PAION AG, Aachen

### **Annual Financial Report**

for the Fiscal Year 2015



#### PAION AG, Aachen

### **Consolidated Financial Statements**

as of 31 December 2015 and

## Group Management Report for the Fiscal Year 2015

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#### Group management report for fiscal year 2015

#### 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 thus mainly determined by the development operations of the subsidiaries, which are presented below.

PAION's portfolio comprises the substances Remimazolam, M6G and GGF2. GGF2 is being developed by Acorda Therapeutics, Inc. (Acorda) in full autonomy since 2002. Furthermore, Remimazolam is being developed by license partners for the markets in China, South Korea, Canada, Russia/CIS, Turkey and the MENA region. For the Japanese market, the development of Remimazolam as previously agreed with the agency, was undertaken and completed for the indication anesthesia by Ono Pharmaceutical (Ono). In November 2014, Ono decided "to discontinue the project on strategic reasons considering issues in pharmacokinetic features, while no adverse events of concern were observed during the clinical trial". The data and technology transfer to PAION was completed in 2015. PAION entered into an exclusive license agreement for the M6G rights in China with Yichang Humanwell in the previous year.

 $\label{eq:Fiscal year 2015 was marked by the concentration of PAION on the further development of Remimazolam.$ 

#### 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 activity and from commercial activities. The development activity both 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.

The commercial activity mainly aims at the subsequent commercialization of Remimazolam. Partnering discussions are being held, but also options for an own commercialization (e. g. U.S. and EU) are being evaluated. The progress of these discussions is being documented and discussed continuously. PAION has already signed several regional licensing agreements. The cooperation partners operate independently in their respective license area. However, the cooperation agreements require the partners to provide each other with information. The central coordination of the information flow is managed by PAION. Moreover, PAION conducts pre-marketing and market access activities in order to prepare the market entry of Remimazolam. All activities are processed based on a project plan and are being reviewed and adjusted 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 B.2 "Presentation of the course of business and development activities".

#### Report on economic position

1. Macroeconomic and sector-specific environment

#### a. Macroeconomic development

The development of the German economy was characterized by a solid and steady growth in 2015. The German gross domestic product raised by 1.7 % in real terms compared to 2014. <sup>1</sup> However, German economy lost part of its momentum in the second half of 2015. Domestic demand is still on a robust development path whereas industry production is declining. <sup>2</sup> In 2016, the economic growth should be on a comparable level to 2015. The German Institute for Economic Research (DIW) expects an increase of the gross domestic product by 1.7 % for 2016 mainly driven by private and public consumption while exports are still being slowed down by problems in the emerging countries. <sup>3</sup>

<sup>&</sup>lt;sup>1</sup> Federal Statistical Office: Press release (No. 044) dated 12 February 2016.

<sup>&</sup>lt;sup>2</sup> German Institute for Economic Research: Industrieschwäche belastet deutsche Wirtschaft, DIW Konjunkturbarometer Februar 2016; dated 2 March 2016.

<sup>&</sup>lt;sup>3</sup> German Institute for Economic Research: Inlandsnachfrage treibt deutsche Wirtschaft an; press release dated 16 December 2015.

In light of the unchanged difficult economic environment within the EU, the economic development of important non-European countries has a significant impact on the export-oriented German economy. In particular, the U.S. economy continued its dynamic growth path and grew by estimated 2.5 % in 2015. <sup>4</sup> The economic development in China continues to weaken; the growth of its gross domestic product amounted to an estimated 6.9 %, the slowest growth in 25 years. <sup>5</sup> The positive dynamics of global economics will slightly intensify in 2016. For the gross world product, the IMF envisages a growth of 3.4 % in 2016 after an increase of 3.1 % in 2015. The strongest impulses emanate from the developed economies while prospects for emerging countries remain difficult. In the U.S., economy keeps growing steadily driven by the loose monetary policy and strong real estate and labor markets. In the euro area, the stronger private consumption overweighs weaker exports. <sup>6</sup>

The development of the stock markets has declined in 2015 compared to 2014. While major stock market indices generally continued to grow, volatilities significantly increased. In total, the DAX increased by 9.6 %, and the EUROSTOXX 50 grew by 3.8 %. Dow Jones Index decreased by 2.2 % in comparison to the prior year's end closing value.

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

For the pharmaceutical industry and biotechnology sector as a whole, 2015 was a mixed year. While the financing environment was still positive in the beginning, it changed in the middle of the year due to the capital market turbulences and the discussion regarding the appropriateness of drug prices in the U.S. <sup>7</sup> The consolidation pressure in the industry persists unabated, resulting in a high number of takeovers and cooperations as well as an increased transaction volume. The consolidation pressure particularly results from the high risks and costs associated with pharmaceutical development, the expiry of patent protection of a number of products in recent years as well as the increasing pressure on drug prices.

The financing environment for pharmaceutical and biotechnology companies has declined compared to previous years. Until mid-2015, the financing environment was still good, indicated by a high number of IPOs again, particularly in the U.S. Since mid-2015, the financing environment has significantly worsened, especially due to the increased market volatility in general and political pressure on drug prices in particular, most notably in the U.S. <sup>8</sup> Valuations of pharma and biotech

- <sup>4</sup> International Monetary Fund: World Economic Outlook Update, 19 January 2016.
- <sup>5</sup> The Wall Street Journal: China's Economic Growth in 2015 Is Slowest in 25 Years, 19 January 2016.
- <sup>6</sup> International Monetary Fund: World Economic Outlook Update, 19 January 2016.
- <sup>7</sup> The Pharma Letter: An all time record year for pharma/biotech M&A in 2015; 7 January 2016.
- $^{8}\,\,$  The Pharma Letter: An all time record year for pharma/biotech M&A in 2015; 7 January 2016.

companies significantly dropped. Nonetheless, important indices still showed a positive trend over the year as a whole. The NASDAQ Biotechnology Index gained 11.4 %, and the DAXsubsector Biotechnology Index of the German Stock Exchange grew by 30.7 %. In 2015, the acquisition and cooperation volume also increased significantly year on year. In 2015, the transaction volume of global acquisitions in the pharmaceutical sector amounted to USD 328 billion compared to USD 218 billion in 2014. 9

The financing environment is expected to remain dominated by the general uncertainty at the capital markets in 2016 until there is more clarity on the further development of the world economy and the monetary policies of the central banks, in particular the Federal Reserve in the U.S. <sup>10</sup> Both the tenor of the further discussion of drug prices in the current presidential campaign in the U.S. as well as the question if investors begin to emphasize chances in the branch again will be crucial for the financing environment in the pharmaceutical industry. <sup>11</sup> Overall, the financing environment is expected to be more difficult than in prior years. In the first months of 2016, NAS-DAQ Biotechnology Index and DAXSubsector Biotechnology Index have dropped in a double-digit percentage range.

#### 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. The two further substances M6G and GGF2 are no significant value drivers for PAION.

#### a. Remimazolam

Remimazolam is an ultra-short-acting intravenous sedative and anesthetic currently in Phase III clinical development for procedural sedation and general anesthesia. Remimazolam is a member of the class of substances known as benzodiazepines. 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 in order to rapidly terminate sedation, if necessary.

In clinical studies, Remimazolam demonstrated efficacy and safety in far more than 1,000 patients. A confirmatory Phase III program in procedural sedation is now in progress. Data so far indicate that Remimazolam has the expected rapid onset and offset of action combined with a favorable hemodynamic stability profile.

In the U.S., Remimazolam is initially being developed for procedural sedation during procedures such as colonoscopies.

<sup>&</sup>lt;sup>9</sup> Pharma-Unternehmen auf Shoppingtour – 2015 übertrifft das Rekordjahr 2014 noch einmal deutlich: Press Release from Ernst & Young dated 3 February 2016 (www.ey.com/DE/de/Newsroom).

<sup>&</sup>lt;sup>10</sup> Handelsblatt: Tempo für Zinserhöhungen könnte sich verlangsamen, 10 February 2016.

FiercePharma: UPDATED: Clinton targets pharma's 'predatory' pricing with new campaign ad featuring Valeant, 1 March 2016.

In the EU and most other major markets, Remimazolam is initially being developed for general anesthesia, including post-operative sedation in post-anesthesia care or intensive care units (ICUs) for up to 24 hours after the operation.

In Japan, a clinical Phase III program in anesthesia has successfully been completed. The Japanese Pharmaceuticals and Medical Devices Agency ("PMDA") confirmed that the clinical and non-clinical data sets are regarded as complete for filing in the indication "Induction and maintenance of general anesthesia" during a pre-NDA meeting held in the beginning of 2016.

Development for ICU sedation is planned following successful completion of development in procedural sedation and general anesthesia. A pediatric development plan has been agreed with the FDA and will be implemented following approval of Remimazolam for adult patients.

#### Procedural sedation (U.S.)

The procedural sedation market for diagnostic procedures in the U.S. has grown significantly in recent years due to the increased emphasis on cancer screening and colon cancer prevention. Partly due to this trend, colon cancer rates have fallen by 30 % during the last 10 years in people aged over 50. There were 29 million unique claims for colonoscopy and endoscopy in 2013. Each year, more than 4 million people turn 50 and are newly eligible for screening.

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 in 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.

Procedural sedation in colonoscopy is usually performed with midazolam or propofol sedation combined with analgesia.

#### General anaesthesia

Approximately 29 million general anesthesias in patients undergoing major surgeries are conducted in the EU each year, of which 55 % are balanced anesthesia (a combination of intravenous agents such as propofol for induction and volatile gases for maintenance) and 20 % are total intravenous anesthesia (TIVA) using propofol. Regional anesthesia also plays a role (for example epidural administration). The current standards of care drugs for general anesthesia are propofol (especially for induction) and narcotic gases; in each case in conjunction with intravenous opioids.

Patient demographics in Europe continue to evolve driven by the aging population and the differences between the functional or biological ages of patients compared to actual age. So, while general anesthesia is more frequently offered to elderly patients than years ago, the choice is an individual one depending on the type of surgery, the underlying disease, and assessment of the general physical health of the patient, including co-morbidities.

The number of surgical procedures worldwide continues to increase driven by population growth and other factors such as obesity, low physical activity levels, dietary habits, smoking, and alcohol. Current estimates place the number of worldwide surgical procedures annually at greater

than 230 million; the majority in the areas of general, orthopaedic/trauma and obstetric/gynaecological surgery.

Remimazolam – far over 1,000 volunteers/patients on drug					
Completed studies *	Ongoing studies *				
Procedural Seda	tion (U.S.)				
Phase I Single bolus in healthy volunteers (81)	Phase I Thorough QT Study (57)				
Phase Ib Multiple bolus in volunteers undergoing colonoscopy (51)	Phase I Renal Impairment (16)				
Phase IIa Single bolus in upper GI endoscopy (100)	Phase I Abuse Liability (40)				
Phase IIb Multiple bolus in colonoscopy (161)	Phase III in colonoscopy (460)				
	Phase III in bronchoscopy (460)				
	ASA III/IV in colonoscopy (75)				
General Anesthe	sia (Japan)				
Phase I Bolus in healthy volunteers (42)					
Phase Ib Infusion in healthy volunteers (10)					
Phase I Hepatic impairment (USA) (20)					
Phase II Induction and maintenance of anesthesia in general surgery (85)					
Phase II/III Induction and maintenance of anesthesia in general surgery (375)					
Phase III in ASA III or higher surgical patients (62)					
General Anesth	esia (EU)				
Phase II in cardiac surgery patients (90)					
Phase III in cardiac surgery patients (discontinued)					
ICU Sedation	(Japan)				
Phase II (discontinued)					

<sup>\*)</sup> Numbers in brackets are total target patient numbers in studies

#### Procedural sedation (Lead indication U.S.)

A total of two Phase I and two Phase II 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 studies.

In March 2015, the first U.S. Phase III study was started. This prospective, double-blind, randomized, placebo- and midazolam-controlled, U.S. multicenter Phase III trial in 460 patients undergoing colonoscopies marks the start of PAION's Phase III clinical development program, which also includes a second pivotal prospective, double-blind, randomized, placebo- and midazolam-controlled, U.S. multicenter Phase III trial in patients undergoing bronchoscopies which started in June 2015, and a smaller safety trial in 75 high risk patients undergoing colonoscopies. In parallel, three Phase I studies are being conducted by PAION.

Patient recruitment in the Phase III program in the U.S. was initially moderate. The Phase III colonoscopy trial is on track and completion of patient recruitment is expected shortly. Currently, 450 patients have been treated. Patient recruitment in the Phase III bronchoscopy trial remains moderate which could possibly extend the completion into 2017. Conditional on successful implementation of ongoing counter measures such as the opening of further study centers and intensified support of the study centers, PAION expects filing for approval end of 2017 at the earliest.

#### General anesthesia (Lead indication in EU + Japan)

A total of three Phase I (Japan), two Phase II (Japan and EU) and two Phase III (Japan) trials have been completed. Specific attention was paid to hemodynamic stability in the clinical program as preclinical data suggested that Remimazolam may lead to a hemodynamic stability, which addresses a current need in general anesthesia.

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 anaesthetic 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 the 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 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 fulfil the requirements for filing in Japan.

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, further confirming the beneficial hemodynamic profile of Remimazolam.

In August 2015, the start of the multi-national, multicenter, randomized, single-blind, propofol-controlled, confirmatory EU Phase III study in patients undergoing major cardiac surgery was announced. Due to the complex study design, the trial faced recruitment challenges. Despite intensive efforts to enhance study recruitment, the trial proved to be difficult to implement in practice. 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 have been observed. Accordingly, PAION will work together with recognized experts on setting up an alternative design in general surgery patients. However, conducting a new study requires further funding.

#### **ICU** sedation

PAION's former partner in Japan, Ono, independently initiated a Phase II trial for sedation in intensive care units (ICUs). Ono discontinued this exploratory trial in August 2013. While all patients were sedated successfully and no significant unexpected adverse events were reported, higher than expected plasma concentrations of Remimazolam were observed in isolated cases after long-term treatment.

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. As a result, PAION is of the opinion that the maximum dose level has now been defined for ICU sedation. Further development of the program "ICU sedation" is part of the future Remimazolam development plan which will be addressed after approval of the lead indications and availability of required funds.

#### Partnering and commercial activities

In total, PAION has completed seven licensing deals with Remimazolam which are summarized in the following table:

Upfront and milestone payments							
Total received Total outstanding Royalty rate							
Ono, Japan (2007) (terminated in 2015)	USD 8 m	None	None				
Yichang Humanwell, China (2012)	EUR 3 m	Up to 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 3.7 m	Double-digit tiered (starting at 15 %)				
Total	~EUR 13.8 m	Up to ~ EUR 21.2 m					

<sup>\*)</sup> 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.

In order to exploit Remimazolam's full potential, PAION favors the attractive possibility of a selfcommercialization or co-commercialization in the U.S. and EU.

For all territories outside the U.S. and EU, it is aimed to find license or distribution partners. After the positive pre-NDA meeting with the Japanese PMDA, during which the details of an approval of Remimazolam in Japan were discussed, PAION is continuing partnering discussions with potential licensees which will however most probably not be completed before the second half of 2016. Alternatively, PAION is also evaluating filing Remimazolam itself.

#### b. GGF2

GGF2 (Glial Growth Factor 2) is known to stimulate the growth and differentiation of a variety of cells including glial cells, the support cells of the nervous system. These glial cells form the myelin sheath that insulates nerve cells and are essential for their survival and proper functioning. In demyelinating diseases such as multiple sclerosis, the myelin sheath is damaged, leading to the degeneration of nerve cells.

In preclinical studies, PAION's license partner Acorda Therapeutics, Inc. (Acorda) demonstrated that GGF2 can stimulate the cell growth necessary to protect and regenerate a damaged myelin sheath. GGF2 is the lead neuregulin in Acorda's portfolio. Neuregulins have also shown the ability to restore cardiac function in preclinical models of heart failure caused by myocardial infarction, heart rhythm disorders and myocardial dysfunctions.

In 2013, Acorda announced positive results of the Phase I trial with GGF2. The study identified a maximum tolerated dose of GGF2 and the preliminary efficacy measures showed that GGF2 improves heart function. Acorda discussed the findings from the study with the FDA and reached

agreement on the next clinical study of GGF2 in heart failure. This Phase Ib study primarily involves the continued investigation of the safety profile but also the efficacy of GGF2 across a range of doses. The start of the study was made public by Acorda in October 2013.

In June 2015, Acorda announced that they had stopped enrolment in the trial based on the occurrence of a case of hepatotoxicity (liver injury) meeting Hy's Law criteria, based on blood test results. Acorda also received a notification of clinical hold from the FDA following the submission of this information. There was one Hy's Law case reported in the previous Phase I study. In both cases the abnormal blood tests resolved within several days. The 22 patients who were dosed in the trial will complete the pre-planned one year of follow up. Outside of the hepatotoxicity case, the safety profile from this trial was consistent with the first Phase I trial, but efficacy data was inconclusive which Acorda believes was in part due to the very small number of patients in the trial. Acorda has ongoing analyses and non-clinical studies to investigate the biological basis for liver effects, and will need to meet with the FDA to review these and other data from the cimaglermin studies and to request that the program be removed from clinical hold.

#### **Cooperation Agreements**

The rights relating to the recombinant GGF2, rh GGF2, were licensed to Acorda in 2002 by PAION UK. In total, further milestone payments of USD 2.5 million become due prior to market approval and an additional milestone payment of USD 5 million is payable upon market authorization; after that PAION will receive royalties depending on net sales.

