

PAION Q2#2016

Consolidated Financial Interim Report for the First Half-Year 2016

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2016

PAION AG



About PAION AG

PAION AG is a publicly listed specialty pharmaceutical company developing and aiming to commercialize innovative drugs to be used in out-patient and hospital-based sedation, anesthesia and critical care services. PAION's lead compound is remimazolam, an intravenous, ultra-short-acting and controllable benzodiazepine sedative/anesthetic drug candidate. Currently, remimazolam is in active Phase III clinical development for use in procedural sedation in the U.S., where PAION is focusing all its business and financial resources on successfully completing its ongoing clinical development program in procedural sedation. Outside the U.S., PAION has so far focused on the development of remimazolam in the indication general anesthesia. Development of remimazolam in the indication intensive care unit (ICU) sedation is also part of the longer term life-cycle plan for remimazolam.

Remimazolam is partnered in the U.S., Canada, China, Russia (CIS), Turkey, the MENA region, and South Korea.

PAION is headquartered in Aachen (Germany) with further sites in Cambridge (United Kingdom) and New Jersey (USA).

PAION's vision is to become an acknowledged "PAIONeer" in sedation and anesthesia.

Key Figures

(all figures in KEUR unless otherwise noted)	Q2 2016	Q2 2015	H1 2016	H1 2015
Revenues	195	6	198	39
Research and development expenses	-5,653	-6,217	-12,155	-11,980
General administrative and selling expenses	-2,070	-1,387	-3,250	-2,724
Result for the period	-6,474	-6,637	-13,203	-11,340
Earnings per share in EUR for the period (basic)	-0.13	-0.13	-0.26	-0.22
Earnings per share in EUR for the period (diluted)	-0.13	-0.13	-0.26	-0.22

	H1 2016	H1 2015
Cash flows from operating activities	-9,606	-12,033
Cash flows from investing activities	-138	-5
Cash flows from financing activities	9,185	22
Change in cash and cash equivalents	-576	-11,951
Average number of group employees	39	27

	30-06-2016	31-12-2015
Intangible assets	2,836	3,362
Cash and cash equivalents	32,104	32,680
Equity	31,360	35,562
Non-current liabilities	36	6
Current liabilities	7,151	7,900
Balance sheet total	38,547	43,468

Interim Group Management Report for the First Half-Year 2016

The First Six Months at a Glance

February

PAION discontinues European remimazolam Phase III Trial in cardiac surgery patients due to insufficient patient recruitment

U.S. Patent & trademark office grants substance patent for remimazolam besylate

PAION reports positive pre-NDA meeting with Japanese authority PMDA

April

PAION successfully completes patient recruitment in pivotal U.S. Phase III study with remimazolam for procedural sedation during colonoscopy

June

PAION reports positive remimazolam headline data in pivotal U.S. Phase III study for procedural sedation during colonoscopy

PAION grants Cosmo Pharmaceuticals (Cosmo) remimazolam license in the U.S., and Cosmo becomes largest shareholder of PAION AG by investing EUR 9.6 million in PAION shares

Development and Commercial Activities

In the first half-year 2016, PAION has focused on the development of remimazolam in procedural sedation for a U.S. approval. The patient recruitment in the first U.S. Phase III study was completed in April 2016, and in June 2016, PAION announced that remimazolam has met its primary efficacy endpoint in the first study of its pivotal U.S. Phase III program in patients undergoing procedural sedation. The study enrolled a total of 461 patients at 13 U.S. sites and was designed to evaluate the efficacy and safety of remimazolam compared to placebo (with midazolam rescue) in patients undergoing colonoscopy. Sedation was provided under the supervision of the endoscopist. The primary outcome measure, success of the procedure without requirement for rescue sedation, was reached in 91.3% of the patients in the remimazolam arm and in 5.0% in the placebo (including midazolam rescue) arm. The safety profile of remimazolam was consistent with that observed in previous studies. This study also included an open label arm in which midazolam was dosed according to U.S. label. Evaluation of the full data set is ongoing and is supposed to be presented in an appropriate scientific, peer-reviewed format in autumn 2016.

The U.S. Phase III program also includes a second confirmatory, prospective, double-blind placebo-controlled, randomized, multi-center open label vs. midazolam trial in 420 patients undergoing bronchoscopies, a smaller safety trial in 75 high-risk patients (double blind vs. placebo and open label vs. midazolam) undergoing colonoscopies, and in addition four ongoing Phase I trials for the purpose of further supporting remimazolam's safety profile.

Several safety reviews have been conducted by an independent data monitoring committee (DMC) since the start of the U.S. Phase III program. All safety reviews led to a positive DMC recommendation to continue the trials as scheduled.

In June 2016, PAION entered into an investment and a U.S. license agreement with Cosmo.

In August 2015, the start of the multi-national, multi-center, 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 patient recruitment, the trial proved to be difficult to implement in practice. Therefore, in February 2016, PAION decided to discontinue the trial in order to avoid a long and expensive study with the existing design. Currently PAION is evaluating how to resume the clinical development of remimazolam in the EU.

A pre-NDA (New Drug Application) meeting with the Japanese Pharmaceuticals and Medical Devices Agency (PMDA) took place in January 2016. The PMDA stated that the non-clinical and the clinical data package of remimazolam were regarded as complete for filing in the indication "Induction and maintenance of general anesthesia". In October 2015, PAION already reported that the PMDA had confirmed that both the raw materials produced by PAION in Europe as well as the finished formulation of remimazolam fulfill the requirements for filing in Japan.

Financial Overview

In the first half-year 2016, revenues amounting to EUR 0.2 million were generated particularly in connection with the U.S. license agreement entered into with Cosmo. Research and development expenses amounted to EUR 12.2 million and slightly increased by EUR 0.2 million compared to the first half-year 2015 due to the ongoing concentration on the development activities with remimazolam, mainly in connection with the conduct of the U.S. Phase III program. General administrative and selling expenses increased compared to the prior-year period mainly as a result of the preparation of potential capital measures that were ultimately not conducted in light of the agreements entered into with Cosmo. In total, a net loss of EUR 13.2 million has been incurred in the first half-year 2016 compared to a net loss of EUR 11.3 million in the prior-year period.

