PAION HI#2019

Consolidated Financial Interim Report for the First Half-Year 2019

Contents

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30.06.
2019

PAION AG

PAION

About PAION AG

PAION AG is a publicly listed specialty pharmaceutical company developing and aiming to commercialize innovative drugs for 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 for which PAION has completed the clinical development for use in procedural sedation in the U.S. and its local licensee Cosmo Pharmaceuticals submitted a New Drug Application in April 2019. In Japan, licensee Mundipharma filed for market approval for remimazolam in general anesthesia in December 2018. In China, licensee Yichang Humanwell filed for market approval for remimazolam in procedural sedation in November 2018.

In Europe, PAION is seeking approval for remimazolam in the indications general anesthesia and procedural sedation. For the development of remimazolam in general anesthesia, PAION is currently conducting a Phase III trial in Europe. The submission of a Marketing Authorization Application in procedural sedation in the EU is planned based on the U.S. development program.

Development of remimazolam for intensive care unit (ICU) sedation is part of the longer-term life-cycle plan for remimazolam.

PAION's vision is to become an acknowledged "PAIONeer" in sedation and anesthesia. PAION is headquartered in Aachen (Germany) with an additional site in Cambridge (United Kingdom).

Key Figures

(all figures in KEUR unless otherwise noted)	Q2 2019	Q2 2018	H1 2019	H1 2018
Revenues	7,500	260	7,500	517
Research and development expenses	-3,110	-3,184	-6,173	-6,544
General administrative and selling expenses	-1,336	-966	-2,321	-1,761
Result for the period	3,827	-3,118	586	-6,243
Earnings per share in EUR for the period (basic)	0.06	-0.05	0.01	-0.10
Earnings per share in EUR for the period (diluted)	0.06	-0.05	0.01	-0.10

	H1 2019	H1 2018
Cash flows from operating activities	1,990	-6,626
Cash flows from investing activities	-4	-12
Cash flows from financing activities	-25	5,067
Change in cash and cash equivalents	1,965	-1,572
Average number of group employees	44	38

	30-06-2019	31-12-2018
Intangible assets	2,119	2,212
Cash and cash equivalents	19,192	17,227
Equity	21,384	20,822
Current liabilities	4,258	3,501
Balance sheet total	25,672	24,323

Interim Group Management Report for the First Half-Year 2019

The First Six Months at a Glance

April

PAION announces submission of New Drug Application (NDA) for remimazolam by its licensee Cosmo Pharmaceuticals (Cosmo) in the U.S.

June

Food & Drug Administration (FDA) accepts NDA for remimazolam in the U.S. for review

PAION and the European Investment Bank (EIB) sign financing agreement for EUR 20 million

Update on development activities and Outlook

U.S.

The NDA in procedural sedation was prepared together with Cosmo and submitted to the FDA by Cosmo beginning of April 2019. The FDA informed Cosmo on 10 June 2019 that the filing has been accepted. The PDUFA date (Prescription Drug User Fee Act) was set for 05 April 2020. The PDUFA date is a target date until which the FDA review is supposed to be completed. However, the FDA has no obligation to actually complete the review by this date.

With a regular course of the approval process, the U.S. market approval and subsequent launch of remimazolam can be expected in 2020.

EU

In Europe, PAION is seeking approval for remimazolam in the indications general anesthesia and now also in procedural sedation. PAION plans to submit a Marketing Authorization Application (MAA) in procedural sedation later this year, after having discussed in the course of a pre-submission meeting with the European Medicines Agency (EMA) held in February 2019 that the existing data package from the U.S. Phase III clinical development program will be sufficient for submitting the MAA for remimazolam in procedural sedation in the EU. The submission is subject to EMA approval of the Pediatric Investigation Plan (PIP). Consequently, PAION overall expects an earlier market entry in Europe. Following approval in procedural sedation, an extension of the dossier, a so-called type-II variation, would allow for an abbreviated application for general anesthesia that is processed significantly faster. The indication can be extended once market approval in procedural sedation has been granted and the data from the ongoing EU Phase III clinical trial in general anesthesia are available. The randomized, single-blind, propofol-controlled, confirmatory Phase III trial with remimazolam for the induction and maintenance of general anesthesia is expected to enroll approx. 500 ASA III/IV patients (American Society of Anesthesiologists classification III to IV) in Europe undergoing non-emergency surgery.