#### c. M6G

Due to the focus of the available resources on anesthesia, PAION is not actively developing M6G. In 2014, this project was licensed to Yichang Humanwell for the Chinese market. Yichang Humanwell received an exclusive license under PAION's know-how regarding M6G for the development, manufacture and commercialization in the People's Republic of China. By concluding the license, PAION receives payments totaling EUR 1.6 million of which PAION has received EUR 1.3 million so far. Additional license fees were not agreed.

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

#### a. Results of operations

	2015 KEUR	2014 KEUR	Change in result KEUR
Revenues	72	3,456	-3,384
Cost of revenues	-11	-4	-7
Gross profit	61	3,452	-3,391
Research and development	-29,385	-11,799	-17,586
General administrative and selling	-5,729	-3,702	-2,027
Other income (expenses)	965	410	555
Operating expenses	-34,149	-15,091	-19,058
Operating result	-34,088	-11,639	-22,449
Financial result	42	66	-24
Income taxes	5,834	2,468	3,366
Net result	-28,212	-9,105	-19,107

As expected, no significant **revenues** were realized in the fiscal year. These amounted to KEUR 72 und decreased by KEUR 3,384 compared to the prior year. Revenues in the prior-year period mainly related to the license agreement with Yichang Humanwell for M6G completed in 2014 (KEUR 1,564), the extension of the license agreement with R-Pharm to include the territory Middle East and North Africa (KEUR 1,500), and a premium that was paid by Pendopharm in the course of a private placement (KEUR 364).

Research and development expenses amounted to KEUR 29,385 and increased by KEUR 17,586 compared to the previous year. The planned increase is related to significantly intensified development activities with Remimazolam, in particular the preparation and conduct of the Phase III programs in the U.S. and the EU, the production development as well as regulatory activities including the dossier preparation.

**General administrative and selling expenses** amounted to KEUR 5,729 and increased by KEUR 2,027 compared to the previous year. Administrative expenses increased by KEUR 516 to

KEUR 3,461 and selling expenses increased by KEUR 1,511 to KEUR 2,268. This rise mainly results from the increase of the number of employees and the conduct of market research as well as premarketing and market access activities.

As in the previous year, **other income (expenses)** in the fiscal year mainly comprises foreign exchange gains (KEUR 907; previous year; KEUR 406). The increase is mainly related to higher amounts of foreign funds held in U.S. Dollar and Pound Sterling on average compared to the prior year.

The **financial result** amounted to KEUR 42, a decrease of KEUR 24 compared to the previous year. This is mainly due to lower interest on sight and short-term deposits.

The **income taxes** of the fiscal year relate to tax credits from the British tax authorities in connection with portions of the research and development costs. The change in comparison to the prior year is associated with the increase of the development costs for Remimazolam.

PAION closes fiscal year 2015 with a **net loss** of KEUR 28,212 after a net loss of KEUR 9,105 in the previous year.

#### b. Net Assets

	31 Dec. 2015 KEUR	31 Dec. 2014 KEUR	Change KEUR
Non-current assets	3,417	3,516	-99
Current assets	40,051	63,032	-22,981
Assets	43,468	66,548	-23,080
Equity	35,562	62,607	-27,045
Non-current liabilities	6	17	-11
Current liabilities	7,900	3,924	3,976
Equity and liabilities	43,468	66,548	-23,080

The **non-current assets** mainly comprise the book value of the development project Remimazolam (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 2014, **current assets** decreased by KEUR 22,981 to KEUR 40,051 and comprised cash and cash equivalents as well as prepaid expenses and other assets as of 31 December 2015. According to schedule, cash and cash equivalents decreased from KEUR 58,912 as of 31 December 2014 by KEUR 26,232 to KEUR 32,680 in the reporting period. Prepaid

expenses and other assets increased from KEUR 3,653 as of prior year's balance sheet date by KEUR 3,718 to KEUR 7,371 per year-end. This increase is substantially due to a by KEUR 3,416 higher tax claim for reimbursement of parts of the research and development costs from the British tax authorities as compared to 31 December 2014 amounting to KEUR 5,855 per year-end.

The decrease in **equity** by KEUR 27,045 compared to 31 December 2014 mainly results from the net loss of the year in the amount of KEUR 28,212. The equity ratio amounts to 81.8 % as of 31 December 2015 (31 December 2014: 94.1 %).

The rise of **current liabilities** by KEUR 3,976 to KEUR 7,900 is mainly due to the increase of trade payables in the amount of KEUR 3,994 compared to 31 December 2014 which was caused by the significant extension of research and development activities for Remimazolam.

#### c. Financial Position

**Cash and cash equivalents** decreased by KEUR 26,232 compared to 31 December 2014 and amounted to KEUR 32,680. The change in cash and cash equivalents stems from the following areas:

	2015 KEUR	2014 KEUR	Change KEUR
Cash flow from operating activities	-26,287	-12,044	-14,243
Cash flow from investing activities	-33	-26	-7
Cash flow from financing activities	22	57,618	-57,596
Effect of exchange rate changes	66	72	-6
Change in cash and cash equivalents	-26,232	45,620	-71,852

The **cash flow from operating activities** primarily results from the net loss of the year in the amount of KEUR 28,212 and tax reimbursements of parts of the research and development costs for fiscal year 2014 from the British tax authorities amounting to KEUR 2,575.

In the fiscal year, the **cash flow from financing activities** results from the exercise of stock options. Prior year's cash flow from financing activities mainly resulted from the capital increases conducted in 2014 and cost of funds in that regard.

#### d. Overall appraisal

The net loss of EUR 28.2 million meets the range of EUR 25 million to EUR 29 million projected for fiscal year 2015 in the previous year. Accordingly, funds decreased to EUR 32.7 million as planned.

The realized revenues and the capital measures conducted in the previous year allowed the significantly intensified investments in the development of Remimazolam, particularly the initiation and conduct of the Phase III programs in the EU and the U.S. and the production development, as well as the initiation of pre-marketing, market access and congress activities as planned. Thus, research and development expenses met the forecasted range of EUR 25 million to EUR 30 million for fiscal year 2015 with EUR 29.4 million. Correspondingly, tax income in the amount of EUR 5.8 million was between EUR 5 million and EUR 6 million as expected. General administrative and selling expenses exceeded the per prior year anticipated range of EUR 4.5 million to EUR 5 million for 2015 with EUR 5.7 million particularly due to intensified pre-marketing and market access activities. As projected, no significant revenues were realized in 2015.

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

#### Headcount

As of 31 December 2015, the total headcount of the PAION Group was 35 employees. By comparison, the headcount as of 31 December 2014 was 21 employees.

#### Changes in the Supervisory Board and Management Board

The Supervisory Board appointed Dr. Jürgen Raths as a new member of the Management Board (Chief Operating Officer) with effect from 1 September 2015.

Dr. Mariola Söhngen resigned from her office as member of the Management Board (Chief Medical Officer) with effect as of 31 October 2015.

#### Remuneration report

#### 1. 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 and stock appreciation rights as well as other remuneration in terms of company car remuneration, insurance premiums and pension contributions. All stock options and stock appreciation rights 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 at the end of each year. Bonuses are not subject to a minimum but are limited to a maximum amount and are paid depending 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.

Under the Employee Participation Plan 2006, a total of 100,000 stock appreciation rights were granted to acting Management Board members at the time of the grant. The stock appreciation rights have a two-year waiting period after which time the holder is entitled to receive a sum of money based on the PAION AG share price. In addition to an annual minimum appreciation, the Employee Participation Plan 2006 also limits the value of the amount payable. The maximum payable amount is 100 % of the exercise price, which is EUR 7.89 for the stock appreciation rights granted in fiscal year 2006. As of 31 December 2015, the exercise hurdle was EUR 11.47.

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. As of 31 December 2015, the exercise hurdle was EUR 1.72 or EUR 2.38 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. As of 31 December 2015, the exercise hurdle was EUR 2.20.

From the Stock Option Plan 2014 approved by the Annual General Meeting on 21 May 2014, a total of 166,500 stock options were granted to acting Management Board members at the time of the grant with effect from 17 January 2015. 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 2.30 per stock option and is based on the average price of the shares in a certain time period before the allocation. As of 31 December 2015, the exercise hurdle was EUR 2.41.

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. Regarding the performance of the stock appreciation rights granted to the Management Board members, which is directly linked to the performance of the PAION share price, a cap has been agreed.

The remuneration of the individual Management Board members in fiscal year 2015 (according to German Corporate Governance Code) can be gathered from the following tables:

Benefits granted in EUR			sin			
	2014	2015	2015 (Min)	2015 (Max)	2014	
Fixed compensation	250,000	262,500	262,500	262,500	50,000	15
Other remuneration	47,401	47,974	47,974	47,974	5,086	1
Total	297,401	310,474	310,474	310,474	55,086	16
One-year variable compensation	120,000	120,000	0	132,000	0	6
Multi-year variable compensation						
Stock Option Plan 2010 - Grant 2014 (Waiting period 2014 to 2018)	270,540	0	-	-	0	
Stock Option Plan 2014 - Grant 2015 (Waiting period 2015 to 2019)	0	62,715	-	-	0	6
Total	687,941	493,189	310,474	442,474	55,086	28
Service cost	0	0	0	0	0	
Total remuneration	687,941	493,189	310,474	442,474	55,086	28

<sup>\*)</sup> Prior year remuneration for Mr. Omari relates to the time period since joining the Management Board
\*\*) For Dr. Mariola Söhngen, target and maximal value of the one-year variable compensation are ex ante realizable values for the whole

Allocation in EUR	Dr. Wolfgang Söhngen CEO		
	2014	2015	
Fixed compensation	250,000	262,500	
Other remuneration	47,401	47,974	
Total	297,401	310,474	
One-year variable compensation	102,000	48,000	
Multi-year variable compensation			
Stock Option Plan 2008 - Grant 2008 (Waiting period 2008 to 2010)	9,829**	0	
Total	409,230	358,474	
Service cost	0	0	
<b>Total remuneration</b>	409,230	358,474	

<sup>\*\*)</sup> Dr. Söhngen exercised 15,873 stock options in financial year 2014

cFO ce 1 September 2014			Dr. Jürgen Raths COO since 1 September 2015				Dr. Mariola Söhngen CMO until 31 October 2015			
2015	2015 (Min)	2015 (Max)	2014	2015	2015 (Min)	2015 (Max)	2014	2015	2015 (Min)	2015 (Max)
,000	150,000	150,000	0	105,000	105,000	105,000	230,000	191,667	191,667	191,667
,127	15,127	15,127	0	42	42	42	38,559	35,853	35,853	35,853
,127	165,127	165,127	0	105,042	105,042	105,042	268,559	227,520	227,520	227,520
),000	0	66,000	0	0	0	0	110,000	110,000**	0	121,000**
0	-	-	0	0	-	-	270,540	0	-	-
,715	-	-	0	0	-	-	0	62,715	-	_
,842	165,127	231,127	0	105,042	105,042	105,042	649,099	400,235	227,520	348,520
0	0	0	0	0	0	0	0	0	0	0
,842	165,127	231,127	0	105,042	105,042	105,042	649,099	400,235	227,520	348,520

Abdelghani Omari *  CFO ince 1 September 2014		Dr. Jürger COO since 1 Septe	0	Dr. Mariola Söhngen CMO until 31 October 2015		
2014	2015	2014	2015	2014	2015	
50,000	150,000	0	105,000	230,000	191,667	
5,086	15,127	0	42	38,559	35,853	
55,086	165,127	0	105,042	268,559	227,520	
0	24,000	0	0	93,500	91,667	
0	0	0	0	0	0	
55,086	189,127	0	105,042	362,059	319,186	
0	0	0	0	0	0	
55,086	189,127	0	105,042	362,059	319,186	

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

Management Board remuneration in fiscal year 2015 amounted to KEUR 1,160 in total (previous year: KEUR 1,358) and is composed as follows:

in EUR	2015	2014
Fixed remuneration	709,167	530,000
Other remuneration	98,997	91,046
Total non-performance based remuneration	808,163	621,046
Short-term variable remuneration	163,667	195,500
Total short-term remuneration	971,830	816,546
Long-term variable remuneration	188,145	541,080
Total long-term remuneration	188,145	541,080
Total remuneration	1,159,975	1,357,626

The decrease of the total remuneration in comparison to the prior year mainly results from two opposed factors: On the one hand, short-term remuneration increased due to the higher average number of Management Board members in fiscal year 2015 compared to the prior year. On the other hand, long-term variable remuneration decreased in the reporting period compared to 2014 since less stock options were granted in the course of the grant from Stock Option Plan 2014 in the reporting period than in the course of the grant from Stock Option Plan 2010 in the previous year.

The Management Board members held the following stock options as of 31 December 2015:

Status of non-exercised stock options at ciation rights as of 31 December 201.		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.	55,500	0	55,500
Stock options 2014 - fair value*	EUR	62,715	-	62,715
Stock Appreciation Rights (SAR) SAR - fair value**	No. EUR	25,000 0	0	0 -

<sup>\*)</sup> Applicable fair value at the time of issuance, calculated using the Black/Scholes option pricing model \*\*) Applicable fair value on the balance sheet date, 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 can only be exerted if the change of control also entails a significant change in business strategy, in responsibilities or in regard to the company domicile.

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

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

Pursuant to the terms of the Stock Option Plans 2008, 2010 and 2014, in the event of a change of control, the waiting period for all stock options issued to Management Board members whose 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 2015:

	Basic remuneration EUR	Per-meeting fees EUR	Total EUR
Dr. Jörg Spiekerkötter	40,000	18,000	58,000
Dr. Karin Dorrepaal	30,000	13,500	43,500
John Dawson	20,000	9,000	29,000

Supervisory Board remuneration in fiscal year 2015 amounted to KEUR 131. In the previous year, the remuneration also amounted to KEUR 131.

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

#### Composition of subscribed capital

As of 31 December 2015, PAION AG had a subscribed capital of EUR 50,659,440.00, divided into 50,659,440 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 share-holder 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 equal or exceeded as of 31 December 2015 10 % of the voting rights 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. The Authorized Capital 2015 has not been used so far.

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 858,121 shares (Conditional Capital 2004 II), 552,064 shares (Conditional Capital 2008 I), 720,000 shares (Conditional Capital 2010 I) and 740,000 shares (Conditional Capital 2014) in connection with the Stock Option Plans 2005, 2008, 2010 and 2014.

### 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 and 2014 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 whose 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.

With the engagement of Greg Papaz as CEO of the subsidiary PAION, Inc., PAION, Inc. entered into an obligation to pay Mr. Papaz an amount of 0.5 % of the realized amount in case of a sale of PAION AG. The term of this agreement ends 30 June 2016. With the engagement of Dr. David Bernstein as non-executive director of PAION, Inc., PAION, Inc. entered into an obligation to pay Dr. Bernstein an amount of 0.1 % of the realized amount in case of a sale of PAION AG. The term of this agreement ends 30 June 2016. Moreover, with the engagement of Mr. Timothy Morris as non-executive director of PAION, Inc., PAION, Inc. entered into an obligation to pay Mr. Morris an amount of 0.075 % of the realized amount in case of a sale of PAION AG. The term of this agreement also ends 30 June 2016.

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 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 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 an 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 therefrom. In addition, PAION has commissioned an external auditor to assume the function of 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 therefrom. 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. 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.

The risk early warning system was revised in the reporting period and adjusted in terms of responsibilities to match the existing matrix organization and in terms of probabilities of occurrence and damage levels to reflect the current position of the group, particularly the progress of the development and the market environment having become relevant in that respect. A detailed overview is illustrated in chapter 3.

### 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 financial statements are 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. Applied categories for likelihoods of occurrence and damage levels as well as the classification of resulting net risks are illustrated in the following table:

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

In the following, identified risks will be outlined together with respective implemented risk-reducing measures and classified according to the illustrated table above. The classification is based on net risks under consideration of risk-mitigating activities. Risks potentially posing a threat to the continued existence of the group are defined as risks with a potential damage level of more than EUR 5 million in case of occurrence. Risks potentially posing a threat to the continued existence of the group are separately denoted accordingly. Net risks with an assessment as "Very low risk" and "Low risk" are not depicted since these do not significantly influence the decisions of a reasonable addressee.

# 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 studies. As is common practice in the pharmaceutical industry, Clinical Research Organizations (CROs) have been assigned to conduct the clinical 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 requiring rework amendments and causing delays in the approval process. In order to reduce this risk, the conduct of 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 which could potentially pose a threat to the continued

existence of the group in case of occurrence. Nearly 40 % of all Phase III projects do not directly lead to approval.  $^{12}$ 

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 analyses potential alternative and prevention scenarios on a need basis in order to be able to initiate these as fast as possible in case of occurrence of this risk. This is a high risk which could potentially pose a threat to the continued existence of the group in case of occurrence.

In this context, please note the report on post-balance sheet date events pointing out the discontinuation of the cardiac surgery EU Phase III trial in general anesthesia due to insufficient patient recruitment. The occurrence of this risk has not induced a threat to the continued existence of the group.

The results of 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 clinical studies, potential dosage modifications and amendments to clinical trial protocols mitigate the risk as far as possible. Unexpected serious adverse events as well as an insufficient study outcome for the U.S. Phase III program are increased risks; an insufficient study outcome of the EU Phase III program is a high risk. In case of occurrence of each of the three risks, the potential damage level could pose a threat to the continued existence of the group.

In this context, please note the report on post-balance sheet date events pointing out the discontinuation of the cardiac surgery EU Phase III trial in general anesthesia due to insufficient patient recruitment inevitably also implying insufficient study outcome. The occurrence of this risk has not induced a threat to the continued existence of the group.

