

PAION HI#2017

Consolidated Financial Interim Report for the First Half-Year 2017

Contents

Interim Group Management Report for the First Half-Year 2017	3
The First Six Months at a Glance	3
Capital Market Environment and PAION Share Performance	7
Overview of Research and Development Activities	8
Net Assets, Financial Position, and Results of Operations	18
Personnel Development	20
Changes in the Supervisory Board and Management Board	20
Risks and Opportunities	20
Significant Events Occurring After the Balance Sheet Date	21
Report on expected developments	21
Condensed Consolidated Interim Financial Statements	24
Consolidated Balance Sheet	24
Consolidated Statement of Comprehensive Income	26
Consolidated Cash Flow Statement	27
Consolidated Statement of Changes in Equity	28
Selected Explanatory Notes to the Consolidated Interim Financial Statements as of 30 June 2017	29
Review Report	33
Information on PAION Shares	34
Corporate Calendar	34

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2017

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 which is in the final stage of clinical development for use in procedural sedation in the U.S. Currently, PAION is mainly focusing 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. A full clinical development program for general anesthesia was completed in Japan and PAION is preparing filing in Japan. In the EU, PAION is currently planning to continue the clinical development program. Development of remimazolam in the indication intensive care unit (ICU) sedation is also part of the longer term life-cycle plan for remimazolam.

PAION is headquartered in Aachen (Germany) with a further site in Cambridge (United Kingdom).

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

Key Figures

(all figures in KEUR unless otherwise noted)	Q2 2017	Q2 2016	H1 2017	H1 2016
Revenues	2,032	195	4,083	198
Research and development expenses	-5,851	-5,653	-9,930	-12,155
General administrative and selling expenses	-980	-2,070	-1,983	-3,250
Result for the period	-3,553	-6,474	-5,771	-13,203
Earnings per share in EUR for the period (basic)	-0.06	-0.13	-0.10	-0.26
Earnings per share in EUR for the period (diluted)	-0.06	-0.13	-0.10	-0.26

	H1 2017	H1 2016
Cash flows from operating activities	-7,634	-9,606
Cash flows from investing activities	-17	-138
Cash flows from financing activities	4,678	9,185
Change in cash and cash equivalents	-2,991	-576
Average number of group employees	31	39

	30-06-2017	31-12-2016
Intangible assets	2,535	2,688
Cash and cash equivalents	27,120	30,111
Equity	23,697	24,943
Current liabilities	8,571	13,040
Balance sheet total	32,268	37,983

Interim Group Management Report for the First Half-Year 2017

The First Six Months at a Glance

February

PAION AG announces successful completion of a capital increase with subscription rights with gross proceeds of EUR 5.0 million.

March

Dr. Raths leaves the Management Board.

PAION reports positive headline data in U.S. clinical safety trial of remimazolam in high-risk patients undergoing colonoscopy.

May

Annual General Meeting elects Dr. Irina Antonijevic and Dr. Chris Tanner to the Supervisory Board.

Canadian remimazolam partner Pharmascience has pre-NDS (New Drug Submission) meeting with the Canadian regulatory authority Health Canada.

June

PAION reports positive headline data in U.S. Phase III trial with remimazolam for procedural sedation during bronchoscopy.

Development activities and outlook

In the first half of 2017, PAION focused on the completion of its Phase III development program for remimazolam in procedural sedation in the U.S.

U.S.

At the end of March 2017, PAION announced the completion of patient recruitment in the second pivotal U.S. Phase III clinical trial with remimazolam in procedural sedation during bronchoscopy, and in June 2017, PAION announced that the primary efficacy endpoint was met. The Phase III trial enrolled 446 patients at 15 U.S. sites and was designed to evaluate the efficacy and safety of remimazolam compared to placebo (with midazolam rescue medication) in procedural sedation in patients undergoing bronchoscopy.

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

Additionally, the patients' subjective impression of time from last dose to "back to normal" was a median of 404 minutes for remimazolam versus 935 minutes for placebo.

In the open label midazolam arm, procedural success was achieved in 34.8% of patients. Midazolam patients showed a median time from start of medication to start of procedure of 16.0 minutes and a median time from end of procedure to return to full alertness of 12.0 minutes. Additionally, time from last dose to "back to normal" as reported by patients on midazolam was a median of 478.5 minutes.

Also in the first half of 2017, PAION announced positive headline data from the U.S. clinical safety trial of remimazolam in ASA III/IV patients (American Society of Anesthesiologists classification) undergoing colonoscopy. The trial enrolled 79 patients and was designed to evaluate the efficacy and safety of remimazolam compared to placebo (with midazolam 'rescue' sedation) in patients undergoing proceduralist-supervised sedation for colonoscopy. This study also included an open label arm in which midazolam was dosed according to U.S. label. The trial confirmed remimazolam's safety profile and tolerability shown in all previous studies in a more vulnerable patient population. Overall, remimazolam demonstrated good respiratory and cardiovascular stability as compared to placebo with midazolam rescue. No adverse events of concern were observed in either group. In addition, the efficacy and efficiency improvements were comparable to the two positive pivotal U.S. Phase III trials in colonoscopy and bronchoscopy patients. Success of the procedure (including no requirement for rescue medication and the application of not more than five doses in any 15-minute interval) was achieved in 84.4% of patients in the remimazolam arm and 0% in the placebo arm. Other relevant endpoints showed a median time from start of medication to start of procedure of 5.0 minutes for remimazolam (placebo: 18.5 minutes) and a median time from end of procedure to return to full alertness of 3.0 minutes (placebo: 5.0 minutes). By comparison, procedural success was achieved in 12.9% of the midazolam patients. Midazolam patients showed a median time from start of medication to start of procedure of 19.0 minutes and a median time from end of procedure to return to full alertness of 7.0 minutes.

Based on the results of preclinical and Phase I studies and in consultation with the FDA, PAION has started additional Phase I studies to further assess the abuse potential of remimazolam. Two aspects are being studied: if remimazolam could inappropriately be used as a knock-out cocktail in combination with alcohol and if it could be abused intranasally. The first trial, the intranasal administration of remimazolam "part 1" with twelve subjects, has already been successfully completed. Currently, the study with oral administration of remimazolam together with alcohol in about 40–50 volunteers is ongoing. The human abuse liability program will be completed by the second part of the intranasal administration. Before conducting this study, interactions with the FDA are planned in the fourth quarter 2017.