Currently, more than 200 patients have been treated. The opening of additional sites has been initiated in order to accelerate the recruitment process. Completion of patient recruitment is expected in the first quarter of 2020. Due to the new approval strategy for Europe, this adjustment will probably have no time implication on the planned start of

commercialization in general anesthesia. The complete data from the EU phase III study, which are required for the regulatory process of an indication extension by general anesthesia, are expected to be available at the time of approval of the MAA in procedural sedation allowing for the timely application for an extension of the remimazolam MAA for the indication general anesthesia afterwards.

Licensee activities in other territories

PAION's licensees are preparing the future filings of remimazolam in their respective territories through regulatory interactions.

Japanese licensee Mundipharma submitted a market approval dossier for remimazolam in the indication general anesthesia to the Japanese Pharmaceuticals and Medical Devices Agency (PMDA) in December 2018. Market approval could be granted end of 2019 at the earliest.

Chinese licensee Yichang Humanwell submitted a market approval dossier for remimazolam in the indication procedural sedation to the Chinese National Medical Products Administration (NMPA) in November 2018. Market approval could be granted end of 2019 at the earliest.

In November 2018, Russian licensee R-Pharm announced the successful completion of a Phase III trial with remimazolam in general anesthesia. R-Pharm currently plans to file for market approval in Russia by the end of 2019. For the license territory Turkey, Middle East and North Africa, it is planned to file for market approval in Turkey based on the U.S. or Japanese dossier.

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

PAION’s licensee Hana Pharm successfully completed patient recruitment of a Phase III trial with remimazolam in general anesthesia in October 2018. Hana Pharm plans to file for market approval by the end of 2019.

Funding activities

In June 2019, PAION and the EIB signed a financing agreement for a loan with a total volume of up to EUR 20 million. The loan will be available until June 2021 and can be drawn down in a total of three tranches based on certain conditions as e.g. the achievement of operational milestones. PAION plans to draw down the first tranche of EUR 5 million within six months after signing. Each tranche has a term of five years and will be repaid beginning in the fourth year after drawdown.

Financial Overview

In the first half-year 2019, revenues amounting to EUR 7.5 million (prior-year period: EUR 0.5 million) were generated resulting from the milestone payment in connection with the submission of the NDA in procedural sedation in the U.S. by licensee Cosmo. Research and development expenses amounted to EUR 6.2 million as compared to EUR 6.5 million in the prior-year period and were mainly incurred in connection with the ongoing EU Phase III study in general anesthesia. General administrative and selling expenses increased by EUR 0.6 million compared to the prior-year period, particularly in the course of activities for the set-up of the supply chain for remimazolam. In total, a net income of EUR 0.6 million has

been incurred in the first half-year 2019 compared to a net loss of EUR 6.2 million in the prior-year period.

Cash and cash equivalents increased by EUR 2.0 million in the first half-year 2019 compared to 31 December 2018 and amounted to EUR 19.2 million as of 30 June 2019. Based on current planning, cash and cash equivalents at hand, including expected tax credits from the British tax authorities on parts of research and development expenses, secure a liquidity runway into the second half of 2020. PAION expects to require further funds of approx. EUR 10 million until filing for market approval in general anesthesia in the EU. This cash requirement could partially or completely be covered by the financing agreement with the EIB. In addition, PAION is looking into complementing financing measures as additional funds will be required in the next years for the planned own commercialization in selected European markets as well as the intended development of the indication ICU sedation and for the multi-year PIP. The magnitude of the required funds will be dependent on the actual setup of commercialization and which European countries PAION will initially focus on as well as the timing and the amount of milestone payments and royalties from licensees.