There is also a risk that authorities impose additional regulatory requirements exceeding the needs originally agreed leading to cost increases or a significant delay in the conduct of studies or necessitating 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. This is a high risk.

<sup>&</sup>lt;sup>12</sup> Tufts Center for the Study of Drug Development (2014): Briefing – Cost of Developing a New Drug.

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 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 a moderate risk.

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 our 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 expects Remimazolam to receive a 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 commercial usability in the U.S. In order to reduce this risk as far as possible, PAION has specifically 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. 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, 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 underlying the business plan 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 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 is working on the preparation of the relevant markets intensively, including bringing in external consultants for communication with the scientific community. This is a high risk.

In order to be able to successfully sell Remimazolam upon market approval, the distribution structure 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, the analysis and description of the distribution structure has already been started. 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 done. 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 avoid 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 cooperates with are experienced in the timely adoption of additional regulatory requirements. This is an increased risk. In case of occurrence, the potential damage level could pose a threat to the continued existence of the group.

Based on 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. This risk particularly exists in regard to a potential license partner in Japan since commercialization could potentially start first in that market. 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 whole distribution 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 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. In case of occurrence, the potential damage level could, based on the specific issue, pose a threat to the continued existence of the group.

#### b. Finance risks

#### aa) Financing risks

PAION expects future payments from tax credits and from existing and possible future cooperation agreements to cover its short- and mid-term financing needs. However, PAION may need additional funding within this timeframe in order to prepare the commercialization or further development 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 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 careful 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, 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 and the pound sterling in respect to the euro could increase the costs for the development and market preparation of Remimazolam. In order to reduce this risk, PAION does maintain foreign currency funds in U.S. dollars and (in lower amounts) of pound sterling. Currency risks also arise from translating the foreign subsidiaries' separate financial statements from pound sterling or U.S. dollar into euros because the pound/U.S. dollar is the functional currency of the UK subsidiaries/U.S. subsidiary.

Currency risks are systematically recorded and monitored based on cautious short-, midand long-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. 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.

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. 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 for diseases or interventions 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 currently is in Phase III development in the U.S. in procedural sedation for minor medical interventions. The development for general anesthesia in Japan is completed, and PAION expects that a new Phase III trial will be required for market approval in the EU. In Japan, PAION is looking for a partner for commercialization. Approval in Japan could give access to specific 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 for application 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.

PAION benefits from the progress of its Remimazolam development partners in China, South Korea, Canada, Russia/CIS, Turkey, and the MENA region in the form of additional development data and benefits financially in the form of milestone payments and royalties from launch onwards. For the U.S. and 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. However, for 2016, main focus is on the U.S. Phase III program since better licensing conditions are being expected with availability of Phase III results. Based on the results of the market research activities performed so far, Remimazolam is an excellent candidate for developing a commercial platform in anesthesia (EU) and procedural sedation (U.S.).

#### Overall evaluation of chances and risks

The ongoing Phase III studies with Remimazolam in the U.S. are an important milestone on the pathway to market approval. However, available cash and cash equivalents have significantly decreased compared to the prior year and will not be sufficient up until market approval which has led to a higher financing risk compared to 2014. As the Phase III trials have not been completed yet, the risk remains that development is not successful. Due to the necessary discontinuation of the EU Phase III trial and the current lack of funds for a new Phase III study, PAION's success is now fully dependent on the successful completion of the development in the U.S. or entering into successful cooperations. Based on the difficult financing environment and the impaired financial situation, PAION needs to focus on the development in the U.S. now. As such, the risk situation has worsened in comparison to the previous year.

It is expected that the upcoming completion of the first Phase III trial in the U.S. in the important indication of procedural sedation for colonoscopies and the generated data in that regard will mark an important milestone for further financing. This could enable PAION to realize the pathway to market approval and commercialization of Remimazolam in the U.S. on its own. The clinical development program in the U.S., the most important market for PAION, has been implemented as scheduled. Following the early discontinuation of the EU Phase III trial, all available resources are now being concentrated on the development program in the U.S. in order to maximize chances for success. Under consideration of the progress of the development in the U.S. in particular, the chance situation has improved in comparison to the previous year.

#### Report on post-balance sheet date events

On 9 February 2016, it was decided to discontinue the European Phase III study in cardiac surgery patients due to insufficient patient recruitment. In order to properly terminate the study, to gather the retrieved data in a study report and to destroy the study medication, cash-effective expenses in the amount of approx. EUR 1 million are expected to be incurred in 2016.

On 18 February 2016, PAION reported that the Japanese Pharmaceuticals and Medical Devices Agency (PMDA) regards the clinical and non-clinical data sets for Remimazolam as complete for filing for market approval in the indication General Anesthesia in Japan based on a so-called pre-NDA meeting. This will presumably not have any effects on the net assets, financial position and results of operations.

There were no further significant events in the period between the reporting date, 31 December 2015, and the preparation of this report.

### Report on expected developments

#### Outlook on development and commercialization

PAION's major goals for 2016 are the conduct of the Phase III development program with Remimazolam in the U.S. and the production development for Remimazolam, in particular the validation of the production at market scale. Moreover, PAION expects the development activities of its Remimazolam cooperation partners Yichang Humanwell, Hana Pharm, R-Pharm, and Pendopharm to continue. PAION benefits from the progress of the development of Remimazolam in the mid and long term in the form of additional development data as well as financially in the form of milestone payments and royalties from launch onwards.

PAION is on its way to evolve into a specialty pharma company with a focus on anesthesia products. In this context, PAION seeks to retain certain marketing rights for Remimazolam for the EU and the U.S. market in order to market Remimazolam itself or together with a partner. In case of a successful out-licensing by way of a development cooperation, PAION would expect to receive substantial payments as upfront payments or through sharing of development costs, development milestone payments and royalties from market approval onwards. In case of a pure marketing cooperation after registration, PAION would expect to receive a comparably higher upfront payment and higher royalties. For this reason, it could also be reasonable and attractive to launch without a partner.

For the U.S. and the EU, PAION aims at an own commercialization. PAION is open to partnerships in both regions if they are more attractive than an own commercialization or complementary to reaching peak sales more rapidly. For all regions outside the U.S. and the EU, it is aimed to find license or distribution partners.

After a positive pre-NDA meeting with the Japanese authority, in the course of which details of a market approval for Remimazolam have been outlined, PAION is continuing partnering discussions with potential licensees which will however most probably not be completed before the second half of 2016. Alternatively, PAION is also evaluating filing for market approval itself. A Japanese dossier could serve as a reference dossier for approval in certain markets.

The Phase III colonoscopy trial is running according to plan; completion of patient recruitment is expected shortly and headline data are expected mid 2016. Currently, 450 patients have been treated. Patient recruitment in the Phase III bronchoscopy trial is still moderate, and completion of patient recruitment could potentially be delayed into 2017. Subject to a successful implementation of ongoing countermeasures, PAION expects filing for market approval end of 2017 at the earliest and market approval end of 2018 at the earliest, accordingly.

#### Financial outlook

PAION currently concentrates on the development of Remimazolam in the U.S. and does not expect revenues in 2016.

Due to the ongoing investments in the development of Remimazolam, research and development expenses will continue being incurred in significant amounts. However, they will be lower compared to 2015 and amount to approximately EUR 24 million to EUR 27 million dependent on the progress of the development. In this context, income from tax credits on parts of the research and development expenses from British tax authorities in the amount of approximately EUR 4 million to EUR 4.5 million is expected. General administrative and selling expenses will decrease compared to the prior year and amount to approximately EUR 4.5 million to EUR 5 million, in particular due to lower selling expenses.

Accordingly, the net loss will decrease compared to prior year and amount to approximately EUR 24.5 million to EUR 27.5 million.

Key assumption for the report on expected developments is the scheduled progress of development activities in the U.S. Otherwise, essential parts of the costs would be shifted to 2017. Moreover, the amount of expected expenses is based on the current status of discussions with the regulatory authority FDA. Should the FDA impose additional requirements, costs could be incurred in higher amounts than planned and lead to a delay of approval.

As of 31 December 2015, PAION Group had cash and cash equivalents of EUR 32.7 million securing cash reach until the end of the first quarter of 2017 including the receipt of expected tax credits in the middle of 2016. Thus, PAION has sufficient funds to conduct the ongoing development with Remimazolam in the U.S. Based on current planning, PAION expects market approval for Remimazolam in the U.S. end of 2018 at the earliest. In the following, cash requirements for important Remimazolam development milestones up until approval are depicted for transparency purposes. Beyond current cash reach, additional funds of approximately EUR 10 million are required until filing, and further funds also amounting to approximately EUR 10 million are required until market approval. Under the assumption of the attractive own commercialization of Remimazolam in the U.S., additional funding in the amount of approximately EUR 30 million would be required until market approval for the establishment of a commercial infrastructure, i. a. for the establishment of a distribution network and the production of market material. This would allow immediate market entry after approval. The financing requirements would correspondingly decrease in case

of partnering. PAION expects to be able to refinance by means of partnering or capital measures in case of successful development of Remimazolam.

Aachen, Germany, 21 March 2016 PAION AG

Dr. Wolfgang Söhngen

Dr Jürgen Rath

# **Consolidated Financial Statements**

PAION AG

# Consolidated Balance Sheet as of 31 December 2015

ASSETS	Note	31 Dec. 2015 EUR	31 Dec. 2014 EUR
Non-current assets			
Intangible assets	1.	3,361,501.93	3,439,847.15
Equipment	2.	55,590.77	76,307.25
Other assets		14.42	14.26
		3,417,107.12	3,516,168.66
Current assets			
Trade receivables	3.	0.00	467,040.00
Prepaid expenses and other assets	4.	7,371,001.85	3,653,061.14
Cash and cash equivalents	5.	32,679,797.20	58,911,883.56
		40,050,799.05	63,031,984.70
Total assets		43,467,906.17	66,548,153.36

EQUITY AND LIABILITIES	Note	31 Dec. 2015 EUR	31 Dec. 2014 EUR
Equity	6.		
Share capital		50,659,440.00	50,641,940.00
Capital reserve		124,236,225.22	123,441,189.40
Translation reserve		-429,475.43	-783,952.04
Loss carryforward		-110,691,994.16	-101,587,224.18
Result for the period		-28,212,364.88	-9,104,769.98
		35,561,830.75	62,607,183.20
Non-current liabilities			
Deferred income		5,555.48	16,666.60
		5,555.48	16,666.60
Current liabilities			
Trade payables	8.	7,332,458.12	3,338,406.64
Provisions	7.	224,365.06	306,349.99
Other current liabilities	9.	304,774.95	253,921.75
Current portion of deferred income		38,921.81	25,625.18
		7,900,519.94	3,924,303.56
Total equity and liabilities		43,467,906.17	66,548,153.36

# Consolidated Statement of Comprehensive Income for Fiscal Year 2015

	Note	2015 EUR	2014 EUR
Revenues	10.	71,614.71	3,455,824.07
Cost of revenues		-10,940.75	-4,148.84
Gross profit		60,673.96	3,451,675.23
Research and development expenses		-29,384,797.19	-11,799,194.16
General administrative and selling expenses		-5,728,973.92	-3,702,051.20
Other income (expenses), net	11.	965,091.67	410,691.11
Operating expenses		-34,148,679.44	-15,090,554.25
Operating result		-34,088,005.48	-11,638,879.02
Financial income	12.	41,689.08	65,804.42
Financial result		41,689.08	65,804.42
Result for the period before taxes		-34,046,316.40	-11,573,074.60
Income taxes	13.	5,833,951.52	2,468,304.62
Result for the period		-28,212,364.88	-9,104,769.98
of which attributable to other shareholders		0.00	0.00
of which attributable to shareholders of PAION AG		-28,212,364.88	-9,104,769.98
Foreign currency translation of subsidiaries		354,476.61	253,450.50
Total income and expense recognized directly in equity that will be			
reclassified to profit or loss when specific conditions are met		354,476.61	253,450.50
Other comprehensive income		354,476.61	253,450.50
Total comprehensive income		-27,857,888.27	-8,851,319.48
of which attributable to other shareholders		0.00	0.00
of which attributable to shareholders of PAION AG		-27,857,888.27	-8,851,319.48
Earnings per share (basic)	14.	-0.56	-0.23
Earnings per share (diluted)	14.	-0.56	-0.23

# Consolidated Cash Flow Statement for Fiscal Year 2015

	2015 EUR	2014 EUR
Cash flows from operating activities:		
Net result for the period	-28,212,364.88	-9,104,769.98
Reconciliation of net profit (loss) for the period to cash flows from operating activities:		
Income taxes	-5,833,951.53	-2,468,304.61
Amortization/depreciation and non-cash exchange rate changes of fixed assets	124,823.24	92,686.10
Loss/Profits from the disposal of non-current assets	7,715.21	197.99
Interest expenses and interest income	-41,689.08	-65,804.42
Release of deferred income	-27,633.43	-18,550.07
Expenses from stock option plans	790,485.82	511,390.53
Changes in assets and liabilities which are not attributable to investing or financing activities:		
Trade receivables	467,040.00	-467,040.00
Prepaid expenses and other assets	-460,976.13	-682,912.55
Trade payables	3,994,051.48	1,424,056.97
Provisions	-81,984.93	-40,871.72
Other current liabilities	50,853.20	29,029.78
Deferred income	29,818.95	21,953.01
Non-cash exchange losses/gains	288,498.80	182,151.01
	-28,905,313.28	-10,586,787.96
Paid income taxes	0.00	-2,243,225.60
Tax payments received	2,575,181.54	722,694.34
Interest received	43,494.51	63,154.05
Net cash used in operating activities	-26,286,637.23	-12,044,165.17
Cash flows from investing activities:		
Cash paid for investments in intangible assets and equipment	-33,476.91	-26,469.52
Net cash used in investing activities	-33,476.91	-26,469.52
Cash flows from financing activities:		
Capital increase	17,500.00	25,262,034.00
Contributions to the capital reserve	4,550.00	36,069,792.17
Payments in connection with raising capital	0.00	-3,713,873.73
Net cash provided from financing activities	22,050.00	57,617,952.44
Change in cash and cash equivalents	-26,298,064.14	45,547,317.75
Effect of exchange rate changes on cash	65,977.78	72,271.18
Cash and cash equivalents at beginning of the period	58,911,883.56	13,292,294.63
Cash and cash equivalents at end of the period	32,679,797.20	58,911,883.56
Composition of cash and cash equivalents at the end of the period:		
Cash and cash equivalents	32,679,797.20	58,911,883.56

# Consolidated Statement of Changes in Equity for Fiscal Year 2015

EUR	Share capital	Capital reserve	Translation reserve	Loss carryforward	Equity
31 December 2013	25,379,906.00	90,573,880.43	-1,037,402.54	-101,587,224.18	13,329,159.71
Total comprehensive income	0.00	0.00	253,450.50	-9,104,769.98	-8,851,319.48
Issue of shares	25,262,034.00	0.00	0.00	0.00	25,262,034.00
Contribution to the capital reserve	0.00	36,069,792.17	0.00	0.00	36,069,792.17
Cost of raising capital	0.00	-3,713,873.73	0.00	0.00	-3,713,873.73
Additional contribution to the capital					
reserve due to the issue of options	0.00	511,390.53	0.00	0.00	511,390.53
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
Cost of raising capital	0.00	0.00	0.00	0.00	0.00
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

# **Consolidated Notes**

PAION AG

# Notes to the consolidated financial statements for fiscal year 2015

#### 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/USA
- 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 innovative drugs in indications for which there is a substantial unmet medical need.

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

The consolidated financial statements as of 31 December 2015 and the group management report for fiscal year 2015 are scheduled for adoption and approval for publication by the Supervisory Board in its meeting on 21 March 2016.

#### 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 2015, 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 2015 according to IAS 1.

The following new and/or revised standards 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.

- IFRSs 2011–2013 Cycle "Annual Improvements to IFRSs 2011–2013" implements changes to the following standards:
- IFRS 1 "First-time Adoption of International Financial Reporting Standards"
- IFRS 3 "Business Combinations"
- IFRS 13 "Fair Value Measurement"
- IAS 40 "Investment Property"

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

- Amendments to IAS 1 "Presentation of Financial Statements":
   The amendments are effective for annual periods beginning on or after 1 January 2016. Earlier adoption is allowed.
- Amendments to IAS 16 "Property, Plant and Equipment" and IAS 38 "Intangible Assets": The amendments are effective for fiscal years beginning on or after 1 January 2016. Earlier adoption is allowed.
- IFRS 9 "Financial Instruments": The new guidelines are effective for fiscal years beginning on or after 1 January 2018.
   Earlier adoption is allowed. The adoption by the EU is still pending.
- Amendments to IFRS 11 "Joint Arrangements": The amendments are effective for fiscal years beginning on or after
   1 January 2016. Earlier adoption is allowed. 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" The changes are effective for annual periods beginning on or after 1 February 2015. Earlier adoption is allowed.
- 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"

  The changes are effective for annual periods beginning on or after 1 January 2016. Earlier adoption is allowed.
- Amendments to IAS 27 "Separate Financial Statements": The amendments are effective for fiscal years beginning on or after 1 January 2016. 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 10 "Consolidated Financial Statements", to IFRS 12 "Disclosure of Interests in Other Entities", and to IAS 28 "Investments in Associates and Joint Ventures":
   The amendments are effective for fiscal years beginning on or after 1 January 2016. 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. 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 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 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. 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.