Cash and cash equivalents decreased by EUR 0.6 million in the first half-year 2016 compared to 31 December 2015 and amounted to EUR 32.1 million as of 30 June 2016. Based on current planning, PAION believes that its total cash and cash equivalents together with EUR 10.0 million upfront payment received from Cosmo after the balance sheet date will enable PAION to complete the ongoing Phase III development including the preparation of filing of remimazolam in the indication procedural sedation in the U.S. Should development, filing and approval go according to plan, PAION will not need additional funding to bring remimazolam to the U.S. market including bearing all the costs for development and preparation of filing.

Regarding the markets in the EU, PAION is currently evaluating how to resume the clinical development of remimazolam. For such a development in the EU, additional funding would be needed.

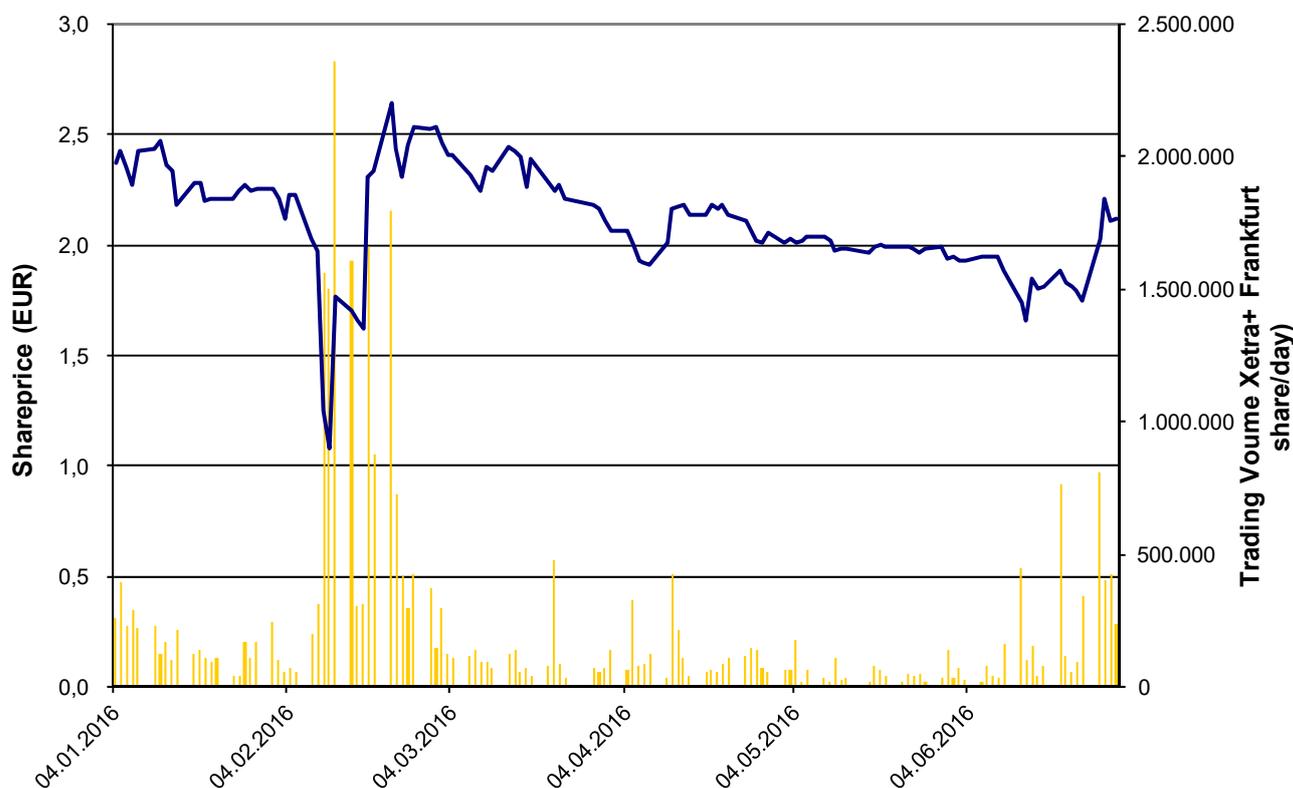
Capital Market Environment and PAION Share Performance

The development of the German capital markets in the first half of 2016 was impacted by low interest rates, the Quantitative Easing of the European Central Bank and political turmoil caused by the “Brexit” which weakened the markets. The DAXsubsector Biotechnology Index declined by 15.4% and the NASDAQ Biotechnology Index also trended lower (-23.9%) in the first six months of 2016.

The PAION share price started the year 2016 at a price of EUR 2.37 (Xetra). The peak price on 22 February 2016 was EUR 2.64 (Xetra). On 11 February 2016, the lowest price in the first half-year of 2016 was marked at EUR 1.08 (Xetra). The closing price on 30 June 2016 was EUR 2.12 (Xetra). This corresponds to a decrease of 6% compared to the closing price on 30 December 2015 (EUR 2.25; Xetra).

The average daily trading volume (Xetra and Frankfurt Stock Exchange) amounted to 233,619 shares during the first half of 2016 (in the year 2015: 220,148 shares). Thereby, 29 million shares were traded during the first half of 2016 (in the year 2015: 56 million shares).

Development of the PAION Share Price and Volume (Xetra) in the First Half-Year 2016



Overview of Research 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.

Remimazolam

Remimazolam is an ultra-short-acting intravenous benzodiazepine sedative/anesthetic, currently in Phase III clinical development for procedural sedation in the U.S. In the human body, remimazolam is rapidly metabolized to an inactive metabolite by tissue esterases and not metabolized by cytochrome-dependent hepatic pathways. Like other benzodiazepines, remimazolam can be reversed with flumazenil to rapidly terminate sedation and anesthesia if necessary.

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

A pediatric development plan has been agreed with the FDA and will be implemented by Cosmo following completion of current development of remimazolam for adult patients. A full clinical development program for general anesthesia has been completed in Japan, and a Phase II study in general anesthesia has been completed in the E.U. Based on the positive results of the Phase II study in Japan, development for ICU sedation beyond 24 hours is considered following successful completion of development in procedural sedation and general anesthesia.