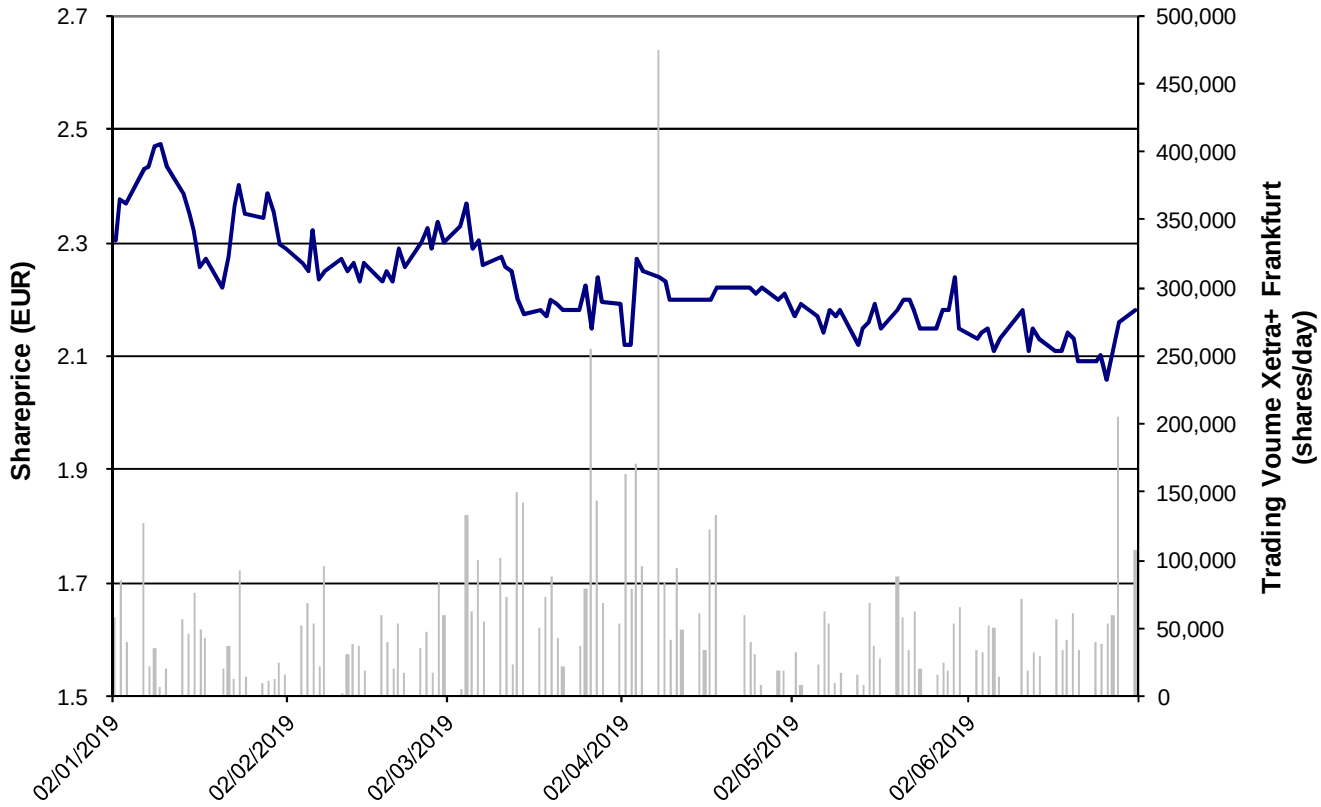
Capital Market Environment and PAION Share Performance

The development of the German capital markets in the first half of 2019 was mainly still impacted by continuously low interest rates, asset purchases by the European Central Bank, U.S. monetary policy and global trade wars. The DAXsubsector Biotechnology Index increased by 26.6% and the NASDAQ Biotechnology Index also increased by 12.6% in the first six months of 2019.

The PAION share started the year 2019 with a price of EUR 2.31 (Xetra closing price). The peak share price in the first half-year 2019 was marked on 10 January 2019 with EUR 2.48 based on Xetra closing prices. On 25 June 2019, the lowest price in the first half-year 2019 was marked at EUR 2.06 (Xetra). The closing price on 28 June 2019 was EUR 2.16 (Xetra). This corresponds to a decrease of approx. 1.4% compared to the closing price on 28 December 2018 (EUR 2.19; Xetra).

The average daily trading volume (Xetra and Frankfurt Stock Exchange) amounted to 57,615 shares during the first half of 2019 (in the year 2018: 60,451 shares). Thereby, 7.2 million shares were traded during the first half of 2019 (in the year 2018: 15 million shares).

Development of the PAION Share Price and Volume (Xetra) in the First Half-Year 2019



Overview of Research and Development Activities

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

Remimazolam

Remimazolam is an ultra-short-acting intravenous benzodiazepine sedative/anesthetic that has shown positive results in clinical Phase III trials. In the human body, remimazolam is rapidly metabolized to an inactive metabolite by tissue esterases and is not metabolized by cytochrome-dependent hepatic pathways. Like other benzodiazepines, remimazolam can be reversed with flumazenil to rapidly terminate sedation or anesthesia if necessary. During clinical studies, remimazolam demonstrated efficacy and safety with around 2,400 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.

PAION has completed clinical development of remimazolam for procedural sedation in the U.S. The U.S. licensee Cosmo submitted an NDA in procedural sedation in the U.S. in April 2019 and is responsible for any further development activities in the U.S. In Japan, licensee Mundipharma filed for market approval in general anesthesia in December 2018. In China, licensee Yichang Humanwell filed for market approval in procedural sedation in November 2018. In Europe, PAION initiated a Phase III study in general anesthesia in July 2018.