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, the achievement of milestones and services to be provided in that regard are recognized once the Management Board deems the underlying critera 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 US dollar for the US-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 2015: 0.7350 GBP/EUR; 1.0892 USD/EUR; exchange rate as of 31 December 2014: 0.7818 GBP/EUR; 1.2166 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 (bandwith in 2015 from 0.7060 GBP/EUR to 0.7810 GBP/EUR and from 1.0720 USD/EUR to 1.1634 USD/EUR; bandwith in 2014 from 0.7879 GBP/EUR to 0.8313 GBP/EUR and from 1.2339 USD/ EUR to 1.2688 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 reported as deferred income and recognized in profit over the probable development life of the products or directly recognized as income depending on the 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 saling 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 capitalised 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 subsidised 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:

Industrial rights
and similar rights
and assets

Acquisition Cost	
1 Jan. 2014	13,456,306.60
Additions	4,059.00
Disposals	22,589.83
Reclassifications	0.00
Exchange rate differences	868,929.35
31 Dec. 2014	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
Accumulated amortization, depreciation and im-	npairment losses
1 Jan. 2014	9,962,442.94
Additions	277,147.38
Disposals	22,539.91
Exchange rate differences	649,807.56
31 Dec. 2014	10,866,857.97
Additions	302,185.17
Disposals	0.00
Exchange rate differences	677,701.51
31 Dec. 2015	11,846,744.65
Carrying amounts as of 31 Dec. 2014	3,439,847.15

Carrying amounts as of 31 Dec. 2015

3,361,501.93

The intangible assets mainly comprise the development project Remimazolam (KEUR 3,347). This development project is 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.

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 costs.

# (2) Equipment

# Equipment developed as follows:

EUR	Plant and machinery	Other plant, factory and office equipment	Tota
Acquisition Cost			
Acquisition Cost 1 Jan. 2014	270,185.77	665,644.31	935,830.08
Additions	15,038.58	7,371.94	22,410.52
Disposals	77,457.00	562.07	78,019.0
Reclassifications	0.00	0.00	0.0
Exchange rate differences	0.00	6,030.96	6,030.9
31 Dec. 2014	207,767.35	678,485.14	886,252.4
Additions	18,830.42	11,632.48	30,462.9
Disposals	54,893.98	2,006.78	56,900.7
Reclassifications	0.00	0.00	0.0
Exchange rate differences	81.41	6,236.28	6,317.6
31 Dec. 2015	171,785.20	694,347.12	866,132.3
Accumulated amortization, depreciation and impairment losses			
1 Jan. 2014	229,110.09	618,014.52	847,124.6
Additions	15,242.08	19,429.04	34,671.1
Disposals	77,448.00	423.00	77,871.0
Exchange rate differences	0.00	6,020.51	6,020.5
31 Dec. 2014	166,904.17	643,041.07	809,945.2
Additions	18,224.77	25,322.77	43,547.5
Disposals	47,178.77	2,006.78	49,185.5
Exchange rate differences	5.96	6,228.36	6,234.3
31 Dec. 2015	137,956.13	672,585.42	810,541.5
Carrying amounts as of 31 Dec. 2014	40,863.18	35,444.07	76,307.2
Carrying amounts as of 31 Dec. 2015	33,829.07	21,761.70	55,590.77

# 3) Trade Receivables

The trade receivables disclosed per prior year-end related to the license agreement for M6G completed with Yichang Humanwell in 2014 in the full amount.

# (4) Prepaid expenses and other assets

Prepaid expenses and other assets substantially comprise claims for reimbursement from the British tax authorities for subsidized research and development activities (KEUR 5,855; previous year: KEUR 2,439), prepaid expenses relating to research and development services for Remimazolam (KEUR 538; previous year: KEUR 748), VAT refund claims (KEUR 418; previous year: KEUR 45), accrued income in connection with the license agreement for M6G with Yichang Humanwell (KEUR 311; previous year: KEUR 311), and prepaid expenses relating to insurance contributions, rents and other prepayments (KEUR 186; previous year: KEUR 85).

# (5) Cash and cash equivalents

Cash and cash equivalents are comprised of the following:

	31 Dec. 2015 KEUR	31 Dec. 2014 KEUR
Current deposits Bank balance and cash in	5,307	43,938
hand	27,373	14,974
	32,680	58,912

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

# (6) Equity

As of 31 December 2015, the share capital amounts to EUR 50,659,440.00 (previous year: EUR 50,641,940.00); it is divided into 50,659,440 no-par value shares (previous year: 50,641,940 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 authorised 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. The still available Authorised Capital 2014 in the amount of EUR 14,137,297.00 was revoked.

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, warrantlinked 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. Conditional Capital 2010 II in the amount of EUR 9,800,000.00 was revoked.

The Annual General Meeting of 5 May 2008 adopted a resolution to reduce Conditional Capital 2004 II to EUR 858,121.00. 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, 46,462 stock

options were issued to (former) employees of the PAION Group as of 31 December 2015. 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, 510,246 stock options were issued to current and former Management Board members and employees of the PAION Group as of 31 December 2015. To date, 208,171 stock options from the Stock Option Plan 2008 have been exercised, thereof 17,500 in fiscal year 2015. The exercises led to cash inflows of EUR 22,050.00 in the fiscal year. As of 31 December 2015, Conditional Capital 2008 I amounts to EUR 552,064.00.

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, 699,750 stock options were issued to current and former Management Board members and employees of the PAION Group as of 31 December 2015. 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, 328,813 stock options were issued to current and former Management Board members and employees of the PAION Group as of 31 December 2015. No stock options have been exercised yet.

Exchange rate gains and losses amounting to KEUR -429 are recognized in equity. Of these, KEUR -4,557 concern exchange rate losses (as of 31 December 2014 exchange rate loss of KEUR -3,146) 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 4,127 concern exchange rate gains (as of 31 December 2014 KEUR 2,362 exchange rate gain) incurred on loans from PAION AG to the British subsidiaries and the U.S. subsidiary. As of 31 December 2015, these loans amount to KEUR 60,180 (previous year: KEUR 33,700).

# (7) Provisions

# Provisions developed as follows:

	Premiums/ Management			
in KEUR	Bonuses	Taxes	Other	Total
31 Dec. 2013	284	2,162	62	2,508
				_
Utilization	255	2,090	0	2,345
Addition	215	0	0	215
Release	0	72	0	72
Addition of accrued interest	0	0	0	0
Change of interest rate	0	0	0	0
Exchange rate differences	0	0	0	0
31 Dec. 2014	244	0	62	306
Utilization	236	0	0	236
Addition	153	0	0	153
Release	0	0	0	0
Addition of accrued interest	0	0	0	0
Change of interest rate	0	0	0	0
Exchange rate differences	1	0	0	1
31 Dec. 2015	162	0	62	224

# (8) Trade payables

Trade payables amounted to KEUR 7,332 as of 31 December 2015 (previous year: KEUR 3,338). These liabilities do not bear interest and are generally due for payment within 30 days.

# (9) Other current liabilities

#### Other current liabilities comprise the following:

	31 Dec. 2015 KEUR	31 Dec. 2014 KEUR
Wage taxes	176	162
Holiday allowances	79	49
Supervisory board remuneration	33	33
Others	17	10
	305	254

# Consolidated statement of comprehensive income disclosures

## (10) Revenues

In the reporting period, no significant revenues were realized. The revenues of the prior year amounted to KEUR 3,456 and mainly related to the license agreement with Yichang Humanwell for M6G completed in 2014 (KEUR 1,564), the extension of the license agreement with R-Pharm to include the territory Middle East and North Africa (KEUR 1,500), and a premium that was paid by Pendopharm in the course of a private placement (KEUR 364).

# (II) Other income (expenses), net

As in the previous year, other income (expenses) in the fiscal year mainly comprises foreign exchange gains (KEUR 907; previous year; KEUR 406). The increase is mainly related to higher amounts of foreign funds held in US Dollar and Pound Sterling on average compared to the prior year.

#### (12) Financial income

#### Financial income consists of the following:

	2015 KEUR	2014 KEUR
Interest income based on amortized costs (bank balances and current deposits)	42 <b>42</b>	66 <b>66</b>

# (I3) Income taxes / Deferred taxes

As of 31 December 2015, the tax losses carried forward by the PAION Germany group (PAION AG and PAION Deutschland GmbH) amounted to about EUR 77 million (previous year: EUR 78 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 86 million per 31 December 2015 (equivalent to EUR 116 million if translated at the exchange rate applicable on the reporting date). In the previous year, these amounted to GBP 79 million or EUR 101 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 335 as of 31 December 2015 (previous year: KUSD 37). According to current tax legislation, these can be carried forward indefinitely.

Overall, the losses carried forward within the Group amount to EUR 193 million (previous year: EUR 179 million). No deferred tax assets were recognized regarding a partial amount of EUR 190 million (previous year: EUR 175 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 was 21 % until 31 March 2015 and was reduced to 20 % from 1 April 2015 onwards. The income tax rate in the United States of America is 34 %. The 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 669 (previous year: KEUR 684) 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 2015, the resulting deferred tax assets would amount to EUR 25 million (previous year: EUR 24 million). Based on the income tax rate of 20 % that is applicable in Great Britain, the losses carried forward in Great Britain as of 31 December 2015 would produce deferred tax assets in an amount of GBP 17 million (equivalent to EUR 23 million if translated at the rate applicable on the reporting date). In the previous year, these amounted to GBP 16 million or EUR 20 million, respectively. The temporary differences between the tax base and the IFRS carrying amount would produce a net balance as

of 31 December 2015 of deferred tax assets in an amount of KEUR 44 (previous year: KEUR 49), of which Germany accounts for KEUR 5 (previous year: KEUR 14) and Great Britain for KEUR 39 (previous year: KEUR 35). Deferred taxes from PAION, Inc. only result in an immaterial amount 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 48 million (previous year: EUR 44 million).

In the fiscal year, the German companies of the PAION Group and PAION Holdings UK Ltd reported small profits; PAION, Inc. and PAION UK Ltd showed net 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 the launch and/or global partnering 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	2015	2014
Result for the period before taxes	-34,046	-11,573
Anticipated tax expense (+) / income (-)	-10,214	-3,472
Non-recognition of deferred taxes on tax losses	3,000	1,690
Revaluation of losses carried forward due to loss carryback	0	153
Revaluation of losses carried forward due to tax rate changes	0	739
Difference between anticipated Group tax rate and actual local tax rates	3,139	706
Effects from currency translation	573	419
Expenses in connection with stock options	219	145
Non-deductible expenses	27	25
Non-recognition of deferred taxes on temporary differences	-6	-31
Tax losses used	-378	-20
Correction of prior years' tax expenses	0	-72
impairment from non-recognition of deferred taxes on tax losses	0	-892
Effects from tax credits	-2,195	-756
Cost in connection with capital increases	0	-1,102
Other	1	0
Actual tax expense (+) / income (-)	-5,834	-2,468

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

# (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:

	2015	2014
Shares outstanding as of 1 January	50,641,940	25,379,906
Weighted average number of shares issued	10,623	14,501,133
Weighted average number of ordinary shares	50,652,563	39,881,039

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

	2015	2014
Net result for the year (in EUR)	-28,212,364.50	-9,104,769.98
Weighted average number of ordinary shares for basic earnings per share	50,652,563	39,881,039
Weighted average number of ordinary shares for diluted earnings per share	50,895,530	40,346,159
Earnings per share (in EUR):		
Basic	-0.56	-0.23
Diluted	-0.56	-0.23

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 four stock option plans in the course of which stock options can be/have been granted to Management Board accordance with the provisions of IFRS 2. All stock option programs include vesting periods, waiting periods and exercise hurdles. The respective programs can be found in the following table:

	Stock Option Plan 2005	Stock Option Pla	
	Approved 30 December 2004	Approved 5 M	
Underlying Capital	Conditional Capital 2004 II	Con	
Term of the options	10 years		
Vesting period	2–4 years		
Waiting period	2–4 years		
Exercise condition	Cumulative stock price increase of 5 % per year since grant in relation to stock price at grant date	Cumulative stock price increas grant in re	
Exercise price *	EUR 8.00 to EUR 9.55		
Weighted average exercise price *	EUR 8.39		
Exercise hurdle as of 31 Dec. 15 *	EUR 11.47 to EUR 14.61		
Weighted average remaining term as of 31 Dec. 2015	1.0 years		
Further grants possible?	No		
Number of totally granted options	1,055,767		
Number of outstanding options as of 31 Dec. 15 **	46,462		
granted to employees	46,462		
granted to Management Board members	0		
Number of outstanding options for which the waiting period has expired as of 31 December 2015	46,462		
Number of totally lapsed options as of 31 Dec. 15	1,009,305		
thereof lapsed in the reporting period	798,881		
Number of totally exercised options until 31 Dec. 15	0		
thereof exercised in the reporting period	0		
Personnel expenses in the reporting period **	0		
Fair value per option at the time of the grant ***	EUR 2.41 to EUR 4.08		
Elements of calculation			
Valuation model	Black/Scholes		
Risk-free rate	3-4.5%		
Volatility	27.81-47.77%		
Staff turnover	6.5% per year		
in relation to outstanding options as of 31 Dec. 2015 *) in relation to employee/Management Board member status at t **) in relation to totally granted options	he time of the grant		

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

Stock Option Plan 2014

Stock Option Plan 2010

an 2008

	4	
ıy 2008	Approved 19 May 2010	Approved 21 May 2014
ditional 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
e 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 2.30 to EUR 2.40
EUR 1.56	EUR 2.01	EUR 2.30
EUR 1.49 to EUR 2.38	EUR 2.20	EUR 2.41 to EUR 2.49
3.9 years	8.1 years	9.1 years
No	No	Yes
817,550	720,000	370,000
510,246	699,750	328,813
274,165	396,000	197,000
236,081	303,750	131,813
506,996	0	0
99,133	20,250	41,187
0	20,250	41,187
208,171	0	0
17,500	0	0
0	KEUR 630	KEUR 160
EUR 0.57 to EUR 2.48	EUR 1.67	EUR 1.13 to EUR 1.39
Black/Scholes	Black/Scholes	Black/Scholes
2.5-4.47%	0.70%	0.01-0.08%
83.31-88.44%	73.75%	82.64-82.89%
0-5% per year	10% per year	10% per year

#### **Employee Participation Plan 2006**

With the consent of the Supervisory Board, the Management Board of PAION AG has launched an employee participation plan granting stock appreciation rights. A stock appreciation right entitles the holder to receive a sum of money based on the PAION AG share price. The maximum amount payable on a stock appreciation right is limited to 100 % of the exercise price. The stock appreciation rights have a term of ten years and can only be exercised after a two-year waiting period, which has been fulfilled for all granted stock appreciation rights. In addition, they may only be exercised when the stock price on the exercise date has increased by a cumulative 5 % each year since issuance. As of 31 December 2015, a total of 134,000 stock appreciation rights from the Employee Participation Plan 2006 were granted.

No more stock appreciation rights can be issued out of the Employee Participation Plan 2006. No stock appreciation rights were exercised in fiscal year 2015. As of 31 December 2015 all stock appreciation rights have vested. The exercise price and the weighted average exercise price for the outstanding stock appreciation rights is EUR 7.89. The minimum appreciation required for exercise had not been achieved by the balance sheet date. As of 31 December 2015, the exercise hurdle was EUR 11.47. The weighted residual term of these virtual stock options was one year on average on the balance sheet date.

The obligations arising from these stock appreciation rights are recognized at fair value on the balance sheet date in accordance with the provisions of IFRS 2 "Share-Based Payment". The fair value is calculated using the Black/Scholes option pricing model. The calculation was based on an exercise price of EUR 7.89, a share price of EUR 2.25 on the balance sheet date, an average residual term of 0.5 years for the stock appreciation rights and a risk-free interest rate of -0.17 %. Since the waiting period for all stock appreciation rights has expired, no staff fluctuation was recognized in the calculations. Dividends were not considered in the calculation. Volatility was assumed to be 79.06 % based on the historical volatility of PAION AG shares. This is based on the assumption that the historical volatility is the best estimate for the expected volatility. Separate option values were calculated to reflect the requisite

conditions for appreciation and the value cap; these were then combined with the value of the actual exercise option. Based on these parameters and assumptions, the fair value of every granted stock appreciation right was EUR 0.00 as of 31 December 2015. The lack of a potential payment obligation arising from this employee participation plan resulted in personnel income of KEUR 8 in fiscal year 2015 (previous year: personnel income: KEUR 20). Accordingly, there is no corresponding provision as of 31 December 2015 anymore (previous year: provision amounting to KEUR 8).

#### 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. 2015 KEUR	31 Dec. 2014 KEUR
Due within one year	332	179
Due after more than one year	156	9
Total	488	188

Rental and lease expenses amounted to KEUR 345 in fiscal year 2015 (previous year: KEUR 274). The long-term rental and lease obligations in the amount of KEUR 156 exist for the years 2017 to 2019. In connection with the lease of office spaces, there are additional financial obligations for 2016 in the amount of KEUR 141 in connection with leasehold improvements.

In the course of assigning Clinical Research Organizations the conduct of clinical studies and having contractual manufacturers perform the production development and manufacture the study mediation, there are contracts in place with

notice periods of up to four months. For these minimum terms, there are financial obligations which cannot be quantified due to the variable and unequal nature of incurrence of these costs.