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

Procedural Sedation (U.S.) market

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

The growth of the procedural sedation market in the U.S. has been driven for many years by the increase in medical interventions requiring procedural sedation, such as colorectal cancer screening using colonoscopy, and an increase in demand for preventive screenings. According to iData Research, which consults an extensive collection of national- and state-level procedure databases to examine historical trends and create procedure forecasts in the U.S., 26.7 million colonoscopy and endoscopy claims were reported in 2015 in the U.S., and the number is expected to grow at an average rate of 2.6% annually through 2020. PAION estimates that 75% of the colonoscopies and endoscopies claimed were conducted in an out-patient setting due to the higher reimbursement fees compared to hospitals.

Regular endoscopic screening for people aged 50 or older is recommended and covered by all major health insurance plans, including those under the Centers for Medicare and Medicaid Services (“CMS”), a U.S. federal agency that administers Medicare (the national social insurance program), since effective prevention is considered to reduce the likelihood of incidence of illnesses such as cancer, thereby reducing the suffering of patients and related financial burden to be borne by the cancer victims and payors. Statistics show that the rate at which people are diagnosed with colon cancer in the U.S. has dropped by 30% in the last 10 years for those aged 50 years and older, partly due to more people getting recommended screening tests. Colorectal cancer is the third most diagnosed cancer and the third leading cause of cancer death in both men and women in the U.S. Despite the decrease 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. The market for endoscopies in gastroenterology represents the most lucrative market segment for remimazolam in procedural sedation with approximately 20 million procedures per year.

Currently, the most widely used products in procedural sedation are Propofol and Midazolam – both generic. PAION estimates that these two drugs each have a market share of approximately 50% in terms of volume of procedures performed in the out-patient market for colonoscopies. The Propofol label mandates the presence of an anesthesia professional throughout the procedure due to Propofol’s potential for respiratory- and cardio-depressive effects, which results in additional cost. Midazolam is considered to be a safer agent, but with longer onset and offset of action times which can impact patient throughput and overall efficiency.

As national health insurance reforms under the Patient Protection and Affordable Care Act (“PPACA”) are ongoing, increased enrollment and screenings are expected to result in a performance-based payment system that will seek to better align payments with high quality of care measures. This would imply that cost-effective medicines with clinical value will be used more extensively and that continued premium will be placed on innovative medicines with strong clinical profile. Thus, PAION believes that concerns related to the overall cost of procedures, driven by the need for anesthesia professionals monitoring during procedures using agents such as Propofol, will impact the choice of drug products for procedural sedation. Costs related to anesthesia services in gastrointestinal endoscopy procedures alone were estimated at USD 1.3 billion in 2009. Accordingly, while the primary target is the users of Midazolam, PAION expects reimbursement regimes under national and commercial healthcare systems, such as Medicare, which differentiate the amounts reimbursed to physicians and/or patients depending on whether an anesthesia professional’s service is used, may also positively impact the demand for products that do not require monitoring by an anesthesia professional.

PAION believes that remimazolam, subject to FDA approval with a safety labeling comparable to that of Midazolam, could benefit from the pending changes in payment policies, given that it could be administered under the supervision of a proceduralist, and would be able to face price-based competition from Midazolam based on its enhanced efficiency profile compared to Midazolam.

General Anesthesia (EU) market

Based on a market research, PAION estimates that in the EU, approximately 29 million procedures requiring general anesthesia are performed each year. Of these, approximately 10 million are performed for high-risk patients (American Society of Anesthesiologists (“ASA”) classifications III or higher) who are particularly prone to hemodynamic instability. 55% of all anesthetics are balanced anesthesia (a combination of intravenous agents for induction and volatile gases for maintenance), 20% are total intravenous anesthetics (“TIVA”) using Propofol, and the remaining 25% include regional anesthesia (for example epidural administration). Based on PAION’s own EU market research, the current standard-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 the EU continue to evolve driven by the aging population. PAION anticipates an increasing number and complexity of medical interventions requiring induction and maintenance of anesthesia in the future driven by an ongoing evolution of the demographic profile in the EU. While general anesthesia is more frequently offered to elderly patients than in the past, 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 comorbidities.

Accordingly, PAION believes that demand for safer agents with low respiratory and cardio-depressive effects will increase over the coming years, creating opportunities for anesthetics with an enhanced safety profile such as remimazolam, even at higher prices compared to existing generic drugs.

Clinical Development

Remimazolam –over 1,000 volunteers/patients on drug	
Completed studies *	Ongoing studies **
Procedural Sedation (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 (24)
Phase IIa Single bolus in upper GI endoscopy (100)	Phase I Abuse Liability (40)
Phase IIb Multiple bolus in colonoscopy (161)	Phase I Oral bioavailability (12)
Phase III in colonoscopy (461)	Phase III in bronchoscopy (420)
	ASA III/IV in colonoscopy (75)
General Anesthesia (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 Anesthesia (EU)	
Phase II in cardiac surgery patients (90)	
Phase III in cardiac surgery patients (23, discontinued)	
ICU Sedation (Japan)	
Phase II (49, discontinued)	

* Numbers in brackets are actually recruited volunteers/patients

** Numbers in brackets are total target volunteer/patient numbers

Procedural sedation (Lead indication U.S.)

A total of two Phase I, two Phase II trials and one Phase III trial 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, the patient recruitment was completed in April 2016, and in June 2016, PAION announced, that remimazolam has met its primary efficacy endpoint in the first study of its pivotal U.S. Phase III program in patients undergoing procedural sedation. The study enrolled a total of 461 patients at 13 U.S. sites and was designed to evaluate the efficacy and safety of remimazolam compared to placebo (with midazolam rescue) in patients undergoing colonoscopy. Sedation was

provided under the supervision of the endoscopist. The primary outcome measure, success of the procedure, was reached in 91.3% of the patients in the remimazolam arm and in 5.0% in the placebo (including midazolam rescue) arm. The safety profile of remimazolam was consistent with that observed in previous studies.