In addition to procedural sedation and general anesthesia, based on positive Phase II study results, ICU sedation beyond 24 hours is another possible attractive indication for further development in the EU by PAION as well as by its licensees in other territories.

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

Procedural Sedation Market

Based on external sources (Symphony Health Solutions, Centers for Disease Control and Prevention) and own projections, PAION estimates that 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 colonoscopies, as well as an increase in general demand for preventive screenings. According to iData Research, which examines historical trends and creates procedure forecasts in the U.S. drawing from an extensive collection of national- and state-level procedure databases, 26.7 million colonoscopy and endoscopy claims were reported in 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.

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

social insurance program), since effective prevention is considered to reduce the likelihood of incidence of illnesses such as cancer, thereby reducing the suffering of patients and related financial burden to be borne by the payors. Statistics show that the rate at which people are diagnosed with colon cancer in the U.S. has dropped by 30% between 2005 and 2015 for those aged 50 years and older, partly due to more people getting recommended screening tests. Colorectal cancer is the third most diagnosed cancer and the third leading cause of cancer death in the U.S. Despite the decrease of colorectal cancer death rates as a result of early screening and detection, it was reported in 2010 that only 59% of people aged 50 or older, for whom screening is recommended, reported having received colorectal cancer testing consistent with current guidelines. The market for endoscopies in gastroenterology represents the most lucrative market segment for remimazolam in procedural sedation with approximately 20 million procedures per year in the U.S.

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

In the U.S. increased enrollment and screenings are expected to result in a performance-based payment system that will seek to better align payments with high quality of care measures. This would imply that cost-efficient medicines with clinical value will be used more extensively and that continued premium prices will be paid for innovative medicines with strong clinical profile. Thus, PAION believes that concerns related to the overall cost of procedures, driven by the need for 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.[1] Accordingly, PAION expects reimbursement regimes under national and commercial healthcare systems, such as Medicare, which differentiate the amounts reimbursed to physicians and/or patients depending on whether an anesthesia professional's service is used, may also positively impact the demand for products that do not require monitoring by an anesthesia professional.

PAION expects that remimazolam, subject to FDA approval with a safety labeling comparable to that of midazolam, could benefit from the pending changes in payment policies. Provided that it could be administered under the supervision of a proceduralist, remimazolam

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

would be able to offer a competitive alternative to midazolam. This is based on its enhanced efficiency profile compared to midazolam.

PAION plans to submit an MAA in procedural sedation later this year, after having discussed at a pre-submission meeting with the EMA in February 2019 that the existing data package from the U.S. Phase III clinical development program will be sufficient for filing for market approval for remimazolam in procedural sedation in the EU. The submission is subject to EMA approval of the PIP.

In the EU, based on its own projections for procedural sedation, PAION currently estimates an annual peak sales potential of approx. EUR 75 million. In contrast to the U.S. market which has a large freestanding ambulatory surgery healthcare infrastructure, procedural sedation in Europe is mainly a hospital-based activity where anesthesiologists have the overall responsibility for the sedation of patients. This entails a high potential for synergies with the planned commercialization of remimazolam for use in general anesthesia.

General Anesthesia Market

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

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

Accordingly, PAION believes that in the EU the demand for safer agents with low respiratory and cardio-depressive effects will increase over the coming years, creating opportunities for anesthetics with an enhanced safety profile such as remimazolam, even at higher prices compared to existing generic drugs. PAION also expects similar developments for the U.S. and other important international markets, subject to further market research. In the EU, based on its own projections for general anesthesia, PAION currently estimates an annual peak sales potential of approx. EUR 150 million to EUR 200 million.

In adults, myocardial injury during noncardiac surgery (MINS) is the most common cardiovascular complication associated with such surgery. Investigations conclude that MINS occurs in about 8% of the approximately 200 million patients yearly worldwide and leads to an increased morbidity. Approximately 10% of patients suffering such injury die within 30

days after surgery. The suspected cause of this is, inter alia, a (too) low blood pressure and a concomitant temporary undersupply of the heart muscle with oxygen during the procedure.[2] Based on the safety data available to date, remimazolam could contribute significantly to reducing this mortality rate by reducing intraoperative blood pressure drops.