Moreover, with the engagement of Greg Papaz as CEO of the subsidiary PAION, Inc., PAION entered into an obligation to grant Mr. Papaz 1 % of the shares of PAION, Inc. or to grant him payments in the amount of 1 % of funds received or revenues at the respective time of realization in case of a successful financing of PAION, Inc. for the initiation of commercialization of Remimazolam in the U.S. or in case of completion of an exclusive license agreement for the U.S. Payments to Mr. Papaz in the context of a license agreement are limited to USD 3 million. In case of a sale of PAION, Inc., PAION is obliged to pay Mr. Papaz an amount of 1 % of the realized amount. In case of a sale of PAION AG, PAION is obliged to pay Mr. Papaz an amount of 0.5 % of the realized amount. The term of this agreement ends 30 June 2016. With the engagement of Dr. David Bernstein as non-executive director of PAION, Inc., PAION, Inc. entered into an obligation to grant Dr. Bernstein 0.2 % of the shares of PAION, Inc. or to grant him 0.2 % of funds received in case of a successful financing of PAION, Inc. for the initiation of commercialization of Remimazolam in the U.S. or in case of completion of an exclusive license agreement for the U.S. In case of a sale of PAION, Inc., PAION is obliged to pay Dr. Bernstein an amount of 0.2 % of the realized amount. In case of a sale of PAION AG, PAION is obliged to pay Dr. Bernstein an amount of 0.1 % of the realized amount. The term of this agreement ends 30 June 2016. Moreover, with the engagement of Timothy Morris as non-executive director of PAION, Inc., PAION, Inc. entered into an obligation to grant Mr. Morris 0.15 % of the shares of PAION, Inc. or to grant him 0.15 % of funds received in case of a successful financing of PAION, Inc. for the initiation of commercialization of Remimazolam in the U.S. or in case of completion of an exclusive license agreement for the U.S. In case of a sale of PAION, Inc., PAION is obliged to pay Mr. Morris an amount of 0.15 % of the realized amount. In case of a sale of PAION AG, PAION is obliged to pay Mr. Morris an amount of 0.075 % of the realized amount. The term of this agreement ends 30 June 2016.

#### Headcount and personnel expenses

In fiscal year 2015, PAION employed an average of 29 persons (previous year: 17 employees). Of these 29 employees, 20 worked in development and nine in administration and sales. PAION UK Group had an average headcount of seven employees, and PAION, Inc. of two employees. As of 31 December 2015, the headcount was 35 (previous year: 21).

The following personnel expenses were incurred in fiscal years 2015 and 2014:

	2015 KEUR	2014 KEUR
Wages and salaries	4,633	3,028
Social security contributions	363	205
Total	4,996	3,233

The personnel expenses stated above include (net) expenses from the granting of stock options in connection with the Stock Option Plan 2010, the Stock Option Plan 2014 and the Employee Participation Plan 2006 in an amount of KEUR 783 (previous year: KEUR 491). The figures also include contributions to the German, British and U.S. social insurance schemes in an amount of KEUR 343 (previous year: KEUR 204).

## **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 Söhngen provides consulting services to the entity since her resignation from the Management Board of PAION AG and qualifies as related party as wife of Dr. Wolfgang Söhngen, acting Chief Executive Officer of PAION AG as of 31 December 2015. In fiscal year 2015, expenses in the amount of KEUR 15 have been incurred for consulting services provided by Dr. Mariola Söhngen. As of 31 December 2015, trade payables to Dr. Mariola Söhngen amount to KEUR 8.

No relationships with related parties existed otherwise.

#### Objectives and methods of financial risk management

PAION's business activities currently focus on the production development, clinical 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 to support the substance through the clinical development and regulatory approval phases and to ensure the availability of the requisite short-term and mid-term funding. This funding is primarily secured by means of equity and through development cooperation agreements, pursuant to which the cooperation partners effect milestone payments and assume direct and indirect responsibility for the development costs. Future possibilities to attract additional equity or receive upfront, technology access and further milestone payments from cooperation partners will depend to a large extent on the positive clinical development progress. 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 US 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.

The expected U.S. dollar share of the costs for the development of Remimazolam amounts to approximately USD 15 million which will nearly completely be incurred in 2016 based on the current schedule. 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 12 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 2015, PAION held an amount of USD 8.0 million. This way, per year-end, about two thirds of the 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 completely for 2016.

The loans granted by PAION AG to its foreign subsidiaries produced exchange rate gains of KEUR 1,765 in 2015, 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 10 % higher on the balance sheet date, the currency component recognized in equity in the reporting period would have decreased by KEUR 4,315 compared to the currency component recognized in equity as of 31 December 2014 and would have

decreased by KEUR 6,080 compared to the change in the currency component actually recognized in equity in 2015. If the EUR/GBP and the EUR/USD exchange rate had been 10 % lower on the balance sheet date, the currency component recognized in equity in the reporting period would have increased by KEUR 7,845 compared to the currency component recognized in equity as of 31 December 2014 and would have increased by KEUR 6,080 compared to the change in the currency component actually recognized in equity in 2015.

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 unprobable. 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 profit by KEUR 46 in fiscal year 2015 (previous year: KEUR 36).

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. The British tax authorities

have not, however, finalized their review of the refund claims filed for 2015 by the balance sheet date. Nevertheless, PAION deems the risk of the refund claims to be unrecoverable unprobable.

#### **Financial instruments**

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

		Carrying amount		Fair value	
in KEUR		31 Dec. 2015	31 Dec. 2014	31 Dec. 2015	31 Dec. 2014
Financial assets:					
Cash and cash equivalents	(1)	32,680	58,912	32,680	58,912
Trade receivables	(1)	0	467	0	467
Other assets	(1)	313	315	313	315
Financial liabilities:					
Provisions	(2)(3)	224	306	224	306
Trade payables	(2)(3)	7,332	3,338	7,332	3,338
Other liabilities	(2)(3)	129	92	129	92

Measurement category according to IAS 39:

- (I) 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, trade receivables, 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 2015, there were no movements between the hierarchy levels.

#### **Members of the Management Board**

The members of the Company's Management Board are:

- Dr. Wolfgang Söhngen, CEO, Chairman
- Abdelghani Omari, CFO
- Dr. Jürgen Raths, COO (since 1 September 2015)
- Dr. Mariola Söhngen, CMO (until 31 October 2015)

Management Board remuneration totalled KEUR 1,160 in fiscal year 2015. As of 31 December 2015, a total of 689,590 stock options (fair value at time of granting: EUR 1,069,024) and 50,000 stock appreciation rights (fair value as of 31 December 2015: EUR 0.00) had been issued to active Management

Board members as of 31 December 2015 and Management Board members that resigned during the fiscal year. For more information on Management Board remuneration, please see the disclosures in the remuneration report, which is part of the management report.

Dr. Wolfgang Söhngen 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. Dr. Mariola Söhngen was also Managing Director of PAION Deutschland GmbH, non-executive director of PAION, Inc., and Managing Director of PAION Holdings UK Ltd and its subsidiaries until her resignation as Management Board member of PAION AG. All Management Board members work full-time for the company and its subsidiaries.

As of 31 December 2015, Dr. Wolfgang Söhngen owned 1.21 % (612,091 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. Söhngen Beteiligungs GmbH, in which Dr. Wolfgang Söhngen 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
- 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
- Grontmij NV, De Bilt/The Netherlands (Vice Chairman of the Supervisory Board) (until 1 October 2015)
- Kerry Group plc, Tralee/Ireland (Non-executive director)
- Humedics GmbH, Berlin/Germany, Chairman (since 1 October 2015)
- 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 131 in fiscal year 2015. For more information on Supervisory Board remuneration, please see the disclosures in the remuneration report of the group management report.

As of 31 December 2015, none of the members of the Supervisory Board owned shares in PAION AG.

#### Financial statements auditor

The Annual General Meeting on 20 May 2015 appointed Ernst & Young GmbH Wirtschaftsprüfungsgesellschaft, Cologne office, Germany, as auditor of the annual and consolidated financial statements for fiscal year 2015. The auditor has received or will invoice the following fees for services rendered to PAION AG and its subsidiaries in fiscal year 2015:

	2015 KEUR	2014 KEUR
Audits of financial statements	99	70
Other assurance services	40	34
Other services	45	318
	184	422

The other assurance services relate to fees for reviewing the interim financial statements. The other services comprise consulting in the course of a sampling examination by the Financial Reporting Enforcement Panel conducted in the reporting period.

#### **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 2015, 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

On 9 February 2016, it was decided to discontinue the European Phase III study in cardiac surgery patients due to insufficient patient recruitment.

On 18 February 2016, PAION reported that the Japanese Pharmaceuticals and Medical Devices Agency (PMDA) regards the clinical and non-clinical data sets for Remimazolam

as complete for filing for market approval in the indication General Anesthesia in Japan based on a so-called pre-NDA meeting.

There were no further significant events in the period between the reporting date, 31 December 2015, and the preparation of this report.

Aachen, Germany, 21 March 2016

PAION AG

Dr. Wolfgang Söhngen

Dr. Jürgen Raths

Responsibility Statement (Bilanzeid) 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, 21 March 2016 PAION AG

Dr. Wolfgang Söhngen

Abdelghani Oma

#### **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 2015 to 31 December 2015. 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 ["Handelsge-setzbuch": 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 Codel 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 and as a whole provides a suitable view of the Group's position and suitably presents the opportunities and risks of future development."

Cologne, 21 March 2016

Ernst & Young GmbH Wirtschaftsprüfungsgesellschaft

(s) Ueberschär(s) GaldenWirtschaftsprüfer[German Public Auditor][German Public Auditors]

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#### PAION AG, Aachen

### **Financial Statements**

as of 31 December 2015

## Management Report for Fiscal Year 2015

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#### Management report for fiscal year 2015

#### 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 thus mainly determined by the development operations of the subsidiaries, which are presented below.

PAION's portfolio comprises the substances Remimazolam, M6G and GGF2. GGF2 is being developed by Acorda Therapeutics, Inc. (Acorda) in full autonomy since 2002. Furthermore, Remimazolam is being developed by license partners for the markets in China, South Korea, Canada, Russia/CIS, Turkey and the MENA region. For the Japanese market, the development of Remimazolam as previously agreed with the agency, was undertaken and completed for the indication anesthesia by Ono Pharmaceutical (Ono). In November 2014, Ono decided "to discontinue the project on strategic reasons considering issues in pharmacokinetic features, while no adverse events of concern were observed during the clinical trial". The data and technology transfer to PAION was completed in 2015. PAION entered into an exclusive license agreement for the M6G rights in China with Yichang Humanwell in the previous year.

 $\label{eq:Fiscal year 2015 was marked by the concentration of PAION on the further development of Remimazolam.$ 

#### 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 activity and from commercial activities. The development activity both 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.

The commercial activity mainly aims at the subsequent commercialization of Remimazolam. Partnering discussions are being held, but also options for an own commercialization (e. g. U.S. and EU) are being evaluated. The progress of these discussions is being documented and discussed continuously. PAION has already signed several regional licensing agreements. The cooperation partners operate independently in their respective license area. However, the cooperation agreements require the partners to provide each other with information. The central coordination of the information flow is managed by PAION. Moreover, PAION conducts pre-marketing and market access activities in order to prepare the market entry of Remimazolam. All activities are processed based on a project plan and are being reviewed and adjusted 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 B.2 "Presentation of the course of business and development activities".

#### Report on economic position

- I. Macroeconomic and sector-specific environment
- a. Macroeconomic development

The development of the German economy was characterized by a solid and steady growth in 2015. The German gross domestic product raised by 1.7 % in real terms compared to 2014. <sup>1</sup> However, German economy lost part of its momentum in the second half of 2015. Domestic demand is still on a robust development path whereas industry production is declining. <sup>2</sup> In 2016, the economic growth should be on a comparable level to 2015. The German Institute for Economic Research (DIW) expects an increase of the gross domestic product by 1.7 % for 2016 mainly driven by private and public consumption while exports are still being slowed down by problems in the emerging

- <sup>1</sup> Federal Statistical Office: Press release (No. 044) dated 12 February 2016.
- <sup>2</sup> German Institute for Economic Research: Industrieschwäche belastet deutsche Wirtschaft, DIW Konjunkturbarometer Februar 2016: dated 2 March 2016.
- <sup>3</sup> German Institute for Economic Research: Inlandsnachfrage treibt deutsche Wirtschaft an; press release dated 16 December 2015.

In light of the unchanged difficult economic environment within the EU, the economic development of important non-European countries has a significant impact on the export-oriented German economy. In particular, the U.S. economy continued its dynamic growth path and grew by estimated 2.5 % in 2015. <sup>4</sup> The economic development in China continues to weaken; the growth of its gross domestic product amounted to an estimated 6.9 %, the slowest growth in 25 years. <sup>5</sup> The positive dynamics of global economics will slightly intensify in 2016. For the gross world product, the IMF envisages a growth of 3.4 % in 2016 after an increase of 3.1 % in 2015. The strongest impulses emanate from the developed economies while prospects for emerging countries remain difficult. In the U.S., economy keeps growing steadily driven by the loose monetary policy and strong real estate and labor markets. In the euro area, the stronger private consumption overweighs weaker exports. <sup>6</sup>

The development of the stock markets has declined in 2015 compared to 2014. While major stock market indices generally continued to grow, volatilities significantly increased. In total, the DAX increased by 9.6 %, and the EUROSTOXX 50 grew by 3.8 %. Dow Jones Index decreased by 2.2 % in comparison to the prior year's end closing value.

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

For the pharmaceutical industry and biotechnology sector as a whole, 2015 was a mixed year. While the financing environment was still positive in the beginning, it changed in the middle of the year due to the capital market turbulences and the discussion regarding the appropriateness of drug prices in the U.S. <sup>7</sup> The consolidation pressure in the industry persists unabated, resulting in a high number of takeovers and cooperations as well as an increased transaction volume. The consolidation pressure particularly results from the high risks and costs associated with pharmaceutical development, the expiry of patent protection of a number of products in recent years as well as the increasing pressure on drug prices.

The financing environment for pharmaceutical and biotechnology companies has declined compared to previous years. Until mid-2015, the financing environment was still good, indicated by a high number of IPOs again, particularly in the U.S. Since mid-2015, the financing environment has significantly worsened, especially due to the increased market volatility in general and political pressure on drug prices in particular, most notably in the U.S. <sup>8</sup> Valuations of pharma and biotech

- <sup>4</sup> International Monetary Fund: World Economic Outlook Update, 19 January 2016.
- $^{\scriptscriptstyle 5}$  The Wall Street Journal: China's Economic Growth in 2015 Is Slowest in 25 Years, 19 January 2016.
- $^{\rm 6}$   $\,$  International Monetary Fund: World Economic Outlook Update, 19 January 2016.
- <sup>7</sup> The Pharma Letter: An all time record year for pharma/biotech M&A in 2015; 7 January 2016.
- $^{\rm 8}~$  The Pharma Letter: An all time record year for pharma/biotech M&A in 2015; 7 January 2016.

companies significantly dropped. Nonetheless, important indices still showed a positive trend over the year as a whole. The NASDAQ Biotechnology Index gained 11.4 %, and the DAXsubsector Biotechnology Index of the German Stock Exchange grew by 30.7 %. In 2015, the acquisition and cooperation volume also increased significantly year on year. In 2015, the transaction volume of global acquisitions in the pharmaceutical sector amounted to USD 328 billion compared to USD 218 billion in 2014. 9

The financing environment is expected to remain dominated by the general uncertainty at the capital markets in 2016 until there is more clarity on the further development of the world economy and the monetary policies of the central banks, in particular the Federal Reserve in the U.S. <sup>10</sup> Both the tenor of the further discussion of drug prices in the current presidential campaign in the U.S. as well as the question if investors begin to emphasize chances in the branch again will be crucial for the financing environment in the pharmaceutical industry. <sup>11</sup> Overall, the financing environment is expected to be more difficult than in prior years. In the first months of 2016, NAS-DAQ Biotechnology Index and DAXSubsector Biotechnology Index have dropped in a double-digit percentage range.

#### 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. The two further substances M6G and GGF2 are no significant value drivers for PAION.

#### a. Remimazolam

Remimazolam is an ultra-short-acting intravenous sedative and anesthetic currently in Phase III clinical development for procedural sedation and general anesthesia. Remimazolam is a member of the class of substances known as benzodiazepines. 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 in order to rapidly terminate sedation, if necessary.

In clinical studies, Remimazolam demonstrated efficacy and safety in far more than 1,000 patients. A confirmatory Phase III program in procedural sedation is now in progress. Data so far indicate that Remimazolam has the expected rapid onset and offset of action combined with a favorable hemodynamic stability profile.

In the U.S., Remimazolam is initially being developed for procedural sedation during procedures such as colonoscopies.

<sup>&</sup>lt;sup>9</sup> Pharma-Unternehmen auf Shoppingtour – 2015 übertrifft das Rekordjahr 2014 noch einmal deutlich: Press Release from Ernst & Young dated 3 February 2016 (www.ey.com/DE/de/Newsroom).

<sup>&</sup>lt;sup>10</sup> Handelsblatt: Tempo für Zinserhöhungen könnte sich verlangsamen, 10 February 2016.

FiercePharma: UPDATED: Clinton targets pharma's 'predatory' pricing with new campaign ad featuring Valeant, 1 March 2016.

In the EU and most other major markets, Remimazolam is initially being developed for general anesthesia, including post-operative sedation in post-anesthesia care or intensive care units (ICUs) for up to 24 hours after the operation.

In Japan, a clinical Phase III program in anesthesia has successfully been completed. The Japanese Pharmaceuticals and Medical Devices Agency ("PMDA") confirmed that the clinical and non-clinical data sets are regarded as complete for filing in the indication "Induction and maintenance of general anesthesia" during a pre-NDA meeting held in the beginning of 2016.

Development for ICU sedation is planned following successful completion of development in procedural sedation and general anesthesia. A pediatric development plan has been agreed with the FDA and will be implemented following approval of Remimazolam for adult patients.