In important secondary endpoints, the remimazolam arm showed a mean time to start of procedure of 5.1 minutes and a mean time from end of procedure to return to full alertness of the patients of 9.25 minutes. Evaluation of the full data set is ongoing and is supposed to be presented in an appropriate scientific, peer-reviewed format in autumn 2016.

This study also included an open label arm in which midazolam was dosed according to U.S. label. The data resulting from this non-comparative arm may be useful for hypothesis generation for future development and pharmacoeconomic modelling.

Although the study designs are not identical, the Phase III study results were in line with findings from a previous U.S. Phase IIb double-blind randomized comparative study between remimazolam and midazolam in 162 patients undergoing routine colonoscopy, where patients in the remimazolam arm showed significantly enhanced colonoscopy success rates and shorter times to start of procedure, shorter times from end of procedure to return to full alertness and, therefore, shorter overall procedure times than patients in the midazolam arm.

The Phase III program also includes a second confirmatory, prospective, double-blind placebo-controlled, randomized, multi-center open label vs. midazolam trial in 420 patients undergoing bronchoscopies which started in June 2015, a smaller safety trial in 75 high-risk patients (double blind vs. placebo and open label vs. midazolam) undergoing colonoscopies, and in addition four ongoing Phase I trials for the purpose of further supporting remimazolam's safety profile.

Patient recruitment for the ongoing U.S. Phase III bronchoscopy trial, which marks the completion of PAION's U.S. clinical development program in procedural sedation, has been slower than anticipated and is now expected to be completed in the second quarter of 2017.

PAION is continuously implementing measures to accelerate patient recruitment of this study. Main elements are the enhancement of study protocol implementability, opening additional study centers and intensifying support for existing study centers. How soon after completion of the clinical development program filing for approval is possible, is subject to ongoing discussions with Cosmo, who are responsible for all approval activities in the U.S.

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 in general anesthesia 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 and pre-clinical data generated outside of Japan. In October 2015, PAION already reported that the PMDA had confirmed that both the raw materials produced by PAION in Europe as well as the finished formulation of remimazolam 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, multi-center, 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 patient recruitment, the trial proved to be difficult to implement in practice. Therefore, in February 2016, PAION decided to discontinue the trial in order to avoid a long and expensive study with the existing design. No drug-related serious adverse events have been observed.

Currently, PAION is evaluating how to resume the clinical development of remimazolam in the EU.

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 availability of required funds.

Cooperation Agreements

In total, PAION has completed eight licensing deals with remimazolam which are summarized in the following table.

Upfront and milestone payments			
	Total received	Maximum outstanding amount	Royalty rate
Ono, Japan (2007) (terminated in 2015)	USD 8 m	None	None
Yichang Humanwell, China (2012)	EUR 3 m	EUR 4 m	10%
Hana Pharm, S. Korea (2013)	EUR 1 m	EUR 2 m	10%
R-Pharm, CIS (2013)	EUR 1 m	EUR 3 m	Low double-digit
(T)R-Pharm, Turkey (2013)	EUR 1 m	EUR 3 m	Low double-digit
(T)R-Pharm, MENA (2014)	EUR 1.5 m	EUR 5.5 m	Low double-digit
Pendopharm, Canada (2014)	EUR 0.4 m*	~ EUR 3.9 m	Tiered (starting at 15%)
Cosmo, USA (2016)	EUR 19.6 m**	EUR 42.9 m****	20%–25%***
Total	EUR 33.4 m	~ EUR 64.3 m	

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

** Comprising EUR 9.6 million received via private placement and EUR 10 million upfront payment received after balance-sheet date.

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

****: Including EUR 0.4 million to be invested in PAION shares.

In June 2016, PAION entered into an investment and a license agreement with Cosmo. In the course of the investment agreement, Cosmo has committed to invest an amount of EUR 10 million in PAION shares which are subject to a 12-month lock-up period upon purchase. In June 2016, Cosmo already invested an amount of EUR 9.6 million in the course of a private placement; the remaining EUR 0.4 million will be invested at a later date.

In the course of the license agreement, Cosmo receives an exclusive license for the development and commercialization of remimazolam in the U.S and bears all future cost for market authorization and sales and distribution of remimazolam. PAION remains responsible for and bears the cost associated with the completion of the ongoing U.S. clinical development program in procedural sedation. PAION in return is entitled to receive an upfront payment in the amount of EUR 10 million that PAION has already received after the balance sheet date, further payments of up to EUR 42.5 million depending on the achievement of certain regulatory milestones in the U.S., as well as tiered royalties upon commercialization ranging

from 20% to 25% of the net sales (which may be adjusted under certain conditions but not to below 15%). Dependent on the progress of certain development components, the upfront payment received after the balance sheet date will presumably be recognized as revenues over the years 2016 and 2017, thereof approximately EUR 4 million in 2016 and EUR 6 million in 2017 based on current planning.

PAION has selectively formed, and seeks to enter into, development and marketing collaborations with partners with local expertise or with a specific therapeutic focus with respect to remimazolam. Such collaborations are an effective way of funding and advancing remimazolam's late-stage development and of assisting PAION with its commercialization in international markets where PAION do not intend to directly conduct sales and marketing activities. PAION expects that the existing collaboration partners will continue the development of remimazolam on the basis of data generated from our U.S., Japanese and European clinical development program, and subsequently PAION may receive additional data and payments under the existing agreements in the medium to long term. PAION's ultimate goal is to participate in the worldwide commercialization of remimazolam. PAION is well positioned to find collaboration partners as pharmaceutical companies have a growing need to add drugs to their pipeline that have already demonstrated proof of concept in advanced stages of clinical trials and also provide a commercially viable alternative in a global healthcare environment characterized by increasing cost consciousness.

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 already received EUR 1.3 million as of the balance sheet date. Additional license fees were not agreed.

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 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.

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.