Intensive care unit (ICU) sedation market

Plans for further development of remimazolam for use in ICU sedation in the future are based on PAIONs expectation that the market for ICU sedation will present an attractive business opportunity. Based on available information from 2012 published in Critical Care Medicine which estimates average days of care in ICUs per year in the U.S., and journal articles published in the Intensive Care Medicine in 2012, which records, among others, the volume of ICU admissions per year and the number of total adult beds in various countries in the EU, PAION estimates that there are approximately 14 million ICU patient days requiring ICU sedation in the U.S. and EU combined per year. PAION expects this number to increase in the years to come, driven by demand from the aging population in both regions. PAION believes that such development, in turn, will foster demand for safer agents such as remimazolam, given the fact that elderly patients are much more likely to suffer from systemic health problems.

Internationally renowned anesthesiologists have repeatedly confirmed to PAION that ICU sedation bears an attractive market potential. However, development would be associated with the highest risk of side effects given the treatment of severely ill patients. For this reason, initially development in general anesthesia has priority for PAION.

[2] Khan, J. et al. (2014): Myocardial injury after noncardiac surgery, Current Opinion in Cardiology, 2014 Jul, 29(4):307-11; Abbott, T. E. F. et al. (2019): Depth of Anesthesia and Postoperative Delirium, in JAMA, 2019, 321(5):459-460.

Phase II and III studies	Phase I studies
Procedural Sedation (U.S.)- completed	
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 • Intravenous administration (40) • Oral bioavailability (14) • Oral administration with alcohol (20) • Intranasal administration (12)
General Anesthesia (Japan)- completed	
Phase II Induction and maintenance of anesthesia in general surgery (85) Phase 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 III in general surgery (approx. 500)**	Phase I PK/PD modeling study (EEG) in healthy volunteers (20)
ICU Sedation (Japan)	
Phase II in ICU patients (49)*	
Studies in other territories	
Phase III in general anesthesia - Russia (150) Phase III in general anesthesia - South Korea (198) Phase II in procedural sedation - China (150) Phase III in procedural sedation - China (480) Phase IIa dose finding study - China (24)	Phase I single ascending dose in China (62) Phase I continuous infusion in China (12)

Patient/volunteer numbers in brackets

* Discontinued studies, no safety concerns

** Ongoing study

Procedural sedation (U.S. + China)

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

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

The first U.S. Phase III study was successfully completed in 2016, and the primary efficacy endpoint was achieved. The Phase III trial enrolled 461 patients at 13 U.S. sites and was designed to evaluate the efficacy and safety of remimazolam compared to placebo (with midazolam rescue) in patients undergoing proceduralist-administered sedation for colonoscopy. In addition, the study had an open-label midazolam arm.

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

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

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

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

Patient satisfaction was similar in all arms of the study.

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

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

The study was successfully completed in 2017, and the primary efficacy endpoint was achieved. The Phase III trial enrolled 446 patients at 15 U.S. sites and was designed to evaluate the efficacy and safety of remimazolam compared to placebo (with midazolam rescue medication) in procedural sedation in patients undergoing bronchoscopy.

The primary outcome measure was a composite endpoint defined as: no need for rescue medication, completion of the procedure and no more than 5 doses within any 15-

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

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

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

Summary of headline data of the three Phase III studies:

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

* not part of label claim

Based on the results of preclinical and Phase I studies and in consultation with the FDA, PAION conducted additional Phase I studies to further assess the abuse potential of remimazolam. Two aspects were being studied: if remimazolam could inappropriately be used as a knock-out cocktail in combination with alcohol and if it could be abused intranasally. In November 2017, the FDA informed PAION that it determines the abuse liability program conducted by PAION as sufficient to provide the necessary data regarding the abuse potential of remimazolam in humans. PAION therefore assumes the clinical development program for remimazolam in procedural sedation in the U.S. as completed and Cosmo filed for market approval in April 2019.

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

A total of six Phase I, three Phase II and four Phase III trials 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 and clinical data confirmed that a better hemodynamic stability can be reached with remimazolam than with propofol.

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

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

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

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

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

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

The randomized, single-blind, propofol-controlled, confirmatory Phase III trial is expected to enroll approx. 500 ASA III/IV patients (American Society of Anesthesiologists classification III to IV) undergoing non-emergency surgery.

The primary objective of the trial is to demonstrate the non-inferiority of remimazolam compared to propofol for the induction and maintenance of general anesthesia during elective surgery. The key secondary objective is to show improved hemodynamic stability (avoidance of intraoperative drop of blood pressure and vasopressor usage) compared to propofol.