In the U.S., certain drug schedules published by the FDA under the Controlled Substance Act (CSA) are in place. The drug classification schedules organize drugs into groups based on risk of abuse. Midazolam e.g. is included in Schedule IV. Substances in this schedule have a lower potential for abuse relative to substances in Schedule III. PAION assumes to receive the same classification for remimazolam as midazolam.

Conditional on successful study results and dependent on interactions with the FDA PAION currently expects to complete the human abuse liability program beginning of 2018.

Canada

In May 2017, PAION's remimazolam licensing partner for Canada, Pendopharm, a division of Pharmascience Inc., together with PAION delegates, had a pre-NDS meeting with Health Canada for remimazolam for the indication conscious sedation. Health Canada is the agency responsible for approving drugs in Canada.

During the meeting, the main questions raised for discussion following the preliminary assessment of remimazolam by Health Canada were clarified. Health Canada stated in the meeting that the non-clinical and the clinical data package, including the human abuse liability data available at the time, were regarded as adequate for filing.

EU

In consultation with key opinion leaders in general anesthesia, PAION is conducting a Phase I study to determine the number of patients required for an EU Phase III study in general anesthesia. The completion of the Phase I study is expected in the last quarter of 2017.

Japan

Based on the positive pre-NDA meeting (NDA = New Drug Application) with the Japanese Pharmaceuticals and Medical Devices Agency ("PMDA") and the successful financing in February 2017, PAION has started to prepare a market approval dossier for remimazolam in Japan. The dossier is being prepared by an experienced contract research organization (CRO) in close consultation with PAION.

Partner activities in other regions

All license partners have activities ongoing to support future filings in their respective territories with a focus on regulatory interactions. PAION's Russian remimazolam licensing partner R-Pharm announced the start of a Phase III study with remimazolam in general anesthesia in August 2017.

Financial Overview

In the first half-year 2017, revenues amounting to EUR 4.1 million were generated particularly in connection with the U.S. license agreement entered into with Cosmo Pharmaceuticals (Cosmo) in the prior year. Research and development expenses amounted to EUR 9.9 million and decreased by EUR 2.2 million compared to the first half-year 2016 mainly due to lower costs for Phase III studies. General administrative and selling expenses decreased by EUR 1.3 million compared to the prior-year period. In total, a net loss of EUR 5.8 million has been incurred in the first half-year 2017 compared to a net loss of EUR 13.2 million in the prior-year period.

Cash and cash equivalents decreased by EUR 3.0 million in the first half-year 2017 compared to 31 December 2016 and amounted to EUR 27.1 million as of 30 June 2017. Based on current plans, PAION believes that cash and cash equivalents enable PAION to complete all remaining development activities in the U.S. Thereafter, PAION expects to receive further payments from Cosmo subject to the achievement of certain regulatory milestones in the U.S., and, once remimazolam is approved, royalties on net sales. Should development, filing and approval go according to plan, PAION will not need additional funding to bring remimazolam to the U.S. market. For the further development in the EU, PAION is currently working on the

continuation of the clinical development program for remimazolam. In order to carry out a development program in general anesthesia in the EU, additional funding of approximately EUR 25 million is required until filing for approval, subject to further coordination with the regulatory authority (European Medicines Agency; EMA). In a first step, funds in the amount of EUR 8 million have been collected in the course of a capital increase conducted after the balance sheet date. Cash and cash equivalents including these funds and including expected tax credits from the British tax authorities on parts of the research and development expenses secure a cash reach into the second half of 2019 without consideration of potential milestone payments and without consideration of potential costs incurred by the targeted continuation of the Phase III development program in the EU.

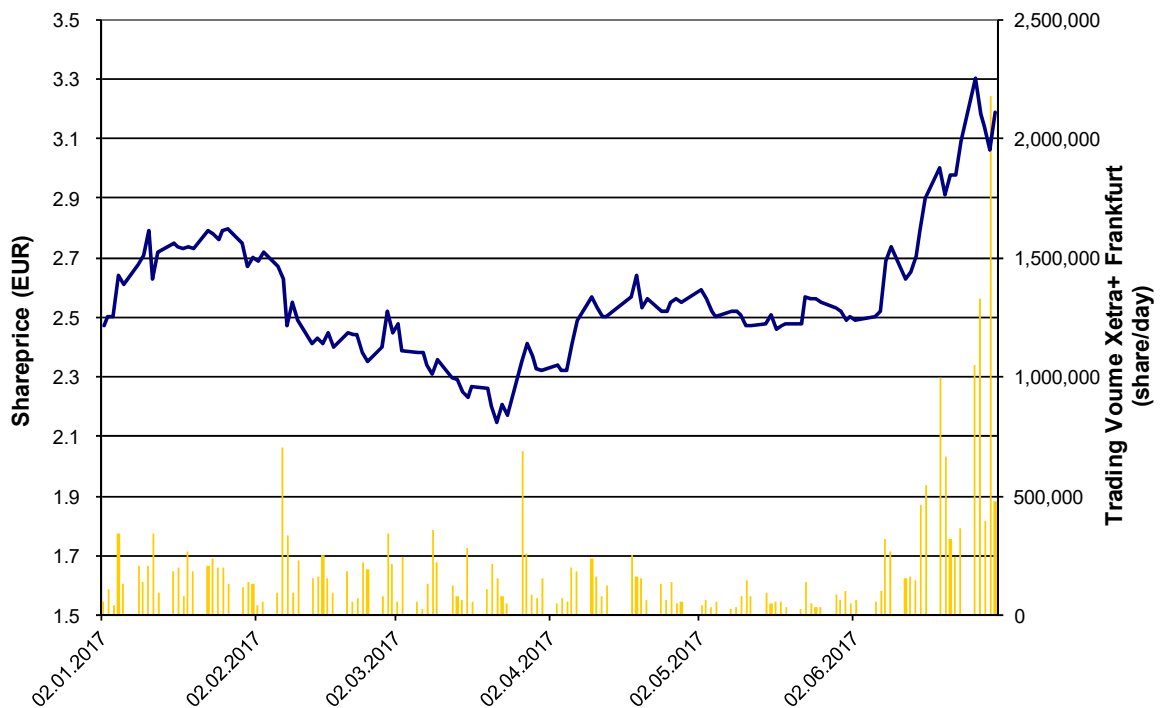
Capital Market Environment and PAION Share Performance

The development of the German capital markets in the first half of 2017 was mainly impacted by continuously low interest rates, the Quantitative Easing of the European Central Bank, U.S. monetary policy and the new U.S. presidency. The DAXsubsector Biotechnology Index increased by 14.4% and the NASDAQ Biotechnology Index also trended higher (+17.1%) in the first six months of 2017.