Net Assets, Financial Position, and Results of Operations

Results of Operations

	Q2 2016	Q2 2015	H1 2016	H1 2015
	KEUR	KEUR	KEUR	KEUR
Revenues	195	6	198	39
Cost of revenues	0	-1	0	-10
Gross profit	195	5	198	29
Research and development expenses	-5,653	-6,217	-12,155	-11,980
General administrative and selling expenses	-2,070	-1,387	-3,250	-2,724
Other income (expenses)	-145	-313	-529	775
Operating expenses	-7,868	-7,917	-15,934	-13,929
Operating result	-7,673	-7,912	-15,736	-13,900
Financial result	6	12	10	23
Income taxes	1,193	1,263	2,523	2,537
Net result for the period	-6,474	-6,637	-13,203	-11,340

Revenues in the first half-year 2016 amounted to KEUR 198 compared to KEUR 39 in the prior-year period and mainly resulted from the license agreement with Cosmo that PAION entered into in June 2016.

Research and development expenses amounted to KEUR 12,155 in the first half-year 2016 and slightly increased by KEUR 175 compared to the prior-year period due to the ongoing concentration on the development activities with remimazolam, mainly in connection with the conduct of the U.S. Phase III program.

General administrative and selling expenses increased by KEUR 526 to KEUR 3,250 in the first half-year 2016 compared to the prior-year period. General administrative expenses increased by KEUR 769 to KEUR 2,473 while selling expenses decreased by KEUR 243 to KEUR 777. The increase in general administrative expenses primarily results from the preparation of potential capital measures that were ultimately not conducted in light of the agreements entered into with Cosmo. Selling expenses mainly comprise costs related to the initiation and preparation of license agreements in the reporting period, while in the first half-year 2015, selling expenses primarily included market research as well as pre-marketing and market access activities.

The **other income (expenses)** includes foreign exchange losses in the amount of KEUR 795 mainly resulting from funds held in U.S. dollar. In the prior-year period, other income (expenses) included foreign exchange gains in the amount of KEUR 786 primarily resulting from funds held in U.S. dollar.

The **financial result** for the first half-year 2016 amounted to KEUR 10 compared to KEUR 23 in the prior-year period.

Income taxes relate to tax claims for reimbursement of parts of the research and development costs from the British tax authorities in the full amount.

The **net loss** for the first half-year 2016 amounted to KEUR 13,203. In the prior-year period, a net loss of KEUR 11,340 had been incurred. The change is primarily attributable to higher general and administrative expenses and higher other expenses than incurred in the prior-year period.

Net Assets

	30-06-2016	31-12-2015	Change
	KEUR	KEUR	KEUR
Non-current assets	3,030	3,417	-387
Current assets	35,517	40,051	-4,534
Total Assets	38,547	43,468	-4,921
Equity	31,360	35,562	-4,202
Non-current liabilities	36	6	30
Current liabilities	7,151	7,900	-749
Total Equity and liabilities	38,547	43,468	-4,921

Non-current assets mainly comprise the development project remimazolam (KEUR 2,823).

Current assets consist of cash and cash equivalents (KEUR 32,104), trade receivables (KEUR 503) as well as prepaid expenses and other assets (KEUR 2,910). The reduction of KEUR 4,534 is mainly attributable to the decrease of tax claims for reimbursement of parts of the research and development costs from the British tax authorities by KEUR 3,475 and the decrease of cash and cash equivalents by KEUR 576.

The decrease in **equity** of KEUR 4,202 compared to 31 December 2015 mainly results from the net loss of the first half-year 2016 in the amount of KEUR 13,203 on the one hand and from net proceeds from the private placement conducted by Cosmo in the amount of KEUR 9,169 on the other hand. As of 30 June 2016, the equity ratio was 81.4% (31 December 2015: 81.8%).

Financial Position

Compared to 31 December 2015, **cash and cash equivalents** decreased by KEUR 576 to KEUR 32,104 at the end of the current reporting period. The change in cash and cash equivalents stems from the following areas:

	H1 2016 KEUR	H1 2015 KEUR
Cash flows from operating activities	-9,606	-12,033
Cash flows from investing activities	-138	-5
Cash flows from financing activities	9,185	22
Effects of exchange rate changes	-17	65
Change in cash and cash equivalents	-576	-11,951

The **cash flows from operating activities** in the first half-year 2016 were KEUR -9,606. These primarily result from the net loss (KEUR 13,203) and the tax credit payment from the British tax authorities received in May 2016 in the amount of KEUR 5,529, adjusted for the current tax credit claim in the amount of KEUR 2,523 towards the British tax authorities which has not had a cash effect yet.

The **cash flows from investing activities** in the first half-year 2016 amounted to KEUR -138 and are mainly attributable to leasehold improvements.

The **cash flows from financing activities** relate to a capital increase conducted via private placement by Cosmo in the amount of KEUR 9,169 and the exercise of stock options in the amount of KEUR 16.

Personnel Development

On average, PAION employed 39 employees in the first six months of 2016 (fiscal year 2015: 29 employees). As of 30 June 2016, the headcount was 37.

Risks and Opportunities

Material risks and opportunities relating to future development are presented in detail in the group management report for fiscal year 2015. Due to the positive results from the U.S. Phase III colonoscopy trial and the agreements entered into with Cosmo, the risk situation has substantially improved. Other than that, material risks and opportunities have not changed significantly in the first half-year of 2016.

Significant Events Occurring After the Balance Sheet Date

There were no significant events in the period between the reporting date, 30 June 2016, and the preparation of this report.

Report on expected developments

Outlook on Development and Commercialization Activities

PAION's major goals for the remainder of 2016 are the continuation of the ongoing Phase III development program with remimazolam in the U.S. and the implementation of the cooperation with Cosmo, including the necessary know-how transfer. In addition, the focus remains on 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.

For the EU, PAION aims at an own commercialization. Subject to completing the ongoing U.S. development activities and the associated know-how transfer to Cosmo, PAION intends to resume development activities. In this context, the next step is to re-evaluate the studies conducted in general anesthesia so far. In close collaboration with recognized EU experts, PAION is currently conducting analyses in regard to design and feasibility of a new development program as basis for discussion with the European Medicines Agency ("EMA"). The recently completed U.S. Phase III colonoscopy trial will be included in the analysis which will allow to explore the EU market opportunity and pathways to regulatory approval in the EU also in indications other than general anesthesia.

For all regions outside the U.S. and the EU, it is aimed to find license or distribution partners. However, PAION is also open to discuss EU partnerships that are value-creating for its shareholders.

