorized Capital 2015). Furthermore, the Management Board was authorized to use up to EUR 5,064,194.00 of the Authorized Capital 2015 to issue new shares for cash by excluding pre-emptive rights.

On 24 June 2016, the Management Board decided with the approval of the Supervisory Board and based on the authorization of the General Meeting to issue 5,064,194 no-par value bearer shares in return for cash contribution by excluding pre-emptive rights for the existing shareholders to Granell Strategic Investment Fund Limited, an affiliated company of the U.S. license partner Cosmo Pharmaceuticals (Cosmo). The new shares were issued at a price of EUR 1.9042. The capital increase led to a gross cash inflow of EUR 9.6 million. As a result, the share capital of the company was increased from EUR 50,672,400.00 by EUR 5,064,194.00 to EUR 55,736,594.00 through the issuing of 5,064,194 new shares. The capital increase was registered in the Commercial Register on 28 June 2016. The Authorized Capital 2015 was reduced

by EUR 5,064,194.00 in the course of this capital measure and amounts to EUR 20,256,776.00 as of 31 December 2016.

Furthermore, by virtue of another resolution adopted by the Annual General Meeting on 20 May 2015, subject to the consent of the Supervisory Board, the Management Board was authorized to issue on or before 19 May 2020, 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 22,433,285.00 in total (Conditional Capital 2015). Furthermore, the Management Board was authorized to use up to EUR 5,064,194.00 of the Conditional Capital 2015 for Bonds against cash by excluding pre-emptive rights. Under consideration of the decision of the Management Board from 24 June 2016 to issue 5,064,194 no-par value bearer shares in return for cash contribution by excluding pre-emptive rights for the existing shareholders, the Conditional Capital 2015 can be no longer used excluding pre-emptive rights.

The Annual General Meeting of 25 May 2016 adopted a resolution to reduce Conditional Capital 2004 II to EUR 34,847.00. 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 2005 exercise their options. Under the Stock Option Plan 2005, 34,847 stock options were issued to (former) employees of the PAION Group as of 31 December 2016. No stock options have been exercised yet.

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, 475,161 stock options were issued to current and former Management Board members and employees of the PAION Group as of 31 December 2016. To date, 241,631 stock options from the Stock Option Plan 2008 have been exercised, thereof 33,460 in fiscal year 2016. The exercises led to cash inflows of EUR 43,899.60 in the fiscal year. As of 31 December 2016, Conditional Capital 2008 I amounts to EUR 518,604.00.

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 2016. 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, 537,225 stock options were issued to current and former Management Board members and employees of the PAION Group as of 31 December 2016. 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, no stock options were issued as of 31 December 2016.

(5) Accruals

The accruals break down as follows:

	31 Dec. 2016 EUR	31 Dec. 2015 EUR
Bonuses	227,357.41	111,325.33
Outstanding invoices	74,538.75	75,956.20
Financial statements and audit	45,409.68	57,666.67
Legal advice	40,000.00	10,000.00
Others	60,150.08	56,610.57
	447,455.92	311,558.77

(6) 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.

(7) Revenues

Revenues resulted entirely from the provision of management and other services to the subsidiaries, of which PAION UK Ltd accounted for KEUR 978 (previous year: KEUR 0) and PAION Deutschland GmbH for KEUR 168 (previous year: KEUR 0). The increase compared to previous year is the result of the first-time application of the BilRUG leading to disclosure of services as revenues from 2016 onward which were previously recognized as other operating income.

(8) Other operating income

Other operating income mainly comprises foreign exchange gains in the amount of KEUR 789 (previous year: KEUR 2,005). Moreover, other operating income includes recharges to the subsidiaries (KEUR 389; previous year: KEUR 1,305), of which PAION UK Ltd accounted for KEUR 341 (previous year: KEUR 1,120) and PAION Deutschland GmbH for KEUR 48 (previous year: KEUR 186). The decrease in income from recharges within the PAION Group compared to the previous year is the result of the first-time application of the BilRUG leading to disclosure of services as revenues from 2016 onward which were previously recognized as other operating income.