The PAION share price started the year 2017 at a price of EUR 2.47 (Xetra). The peak price on 26 June 2017 was EUR 3.30 (Xetra). On 22 March 2017, the lowest price in the first half-year of 2017 was marked at EUR 2.15 (Xetra). The closing price on 30 June 2017 was EUR 3.19 (Xetra). This corresponds to an increase of 30% compared to the closing price on 30 December 2016 (EUR 2.45; Xetra).

The average daily trading volume (Xetra and Frankfurt Stock Exchange) amounted to 201,580 shares during the first half of 2017 (in the year 2016: 233,619 shares). Thereby, 25 million shares were traded during the first half of 2017 (in the year 2016: 49 million shares).

Development of the PAION Share Price and Volume (Xetra) in the First Half-Year 2017



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.

Remimazolam

Remimazolam is an ultra-short-acting intravenous benzodiazepine sedative/anesthetic that has already shown positive results in clinical Phase III trials. 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 1,500 volunteers and patients. Data so far indicate that remimazolam has a rapid onset and offset of action combined with a favorable cardio-respiratory safety profile.

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

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

Procedural Sedation Market (U.S. lead indication)

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

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

Regular endoscopic screening for people aged 50 or older is recommended and covered by all major health insurance plans, including those under the Centers for Medicare and Medicaid Services (“CMS”), a U.S. federal agency that administers Medicare (the national

social insurance program), since effective prevention is considered to reduce the likelihood of incidence of illnesses such as cancer, thereby reducing the suffering of patients and related financial burden to be borne by the cancer victims and payors. Statistics show that the rate at which people are diagnosed with colon cancer in the U.S. has dropped by 30% in the last 10 years for those aged 50 years and older, partly due to more people getting recommended screening tests. Colorectal cancer is the third most diagnosed cancer and the third leading cause of cancer death in both men and women in the U.S. Despite the decrease of colorectal cancer death rates as a result of early screening and detection, it was reported in 2010 that only 59% of people aged 50 or older, for whom screening is recommended, reported having received colorectal cancer testing consistent with current guidelines. The market for endoscopies in gastroenterology represents the most lucrative market segment for remimazolam in procedural sedation with approximately 20 million procedures per year.

Currently, the most widely used products in procedural sedation are propofol and midazolam – both generic. PAION estimates that these two drugs each have a market share of approximately 50% in terms of volume of procedures performed in the out-patient market for colonoscopies. The propofol label mandates the presence of an anesthesia professional throughout the procedure due to propofol's potential for respiratory- and cardio-depressive effects, which results in additional cost. For midazolam, these side effects are less pronounced and have a different relevance, since an undesirably deep sedation can be reversed with flumazenil. Midazolam has a slower onset and a longer duration of action which can impact patient throughput and overall efficiency.

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

PAION believes that remimazolam, subject to FDA approval with a safety labeling comparable to that of midazolam, could benefit from the pending changes in payment policies. Provided that it could be administered under the supervision of a proceduralist, remimazolam would be able to offer a competitive alternative to midazolam. This is based on its enhanced efficiency profile compared to midazolam.

General Anesthesia Market (Japan + EU lead indication)

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

Patient demographics in the EU will presumably continue to evolve driven by the aging population. PAION anticipates an increasing number and complexity of medical interventions requiring induction and maintenance of anesthesia in the EU in the future also driven by an ongoing ageing of the population. General anesthesia is more frequently offered to elderly patients than in the past, therefore the choice of a tailored anesthesia is made depending on the type of surgery, the underlying disease, and an assessment of the general physical health of the patient, including co-morbidities.

Accordingly, PAION believes that in the EU the demand for safer agents with low respiratory and cardio-depressive effects will increase over the coming years, creating opportunities for anesthetics with an enhanced safety profile such as remimazolam, even at higher prices compared to existing generic drugs. PAION also expects similar developments for the U.S. and other important international markets, subject to further market research.

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

Clinical Development

Plan to have tested remimazolam on more than 1,500 volunteers/patients at FDA filing	
Phase II and III studies	Phase I studies
Procedural Sedation (U.S.)	
Phase IIa Single bolus in upper GI endoscopy (100) Phase IIb Multiple bolus in colonoscopy (161) Phase III in colonoscopy (461) Phase III ASA III/IV in colonoscopy (79) Phase III in bronchoscopy (446)	Phase I Single bolus in healthy volunteers (81) Phase Ib Multiple bolus in volunteers undergoing colonoscopy (51) Phase I Renal Impairment (22) Phase I Thorough QT (54) Phase I Abuse Liability <ul style="list-style-type: none"> • Intravenous administration (40) • Oral bioavailability (14) Phase I Abuse Liability <ul style="list-style-type: none"> • Oral administration in combination with alcohol (approx. 40–50)* • Intranasal administration part 1 (12) • Intranasal administration part 2 (approx. 16)*
General Anesthesia (Japan)	
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)	Phase I Bolus in healthy volunteers (42) Phase Ib Infusion in healthy volunteers (10) Phase I Hepatic impairment (U.S.) (20)
General Anesthesia (EU)	
Phase II in cardiac surgery patients (90) Phase III in cardiac surgery patients (23)**	Phase I PK/PD modeling study (EEG) in healthy volunteers (approx. 20)*
ICU Sedation (Japan)	
Phase II in ICU patients (49)**	

Patient/volunteer numbers in brackets

* Studies not yet completed

** Discontinued studies, no safety concerns

Procedural sedation (Lead indication in the U.S)

Remimazolam is currently in the final stage of clinical development for procedural sedation in the U.S. A total of seven Phase I, two Phase II and three Phase III trials have been completed in procedural sedation. The first in-human trial explored a broad range of doses from no effect to loss of consciousness (not wanted for procedural sedation but indicative for induction of general anesthesia). Based on this trial, the next set of trials covered a colonoscopy study in healthy volunteers and a Phase IIa study in upper GI endoscopy. These studies confirmed the need for an approximately 50% dose reduction in combination with opioids (colonoscopy) and were the basis for the Phase IIb study in colonoscopy patients. In this study, a fixed dose regime consisting of starting dose and top-ups was tested with the lowest of the starting doses being selected for use in the shortly completed Phase III program.