#### Procedural sedation (U.S.)

The procedural sedation market for diagnostic procedures in the U.S. has grown significantly in recent years due to the increased emphasis on cancer screening and colon cancer prevention. Partly due to this trend, colon cancer rates have fallen by 30 % during the last 10 years in people aged over 50. There were 29 million unique claims for colonoscopy and endoscopy in 2013. Each year, more than 4 million people turn 50 and are newly eligible for screening.

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 in 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.

Procedural sedation in colonoscopy is usually performed with midazolam or propofol sedation combined with analgesia.

#### General anaesthesia

Approximately 29 million general anesthesias in patients undergoing major surgeries are conducted in the EU each year, of which 55 % are balanced anesthesia (a combination of intravenous agents such as propofol for induction and volatile gases for maintenance) and 20 % are total intravenous anesthesia (TIVA) using propofol. Regional anesthesia also plays a role (for example epidural administration). The current standards of care drugs for general anesthesia are propofol (especially for induction) and narcotic gases; in each case in conjunction with intravenous opioids.

Patient demographics in Europe continue to evolve driven by the aging population and the differences between the functional or biological ages of patients compared to actual age. So, while general anesthesia is more frequently offered to elderly patients than years ago, the choice is an individual one depending on the type of surgery, the underlying disease, and assessment of the general physical health of the patient, including co-morbidities.

The number of surgical procedures worldwide continues to increase driven by population growth and other factors such as obesity, low physical activity levels, dietary habits, smoking, and alcohol. Current estimates place the number of worldwide surgical procedures annually at greater

than 230 million; the majority in the areas of general, orthopaedic/trauma and obstetric/gynaecological surgery.

Remimazolam – far over 1,000 vo	Remimazolam – far over 1,000 volunteers/patients on drug				
Completed studies *	Ongoing studies *				
Procedural Seda	tion (U.S.)				
Phase I Single bolus in healthy volunteers (81)	Phase I Thorough QT Study (57)				
Phase Ib Multiple bolus in volunteers undergoing colonoscopy (51)	Phase I Renal Impairment (16)				
Phase IIa Single bolus in upper GI endoscopy (100)	Phase I Abuse Liability (40)				
Phase IIb Multiple bolus in colonoscopy (161)	Phase III in colonoscopy (460)				
	Phase III in bronchoscopy (460)				
	ASA III/IV in colonoscopy (75)				
General Anesthes	sia (Japan)				
Phase I Bolus in healthy volunteers (42)					
Phase Ib Infusion in healthy volunteers (10)					
Phase I Hepatic impairment (USA) (20)					
Phase II Induction and maintenance of anesthesia in general surgery (85)					
Phase II/III Induction and maintenance of anesthesia in general surgery (375)					
Phase III in ASA III or higher surgical patients (62)					
General Anesth	esia (EU)				
Phase II in cardiac surgery patients (90)					
Phase III in cardiac surgery patients (discontinued)					
ICU Sedation (	ICU Sedation (Japan)				
Phase II (discontinued)	Phase II (discontinued)				

<sup>\*)</sup> Numbers in brackets are total target patient numbers in studies

#### Procedural sedation (Lead indication U.S.)

A total of two Phase I and two Phase II 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 studies.

In March 2015, the first U.S. Phase III study was started. This prospective, double-blind, randomized, placebo- and midazolam-controlled, U.S. multicenter Phase III trial in 460 patients undergoing colonoscopies marks the start of PAION's Phase III clinical development program, which also includes a second pivotal prospective, double-blind, randomized, placebo- and midazolam-controlled, U.S. multicenter Phase III trial in patients undergoing bronchoscopies which started in June 2015, and a smaller safety trial in 75 high risk patients undergoing colonoscopies. In parallel, three Phase I studies are being conducted by PAION.

Patient recruitment in the Phase III program in the U.S. was initially moderate. The Phase III colonoscopy trial is on track and completion of patient recruitment is expected shortly. Currently, 450 patients have been treated. Patient recruitment in the Phase III bronchoscopy trial remains moderate which could possibly extend the completion into 2017. Conditional on successful implementation of ongoing counter measures such as the opening of further study centers and intensified support of the study centers, PAION expects filing for approval end of 2017 at the earliest.

#### General anesthesia (Lead indication in EU + Japan)

A total of three Phase I (Japan), two Phase II (Japan and EU) and two Phase III (Japan) trials have been completed. Specific attention was paid to hemodynamic stability in the clinical program as preclinical data suggested that Remimazolam may lead to a hemodynamic stability, which addresses a current need in general anesthesia.

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 anaesthetic 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 the 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 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 fulfil the requirements for filing in Japan.

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, further confirming the beneficial hemodynamic profile of Remimazolam.

In August 2015, the start of the multi-national, multicenter, randomized, single-blind, propofol-controlled, confirmatory EU Phase III study in patients undergoing major cardiac surgery was announced. Due to the complex study design, the trial faced recruitment challenges. Despite intensive efforts to enhance study recruitment, the trial proved to be difficult to implement in practice. 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 have been observed. Accordingly, PAION will work together with recognized experts on setting up an alternative design in general surgery patients. However, conducting a new study requires further funding.

#### ICU sedation

PAION's former partner in Japan, Ono, independently initiated a Phase II trial for sedation in intensive care units (ICUs). Ono discontinued this exploratory trial in August 2013. While all patients were sedated successfully and no significant unexpected adverse events were reported, higher than expected plasma concentrations of Remimazolam were observed in isolated cases after long-term treatment.

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. As a result, PAION is of the opinion that the maximum dose level has now been defined for ICU sedation. Further development of the program "ICU sedation" is part of the future Remimazolam development plan which will be addressed after approval of the lead indications and availability of required funds.

#### Partnering and commercial activities

In total, PAION has completed seven licensing deals with Remimazolam which are summarized in the following table:

Upfront and milestone payments						
Total received Total outstanding Royalty rate						
Ono, Japan (2007) (terminated in 2015)	USD 8 m	None	None			
Yichang Humanwell, China (2012)	EUR 3 m	Up to 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 3.7 m	Double-digit tiered (starting at 15 %)			
Total	~EUR 13.8 m	Up to ~ EUR 21.2 m				

<sup>\*)</sup> 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.

In order to exploit Remimazolam's full potential, PAION favors the attractive possibility of a self-commercialization or co-commercialization in the U.S. and EU.

For all territories outside the U.S. and EU, it is aimed to find license or distribution partners. After the positive pre-NDA meeting with the Japanese PMDA, during which the details of an approval of Remimazolam in Japan were discussed, PAION is continuing partnering discussions with potential licensees which will however most probably not be completed before the second half of 2016. Alternatively, PAION is also evaluating filing Remimazolam itself.

#### b. GGF2

GGF2 (Glial Growth Factor 2) is known to stimulate the growth and differentiation of a variety of cells including glial cells, the support cells of the nervous system. These glial cells form the myelin sheath that insulates nerve cells and are essential for their survival and proper functioning. In demyelinating diseases such as multiple sclerosis, the myelin sheath is damaged, leading to the degeneration of nerve cells.

In preclinical studies, PAION's license partner Acorda Therapeutics, Inc. (Acorda) demonstrated that GGF2 can stimulate the cell growth necessary to protect and regenerate a damaged myelin sheath. GGF2 is the lead neuregulin in Acorda's portfolio. Neuregulins have also shown the ability to restore cardiac function in preclinical models of heart failure caused by myocardial infarction, heart rhythm disorders and myocardial dysfunctions.

In 2013, Acorda announced positive results of the Phase I trial with GGF2. The study identified a maximum tolerated dose of GGF2 and the preliminary efficacy measures showed that GGF2 improves heart function. Acorda discussed the findings from the study with the FDA and reached agreement on the next clinical study of GGF2 in heart failure. This Phase Ib study primarily involves the continued investigation of the safety profile but also the efficacy of GGF2 across a range of doses. The start of the study was made public by Acorda in October 2013.

In June 2015, Acorda announced that they had stopped enrolment in the trial based on the occurrence of a case of hepatotoxicity (liver injury) meeting Hy's Law criteria, based on blood test results. Acorda also received a notification of clinical hold from the FDA following the submission of this information. There was one Hy's Law case reported in the previous Phase I study. In both cases the abnormal blood tests resolved within several days. The 22 patients who were dosed in the trial will complete the pre-planned one year of follow up. Outside of the hepatotoxicity case, the safety profile from this trial was consistent with the first Phase I trial, but efficacy data was inconclusive which Acorda believes was in part due to the very small number of patients in the trial. Acorda has ongoing analyses and non-clinical studies to investigate the biological basis for liver effects, and will need to meet with the FDA to review these and other data from the cimaglermin studies and to request that the program be removed from clinical hold.

#### **Cooperation Agreements**

The rights relating to the recombinant GGF2, rh GGF2, were licensed to Acorda in 2002 by PAION UK. In total, further milestone payments of USD 2.5 million become due prior to market approval and an additional milestone payment of USD 5 million is payable upon market authorization; after that PAION will receive royalties depending on net sales.

#### c. M6G

Due to the focus of the available resources on anesthesia, PAION is not actively developing M6G. In 2014, this project was licensed to Yichang Humanwell for the Chinese market. Yichang Humanwell received an exclusive license under PAION's know-how regarding M6G for the development, manufacture and commercialization in the People's Republic of China. By concluding the license, PAION receives payments totaling EUR 1.6 million of which PAION has received EUR 1.3 million so far. Additional license fees were not agreed.

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

#### a. Results of operations

The net result increased by KEUR 4,715 from a net loss of KEUR 4,177 in the prior year to a net income of KEUR 538 in fiscal year 2015. This change compared to the previous year resulted from multiple factors. On the one hand, the capital increases conducted in 2014 led to significantly higher other operating expenses in the prior year than in the reporting period. Moreover, in the course of the extension of development activities of the subsidiary PAION UK Ltd in the reporting period, higher other operating income from providing management and other services as well as higher interest income from the loan granted to the subsidiary have been realized in 2015. Furthermore, due to higher amounts of foreign funds held in U.S. dollar and Pound Sterling on average compared to the prior year, higher (net) foreign exchange gains were recognized than in 2014.

The deviation from a net loss in a low single-digit million range forecasted per prior year for 2015 mainly results from higher than expected income from services provided to subsidiaries as well as from (net) significant foreign exchange gains.

	2015 KEUR	2014 KEUR	Change in result KEUR
Other operating income	3,327	1,316	2,011
Personnel expenses	-1,517	-1,220	-297
Depreciation and amortization	-5	-6	1
Other operating expenses	-3,190	-5,285	2,095
Taxes (excl. income taxes)	0	-1	1
Operating result  Financial result	-1,385	-5,196	3,811
rmanciai resuit	1,923	1,269	654
Depreciation on financial assets	0	-250	250
Net result	538	-4,177	4,715

**Other operating income** has increased by KEUR 2,011 in the reporting period and mainly comprises income from the provision of management and other services to the subsidiaries

(KEUR 1,305; previous year: KEUR 969), of which PAION UK Ltd accounted for KEUR 1,120 (previous year: KEUR 747) and PAION Deutschland GmbH for KEUR 186 (previous year: KEUR 222). Moreover, foreign exchange gains in the amount of KEUR 2,005 (previous year: KEUR 331) mainly resulting from funds held in U.S. dollar and Pound Sterling have been recognized.

**Personnel expenses** increased by KEUR 297 to KEUR 1,517. This development is mainly due to the higher average number of Management Board members in the reporting period.

Year on year, **other operating expenses** decreased by KEUR 2,095 to KEUR 3,190 and mainly include legal and consulting fees (KEUR 919; previous year: KEUR 4,181), insurance, contributions and fees (KEUR 276; previous year: KEUR 277), travel expenses (KEUR 249; previous year: KEUR 241), services rendered by PAION Deutschland GmbH (KEUR 184; previous year: KEUR 58), expenses in connection with Supervisory Board remuneration (KEUR 131; previous year: KEUR 131) as well as audit costs and costs for the annual report (KEUR 120; previous year: KEUR 74). In the reporting period, foreign exchange losses in the amount of KEUR 1,064 (previous year: KEUR 25) have been recognized. The decrease of the other operating expenses, in particular the legal and consulting fees, is mainly connected to the capital increases conducted in 2014.

Compared to the previous year, the **financial result** has improved by KEUR 654 to KEUR 1,923. 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 1,881; previous year: KEUR 1,205).

The **depreciation on financial assets** in the previous year completely related to the writeoff of the shares in PAION Deutschland GmbH due to a presumably permanent impairment.

#### b. Net assets and financial position

The balance sheet total as of 31 December 2015 amounts to KEUR 104,922 and has increased by KEUR 454 compared to the previous year. The equity ratio improved by 0.1 %-points from 99.4 % in the prior year to 99.5 % at the current balance sheet date. As of 31 December 2015, cash and cash equivalents amounted to KEUR 31,475 and decreased by KEUR 26,139 compared to the previous year.

	31 Dec. 2015 KEUR	31 Dec. 2014 KEUR	Change KEUR
Fixed assets	12,786	12,792	-6
Current assets and prepaid expenses	92,136	91,676	460
Assets	104,922	104,468	454
Equity	104,438	103,878	560
Current liabilities	484	590	-106
Shareholders' equity and liabilities	104,922	104,468	454

**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 460 in fiscal year 2015. On the one hand, loans granted to the subsidiaries have increased by KEUR 26,480 to KEUR 60,180. On the other hand, cash and cash equivalents have decreased from KEUR 57,614 to KEUR 31,475.

The reduction of **current liabilities** by KEUR 106 to KEUR 484 mainly results from lower bonus provisions in the reporting period.

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

	2015 KEUR	2014 KEUR
Cash flow from operating activities	319	-744
Cash flow from investing activities	0	-8
Cash flow from financing activities	-26,458	48,432
Change in cash and cash equivalents	-26,139	47,680

The **cash flow from operating activities** mainly resulted from the net result of the year and working capital changes.

The **cash flow from financing activities** results from the (net) grant of loans to subsidiaries (KEUR 26,480) and the exercise of stock options (KEUR 22). In the previous year, the cash flow from financing activities resulted from the capital increases conducted in 2014 (KEUR 61,695 including the exercise of stock options), the (net) grant of loans to subsidiaries (KEUR 9,550) and cost of funds (KEUR 3,714).

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

The Group generated a consolidated net loss of KEUR 28,212 in fiscal year 2015 (previous year: net loss of KEUR 9,105). The key items in the consolidated balance sheet as of 31 December 2015 were cash and cash equivalents (KEUR 32,680; previous year: KEUR 58,912) and equity (KEUR 35,562; previous year: KEUR 62,607).

#### Headcount

As of 31 December 2015, the total headcount of the PAION Group was 35 employees, of whom nine work for PAION UK Group and three work for PAION, Inc. By comparison, the headcount as of 31 December 2014 was 21 employees. As of 31 December 2015, the headcount at PAION AG totalled eight employees (previous year: five employees).

#### Changes in the Supervisory Board and Management Board

The Supervisory Board appointed Dr. Jürgen Raths as a new member of the Management Board (Chief Operating Officer) with effect from 1 September 2015.

Dr. Mariola Söhngen resigned from her office as member of the Management Board (Chief Medical Officer) with effect as of 31 October 2015.

#### Remuneration report

#### 1. 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 and stock appreciation rights as well as other remuneration in terms of company car remuneration, insurance premiums and pension contributions. All stock options and stock appreciation rights 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 at the end of each year. 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.

Under the Employee Participation Plan 2006, a total of 100,000 stock appreciation rights were granted to acting Management Board members at the time of the grant. The stock appreciation rights have a two-year waiting period after which time the holder is entitled to receive a sum of money based on the PAION AG share price. In addition to an annual minimum appreciation, the Employee Participation Plan 2006 also limits the value of the amount payable. The maximum payable amount is 100 % of the exercise price, which is EUR 7.89 for the stock appreciation rights granted in fiscal year 2006. As of 31 December 2015, the exercise hurdle was EUR 11.47.

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. As of 31 December 2015, the exercise hurdle was EUR 1.72 or EUR 2.38 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. As of 31 December 2015, the exercise hurdle was EUR 2.20.

From the Stock Option Plan 2014 approved by the Annual General Meeting on 21 May 2014, a total of 166,500 stock options were granted to acting Management Board members at the time of the grant with effect from 17 January 2015. 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 2.30 per stock option and is based on the average price of the shares in a certain time period before the allocation. As of 31 December 2015, the exercise hurdle was EUR 2.41.