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

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

ICU sedation

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

The observed phenomenon of elevated remimazolam plasma concentrations was subsequently thoroughly investigated using a series of preclinical tests and pharmacokinetic models. None of these experiments was able to reproduce the findings or

provide a mechanistic explanation for the elevated plasma concentrations. Further analysis has revealed that such pharmacokinetic deviations are common for utilization of sedatives like midazolam and propofol on the ICU and the most likely explanation is the underlying serious condition of patients presenting on the ICU. Further development of the program "ICU sedation" is part of the future remimazolam development plan which could be addressed after availability of required funds.

Pediatric development

Another field of high clinical need is pediatric use, which is a development requirement for both the EU and U.S. after the respective first approval.

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

Partnerships, regulatory and commercial activities

Development and commercialization collaborations with partners with local expertise or with a specific therapeutic focus with respect to remimazolam are an effective way of funding and advancing remimazolam's development and of assisting PAION with its commercialization in international markets where PAION does not intend to directly conduct sales and marketing activities. PAION expects that the existing licensees 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. In order to exploit remimazolam's full potential, it is PAION's defined target to commercialize remimazolam on its own in selected European markets immediately after a potential market approval. PAION is well positioned to find further licensees. Pharmaceutical companies have a growing need to add drugs to their pipeline that have already demonstrated proof of concept in advanced stages of clinical trials and also provide a commercially viable alternative in a global healthcare environment characterized by increasing cost consciousness.

Remimazolam is partnered in the U.S. (Cosmo Pharmaceuticals), Japan (Mundipharma), China (Yichang Humanwell), Canada (Pharmascience), Russia/CIS, Turkey

and the MENA region (R-Pharm) as well as South Korea (Hana Pharm). For all other markets outside the EU, remimazolam is available for licensing.

PAION's U.S. licensee Cosmo filed an NDA for remimazolam in procedural sedation with the FDA in April 2019. With a regular course of the approval process, approval is expected in 2020.

Japanese licensee Mundipharma submitted a market approval dossier for remimazolam in the indication general anesthesia to the Japanese regulatory authority PMDA in December 2018. Market approval could be granted end of 2019 at the earliest.

Chinese licensee Yichang Humanwell submitted a market approval dossier for remimazolam in the indication procedural sedation to the Chinese regulatory authority NMPA in November 2018. Market approval could be granted end of 2019 at the earliest.

In November 2018, Russian licensee R-Pharm announced the successful completion of a Phase III trial with remimazolam in general anesthesia. R-Pharm currently plans to file for market approval in Russia by the end of 2019. For the license territory Turkey, the Middle East and North Africa, it is planned to file for market approval in Turkey based on the U.S. or Japanese dossier.

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

PAION's licensee Hana Pharm successfully completed patient recruitment of a Phase III trial with remimazolam in general anesthesia in October 2018. Hana Pharm plans to file for market approval by the end of 2019.

In Europe, PAION is seeking approval for remimazolam in the indications general anesthesia and now also in procedural sedation. PAION plans to submit an MAA in procedural sedation later this year, after having discussed in the course of a pre-submission meeting with the EMA held in February 2019 that the existing data package from the U.S. Phase III clinical development program will be sufficient for submitting the MAA for remimazolam in procedural sedation in the EU. The submission is subject to EMA approval of the PIP. Consequently, PAION overall expects an earlier market entry in Europe. Following approval in procedural sedation, an extension of the dossier, a so-called type-II variation, would allow for an abbreviated application for general anesthesia that is processed significantly faster. The indication can be extended once market approval in procedural sedation has been granted and the data from the ongoing EU Phase III clinical trial in general anesthesia are available.

Upfront and milestone payments			
	Total received	Maximum outstanding amount	Royalty rate
Ono, Japan (2007) (terminated in 2015)	USD 8 m	None	None
Yichang Humanwell, China (2012)	EUR 3.5 m[5]	EUR 0.5 m	10%[5]
Hana Pharm, S. Korea (2013)	EUR 1.5 m	EUR 1.5 m	10%
R-Pharm, CIS (2013)	EUR 1 m	EUR 3 m	Low double-digit
R-Pharm, Turkey (2013)	EUR 1 m	EUR 3 m	Low double-digit
R-Pharm, MENA (2014)	EUR 1.5 m	EUR 5.5 m	Low double-digit
Pharmascience, Canada (2014)	EUR 0.4 m[1]	~ EUR 3.8 m	Tiered (starting at 15%)
Cosmo, U.S. (2016)	EUR 27.5 m[2]	EUR 35 m	20%–25%[3]
Mundipharma, Japan (2017)	EUR 2 m	EUR 24 m	Up to over 20%[4]
Total	EUR 44.3 m	~ EUR 76.3 m	

1) This amount relates to the premium received in the course of the private placement in the amount of EUR 4 million in July 2014 which was disclosed as revenues in 2014.
2) Comprising EUR 10 million received via private placement in June 2016 and via capital increase with subscription rights conducted in February 2017, the upfront payment of EUR 10 million received in 2016 as well as the the milestone payment of EUR 7.5 million received in 2019
3) Subject to adjustments under specific circumstances, but not below 15% of net sales
4) Tiered royalties starting in the low double-digits to over 20%
5) In case of occurrence of certain market conditions in China, PAION is obliged to pay back 50% of the milestone payments already received (partially to bet set off against royalties). In this case, royalties would drop to 5%.