In March 2015, the first U.S. Phase III study was started, the patient recruitment was completed in April 2016, and in June 2016, PAION announced that the primary efficacy endpoint was met. The Phase III trial enrolled 461 patients at 13 U.S. sites and was designed to evaluate the efficacy and safety of remimazolam compared to placebo (with midazolam rescue) in patients undergoing proceduralist-administered sedation for colonoscopy.

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

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

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

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

Patient satisfaction was similar in all arms of the study.

The open label midazolam patients showed a median time from start of medication to start of procedure of 19.0 minutes and a mean time from end of procedure to return to full alertness of 15.7 minutes. Midazolam patients took 553 minutes to be back to normal. Hypotension was 67.3% with midazolam and hypoxia occurred in 1.0% of patients given midazolam.

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

In June 2015, the study was started, the patient recruitment was completed in March 2017, and in June 2017, PAION announced that the primary efficacy endpoint was met. The Phase III trial enrolled 446 patients at 15 U.S. sites and was designed to evaluate

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

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

In the open label midazolam arm, procedural success was achieved in 34.8% of patients. Midazolam patients showed a median time from start of medication to start of procedure of 16.0 minutes and a median time from end of procedure to return to full alertness of 12.0 minutes. Additionally, time from last dose to "back to normal" as reported by patients on midazolam was a median of 478.5 minutes.

As part of the U.S. development program, also a safety study in ASA III/IV patients undergoing colonoscopy (American Society of Anesthesiologists classification) was performed. In December 2016, successful completion of patient recruitment was announced, and in March 2017, PAION announced positive headline data from the U.S. clinical safety trial of remimazolam in ASA III/IV patients (American Society of Anesthesiologists classification) undergoing colonoscopy. The trial enrolled 79 patients and was designed to evaluate the efficacy and safety of remimazolam compared to placebo (with midazolam 'rescue' sedation) in patients undergoing proceduralist-supervised sedation for colonoscopy. This study also included an open label arm in which midazolam was dosed according to U.S. label. The trial confirmed remimazolam's safety profile and tolerability shown in all previous studies in a more vulnerable patient population. Overall, remimazolam demonstrated good respiratory and cardiovascular stability as compared to placebo with midazolam rescue. No adverse events of concern were observed in either group. In addition, the efficacy and efficiency improvements were comparable to the two positive pivotal U.S. Phase III trials in colonoscopy and bronchoscopy patients. Success of the procedure (including no requirement for rescue medication and the application of not more than five doses in any 15-minute interval) was achieved in 84.4% of patients in the remimazolam arm and 0% in the placebo arm. Other relevant endpoints showed a median time from start of medication to start of procedure of 5.0 minutes for remimazolam (placebo: 18.5 minutes) and a median time from end of procedure to return to full alertness of 3.0 minutes (placebo: 5.0 minutes). By comparison, procedural success was achieved in 12.9% of the midazolam patients. Midazolam patients showed a median time from start of medication to start of procedure of 19.0 minutes and a median time from end of procedure to return to full alertness of 7.0 minutes.

Summary of headline data of the three Phase III studies:

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

* not part of label claim

Based on the results of preclinical and Phase I studies and in consultation with the FDA, PAION has started additional Phase I studies to further assess the abuse potential of remimazolam. Two aspects are being studied: if remimazolam could inappropriately be used as a knock-out cocktail in combination with alcohol and if it could be abused intranasally. The first trial, the intranasal administration of remimazolam "part 1" with twelve volunteers, was already successfully completed. Currently, the study with oral administration of remimazolam together with alcohol in about 40–50 volunteers is ongoing. The human abuse liability program will be completed by the second part of the intranasal administration. Before conducting this study, interactions with the FDA are planned in the fourth quarter 2017.

In the U.S., certain drug schedules published by the FDA under the Controlled Substance Act (CSA) are in place. The drug classification schedules organize drugs into groups based on risk of abuse; e.g. midazolam is included in Schedule IV. Substances in this schedule have a lower potential for abuse relative to substances in Schedule III. PAION assumes to receive the same classification for remimazolam as midazolam.

Conditional on successful study results and dependent on interactions with the FDA PAION currently expects to complete the human abuse liability program beginning of 2018.

General anesthesia (Lead indication in Japan + EU)

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

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

Based upon the successful completion of Phase III in Japan, a pre-NDA meeting with the PMDA took place in January 2016. During the meeting, all open questions raised for discussion following the preliminary assessment of the PMDA were clarified. The PMDA stated

that the non-clinical and clinical data package were regarded as complete for filing in the indication "Induction and maintenance of general anesthesia". The clinical development program fully carried out in Japan by PAION's former partner Ono Pharmaceutical Co., Ltd. (Ono) in general anesthesia was complemented by PAION's growing data sets in all aspects from CMC (chemistry, manufacturing, control) to clinical and pre-clinical data generated outside of Japan. In October 2015, PAION already reported that the PMDA had confirmed that both the raw materials produced by PAION in Europe as well as the finished formulation of remimazolam fulfill the requirements for filing in Japan. PAION is now working on the preparation of a filing dossier for remimazolam in Japan. The required approval dossier is being prepared by an experienced CRO in close consultation with PAION. Such a dossier could serve as a reference dossier in certain other markets. This would significantly reduce the necessary additional investment for partners in the respective markets depending on the specific regulatory environment.