After a positive pre-NDA meeting with the Japanese authority in the beginning of 2016, in the course of which details of a market approval for remimazolam have been outlined, PAION is continuing partnering discussions with potential licensees and is also evaluating filing for market approval itself alternatively A Japanese dossier could serve as a reference dossier for approval in certain markets.

Patient recruitment for the ongoing U.S. Phase III bronchoscopy trial, which marks the completion of PAION's U.S. clinical development program in procedural sedation, has been slower than anticipated and is now expected to be completed in the second quarter of 2017. PAION is continuously implementing measures to accelerate patient recruitment of this study. How soon after completion of the clinical development program filing for approval is possible, is subject to ongoing discussions with Cosmo, who are responsible for all approval activities in the U.S.

Financial Outlook

PAION expects revenues of approximately EUR 4 million in 2016 mainly resulting from the U.S. license agreement for remimazolam entered into with Cosmo in June 2016. This is based on the assumption that no further license agreements will be conducted 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 amount to approximately EUR 5.5 million.

Accordingly, the net loss will decrease compared to prior year and amount to approximately EUR 21.5 million to EUR 24 million. The change in comparison to the outlook given in the group management report for fiscal year 2015 mainly results from the U.S. license agreement for remimazolam entered into with Cosmo in June 2016.

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.

Based on current planning, PAION believes that its total cash and cash equivalents of EUR 32.1 million as of 30 June 2016, together with EUR 10.0 million upfront payment received from Cosmo after the balance sheet date will enable PAION to complete ongoing Phase III development including the preparation of filing of remimazolam in the indication procedural sedation in the U.S. Thereafter, PAION expects to receive milestone payments from Cosmo and after a potential market approval royalties on net sales. Should development, filing and approval go according to plan, PAION will not need additional funding to bring remimazolam to the U.S. market including bearing all the costs for development and preparation of filing. Regarding the markets in the EU, PAION is currently evaluating how to resume the clinical development of remimazolam. For such a development in the EU, additional funding would be needed. The amount will only be specified after evaluation of a potential new development program has been finalized.

Aachen, Germany, 10 August 2016

PAION AG



Dr. Wolfgang Söhnngen



Dr. Jürgen Rath



Abdelghani Omari

Condensed Consolidated Interim Financial Statements

Consolidated Balance Sheet

ASSETS	30 June 2016 EUR	31 Dec. 2015 EUR
Non-current assets		
Intangible assets	2,835,603.83	3,361,501.93
Equipment	194,051.41	55,590.77
Other assets	14.1	14.42
	3,029,669.34	3,417,107.12
Current assets		
Trade receivables	503,667.69	0.00
Prepaid expenses and other assets	2,910,481.23	7,371,001.85
Cash and cash equivalents	32,103,578.29	32,679,797.20
	35,517,727.21	40,050,799.05
Total assets	38,547,396.55	43,467,906.17

EQUITY AND LIABILITIES	30 June 2016	31 Dec. 2015
	EUR	EUR
Equity		
Share capital	55,736,594.00	50,659,440.00
Capital reserve	128,442,250.56	124,236,225.22
Translation reserve	-711,354.85	-429,475.43
Loss carryforward	-138,904,359.04	-110,691,994.16
Result for the period	-13,203,258.84	-28,212,364.88
	31,359,871.83	35,561,830.75
Non-current liabilities		
Provisions	35,988.48	0.00
Deferred income	0.00	5,555.48
	35,988.48	5,555.48
Current liabilities		
Trade payables	6,225,674.62	7,332,458.12
Provisions	589,657.21	224,365.06
Other current liabilities	314,590.29	304,774.95
Current portion of deferred income	21,614.12	38,921.81
	7,151,536.24	7,900,519.94
Total equity and liabilities	38,547,396.55	43,467,906.17

Consolidated Statement of Comprehensive Income

EUR	1. April – 30 June 2016	1. April – 30 June 2015	1 January – 30 June 2016	1 January – 30 June 2015
Revenues	195,085.39	6,056.93	197,863.17	39,174.52
Cost of revenues	0.00	-1,861.16	0.00	-10,498.20
Gross profit	195,085.39	4,195.77	197,863.17	28,676.32
Research and development expenses	-5,652,857.07	-6,216,973.92	-12,155,291.14	-11,980,055.25
General administrative and selling expenses	-2,069,883.67	-1,386,984.01	-3,249,763.62	-2,724,075.77
Other income (expenses), net	-145,610.05	-312,746.34	-529,171.77	775,084.71
Operating expenses	-7,868,350.79	-7,916,704.27	-15,934,226.53	-13,929,046.31
Operating result	-7,673,265.40	-7,912,508.50	-15,736,363.36	-13,900,369.99
Financial income	5,968.39	12,177.41	10,171.70	23,123.30
Financial result	5,968.39	12,177.41	10,171.70	23,123.30
Result for the period before taxes	-7,667,297.01	-7,900,331.09	-15,726,191.66	-13,877,246.69
Income taxes	1,193,288.36	1,263,413.27	2,522,932.82	2,537,099.79
Result for the period	-6,474,008.65	-6,636,917.82	-13,203,258.84	-11,340,146.90
of which attributable to other shareholders	0.00	0.00	0.00	0.00
of which attributable to shareholders of PAION	-6,474,008.65	-6,636,917.82	-13,203,258.84	-11,340,146.90
Foreign currency translation	76,521.45	112,993.47	-281,879.42	522,022.31
Total income and expense recognized directly in equity that will be reclassified to profit or loss when specific conditions are met	76,521.45	112,993.47	-281,879.42	522,022.31
Other comprehensive income	76,521.45	112,993.47	-281,879.42	522,022.31
Total comprehensive income	-6,397,487.20	-6,523,924.35	-13,485,138.26	-10,818,124.59
of which attributable to other shareholders	0.00	0.00	0.00	0.00
of which attributable to shareholders of PAION	-6,397,487.20	-6,523,924.35	-13,485,138.26	-10,818,124.59
Earnings per share (basic)	-0.13	-0.13	-0.26	-0.22
Earnings per share (diluted)	-0.13	-0.13	-0.26	-0.22