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. Regarding the performance of the stock appreciation rights granted to the Management Board members, which is directly linked to the performance of the PAION share price, a cap has been agreed. The remuneration of the individual Management Board members in fiscal year 2015 (according to German Corporate Governance Code) can be gathered from the following tables:

		F				
Benefits granted in EUR						sin
	2014	2015	2015 (Min)	2015 (Max)	2014	
Fixed compensation	250,000	262,500	262,500	262,500	50,000	15
Other remuneration	47,401	47,974	47,974	47,974	5,086	1
Total	297,401	310,474	310,474	310,474	55,086	16
One-year variable compensation	120,000	120,000	0	132,000	0	6
Multi-year variable compensation						
Stock Option Plan 2010 - Grant 2014 (Waiting period 2014 to 2018)	270,540	0	-	-	0	
Stock Option Plan 2014 - Grant 2015 (Waiting period 2015 to 2019)	0	62,715	-	-	0	6
Total	687,941	493,189	310,474	442,474	55,086	28
Service cost	0	0	0	0	0	
Total remuneration	687,941	493,189	310,474	442,474	55,086	28

<sup>\*)</sup> Prior year remuneration for Mr. Omari relates to the time period since joining the Management Board
\*\*) For Dr. Mariola Söhngen, target and maximal value of the one-year variable compensation are ex ante realizable values for the whole

Allocation in EUR	Dr. Wolfgang Söhngen CEO			
	2014	2015		
Fixed compensation	250,000	262,500		
Other remuneration	47,401	47,974		
Total	297,401	310,474		
One-year variable compensation	102,000	48,000		
Multi-year variable compensation				
Stock Option Plan 2008 - Grant 2008 (Waiting period 2008 to 2010)	9,829**	0		
Total	409,230	358,474		
Service cost	0	0		
Total remuneration	409,230	358,474		

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

	ghani Omari * Dr. Jürgen Raths Dr. Mariola Söhngen CFO COO CMO									
	2 1 September 2014			since 1 September 2015			until 31 October 2015			
2015	2015 (Min)	2015 (Max)	2014	2015	2015 (Min)	2015 (Max)	2014	2015	2015 (Min)	2015 (Max)
0,000	150,000	150,000	0	105,000	105,000	105,000	230,000	191,667	191,667	191,667
5,127	15,127	15,127	0	42	42	42	38,559	35,853	35,853	35,853
5,127	165,127	165,127	0	105,042	105,042	105,042	268,559	227,520	227,520	227,520
0,000	0	66,000	0	0	0	0	110,000	110,000**	0	121,000**
0	-	-	0	0	-	-	270,540	0	-	-
2,715	-	-	0	0	-	-	0	62,715	-	-
7,842	165,127	231,127	0	105,042	105,042	105,042	649,099	400,235	227,520	348,520
0	0	0	0	0	0	0	0	0	0	0
7,842	165,127	231,127	0	105,042	105,042	105,042	649,099	400,235	227,520	348,520
reporting p	eriod.									

* 014	C00		Dr. Mariola Söhngen CMO until 31 October 2015		
2015	2014	2015	2014	2015	
150,000	0	105,000	230,000	191,667	
15,127	0	42	38,559	35,853	
165,127	0	105,042	268,559	227,520	
24,000	0	0	93,500	91,667	
0	0	0	0	0	
189,127	0	105,042	362,059	319,186	
0	0	0	0	0	
189,127	0	105,042	362,059	319,186	
	2015 150,000 15,127 165,127 24,000	COO since 1 September 2  2015 2014 150,000 0 15,127 0 165,127 24,000 0  189,127 0 0 0 0	COO since 1 September 2015  2015 2014 2015 150,000 0 15,127 0 42 165,127 0 105,042 24,000 0 0 0 189,127 0 0 0 0 0 0 0 0 0 0 0 0 0 0 0 0 0 0 0	COO since 1 September 2015 until 31 October 20  2015 2014 2015 2014  150,000 0 105,000 230,000  15,127 0 42 38,559  165,127 0 105,042 268,559  24,000 0 0 0 93,500  0 189,127 0 105,042 362,059  0 0 0 0 0	

Management Board remuneration in fiscal year 2015 amounted to KEUR 1,160 in total (previous year: KEUR 1,358) and is composed as follows:

in EUR	2015	2014
Fixed remuneration	709,167	530,000
Other remuneration	98,997	91,046
Total non-performance based remuneration	808,163	621,046
Short-term variable remuneration	163,667	195,500
Total short-term remuneration	971,830	816,546
Long-term variable remuneration	188,145	541,080
Total long-term remuneration	188,145	541,080
Total remuneration	1,159,975	1,357,626

The decrease of the total remuneration in comparison to the prior year mainly results from two opposed factors: On the one hand, short-term remuneration increased due to the higher average number of Management Board members in fiscal year 2015 compared to the prior year. On the other hand, long-term variable remuneration decreased in the reporting period compared to 2014 since less stock options were granted in the course of the grant from Stock Option Plan 2014 in the reporting period than in the course of the grant from Stock Option Plan 2010 in the previous year.

The Management Board members held the following stock options as of 31 December 2015:

Status of non-exercised stock options a ciation rights as of 31 December 201	* *	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.	55,500	0	55,500
Stock options 2014 - fair value*	EUR	62,715	-	62,715
Stock Appreciation Rights (SAR) SAR - fair value**	No. EUR	25,000 0	0	0

<sup>\*)</sup> Applicable fair value at the time of issuance, calculated using the Black/Scholes option pricing model \*\*) Applicable fair value on the balance sheet date, 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 can only be exerted if the change of control also entails a significant change in business strategy, in responsibilities or in regard to the company domicile.

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

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

Pursuant to the terms of the Stock Option Plans 2008, 2010 and 2014, in the event of a change of control, the waiting period for all stock options issued to Management Board members whose 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 2015:

	Basic remuneration EUR	Per-meeting fees EUR	Total EUR
Dr. Jörg Spiekerkötter	40,000	18,000	58,000
Dr. Karin Dorrepaal	30,000	13,500	43,500
John Dawson	20,000	9,000	29,000

Supervisory Board remuneration in fiscal year 2015 amounted to KEUR 131. In the previous year, the remuneration also amounted to KEUR 131.

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

#### Composition of subscribed capital

As of 31 December 2015, PAION AG had a subscribed capital of EUR 50,659,440.00, divided into 50,659,440 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 share-holder 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 equal or exceeded as of 31 December 2015 10 % of the voting rights 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' preemptive 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. The Authorized Capital 2015 has not been used so far.

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 858,121 shares (Conditional Capital 2004 II), 552,064 shares (Conditional Capital 2008 I), 720,000 shares (Conditional Capital 2010 I) and 740,000 shares (Conditional Capital 2014) in connection with the Stock Option Plans 2005, 2008, 2010 and 2014.

### 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 and 2014 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 whose 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.

With the engagement of Greg Papaz as CEO of the subsidiary PAION, Inc., PAION, Inc. entered into an obligation to pay Mr. Papaz an amount of 0.5 % of the realized amount in case of a sale of PAION AG. The term of this agreement ends 30 June 2016. With the engagement of Dr. David

Bernstein as non-executive director of PAION, Inc., PAION, Inc. entered into an obligation to pay Dr. Bernstein an amount of 0.1 % of the realized amount in case of a sale of PAION AG. The term of this agreement ends 30 June 2016. Moreover, with the engagement of Mr. Timothy Morris as non-executive director of PAION, Inc., PAION, Inc. entered into an obligation to pay Mr. Morris an amount of 0.075 % of the realized amount in case of a sale of PAION AG. The term of this agreement also ends 30 June 2016.

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 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 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 an 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 therefrom. In addition, PAION has commissioned an external auditor to assume the function of 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 therefrom. 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. 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.

The risk early warning system was revised in the reporting period and adjusted in terms of responsibilities to match the existing matrix organization and in terms of probabilities of occurrence and damage levels to reflect the current position of the group, particularly the progress of the development and the market environment having become relevant in that respect. A detailed overview is illustrated in chapter 3.

### 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 financial statements are 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. Applied categories for likelihoods of occurrence and damage levels as well as the classification of resulting net risks are illustrated in the following table:

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

# 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 studies. As is common practice in the pharmaceutical industry, Clinical Research Organizations (CROs) have been assigned to conduct the clinical 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 requiring rework amendments and causing delays in the approval process. In order to reduce this risk, the conduct of 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 which could potentially pose a threat to the continued

existence of the group in case of occurrence. Nearly 40 % of all Phase III projects do not directly lead to approval.  $^{\rm 12}$ 

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 analyses potential alternative and prevention scenarios on a need basis in order to be able to initiate these as fast as possible in case of occurrence of this risk. This is a high risk which could potentially pose a threat to the continued existence of the group in case of occurrence.

In this context, please note the report on post-balance sheet date events pointing out the discontinuation of the cardiac surgery EU Phase III trial in general anesthesia due to insufficient patient recruitment. The occurrence of this risk has not induced a threat to the continued existence of the group.

The results of 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 clinical studies, potential dosage modifications and amendments to clinical trial protocols mitigate the risk as far as possible. Unexpected serious adverse events as well as an insufficient study outcome for the U.S. Phase III program are increased risks; an insufficient study outcome of the EU Phase III program is a high risk. In case of occurrence of each of the three risks, the potential damage level could pose a threat to the continued existence of the group.

In this context, please note the report on post-balance sheet date events pointing out the discontinuation of the cardiac surgery EU Phase III trial in general anesthesia due to insufficient patient recruitment inevitably also implying insufficient study outcome. The occurrence of this risk has not induced a threat to the continued existence of the group.

There is also a risk that authorities impose additional regulatory requirements exceeding the needs originally agreed leading to cost increases or a significant delay in the conduct of studies or necessitating 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. This is a high risk.

<sup>&</sup>lt;sup>12</sup> Tufts Center for the Study of Drug Development (2014): Briefing – Cost of Developing a New Drug.

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 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 a moderate risk.

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 our 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 expects Remimazolam to receive a 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 commercial usability in the U.S. In order to reduce this risk as far as possible, PAION has specifically 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. 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, 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 underlying the business plan 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 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 is working on the preparation of the relevant markets intensively, including bringing in external consultants for communication with the scientific community. This is a high risk.

In order to be able to successfully sell Remimazolam upon market approval, the distribution structure 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, the analysis and description of the distribution structure has already been started. 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 done. 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 avoid 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 cooperates with are experienced in the timely adoption of additional regulatory requirements. This is an increased risk. In case of occurrence, the potential damage level could pose a threat to the continued existence of the group.

Based on 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. This risk particularly exists in regard to a potential license partner in Japan since commercialization could potentially start first in that market. 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 whole distribution 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 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. In case of occurrence, the potential damage level could, based on the specific issue, pose a threat to the continued existence of the group.

#### b. Finance risks

#### aa) Financing risks

PAION expects future payments from tax credits and from existing and possible future cooperation agreements to cover its short- and mid-term financing needs. However, PAION may need additional funding within this timeframe in order to prepare the commercialization or further development 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 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 careful 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, 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 and the pound sterling in respect to the euro could increase the costs for the development and market preparation of Remimazolam. In order to reduce this risk, PAION does maintain foreign currency funds in U.S. dollars and (in lower amounts) of pound sterling. Currency risks also arise from translating the foreign subsidiaries' separate financial statements from pound sterling or U.S. dollar into euros because the pound/U.S. dollar is the functional currency of the UK subsidiaries/U.S. subsidiary.

Currency risks are systematically recorded and monitored based on cautious short-, midand long-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. 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.

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. 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 for diseases or interventions 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 currently is in Phase III development in the U.S. in procedural sedation for minor medical interventions. The development for general anesthesia in Japan is completed, and PAION expects that a new Phase III trial will be required for market approval in the EU. In Japan, PAION is looking for a partner for commercialization. Approval in Japan could give access to specific 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 for application 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.

PAION benefits from the progress of its Remimazolam development partners in China, South Korea, Canada, Russia/CIS, Turkey, and the MENA region in the form of additional development data and benefits financially in the form of milestone payments and royalties from launch onwards. For the U.S. and 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. However, for 2016, main focus is on the U.S. Phase III program since better licensing conditions are being expected with availability of Phase III results. Based on the results of the market research activities performed so far, Remimazolam is an excellent candidate for developing a commercial platform in anesthesia (EU) and procedural sedation (U.S.).

#### Overall evaluation of chances and risks

The ongoing Phase III studies with Remimazolam in the U.S. are an important milestone on the pathway to market approval. However, available cash and cash equivalents have significantly decreased compared to the prior year and will not be sufficient up until market approval which has led to a higher financing risk compared to 2014. As the Phase III trials have not been completed yet, the risk remains that development is not successful. Due to the necessary discontinuation of the EU Phase III trial and the current lack of funds for a new Phase III study, PAION's success is now fully dependent on the successful completion of the development in the U.S. or entering into successful cooperations. Based on the difficult financing environment and the impaired financial situation, PAION needs to focus on the development in the U.S. now. As such, the risk situation has worsened in comparison to the previous year.

It is expected that the upcoming completion of the first Phase III trial in the U.S. in the important indication of procedural sedation for colonoscopies and the generated data in that regard will mark an important milestone for further financing. This could enable PAION to realize the pathway to market approval and commercialization of Remimazolam in the U.S. on its own. The clinical development program in the U.S., the most important market for PAION, has been implemented as scheduled. Following the early discontinuation of the EU Phase III trial, all available resources are now being concentrated on the development program in the U.S. in order to maximize chances for success. Under consideration of the progress of the development in the U.S. in particular, the chance situation has improved in comparison to the previous year.

#### Report on post-balance sheet date events

On 9 February 2016, it was decided to discontinue the European Phase III study in cardiac surgery patients due to insufficient patient recruitment. In order to properly terminate the study, to gather the retrieved data in a study report and to destroy the study medication, cash-effective expenses in the amount of approx. EUR 1 million are expected to be incurred on group level in 2016 resulting in indirect effects on PAION AG's net assets, financial position and results of operations. Direct effects on PAION AG's net assets, financial position and results of operations will presumably not be induced.

On 18 February 2016, PAION reported that the Japanese Pharmaceuticals and Medical Devices Agency (PMDA) regards the clinical and non-clinical data sets for Remimazolam as complete for filing for market approval in the indication General Anesthesia in Japan based on a so-called pre-NDA meeting. This will presumably not have any effects on the net assets, financial position and results of operations.

There were no further significant events in the period between the reporting date, 31 December 2015, and the preparation of this report.

#### Report on expected developments

#### Outlook on development and commercialization (PAION group)

PAION's major goals for 2016 are the conduct of the Phase III development program with Remimazolam in the U.S. and the production development for Remimazolam, in particular the validation of the production at market scale. Moreover, PAION expects the development activities of its Remimazolam cooperation partners Yichang Humanwell, Hana Pharm, R-Pharm, and Pendopharm to continue. PAION benefits from the progress of the development of Remimazolam in the mid and long term in the form of additional development data as well as financially in the form of milestone payments and royalties from launch onwards.

PAION is on its way to evolve into a specialty pharma company with a focus on anesthesia products. In this context, PAION seeks to retain certain marketing rights for Remimazolam for the EU and the U.S. market in order to market Remimazolam itself or together with a partner. In case of a successful out-licensing by way of a development cooperation, PAION would expect to receive substantial payments as upfront payments or through sharing of development costs, development milestone payments and royalties from market approval onwards. In case of a pure marketing cooperation after registration, PAION would expect to receive a comparably higher upfront payment and higher royalties. For this reason, it could also be reasonable and attractive to launch without a partner.

For the U.S. and the EU, PAION aims at an own commercialization. PAION is open to partnerships in both regions if they are more attractive than an own commercialization or complementary to reaching peak sales more rapidly. For all regions outside the U.S. and the EU, it is aimed to find license or distribution partners.

After a positive pre-NDA meeting with the Japanese authority, in the course of which details of a market approval for Remimazolam have been outlined, PAION is continuing partnering discussions with potential licensees which will however most probably not be completed before the second half of 2016. Alternatively, PAION is also evaluating filing for market approval itself. A Japanese dossier could serve as a reference dossier for approval in certain markets.

The Phase III colonoscopy trial is running according to plan; completion of patient recruitment is expected shortly and headline data are expected mid 2016. Currently, 450 patients have been treated. Patient recruitment in the Phase III bronchoscopy trial is still moderate, and completion of patient recruitment could potentially be delayed into 2017. Subject to a successful implementation of ongoing countermeasures, PAION expects filing for market approval end of 2017 at the earliest and market approval end of 2018 at the earliest, accordingly.

#### Financial outlook (PAION group)

PAION currently concentrates on the development of Remimazolam in the U.S. and does not expect revenues in 2016.

Due to the ongoing investments in the development of Remimazolam, research and development expenses will continue being incurred in significant amounts. However, they will be lower compared to 2015 and amount to approximately EUR 24 million to EUR 27 million dependent on the progress of the development. In this context, income from tax credits on parts of the research and development expenses from British tax authorities in the amount of approximately EUR 4 million to EUR 4.5 million is expected. General administrative and selling expenses will decrease compared to the prior year and amount to approximately EUR 4.5 million to EUR 5 million, in particular due to lower selling expenses.

Accordingly, the net loss will decrease compared to prior year and amount to approximately EUR 24.5 million to EUR 27.5 million.

Key assumption for the report on expected developments is the scheduled progress of development activities in the U.S. Otherwise, essential parts of the costs would be shifted to 2017. Moreover, the amount of expected expenses is based on the current status of discussions with the regulatory authority FDA. Should the FDA impose additional requirements, costs could be incurred in higher amounts than planned and lead to a delay of approval.

As of 31 December 2015, PAION Group had cash and cash equivalents of EUR 32.7 million securing cash reach until the end of the first quarter of 2017 including the receipt of expected tax credits in the middle of 2016. Thus, PAION has sufficient funds to conduct the ongoing development with Remimazolam in the U.S. Based on current planning, PAION expects market approval for Remimazolam in the U.S. end of 2018 at the earliest. In the following, cash requirements for important Remimazolam development milestones up until approval are depicted for transparency purposes. Beyond current cash reach, additional funds of approximately EUR 10 million are required until filing, and further funds also amounting to approximately EUR 10 million are required until market approval. Under the assumption of the attractive own commercialization of Remimazolam in the U.S., additional funding in the amount of approximately EUR 30 million would be required until market approval for the establishment of a commercial infrastructure, i. a. for the establishment of a distribution network and the production of market material. This would allow immediate market entry after approval. The financing requirements would correspondingly decrease in case of partnering. PAION expects to be able to refinance by means of partnering or capital measures in case of successful development of Remimazolam.

Under consideration of the current cost structures, a net loss of approximately EUR 0.5 million to EUR 1.5 million is expected for PAION AG in fiscal year 2016.