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

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

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

Based on current planning and conditional on the necessary scientific consultations with the relevant European regulatory authority EMA, the start of the new European Phase III study is expected in 2018.

ICU sedation

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

The observed phenomenon of elevated remimazolam plasma concentrations was subsequently thoroughly investigated using a series of preclinical tests and pharmacokinetic models. None of these experiments was able to reproduce the findings or provide a mechanistic explanation for the elevated plasma concentrations. Further analysis has revealed that such pharmacokinetic deviations are common for utilization of sedatives like midazolam and propofol on the ICU and the most likely explanation is the underlying serious condition of the patient presenting on the ICU. Further development of the program “ICU sedation” is part of the future remimazolam development plan which could be addressed after availability of required funds.

Partnering

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

	Upfront and milestone payments		
	Total received	Maximum outstanding amount	Royalty rate
Ono, Japan (2007) (terminated in 2015)	USD 8 m	None	None
Yichang Humanwell, China (2012)	EUR 3 m	EUR 4 m	10%
Hana Pharm, S. Korea (2013)	EUR 1 m	EUR 2 m	10%
R-Pharm, CIS (2013)	EUR 1 m	EUR 3 m	Low double-digit
(T)R-Pharm, Turkey (2013)	EUR 1 m	EUR 3 m	Low double-digit
(T)R-Pharm, MENA (2014)	EUR 1.5 m	EUR 5.5 m	Low double-digit
Pendopharm, Canada (2014)	EUR 0.4 m*	~ EUR 3.8 m	Tiered (starting at 15%)
Cosmo, U.S. (2016)	EUR 20 m**	EUR 42.5 m	20%–25%***
Total	EUR 33.8 m	~ EUR 63.8 m	

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

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

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

In June 2016, PAION entered into an investment and a license agreement with Cosmo. In the course of the investment agreement, Cosmo has committed to invest an amount of EUR 10 million in PAION shares. Cosmo invested an amount of EUR 9.6 million in the course

of a capital increase under exclusion of shareholders' subscription rights ("private placement") in June 2016 and the remaining EUR 0.4 million in the course of a capital increase with subscription rights in February 2017.

In the course of the license agreement, Cosmo has received an exclusive license for the development and commercialization of remimazolam in the U.S and is responsible for 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. In addition to an upfront payment in the amount of EUR 10 million already received, PAION in return is entitled to receive further payments of up to EUR 42.5 million depending on the achievement of certain regulatory milestones in total for all of the three indications in the U.S., as well as tiered royalties upon commercialization ranging from 20% to 25% of the net sales (which may be adjusted under certain conditions but not to below 15%). EUR 4.3 million of the received upfront payment were recognized as revenues in 2016, and EUR 5.7 million will presumably be recognized as revenues in fiscal year 2017.

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

Net Assets, Financial Position, and Results of Operations

Results of Operations

	Q2 2017	Q2 2016	H1 2017	H1 2016
	KEUR	KEUR	KEUR	KEUR
Revenues	2,032	195	4,083	198
Gross profit	2,032	195	4,083	198
Research and development expenses	-5,851	-5,653	-9,930	-12,155
General administrative and selling expenses	-980	-2,070	-1,983	-3,250
Other income (expenses)	22	-145	9	-529
Operating expenses	-6,809	-7,868	-11,904	-15,934
Operating result	-4,777	-7,673	-7,821	-15,736
Financial result	3	6	7	10
Income taxes	1,221	1,193	2,043	2,523
Net result for the period	-3,553	-6,474	-5,771	-13,203

Revenues in the first half-year 2017 amounted to KEUR 4,083 compared to KEUR 198 in the prior-year period and mainly resulted from the upfront payment received from Cosmo under the remimazolam license agreement entered into in 2016.

Research and development expenses amounted to KEUR 9,930 in the first half-year 2017 and mainly relate to the clinical development program for remimazolam in the U.S. The decrease of KEUR 2,225 compared to the prior-year period is mainly due to lower costs for Phase III studies on the one hand and higher costs for Phase I studies on the other hand.

General administrative and selling expenses decreased by KEUR 1,267 to KEUR 1,983 in the first half-year 2017 compared to the prior-year period. General administrative expenses decreased by KEUR 814 to KEUR 1,659 and selling expenses decreased by KEUR 453 to KEUR 324. Higher general administrative expenses incurred in the prior-year period mainly resulted from the preparation of potential capital measures that were ultimately not conducted, while selling expenses recognized in the prior-year period comprised essential costs related to the initiation and preparation of license agreements which have not been incurred in the first half-year 2017.

Income taxes amounted to KEUR 2,043 in the first half-year 2017 (prior-year period: KEUR 2,523) and mainly relate to tax claims for reimbursement of parts of the research and development costs from the British tax authorities. The decrease is primarily attributable to lower research and development costs.

The **net loss** for the first half-year 2017 amounted to KEUR 5,771. In the prior-year period, a net loss of KEUR 13,203 was reported. This means a decrease of the net loss in the amount of KEUR 7,432 compared to the prior-year period. The change is mainly attributable to higher revenues and lower research and development expenses than in the prior-year period.

Net Assets

	30-06-2017	31-12-2016	Change
	KEUR	KEUR	KEUR
Non-current assets	2,675	2,855	-180
Current assets	29,593	35,128	-5,535
Total Assets	32,268	37,983	-5,715
Equity	23,697	24,943	-1,246
Current liabilities	8,571	13,040	-4,469
Total Equity and liabilities	32,268	37,983	-5,715

Non-current assets mainly comprise the development project remimazolam (KEUR 2,469).

Current assets consist of cash and cash equivalents (KEUR 27,120) as well as prepaid expenses and other assets (KEUR 2,473). The reduction of KEUR 5,535 is mainly attributable to the decrease of cash and cash equivalents by KEUR 2,991 and the decrease of tax claims for reimbursement of parts of the research and development costs from the British tax authorities by KEUR 2,679.

The decrease in **equity** of KEUR 1,246 compared to 31 December 2016 mainly results from the net loss of the first half-year 2017 in the amount of KEUR 5,771 on the one hand and from net proceeds from the capital increase with subscription rights conducted in February 2017 in the amount of KEUR 4,591 on the other hand. As of 30 June 2017, the equity ratio was 73.4% (31 December 2016: 65.7%).