Vision: Specialty Pharma Company with own sales in the EU

In order to become a leader in the anesthesia field, forward integration in the EU is essential for PAION in the near future. For PAION, forward integration does not only imply the buildup of an own distribution for the future commercialization of remimazolam in selected markets in the EU, but also the use of these structures as a platform for future products in order to develop the greatest possible synergy potential. Forward integration provides an opportunity to capture more value. The goal is to grow significantly in the medium to long term. Until then, the product portfolio in the field of anesthesia and critical care is planned to be enriched with innovative medicines.

Net Assets, Financial Position, and Results of Operations

Results of Operations

	Q2 2019 KEUR	Q2 2018 KEUR	H1 2019 KEUR	H1 2018 KEUR
Revenues	7,500	260	7,500	517
Gross profit	7,500	260	7,500	517
Research and development expenses	-3,110	-3,184	-6,173	-6,544
General administrative and selling expenses	-1,336	-966	-2,321	-1,761
Other income (expenses)	275	30	415	52
Operating expenses	-4,171	-4,120	-8,079	-8,253
Operating result	3,329	-3,860	-579	-7,736
Financial result	-1	2	-1	4
Income taxes	499	740	1,166	1,489
Net result for the period	3,827	-3,118	586	-6,243

Revenues in the first half-year 2019 amounted to KEUR 7,500 and entirely resulted from the milestone payment from U.S. licensee Cosmo in connection with the submission of the NDA for remimazolam in the indication procedural sedation in the U.S. Revenues in the prior-year period primarily resulted from the license agreement with Japanese remimazolam licensee Mundipharma.

Research and development expenses amounted to KEUR 6,173 in the first half-year 2019 (prior-year period: KEUR 6,544) and mainly relate to the EU Phase III trial in general anesthesia.

General administrative and selling expenses increased by KEUR 560 to KEUR 2,321 in the first half-year 2019 compared to the prior-year period. General administrative expenses increased by KEUR 185 to KEUR 1,790 and selling expenses increased by KEUR 375 to KEUR 531. The increase of selling expenses particularly relates to the set-up of the supply chain for remimazolam.

Other income (expenses) includes (net) foreign exchange gains of KEUR 239 in the first half-year 2019 (prior-year period: KEUR 20).

Income taxes amounted to KEUR 1,166 in the first half-year 2019 (prior-year period: KEUR 1,489) and relate to tax claims for reimbursement of parts of the research and development expenses from the British tax authorities. The decrease is primarily attributable to a cap of the claim based on the net result.

The **net income** for the first half-year 2019 amounted to KEUR 586 compared to a net loss of KEUR 6,243 in the prior-year period. This means an increase of the net result in the amount of KEUR 6,829 compared to the first half-year 2018 which is mainly attributable to higher revenues than in the prior-year period.

Net Assets

	30-06-2019 KEUR	31-12-2018 KEUR	Change KEUR
Non-current assets	2,258	2,286	-28
Current assets	23,414	22,037	1,377
Total Assets	25,672	24,323	1,349
Equity	21,384	20,822	562
Non-current liabilities	30	0	30
Current liabilities	4,258	3,501	757
Total Equity and liabilities	25,672	24,323	1,349

Non-current assets mainly comprise the development project remimazolam (KEUR 2,075).

Current assets consist of cash and cash equivalents (KEUR 19,192) as well as prepaid expenses and other assets (KEUR 4,222). The increase of KEUR 1,377 as compared to 31 December 2018 is attributable to an increase of cash and cash equivalents by KEUR 1,965 and prepaid expenses and other assets by KEUR 912 as well as a decrease of trade receivables by KEUR 1,500. The increase of prepaid expenses and other assets mainly stems from a KEUR 1,139 higher tax claim for reimbursement of parts of the research and development expenses from the British tax authorities as compared to 31 December 2018, and the decrease of trade receveivables results from the receipt of payments of receivables recognized on the balance sheet as of 31 December 2018 in connection with the filing of the market approval dossier for remimazolam in Japan.