Consolidated Cash Flow Statement

EUR	1 January – 30 June 2016	1 January – 30 June 2015
Cash flows from operating activities:		
Result for the period	-13,203,258.84	-11,340,146.90
Reconciliation of net result for the period to cash flows from operating activities:		
Income taxes	-2,522,932.82	-2,537,099.79
Amortization/depreciation and non-cash exchange rate changes of fixed assets	524,963.85	-177,503.42
Loss/Profits from the disposal of non-current assets	0.00	0.00
Interest expenses and interest income	-10,171.70	-23,123.30
Release of deferred income	-21,845.85	-23,197.03
Expenses from stock option plans	97,988.16	339,205.88
Change in assets and liabilities which are not attributable to investing or financing activities:		
Trade receivables	-503,667.69	467,040.00
Prepaid expenses and other assets	1,453,576.51	-121,860.11
Trade payables	-1,106,783.50	840,168.92
Provisions	275,901.85	63,263.84
Other current liabilities	9,815.34	-14,236.11
Deferred income	-1,017.32	14,440.41
Non-cash exchange losses/gains	-138,902.90	456,780.83
	-15,146,334.91	-12,056,266.78
Paid income taxes	0.00	0.00
Tax payments received	5,529,216.50	0.00
Interest received	10,832.12	23,312.80
Cash flows from operating activities	-9,606,286.29	-12,032,953.98
Cash flows from investing activities:		
Cash paid for investments in intangible assets and equipment	-137,526.07	-5,550.89
Cash flows from investing activities	-137,526.07	-5,550.89
Cash flows from financing activities:		
Capital increase	5,077,154.00	17,500.00
Contributions to the capital reserve	4,582,413.82	4,550.00
Payments in connection with raising capital	-474,376.64	0.00
Cash flows from financing activities	9,185,191.18	22,050.00
Change in cash and cash equivalents	-558,621.18	-12,016,454.87
Effect of exchange rate changes on cash	-17,597.73	65,241.48
Cash and cash equivalents at beginning of the period	32,679,797.20	58,911,883.56
Cash and cash equivalents at end of the period	32,103,578.29	46,960,670.17
Composition of cash and cash equivalents at the end of the period:		
Cash and cash equivalents	32,103,578.29	46,960,670.17

Consolidated Statement of Changes in Equity

EUR	Share capital	Capital reserve	Translation		Equity
			reserve	Loss carryforward	
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	522,022.31	-11,340,146.90	-10,818,124.59
Issue of shares	17,500.00	0.00	0.00	0.00	17,500.00
Contribution to the capital reserve	0.00	4,550.00	0.00	0.00	4,550.00
Additional contribution to the capital reserve due to the issue of options	0.00	339,205.88	0.00	0.00	339,205.88
30 June 2015	50,659,440.00	123,784,945.28	-261,929.73	-122,032,141.06	52,150,314.49
Total comprehensive income	0.00	0.00	-167,545.70	-16,872,217.98	-17,039,763.68
Issue of shares	0.00	0.00	0.00	0.00	0.00
Contribution to the capital reserve	0.00	0.00	0.00	0.00	0.00
Additional contribution to the capital reserve due to the issue of options	0.00	451,279.94	0.00	0.00	451,279.94
31 December 2015	50,659,440.00	124,236,225.22	-429,475.43	-138,904,359.04	35,561,830.75
Total comprehensive income	0.00	0.00	-281,879.42	-13,203,258.84	-13,485,138.26
Issue of shares	5,077,154.00	0.00	0.00	0.00	5,077,154.00
Contribution to the capital reserve	0.00	4,582,413.82	0.00	0.00	4,582,413.82
Cost of raising capital	0.00	-474,376.64	0.00	0.00	-474,376.64
Additional contribution to the capital reserve due to the issue of options	0.00	97,988.16	0.00	0.00	97,988.16
30 June 2016	55,736,594.00	128,442,250.56	-711,354.85	-152,107,617.88	31,359,871.83

Selected Explanatory Notes to the Consolidated Interim Financial Statements as of 30 June 2016

General

The half-year financial report of PAION AG includes interim consolidated financial statements and an interim group management report in accordance with the provisions of Sec. 37w (2) WpHG [“Wertpapierhandelsgesetz”: German Securities Trading Act] in conjunction with Sec. 37y WpHG as well as a statement of the management board according to Secs. 264 (2) sentence 3 and 289 (1) sentence 5 HGB [“Handelsgesetzbuch”: German Commercial Code]. The consolidated financial statements were prepared in accordance with the provisions of the International Financial Reporting Standards (IFRSs) for interim financial reporting. The interim group management report was prepared in accordance with the relevant provisions of the German Securities Trading Act.

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

- PAION Deutschland GmbH, Aachen/Germany
- PAION Holdings UK Ltd, Cambridge/UK
- PAION UK Ltd, Cambridge/UK
- PAION, Inc., Delaware/USA
- TheraSci Limited, Cambridge/UK

Basis of Accounting

The interim consolidated financial statements have been prepared in accordance with Sec. 315a HGB [“Handelsgesetzbuch”: German Commercial Code] and IFRSs, as adopted by the EU, and the interpretations of the International Financial Reporting Interpretations Committee (IFRIC). The consolidation principles and accounting policies adopted in the preparation of the interim condensed consolidated financial statements are consistent with those followed in the preparation of the Group’s annual consolidated financial statements for the year ended 31 December 2015, except for the adoption of

the following new or revised standards effective for the current reporting period:

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

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

The provisions of IAS 34, “Interim Financial Reporting”, have been applied. The interim financial statements as of 30 June 2016 should be read in conjunction with the consolidated financial statements as of 31 December 2015.

The preparation of interim consolidated financial statements in accordance with IFRSs requires

management to make estimates and assumptions which have an effect on the amount of recognised assets and liabilities, income and expenses and contingent liabilities. Actual amounts may differ from these estimates.