Current liabilities decreased by KEUR 4,469 compared to 31 December 2016 mainly due to the recognition of deferred income as revenues from the upfront payment received from Cosmo in 2016.

Financial Position

Compared to 31 December 2016, **cash and cash equivalents** decreased by KEUR 2,991 to KEUR 27,120 at the end of the current reporting period. The change in cash and cash equivalents stems from the following areas:

	H1 2017 KEUR	H1 2016 KEUR
Cash flows from operating activities	-7,634	-9,606
Cash flows from investing activities	-17	-138
Cash flows from financing activities	4,678	9,185
Effects of exchange rate changes	-18	-17
Change in cash and cash equivalents	-2,991	-576

The **cash flows from operating activities** in the first half-year 2017 were KEUR -7,634. These primarily result from the net loss (KEUR 5,771) and the tax credit payment from the British tax authorities received in June 2017 in the amount of KEUR 4,597, adjusted for the current tax credit claim in the amount of KEUR 2,044 towards the British tax authorities which has not had a cash effect yet.

The **cash flows from financing activities** of KEUR 4,678 in the first half-year 2017 mainly relate to the capital increase with subscription rights conducted in February 2017 (KEUR 4,591).

Personnel Development

On average, PAION employed 31 employees in the first six months of 2017 (fiscal year 2016: 36 employees). As of 30 June 2017, the headcount was 33.

Changes in the Supervisory Board and Management Board

Dr. Jürgen Raths left the Management Board in March 2017.

In the course of extending the size of the Supervisory Board from three to five members, the Annual General Meeting on 17 May 2017 elected Dr. Dr. Irina Antonijevic and Dr. Chris Tanner to the Supervisory Board.

Risks and Opportunities

Material risks and opportunities relating to future development are presented in detail in the group management report for fiscal year 2016 and have not changed significantly in the first half-year of 2017.

Significant Events Occurring After the Balance Sheet Date

In July 2017, a capital increase under exclusion of subscription rights of the shareholders with gross proceeds of EUR 8.0 million was successfully completed. By utilization of the Authorized Capital 2017 in the amount of EUR 2,824,515.00, the share capital of PAION AG was increased from EUR 58,256,591.00 to EUR 61,081,106.00 by issuing 2,824,515 new shares. The remaining Authorized Capital 2017 amounts to EUR 26,273,543.00 after this transaction.

There were no further significant events in the period between the reporting date, 30 June 2017, and the preparation of this report.

Report on expected developments

Outlook on Development and Commercialization Activities

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

In the U.S., PAION is allocating significant resources to achieve the planned completion of the clinical development program. Regular interactions with the FDA in this regard are being maintained in order to ensure that all data relevant for the regulatory authority have been collected. This will be followed by an integrated "overall" analysis of all clinical studies with remimazolam. Subject to the successful completion of the clinical development program, including the completion of all analyses and reports, filing for approval in the U.S. could take place subsequently after finalization of a market approval dossier. Before filing, usually a pre-NDA meeting with the U.S. regulatory authority FDA is held, which Cosmo currently plans shortly before filing for approval. The necessary coordination and preparatory work are currently being conducted together with Cosmo, U.S. key opinion leaders and regulatory experts. Filing for market approval will take place under Cosmo's responsibility. Cosmo currently expects filing for approval in the second half of 2018.

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

Based on the positive pre-NDA meeting with the Japanese authority PMDA in the beginning of 2016 and the financing in February 2017, PAION is preparing an application dossier for market approval of remimazolam in Japan. This creates important prerequisites to further continuing partnering discussions with potential licensees in parallel with the aim to partner the Japanese market during the process of dossier preparation or subsequently.

The preparation includes, among other things, the necessary validation of commercial-scale production for the Japanese market. Such a dossier could serve as a reference dossier for market approval in certain other markets. This would significantly reduce the necessary additional investment volume for partners in the respective markets depending on the specific regulatory environment. Subject to further coordination with the regulatory authority, filing for market approval in Japan is expected mid-2018.

Financial outlook

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

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

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

Based on current plans, PAION believes that cash and cash equivalents of EUR 27.1 million as of 30 June 2017 enable PAION to complete all remaining development activities in the indication procedural sedation in the U.S. Thereafter, PAION expects to receive further payments from Cosmo subject to the achievement of certain regulatory milestones in the U.S., and, once remimazolam is approved, royalties on net sales. Should development, filing and approval go according to plan, PAION will not need additional funding to bring remimazolam to the U.S. market. For the further development in the EU, PAION is currently working on the continuation of the clinical development program for remimazolam. In order to carry out a development program in the EU, funding of approximately EUR 25 million is required until filing for approval, subject to further coordination with the regulatory authority. In a first step, funds in the amount of EUR 8 million have been collected in the course of a capital increase conducted after the balance sheet date. Cash and cash equivalents including these funds and including expected tax credits from the British tax authorities on parts of the research and development expenses secure a cash reach into the second half of 2019 without

consideration of potential milestone payments and without consideration of potential costs incurred by the targeted continuation of the Phase III development program in the EU.

Aachen, Germany, 09 August 2017

PAION AG



Dr. Wolfgang Söhngen



Abdelghani Omari

Condensed Consolidated Interim Financial Statements

Consolidated Balance Sheet

ASSETS	30 June 2017 EUR	31 Dec. 2016 EUR
Non-current assets		
Intangible assets	2,534,847.81	2,687,855.47
Equipment	140,464.13	167,210.31
Other assets	13.98	14.04
	2,675,325.92	2,855,079.82
Current assets		
Prepaid expenses and other assets	2,472,891.60	5,017,115.86
Cash and cash equivalents	27,120,392.05	30,111,355.87
	29,593,283.65	35,128,471.73
Total assets	32,268,609.57	37,983,551.55