Aachen, Germany, 21 March 2016 PAION AG

Dr. Wolfgang Söhngen

7. Rossy Shall

Dr. Jürgen Raths

# **Financial Statements**

PAION AG

## Balance Sheet as of 31 December 2015

ASSETS	31 Dec. 2015 EUR	31 Dec. 2014 EUR
Fixed assets		
Intangible assets		
Franchises, trademarks, patents, licenses and similar rights	10,316.00	15,698.00
Financial assets  Shares in affiliated companies	12 775 020 67	12 775 020 67
Securities	12,775,929.67 11.70	12,775,929.67 11.70
Securities		
	12,775,941.37 12,786,257.37	12,775,941.37 12,791,639.37
	12,700,237.37	12,771,037.37
Current assets		
Receivables and other assets		
Receivables from affiliated companies	60,492,032.59	33,969,644.54
Other assets	93,927.49	41,580.80
	60,585,960.08	34,011,225.34
Cash on hand and bank balances	31,474,947.56	57,613,655.72
	92,060,907.64	91,624,881.06
Prepaid expenses	75,274.27	51,819.70
	104,922,439.28	104,468,340.13

EQUITY AND LIABILITIES	31 Dec. 2015 EUR	31 Dec. 2014 EUR
Facility		
Equity Subscribed capital	50,659,440.00	50,641,940.00
thereof: 50,659,440 no-par value shares (prior year: 50,641,940 no-par value shares)	50,055,440.00	30,041,740.00
Conditional capital: EUR 25,303,470.00 (prior year: EUR 12,687,685.00)		
Capital reserve	134,251,540.26	134,246,990.26
Accumulated loss	-80,472,839.18	-81,010,740.88
	104,438,141.08	103,878,189.38
Accruals		
Other accruals	311,558.77	428,209.07
Liabilities		
Trade payables	60,068.53	67,374.32
thereof due in up to one year: EUR 60,068.53 (prior year: EUR 67,374.32)		
Liabilities to affiliated companies	15,577.02	12,895.16
thereof due in up to one year: EUR 15,577.02 (prior year: EUR 12,895.16)		
Other liabilities	97,093.88	81,672.20
thereof due in up to one year: EUR 97,093.88 (prior year: EUR 81,672.20)		
thereof for taxes: EUR 64,383.88 (prior year: EUR 48,856.11)		
	172,739.43	161,941.68
	104,922,439.28	104,468,340.13

## Income Statement for Fiscal Year 2015

	2015 EUR	2014 EUR
Other operating income	3,327,100.00	1,316,068.59
Personnel expenses		
Wages and salaries	-1,444,200.73	-1,164,481.16
Social security	-72,479.75	-56,137.13
	-1,516,680.48	-1,220,618.29
Depreciation of intangible assets	-5,382.00	-5,853.25
Other operating expenses	-3,189,987.71	-5,285,027.06
Other interest and similar income	1,922,847.24	1,269,240.96
thereof from affiliated companies:		
EUR 1,881,142.00 (previous year: EUR 1,205,034.98)		
Result from ordinary activities	537,897.05	-3,926,189.05
Depreciation of financial assets	0.00	-250,000.00
Other taxes	4.65	-873.16
Net result	537,901.70	-4,177,062.21
Loss carryforward	-81,010,740.88	-76,833,678.67
Accumulated loss	-80,472,839.18	-81,010,740.88

# Notes PAION AG

### Notes to the financial statements for fiscal year 2015

#### Preliminary remarks

The financial statements for the fiscal year from 1 January 2015 to 31 December 2015 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.

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

#### (I) Financial assets

The shareholdings in affiliated companies as of 31 December 2015 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 shown on the schedule of fixed assets (exhibit A).

#### (2) Receivables from affiliated companies

The receivables from affiliated companies are comprised as follows:

EUR	Total	of which:	of which: services and interest
PAION UK Ltd	55,729,105.41	55,460,000.00	269,105.41
PAION Holdings UK Ltd	4,324,383.43	4,310,000.00	14,383.43
PAION, Inc.	423,094.17	410,000.00	13,094.17
PAION Deutschland GmbH	15,449.58	0.00	15,449.58
	60,492,032.59	60,180,000.00	312,032.59

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

#### (3) Other assets

As of 31 December 2015, other assets are comprised substantially of VAT receivables (KEUR 71; previous year: KEUR 35).

#### (4) Equity

As of 31 December 2015, the share capital amounts to EUR 50,659,440.00 (previous year: EUR 50,641,940.00); it is divided into 50,659,440 no-par value shares (previous year: 50,641,940 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. The still available Authorized Capital 2014 in the amount of EUR 14,137,297.00 was revoked.

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. Conditional Capital 2010 II in the amount of EUR 9,800,000.00 was revoked.

The Annual General Meeting of 5 May 2008 adopted a resolution to reduce Conditional Capital 2004 II to EUR 858,121.00. 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, 46,462 stock options were issued to (former) employees of the PAION Group as of 31 December 2015. 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, 510,246 stock options were issued to current and former Management Board members and employees of the PAION Group as of 31 December 2015. To date, 208,171 stock options from the Stock Option Plan 2008 have been exercised, thereof 17,500 in fiscal year 2015. The exercises led to cash inflows of EUR 22,050.00 in the fiscal year. As of 31 December 2015, Conditional Capital 2008 I amounts to EUR 552,064.00.

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, 699,750 stock options were issued to current and former Management Board members and employees of the PAION Group as of 31 December 2015. 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, 328,813 stock options were issued to current and former Management Board members and employees of the PAION Group as of 31 December 2015. No stock options have been exercised yet.

#### (5) Accruals

The accruals break down as follows:

	31 Dec. 2015 EUR	31 Dec. 2014 EUR
Bonuses	111,325.33	235,500.00
Outstanding invoices	75,956.20	80,582.34
Financial statements and	57,666.67	53,750.00
audit		
Legal advice	10,000.00	7,500.00
Others	56,610.57	50,876.73
	311,558.77	482,709.07

#### (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) Other operating income

Other operating income mainly comprises income from the provision of management and other services to the subsidiaries (KEUR 1,305; previous year: KEUR 969), of which PAION UK Ltd accounted for KEUR 1,120 (previous year: KEUR 747) and PAION Deutschland GmbH for KEUR 186 (previous year: KEUR 222). Moreover, foreign exchange gains in the amount of KEUR 2,005 (previous year: KEUR 331) mainly resulting from funds held in U.S. dollar and Pound Sterling have been recognized.

#### (8) Other operating expenses

Other operating expenses mainly include legal and consulting fees (KEUR 919; previous year: KEUR 4,181), insurance, contributions and fees (KEUR 276; previous year: KEUR 277), travel expenses (KEUR 249; previous year: KEUR 241), services rendered by PAION Deutschland GmbH (KEUR 184; previous year: KEUR 158), expenses in connection with Supervisory Board remuneration (KEUR 131; previous year: KEUR 131) as well as audit costs and costs for the annual report (KEUR 120; previous year: KEUR 74). In the reporting period, foreign exchange losses in the amount of KEUR 1,064 (previous year: KEUR 25) have been recognized. The decrease of the other operating expenses, in particular the legal and consulting fees, is mainly connected to the capital measures conducted in 2014.

#### (9) Income attributable to other periods

In fiscal year 2015, income that is attributable to other periods amounted to KEUR 4 and refers to income from the reversal of accruals.

#### (IO) Taxes

As of 31 December 2015, the company's tax losses carried forward relating to corporate income tax amounted to about EUR 32.0 million (previous year: EUR 32.6 million) and

relating to trade tax to about EUR 30.8 million (previous year: EUR 31.4 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 2015, the resulting deferred tax assets would amount to KEUR 10,195 (previous year: KEUR 10,390).

The temporary differences between the tax base and the HGB carrying amount would produce a net balance as of 31 December 2015 of deferred tax assets in an amount of KEUR 0 (previous year: KEUR 5). It was opted to not recognize deferred tax assets.

#### Other compulsory disclosures

#### (I) Average number of employees

In fiscal year 2015, the company had an average of five employees (previous year: four employees).

### (2) Other financial obligations

The loan facility granted to the subsidiary PAION UK Ltd of up to KEUR 65,000 will be granted until further notice. As of 31 December 2015, the utilization amounts to KEUR 55,460.

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 2015, the utilization amounts to KEUR 4,310.

The loan facility granted to the subsidiary PAION, Inc. of up to KEUR 500 will be granted until further notice. As of 31 December 2015, the utilization amounts to KEUR 410.

## (3) Stock Option Plans

PAION has implemented a total of four stock option plans in the course of which stock options can be/have been granted to Management Board periods, waiting periods and exercise hurdles. The respective exercise price is based on the average stock price during a certain period of time be

	Stock Option Plan 2005 Approved 30 December 2004	Stock Option Pl Approved 5 Ma
Underlying Capital	Conditional Capital 2004 II	Con
Term of the options	10 years	
Vesting period	2-4 years	
Waiting period	2–4 years	
Exercise condition	Cumulative stock price increase of 5 % per year since grant in relation to stock price at grant date	Cumulative stock price increas grant in re
Exercise price *	EUR 8.00 to EUR 9.55	
Weighted average exercise price *	EUR 8.39	
Exercise hurdle as of 31 Dec. 15 *	EUR 11.47 to EUR 14.61	
Weighted average remaining term as of 31 Dec. 2015	1.0 years	
Further grants possible?	No	
Number of totally granted options	1,055,767	
Number of outstanding options as of 31 Dec. 15 **	46,462	
granted to employees	46,462	
granted to Management Board members	0	
Number of outstanding options for which the waiting period has expired as of 31 December 2015	46,462	
Number of totally lapsed options as of 31 Dec. 15	1,009,305	
thereof lapsed in the reporting period	798,881	
Number of totally exercised options until 31 Dec. 15	0	
thereof exercised in the reporting period	0	
*) in relation to outstanding options as of 31 Dec. 2015 **) in relation to employee/Management Board member status	s at the time of the grant	

members and employees of PAION AG and its subsidiaries at the time of the grant. All stock option programs include vesting efore the grant. Details of the individual programs can be found in the following table:

Stock Option Plan 2014

Stock Option Plan 2010

an 2008

y 2008	Approved 19 May 2010	Approved 21 May 2014
ditional 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
e 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 2.30 to EUR 2.40
EUR 1.56	EUR 2.01	EUR 2.30
EUR 1.49 to EUR 2.38	EUR 2.20	EUR 2.41 to EUR 2.49
3.9 years	8.1 years	9.1 years
No	No	Yes
817,550	720,000	370,000
510,246	699,750	328,813
274,165	396,000	197,000
236,081	303,750	131,813
506,996	0	0
99,133	20,250	41,187
0	20,250	41,187
208,171	0	0
17,500	0	0
	'	'

#### (4) Employee Participation Plan 2006

With the consent of the Supervisory Board, the Management Board of PAION AG has launched an employee participation plan granting stock appreciation rights. A stock appreciation right entitles the holder to receive a sum of money based on the PAION AG share price. The maximum amount payable on a stock appreciation right is limited to 100 % of the exercise price. The stock appreciation rights have a term of ten years and can only be exercised after a two-year waiting period, which has been fulfilled for all granted stock appreciation rights. In addition, they may only be exercised when the stock price on the exercise date has increased by a cumulative 5 % each year since issuance. No more stock appreciation rights can be issued out of the employee participation plan 2006. As of 31 December 2015, a total of 134,000 stock appreciation rights had been issued, 100,000 to current and former Management Board members as well as 34,000 to current and former PAION Group employees. The stock appreciation rights have not yet been exercised. As of 31 December 2015, the exercise hurdle was EUR 11.47.

PAION AG's payment obligation that is directly attributable to this employee participation plan is recognized as an accrual and measured at fair value on the balance sheet date. The expenses are recorded over the service period of two years. The fair value is determined using the Black/Scholes option pricing model. The expenses attributable to Management Board members and PAION AG employees are disclosed as personnel expenses. The portion of expenses attributable to employees of PAION Deutschland GmbH is recorded under other operating expenses. Under a contractual agreement, these expenses are borne by PAION Deutschland GmbH; the corresponding refund claims against PAION Deutschland GmbH are therefore shown under other operating income. Since the fair value of the granted Stock Appreciation Rights as of 31 December 2015 amounts to EUR 0.00, no accrual for the payment obligation resulting from the employee participation plan is recognized as of 31 December 2015; the corresponding refund claims against PAION Deutschland GmbH came to EUR 0.00 accordingly.

#### (5) Management Board and Supervisory Board

The members of the company's Management Board are:

- Dr. Wolfgang Söhngen, CEO, Chairman
- Abdelghani Omari, CFO
- Dr. Jürgen Raths, COO (since 1 September 2015)
- Dr. Mariola Söhngen, CMO (until 31 October 2015)

Management Board remuneration totalled KEUR 1,160 in fiscal year 2015. As of 31 December 2015, a total of 689,590 stock options (fair value at time of granting: EUR 1,069,024) and 50,000 stock appreciation rights (fair value as of 31 December 2015: EUR 0.00) had been issued to active Management Board members as of 31 December 2015 and Management Board members that resigned during the fiscal year. For more information on Management Board remuneration, please see the disclosures in the remuneration report, which is part of the management report.

Dr. Wolfgang Söhngen 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. Dr. Mariola Söhngen was also Managing Director of PAION Deutschland GmbH, non-executive director of PAION, Inc., and Managing Director of PAION Holdings UK Ltd and its subsidiaries until her resignation as Management Board member of PAION AG. All Management Board members work full-time for the company and its subsidiaries

As of 31 December 2015, Dr. Wolfgang Söhngen owned 1.21 % (612,091 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. Söhngen Beteiligungs GmbH, in which Dr. Wolfgang Söhngen holds 50 %.

The members of the Supervisory Board are:

- Dr. Jörg Spiekerkötter, Kleinmachnow, Germany, Chairman;
   Managing Partner of JSP-Invest GmbH, Potsdam
- 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
- Grontmij NV, De Bilt/The Netherlands, Vice Chairman of the Supervisory Board (until 1 October 2015)
- Kerry Group plc, Tralee/Ireland, Non-executive director
- Humedics GmbH, Berlin/Germany, Chairman (since 1 October 2015)
- 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 131 in fiscal year 2015. For more information on Supervisory Board remuneration, please see the disclosures in the remuneration report in the management report.

As of 31 December 2015, 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. 2015*	Result 2015*
PAION Deutschland GmbH, Aachen	100	EUR	935,897.13	478,150.25
PAION Holdings UK Ltd, Cambridge/UK	100	GBP	4,742,628.68	104,944.38
PAION UK Ltd, Cambridge/UK	100	GBP	-22,006,061.09	-19,082,244.62
PAION, Inc., Delaware/USA	100	USD	-304,535.50	-277,914.85
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 2I 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 2015:

• 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.

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 2015:

• College Retirement Equities Fund (TIAA-CREF)

#### (8) Financial statements auditor

The Annual General Meeting on 20 May 2015 appointed Ernst & Young GmbH Wirtschaftsprüfungsgesellschaft, Cologne office, Germany, as auditor of the annual and consolidated financial statements for fiscal year 2015. The auditor has received or will invoice the following fees for services rendered to PAION AG and its subsidiaries in fiscal year 2015:

	2015 KEUR	2014 KEUR
Audits of financial statements Other assurance services Other services	99 40 45 <b>184</b>	70 34 318 <b>422</b>

The other assurance services relate to fees for reviewing the interim financial statements. The other services comprise consulting in the course of a sampling examination by the Financial Reporting Enforcement Panel conducted in the reporting period.

#### (12) 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 2015, 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/).

#### (13) Report on post-balance sheet date events

On 9 February 2016, it was decided to discontinue the European Phase III study in cardiac surgery patients due to insufficient patient recruitment.

On 18 February 2016, PAION reported that the Japanese Pharmaceuticals and Medical Devices Agency (PMDA) regards the clinical and non-clinical data sets for Remimazolam as complete for filing for market approval in the indication General Anesthesia in Japan based on a so-called pre-NDA meeting.

There were no further significant events in the period between the reporting date, 31 December 2015, and the preparation of this report.

Dr. Jürgen Raths

Aachen, 21 March 2016

Dr. Wolfgang Söhngen

PAION AG

# Appendix A: Fixed Assets Movement for Fiscal Year 2015

	Historic Costs			
	1 Jan. 2015	Additions	Disposals	31 Dec. 2015
	EUR	EUR	EUR	EUR
Intangible assets				
Franchises, trademarks, patents, licenses and similar rights	59,595.05	0.00	0.00	59,595.05
	59,595.05	0.00	0.00	59,595.05
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	0.00	0.00	60,034,033.52

Depreciation			Net Book V	alues	
1 Jan. 2015	Additions	Disposals	31 Dec. 2015	31 Dec. 2015	31 Dec. 2014
EUR	EUR	EUR	EUR	EUR	EUR
43,897.05	5,382.00	0.00	49,279.05	10,316.00	15,698.00
43,897.05	5,382.00	0.00	49,279.05	10,316.00	15,698.00
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
47,242,394.15	5,382.00	0.00	47,247,776.15	12,786,257.37	12,791,639.37

Responsibility Statement (Bilanzeid) 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, 21 March 2016 PAION AG

Dr. Wolfgang Söhngen

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## **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 2015 to 31 December 2015. 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 and as a whole provides a suitable view of the Company's position and suitably presents the opportunities and risks of future development."

Cologne, 21 March 2016

Ernst & Young GmbH Wirtschaftsprüfungsgesellschaft

(s) Ueberschär (s) Galden Wirtschaftsprüfer Wirtschaftsprüfer

[German Public Auditor] [German Public Auditor]