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

Foreign Currency Translation

The consolidated financial statements are shown in Euro, which is the functional currency of PAION AG and the reporting currency of the Group. Each company within the Group defines its own functional currency. This is the Euro in the case of the German companies and the U.S. dollar for the U.S.-based subsidiary PAION, Inc. whereas the UK-based companies use Pound Sterling as their functional currency. All items on the respective financial statements of each company are initially converted to the functional currency at the exchange rate applicable on the transaction date. Monetary assets and liabilities denominated in a foreign currency are translated into the functional currency on the reporting date at the exchange rate applicable on that date. All ensuing currency differences are recognised in profit or loss with the exception of exchange rate gains and losses from intra-Group loans classified in accordance with IAS 21 as net investments in foreign business operations; these are recognised in equity.

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

Stock options

On 24 May 2016, the Management Board members and the Supervisory Board decided to issue 370,000 stock options from the Stock Option Plan 2014. The grant date was 24 June 2016.

The stock options are accounted for in accordance with the provisions of IFRS 2 "Share-Based Payment". The fair value of the stock options was EUR 1.02 per stock option at the granting date and was calculated using the Black/Scholes option pricing model and is recognized in profit or loss as a personnel expense over the vesting period. The calculations were based on a risk-free interest rate of -0.26 % according to the four-year waiting period. The expected volatility of 83.76% was calculated based on the historical volatility of the last four years prior to the grant date. This is based on the assumption that the historical volatility is the best estimate for the expected volatility. Dividends were not considered in the calculation. Furthermore, an annual staff fluctuation of 10% was assumed.

In connection with the granted stock options from the Stock Option Plan 2014 (including stock options granted on 17 January 2015), personnel expenses in the amount of KEUR 77 were recognized in the first half-year 2016.

In connection with the stock options from the Stock Option Plan 2010 granted in 2014, personnel expenses in the amount of KEUR 21 were recognized in the first half-year 2016.

In the first half-year 2016, 12,960 stock options were exercised from the Stock Option Plan 2008. This led to cash inflows of KEUR 16. The new shares have not been recorded in the commercial register so far.

Tax Effects on Other Comprehensive Income

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

Fair value of financial assets and liabilities

As of 30 June 2016 as well as of 31 December 2015, the fair value of financial assets and liabilities was identical to the respective book value.

in KEUR	Book value		Fair Value		
	30 June 2016	31 Dec. 2015	30 June 2016	31 Dec. 2015	
Financial assets					
Cash and cash equivalents	(1)	32,104	32,680	32,104	32,680
Trade receivables	(1)	503	0	503	0
Other assets	(1)	1	313	1	313
Financial liabilities					
Provisions	(2),(3)	590	224	590	224
Trade payables	(2),(3)	6,226	7,332	6,226	7,332
Other liabilities	(2),(3)	198	129	198	129

Measurement category according to IAS 39:

- (1) Loans and receivables
- (2) Liabilities recognised at amortised cost
- (3) Lead to cash outflows

The determination of the fair values of these financial instruments was based on unobservable input factors (Level 3 inputs according to IFRS 13). In the first half-year 2016, there were no movements between the hierarchy levels.

Related Parties

The relationships with related parties have not changed in comparison to those applied in the consolidated financial statements as of 31 December 2015. In the first half-year 2016, expenses in the amount of KEUR 15 have been incurred for consulting services provided by Dr. Mariola Söhngen. As of 30 June 2016, trade payables to Dr. Mariola Söhngen amount to KEUR 0.

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

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

Aachen, Germany, 10 August 2016

PAION AG



Dr. Wolfgang Söhngen



Dr. Jürgen Raths



Abdelghani Omari

Review Report

To PAION AG, Aachen:

We have reviewed the interim condensed consolidated financial statements, comprising the condensed statement of financial position, the condensed statement of comprehensive income, the condensed statement of cash flows, the condensed statement of changes in equity and selected explanatory notes, and the interim group management report of PAION AG, Aachen, for the period from January 1 to June 30, 2016, which are part of the six-monthly financial report pursuant to Sec. 37w WpHG (“Wertpapier-handelsgesetz”: German Securities Trading Act. The preparation of the interim condensed consolidated financial statements in accordance with IFRSs [International Financial Reporting Standards] on interim financial reporting as adopted by the EU and of the group management report in accordance with the requirements of the WpHG applicable to interim group management reports is the responsibility of the Company’s management. Our responsibility is to issue a report on the interim condensed consolidated financial statements and the interim group management report based on our review.

We conducted our review of the interim condensed consolidated financial statements and the interim group management report in accordance with German generally accepted standards for the review of financial statements promulgated by the Institut der Wirtschaftsprüfer (Institute of Public Auditors in Germany (IDW)). Those standards require that we plan and perform the review to obtain a certain level of assurance in our critical appraisal to preclude that the interim condensed consolidated financial statements are not prepared, in all material respects, in accordance with IFRSs on interim financial reporting as adopted by the EU and that the interim group management report is not prepared, in all material respects, in accordance with the provisions of the WpHG applicable to interim group management reports. A review is limited primarily to making inquiries of company personnel and applying analytical procedures and thus does not provide the assurance that we would obtain from an audit of financial statements. In accordance with our engagement, we have not performed an audit and, accordingly, we do not express an audit opinion.

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

Cologne, Germany, August 10, 2016

Ernst & Young GmbH

Wirtschaftsprüfungsgesellschaft

Ueberschär	Galden
Wirtschaftsprüfer	Wirtschaftsprüfer
German Public Auditor	German Public Auditor

Information on PAION Shares

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

Key figures	H1 2016	2015
Numbers of shares at the end of the period	55,736,594	50,659,440
Average daily trading volume (Xetra, FSE)	233,619	220,148
Year high (Xetra closing price)	EUR 2.64 (22 Feb. 2016)	EUR 2.86 (4 May 2015)
Year low (Xetra closing price)	EUR 1.08 (11 Feb. 2016)	EUR 1.88 (3 Feb. 2015)
Share price at the end of the period	EUR 2.12	EUR 2.25
Market capitalization at the end of the period (Xetra)	EUR 118 m	EUR 114 m

Corporate Calendar

22 March 2016	Publication of the financial results 2015
11 May 2016	Publication of the financial results of the first quarter 2016
25 May 2016	Annual General Meeting, Aachen
10 August 2016	Publication of the financial results of the second quarter and the first half-year 2016
9 November 2016	Publication of the financial results of the third quarter and the first nine months of 2016

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