EQUITY AND LIABILITIES	30 June 2017	31 Dec. 2016
	EUR	EUR
Equity		
Share capital	58,256,591.00	55,757,094.00
Capital reserve	130,785,776.74	128,548,802.57
Translation reserve	-552,132.57	-340,777.37
Loss carryforward	-159,021,995.85	-138,904,359.04
Result for the period	-5,770,931.95	-20,117,636.81
	23,697,307.37	24,943,123.35
Current liabilities		
Trade payables	6,200,068.92	6,352,616.12
Provisions	441,957.24	554,962.54
Other current liabilities	279,144.24	358,814.11
Deferred income	1,650,131.80	5,774,035.43
	8,571,302.20	13,040,428.20
Total equity and liabilities	32,268,609.57	37,983,551.55

Consolidated Statement of Comprehensive Income

EUR	1. April – 30 June 2017	1. April – 30 June 2016	1 January – 30 June 2017	1 January – 30 June 2016
Revenues	2,031,955.50	195,085.39	4,082,785.14	197,863.17
Gross profit	2,031,955.50	195,085.39	4,082,785.14	197,863.17
Research and development expenses	-5,851,292.97	-5,652,857.07	-9,930,304.60	-12,155,291.14
General administrative and selling expenses	-979,822.20	-2,069,883.67	-1,982,800.39	-3,249,763.62
Other income (expenses), net	22,840.97	-145,610.05	9,621.05	-529,171.77
Operating expenses	-6,808,274.20	-7,868,350.79	-11,903,483.94	-15,934,226.53
Operating result	-4,776,318.70	-7,673,265.40	-7,820,698.80	-15,736,363.36
Financial income	2,645.02	5,968.39	7,026.90	10,171.70
Financial result	2,645.02	5,968.39	7,026.90	10,171.70
Result for the period before taxes	-4,773,673.68	-7,667,297.01	-7,813,671.90	-15,726,191.66
Income taxes	1,220,982.10	1,193,288.36	2,042,739.95	2,522,932.82
Result for the period	-3,552,691.58	-6,474,008.65	-5,770,931.95	-13,203,258.84
of which attributable to other shareholders	0.00	0.00	0.00	0.00
of which attributable to shareholders of PAION	-3,552,691.58	-6,474,008.65	-5,770,931.95	-13,203,258.84
Foreign currency translation	-197,330.36	76,521.45	-211,355.20	-281,879.42
Total income and expense recognized directly in equity that will be reclassified to profit or loss when specific conditions are met	-197,330.36	76,521.45	-211,355.20	-281,879.42
Other comprehensive income	-197,330.36	76,521.45	-211,355.20	-281,879.42
Total comprehensive income	-3,750,021.94	-6,397,487.20	-5,982,287.15	-13,485,138.26
of which attributable to other shareholders	0.00	0.00	0.00	0.00
of which attributable to shareholders of PAION	-3,750,021.94	-6,397,487.20	-5,982,287.15	-13,485,138.26
Earnings per share (basic)	-0.06	-0.13	-0.10	-0.26
Earnings per share (diluted)	-0.06	-0.13	-0.10	-0.26

Consolidated Cash Flow Statement

EUR	1 January – 30 June 2017	1 January – 30 June 2016
Cash flows from operating activities:		
Result for the period	-5,770,931.95	-13,203,258.84
Reconciliation of net result for the period to cash flows from operating activities:		
Income taxes	-2,042,739.95	-2,522,932.82
Amortization/depreciation and non-cash changes of fixed assets	195,932.29	524,963.85
Loss/Profits from the disposal of non-current assets	1,167.78	0.00
Interest expenses and interest income	-7,026.90	-10,171.70
Release of deferred income	-3,870,104.47	-21,845.85
Expenses from stock option plans	58,520.87	97,988.16
Change in assets and liabilities which are not attributable to investing or financing activities:		
Trade receivables	0.00	-503,667.69
Prepaid expenses and other assets	-10,866.64	1,453,576.51
Trade payables	-152,547.21	-1,106,783.50
Provisions	-94,507.89	275,901.85
Other current liabilities	-79,669.87	9,815.34
Deferred income	-253,799.16	-1,017.32
Non-cash exchange losses/gains	-194,136.44	-138,902.90
	-12,220,709.54	-15,146,334.91
Paid income taxes	-19,696.15	0.00
Tax payments received	4,596,583.91	5,529,216.50
Interest received	9,472.62	10,832.12
Cash flows from operating activities	-7,634,349.16	-9,606,286.29
Cash flows from investing activities:		
Cash paid for investments in intangible assets and equipment	-17,346.17	-137,526.07
Cash flows from investing activities	-17,346.17	-137,526.07
Cash flows from financing activities:		
Capital increase	2,499,497.00	5,077,154.00
Contributions to the capital reserve	2,587,574.29	4,582,413.82
Payments in connection with raising capital	-409,120.99	-474,376.64
Cash flows from financing activities	4,677,950.30	9,185,191.18
Change in cash and cash equivalents	-2,973,745.03	-558,621.18
Effect of exchange rate changes on cash	-17,218.79	-17,597.73
Cash and cash equivalents at beginning of the period	30,111,355.87	32,679,797.20
Cash and cash equivalents at end of the period	27,120,392.05	32,103,578.29
Composition of cash and cash equivalents at the end of the period:		
Cash and cash equivalents	27,120,392.05	32,103,578.29

Consolidated Statement of Changes in Equity

EUR	Share capital	Capital reserve	Translation reserve	Loss carryforward	Equity
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
Total comprehensive income	0.00	0.00	370,577.48	-6,914,377.97	-6,543,800.49
Issue of shares	20,500.00	0.00	0.00	0.00	20,500.00
Contribution to the capital reserve	0.00	7,070.00	0.00	0.00	7,070.00
Cost of raising capital	0.00	-895.30	0.00	0.00	-895.30
Additional contribution to the capital reserve due to the issue of options	0.00	100,377.31	0.00	0.00	100,377.31
31 December 2016	55,757,094.00	128,548,802.57	-340,777.37	-159,021,995.85	24,943,123.35
Total comprehensive income	0.00	0.00	-211,355.20	-5,770,931.95	-5,982,287.15
Issue of shares	2,499,497.00	0.00	0.00	0.00	2,499,497.00
Contribution to the capital reserve	0.00	2,587,574.29	0.00	0.00	2,587,574.29
Cost of raising capital	0.00	-409,120.99	0.00	0.00	-409,120.99
Additional contribution to the capital reserve due to the issue of options	0.00	58,520.87	0.00	0.00	58,520.87
30 June 2017	58,256,591.00	130,785,776.74	-552,132.57	-164,792,927.80	23,697,307.37

Selected Explanatory Notes to the Consolidated Interim Financial Statements as of 30 June 2017

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

It is planned to dissolve PAION, Inc. in the course of fiscal year 2017.