(9) Other operating expenses

Other operating expenses mainly include legal and consulting fees (KEUR 2,067; previous year: KEUR 919), insurance, contributions and fees (KEUR 243; previous year: KEUR 276), travel expenses (KEUR 217; previous year: KEUR 249), services rendered by PAION Deutschland GmbH (KEUR 190; previous year: KEUR 184), expenses in connection with Supervisory Board remuneration (KEUR 122; previous year: KEUR 131) as well as audit costs and costs for the annual report (KEUR 73; previous year: KEUR 120). In the reporting period, an impairment on trade receivables from PAION, Inc. in the amount of KEUR 350 is included in other operating expenses and foreign exchange losses in the amount of KEUR 1,220 (previous year: KEUR 1,064) have been recognized. Compared to the previous year, the significant increase of the other operating expenses is mainly due to the preparation of potential capital measures, which were ultimately not conducted due to the conclusion of a license agreement and an investment agreement with the U.S. license partner Cosmo, as well as expenses incurred in connection with the private placement conducted with Cosmo in June 2016.

(10) Income attributable to other periods

In fiscal year 2016, income that is attributable to other periods amounts to KEUR 64 and results from income from the reversal of accruals in amount of KEUR 41 and from reimbursement of contributions in the amount of KEUR 23.

(II) Taxes

As of 31 December 2016, the company's tax losses carried forward relating to corporate income tax amounted to about EUR 33.2 million (previous year: EUR 32.0 million) and relating to trade tax to about EUR 32.0 million (previous year: EUR 30.8 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 2016, the resulting deferred tax assets would amount to KEUR 10,573 (previous year: KEUR 10,195).

Temporary differences between the tax base and the HGB carrying amount do not exist as of 31 December 2016 and did not exist as of the previous year's reporting date.

Other compulsory disclosures

(1) Average number of employees

In fiscal year 2016, the company had an average of eight employees (previous year: five employees).

(2) Other financial obligations

The loan facility granted to the subsidiary PAION UK Ltd of up to KEUR 80,000 will be granted until further notice. As of 31 December 2016, the utilization amounts to KEUR 67,465.

The loan facility granted to the subsidiary PAION Holdings UK Ltd of up to KEUR 4,500 will be granted until further notice. As of 31 December 2016, the utilization amounts to KEUR 4,470.

(3) Stock Option Plans

PAION has implemented a total of five stock option plans in the course of which stock options can be/have been granted to Management Board members, employees, 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 (the period for the Stock Option Plan 2005, from which no stock options have yet been issued, is omitted):

	Stock Option Plan 2005 Approved 30 December 2004	Stock Option Plan 2006 Approved 5 March 2006
Underlying Capital	Conditional Capital 2004 II	Conditional Capital 2006 I
Term of the options	10 years	10 years
Vesting period	2–4 years	2–4 years
Waiting period	2–4 years	2–4 years
Number of outstanding options for which the waiting period has expired as of 31 December 2016	34,847	34,847
Exercise condition	Cumulative stock price increase of 5% per year since grant in relation to stock price at grant date	Cumulative stock price increase of 5% per year since grant in relation to stock price at grant date
Exercise price *	EUR 8.00	EUR 8.00
Weighted average exercise price *	EUR 8.00	EUR 8.00
Exercise hurdle as of 31 Dec. 2016 *	EUR 11.87	EUR 11.87
Weighted average remaining term as of 31 Dec. 2016	0.3 years	0.3 years
Further grants possible?	No	No
Number of totally granted options	1,055,767	1,055,767
Number of outstanding options as of 31 Dec. 2016 **	34,847	34,847
granted to employees	34,847	34,847
granted to Management Board members	0	0
Number of totally lapsed options as of 31 Dec. 2016	1,020,920	1,020,920
thereof lapsed in the reporting period	11,615	11,615
Number of totally exercised options until 31 Dec. 2016	0	0
thereof exercised in the reporting period	0	0
<p>*) in relation to outstanding options as of 31 Dec. 2016 **) in relation to employee/Management Board member status at the time of the grant</p>		

members and employees of PAION AG and its subsidiaries at the time of the grant. All stock option plans include vesting periods and conditions for the grant. Details of the individual programs can be found in the following table (the presentation of the Stock Option Plan

Plan 2008 May 2008	Stock Option Plan 2010 Approved 19 May 2010	Stock Option Plan 2014 Approved 21 May 2014
Conditional Capital 2008 I 10 years 2-4 years 2-4 years	Conditional Capital 2010 I 10 years 2-4 years 4 years	Conditional Capital 2014 10 years 2-4 years 4 years
475,161	0	0
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 1.11 to EUR 2.69 EUR 1.58	EUR 2.01 EUR 2.01	EUR 1.99 to EUR 2.40 EUR 2.14
EUR 1.55 to EUR 3.61 2.4 years	EUR 2.30 7.1 years	EUR 2.04 to EUR 2.61 8.8 years
No	No	Yes
817,550	720,000	684,500
475,161	696,626	537,225
259,580	392,876	294,412
215,581	303,750	242,813
100,758	23,374	147,275
1,625	3,124	106,088
241,631	0	0
33,460	0	0