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 2016, except for the adoption of the following new or revised standards effective for the current reporting period:

- IFRSs 2014–2016 Cycle “Annual Improvements to IFRSs 2014–2016”: Amendments to IFRS 12 “Disclosure of Interests in Other Entities”
- Amendments to IAS 12 “Income Taxes”
- Amendments to IAS 7 “Statement of Cash Flows”

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 2017 should be read in conjunction with the consolidated financial statements as of 31 December 2016.

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.

Equity

On 7 February 2017, the Management Board decided with the approval of the Supervisory Board and based on the authorization by the General Meeting to issue 2,439,023 new, no-par value bearer shares at a subscription price of EUR 2.05, granting pre-emptive rights to existing shareholders. The existing shareholders were able to subscribe the new shares at a subscription ratio of 23:1 in the subscription period from 10 February 2017 to 27 February 2017. A U.S. institutional investor had committed to acquire any new shares not subscribed for by existing shareholders or other investors in connection with the rights offering at the subscription price. Upon completion of the capital increase, the company's share capital increased from EUR 55,757,094.00 by EUR 2,439,023.00 to EUR 58,196,117.00 through the issuing of 2,439,023 new shares. The capital increase with gross proceeds of EUR 4.99 million was recorded in the commercial register on 1 March 2017. Authorized Capital 2015 correspondingly decreased to EUR 17,817,753.00

Stock options

On 29 June 2017, the Management Board members decided to issue 231,000 stock options from the Stock Option Plan 2016. The stock options were granted on 29 July 2017.

In connection with the stock options from the Stock Option Plan 2014 granted in 2015 and 2016, personnel expenses in the amount of KEUR 59 were recognized in the first half-year 2017.

In the first half-year 2017, 60,474 stock options were exercised from the Stock Option Plan 2008. This led to cash inflows of KEUR 87. 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 2017 and as of 31 December 2016, the fair value of financial assets and liabilities was identical to the respective book value.

in KEUR		Book value		Fair Value	
		30 June 2017	31 Dec. 2016	30 June 2017	31 Dec. 2016
Financial assets					
Cash and cash equivalents	(1)	27,120	30,111	27,120	30,111
Other assets	(1)	1	3	1	3
Financial liabilities					
Provisions	(2),(3)	442	537	442	537
Trade payables	(2),(3)	6,200	6,353	6,200	6,353
Other liabilities	(2),(3)	196	165	196	165

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 2017, there were no movements between the hierarchy levels.

Related Parties

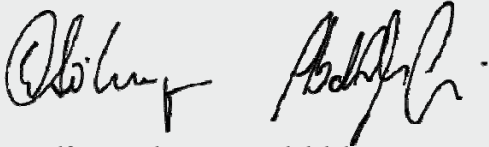
The relationships with related parties have not changed in comparison to those applied in the consolidated financial statements as of 31 December 2016.

**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, 09 August 2017

PAION AG

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

Dr. Wolfgang Söhngen

Abdelghani Omari

Review Report

To PAION AG, Aachen:

We have reviewed the condensed consolidated interim 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 - together with the interim group management report of PAION AG, Aachen, for the period from January 1 to June 30, 2017, part of the six-monthly financial report pursuant to § (Article) 37w WpHG ("Wertpapierhandelsgesetz": German Securities Trading Act). The preparation of the condensed consolidated interim financial statements in accordance with the IFRS applicable to interim financial reporting as adopted by the EU and of the interim group management report in accordance with the provisions of the German Securities Trading Act applicable to interim group management reports is the responsibility of the parent Company's Board of Managing Directors. Our responsibility is to issue a review report on the condensed consolidated interim financial statements and on the interim group management report based on our review.

We conducted our review of the condensed consolidated interim 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) and additionally in accordance with the International Standard on Review Engagements "Review of Interim Financial Information Performed by the Independent Auditor of the Entity" (ISRE 2410). Those standard require that we plan and perform the review so that we can preclude through critical evaluation, with moderate assurance, that the condensed consolidated interim financial statements have not been prepared, in all material respects, in accordance with the IFRS applicable to interim financial reporting as adopted by the EU and that the interim group management report has not been prepared, in all material respects, in accordance with the provisions of the German Securities Trading Act applicable to interim group management reports. A review is limited primarily to inquiries of company personnel and analytical procedures and thus provides less assurance than an audit. Since, in accordance with our engagement, we have not performed a financial statement audit, we cannot express an audit opinion.

Based on our review, no matters have come to our attention that cause us to presume that the condensed consolidated interim financial statements have not been prepared, in all material respects, in accordance with the IFRS applicable to interim financial reporting as adopted by the EU nor that the interim group management report has not been prepared, in all material respects, in accordance with the provisions of the German Securities Trading Act applicable to interim group management reports.

Cologne, Germany, August 9, 2017

Ernst & Young GmbH

Wirtschaftsprüfungsgesellschaft

(s) Gockel

(s) Conrad

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 2017	2016
Numbers of shares at the end of the period	58,256,591	55,757,094
Average daily trading volume (Xetra, FSE)	201,580	194,107
Year high (Xetra closing price)	EUR 3.30 (26 June 2017)	EUR 2.95 (17 Oct 2016)
Year low (Xetra closing price)	EUR 2,15 (22 Mar 2017)	EUR 1.08 (11 Feb 2016)
Share price at the end of the period	EUR 3.19	EUR 2.45
Market capitalization at the end of the period (Xetra)	EUR 186 m	EUR 137 m

Corporate Calendar

16 March 2017	Publication of the financial results 2016
10 May 2017	Publication of the financial results of the first quarter 2017
17 May 2017	Annual General Meeting, Aachen
09 August 2017	Publication of the financial results of the second quarter and the first half-year 2017
08 November 2017	Publication of the financial results of the third quarter and the first nine months of 2017

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