(4) Employee Participation Plan 2006

With the consent of the Supervisory Board, the Management Board of PAION AG had launched an employee participation plan granting stock appreciation rights. A stock appreciation right entitled the holder to receive a sum of money based on the PAION AG share price. The maximum amount payable on a stock appreciation right was limited to 100% of the exercise price. The stock appreciation rights had a term of ten years and could only be exercised after a two-year waiting period. In addition, they could only be exercised when the stock price on the exercise date had increased by a cumulative 5% each year since issuance. As of 31 December 2016, all previously issued stock appreciation rights from the Employee Participation Plan 2006 had expired, thereof 134,000 stock appreciation rights in fiscal year 2016.

No more stock appreciation rights can be issued from the Employee Participation Plan 2006.

PAION AG's payment obligation that was directly attributable to this employee participation plan was measured at fair value on the balance sheet date. As a result of the expiration of the last issued stock appreciation rights of the Employee Participation Plan 2006 in the reporting period there is no longer any potential payment obligation as of 31 December 2016 and no expense or income in regard to the Employee Participation Plan 2006 was recognized in the reporting year.

(5) Management Board and Supervisory Board

The members of the company's Management Board are:

- Dr. Wolfgang Söhnngen, CEO, Chairman
- Abdelghani Omari, CFO
- Dr. Jürgen Raths, COO (until 14 March 2017)

Other positions:

- Vesselon, Inc., Norwalk (Connecticut)/U.S., Member of the Board of Directors
- MSPI Medical Specialty Partners International AG, Zug/Switzerland, Member of the Supervisory Board

Management Board remuneration totalled KEUR 1,151 in fiscal year 2016. As of 31 December 2016, a total of 562,067 stock options (fair value at time of granting: EUR 806,699) had been issued to active Management Board members as of 31 December 2016. For more information on Management Board remuneration, please see the disclosures in the remuneration report, which is part of the management report.

Dr. Wolfgang Söhnngen and Mr. Abdelghani Omari are also Managing Directors of PAION Deutschland GmbH and non-executive directors of PAION, Inc. Mr. Abdelghani Omari is also Managing Director of PAION Holdings UK Ltd and its subsidiaries. All Management Board members work full-time for the company and its subsidiaries.

As of 31 December 2016, Dr. Wolfgang Söhnngen owned 1.12% (621,791 voting rights) of the shares in PAION AG. This equity interest includes 0.01% (6,425 voting rights) of the shares in PAION AG that are held by Dres. Söhnngen Beteiligungs GmbH, in which Dr. Wolfgang Söhnngen holds 50%.

The members of the Supervisory Board are:

- Dr. Jörg Spiekerkötter, Kleinmachnow/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 (since 1 August 2016)
- Dr. Karin Louise Dorrepaal, Amsterdam/The Netherlands, Vice Chairman; former Member of the Management Board of Schering AG
Other supervisory board memberships or similar positions:
 - Gerresheimer AG, Düsseldorf/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
 - Julius Clinical Research BV, Bunnik/The Netherlands, Member of the Supervisory Board (since 1 October 2016)

– John Dawson, Fetcham/England, Chairman of the Audit Committee; CEO of Oxford BioMedica plc, Oxford/England

Remuneration to the members of the Supervisory Board totalled KEUR 122 in fiscal year 2016. For more information on Supervisory Board remuneration, please see the disclosures in the remuneration report of the group management report.

As of 31 December 2016, none of the members of the Supervisory Board owned shares in PAION AG.

(6) Shareholdings

The company owns the following direct and indirect shareholdings:

	Shares in in %	Currency	Equity as of 31 Dec. 2016*	Result 2016*
PAION Deutschland GmbH, Aachen	100	EUR	1,123,470.17	187,573.04
PAION Holdings UK Ltd, Cambridge/UK	100	GBP	4,089,214.44	-653,414.24
PAION UK Ltd, Cambridge/UK	100	GBP	-63,421,932.77	-22,404,416.65
PAION, Inc., Delaware/U.S.	100	USD	-286,199.06	18,336.44
TheraSci Limited, Cambridge/UK	100	GBP	0.00	0.00
*) Reporting according to local reporting standards				

(7) Reportable equity investments in PAION AG pursuant to section 21 WpHG

The following notifications in respect of reportable equity investments pursuant to Section 21 (1) and (1a) WpHG, which were published in accordance with the stipulations of Section 26 (1) WpHG, are relevant for assessing which shareholders held more than 3% of the shares as of 31 December 2016:

- 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 21 WpHG, the following companies or individuals held shares of more than 3% in the voting rights of PAION AG as of 31 December 2016:

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

(8) Financial statements auditor

The Annual General Meeting on 25 May 2016 appointed Ernst & Young GmbH Wirtschaftsprüfungsgesellschaft, Cologne office, Germany, as auditor of the annual and consolidated financial statements for fiscal year 2016. The auditor has received or will invoice the following fees for services rendered to PAION AG and its subsidiaries in fiscal year 2016:

	2016 KEUR	2015 KEUR
Audits of financial statements	105	99
Other assurance services	23	40
Other services	203	45
	331	184

The other assurance services relate to fees for reviewing the interim financial statements. The other services comprise the preparation of a comfort letter in the context of the preparation of a potential capital increase, which was ultimately not conducted due to the cooperation with Cosmo.

(9) 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.

The company complies with the recommendations set forth in the most recent version of the German Corporate

Governance Code dated 5 May 2015 with one exception. In December 2016, the Supervisory Board and the Management Board issued the declaration of compliance with the Corporate Governance Code pursuant to Section 161 AktG. This declaration of compliance is published on PAION AG's website (<http://www.paion.com/media-and-investors/corporate-governance/declaration-of-conformity/>).

(10) Report on post-balance sheet date events

In February 2017, a capital increase with subscription rights and gross proceeds of EUR 4.99 million was successfully completed. By utilization of the Authorized Capital 2015 in the amount of EUR 2,439,023.00, the share capital of PAION AG was increased from EUR 55,757,094.00 to EUR 58,196,117.00 by issuing 2.439.023 new shares. The remaining Authorized Capital 2015 amounts to EUR 17,817,753.00 after this transaction.

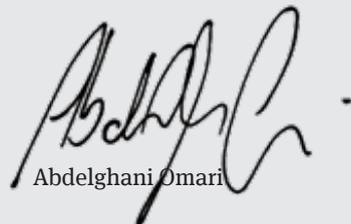
Dr. Jürgen Raths resigned from his office as Chief Operating Officer of PAION AG as of the end of 14 March 2017.

There were no further significant events in the period between the reporting date, 31 December 2016, and the preparation of this report.

Aachen, 15 March 2017

PAION AG


 Dr. Wolfgang Söhngen


 Abdelghani Omari

Responsibility Statement (Bilanzaid) in accordance with section 37v(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, 15 March 2017

PAION AG



Dr. Wolfgang Söhnngen Abdelghani Omari

Audit Opinion

We issued the following opinion on the financial statements and management report:

“We have audited the annual financial statements, comprising the balance sheet, the income statement and the notes to the financial statements, together with the bookkeeping system, and the management report of PAION AG, Aachen, for the fiscal year from 1 January 2016 to 31 December 2016. The maintenance of the books and records and the preparation of the annual financial statements and management report in accordance with German commercial law are the responsibility of the Company’s management. Our responsibility is to express an opinion on the annual financial statements, together with the bookkeeping system, and the management report based on our audit.

We conducted our audit of the annual financial statements in accordance with Sec. 317 HGB [“Handelsgesetzbuch”: German Commercial Code] and German generally accepted standards for the audit of financial statements promulgated by the Institut der Wirtschaftsprüfer [Institute of Public Auditors in Germany] (IDW). Those standards require that we plan and perform the audit such that misstatements materially affecting the presentation of the net assets, financial position and results of operations in the annual financial statements in accordance with German principles of proper accounting and in the management report are detected with reasonable assurance. Knowledge of the business activities and the economic and legal environment of the Company and expectations as to possible misstatements are taken into account in the determination of audit procedures. The effectiveness of the accounting-related internal control system and the evidence supporting the disclosures in the books and records, the annual financial statements and the management report are examined primarily on a test basis within the framework of the audit. The audit includes assessing the accounting principles used and significant estimates made by management, as well as evaluating the overall presentation of the annual financial statements and management report. We believe that our audit provides a reasonable basis for our opinion.

Our audit has not led to any reservations.

In our opinion, based on the findings of our audit, the annual financial statements comply with the legal requirements and give a true and fair view of the net assets, financial position and results of operations of the Company in accordance with German principles of proper accounting. The management report is consistent with the annual financial statements, complies with the legal requirements and as a whole provides a suitable view of the Company’s position and suitably presents the opportunities and risks of future development.”

Cologne, 15 March 2017

Ernst & Young GmbH
Wirtschaftsprüfungsgesellschaft

(s) Ueberschär
Wirtschaftsprüfer
[German Public Auditor]

(s) Galden
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