The increase in **equity** of KEUR 562 compared to 31 December 2018 mainly results from the net result of the first half-year 2019 in the amount of KEUR 586. As of 30 June 2019, the equity ratio was 83.3% (31 December 2018: 85.6%).

Non-current liabilities comprise lease liabilities.

Current liabilities increased by KEUR 757 compared to 31 December 2018 mainly due to an increase of trade payables by KEUR 735.

Financial Position

Compared to 31 December 2018, **cash and cash equivalents** increased by KEUR 1,965 to KEUR 19,192 at the end of the current reporting period. The change in cash and cash equivalents stems from the following areas:

	H1 2019 KEUR	H1 2018 KEUR
Cash flows from operating activities	1,990	-6,626
Cash flows from investing activities	-4	-12
Cash flows from financing activities	-25	5,067
Effects of exchange rate changes	4	-1
Change in cash and cash equivalents	1,965	-1,572

The **cash flows from operating activities** in the first half-year 2019 were KEUR 1,990 and primarily resulted from the net income, adjusted for the current tax credit claim towards the British tax authorities which has not had a cash effect yet, receipt of the milestone payments from Mundipharma and Hana Pharm recognized as trade receivables at the beginning of the fiscal year as well as (further) changes of the working capital.

The **cash flows from financing activities** of KEUR -25 in the first half-year 2019 entirely related to the principal portion of lease payments.

Personnel Development

On average, PAION employed 44 employees in the first six months of 2019 (fiscal year 2018: 39 employees). As of 30 June 2019, the headcount was 46.

Changes in the Supervisory Board

At the Annual General Meeting on 22 May 2019, Dr. Markus Leyck Dieken was elected to the Supervisory Board as successor of Mr. John Dawson.

Risks and Opportunities

Material risks and opportunities relating to future development are presented in detail in the group management report for the fiscal year 2018 and have not changed significantly in the first half-year 2019.

Significant Events Occurring After the Balance Sheet Date

There were no significant events in the period between the reporting date, 30 June 2019, and the preparation of this report.

Report on expected developments

Outlook on Development and Commercialization Activities

PAION's major focus for the remainder of 2019 is on the development program in Europe, the ongoing global regulatory processes as well as the manufacture of and supply chain for remimazolam. Moreover, PAION expects the development and approval activities in all territories to also further promote the other indications.

Europe

For the EU, PAION is working on the advancement of the clinical development program of remimazolam. Focus for 2019 are the conduct of the ongoing Phase III study in general anesthesia as well as initial development work to address the PIP stretching over several years. As a result of the consultation with EMA, PAION plans to file for market approval in procedural sedation in the EU based on the data from the U.S. development program still in 2019.

U.S.

In the U.S., supporting licensee Cosmo in answering possible questions from the FDA following the submission of the NDA in procedural sedation has the highest priority. With a regular course of the approval process, start of commercialization of remimazolam in the U.S. can be expected in 2020.

Rest of the World

PAION supports its licensees in the preparation and filing of approval dossiers. In China, licensee Yichang Humanwell filed for market approval of remimazolam in November 2018 leading to a possible market approval end of 2019 at the earliest in case of a positive approval process. In Japan, licensee Mundipharma filed for market approval of remimazolam in December 2018; market approval could be granted end of 2019 at the earliest.

PAION expects its other regional remimazolam licensees to continue their remimazolam development activities and/or the preparation of market approval dossiers. Licensee R-Pharm plans to file for market approval in Russia by the end of 2019. Hana Pharm expects to file for market approval in South Korea by the end of 2019.

Further activities

PAION is working on setting up the supply chain in order to be able to provide remimazolam product to the licensees timely for commercial use as well as having it available early enough for PAION's own commercialization.

Also, PAION is conducting small-scale pre-marketing activities for the preparation of an own commercialization for remimazolam in selected European markets.

Financial outlook 2019

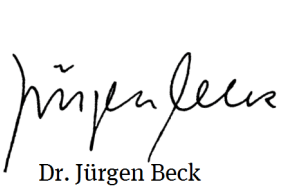
PAION expects revenues of about EUR 8 million in 2019, thereof EUR 7.5 million already recognized in connection with the regulatory filing for remimazolam in the U.S. by Cosmo, which took place in April 2019. Moreover, EUR 0.5 million are related to revenues from R-Pharm in connection with the transfer of the Japanese filing dossier translated into English or transfer of the U.S. filing dossier.

Due to the ongoing investment in the development of remimazolam including the EU Phase III study, PAION expects research and development expenses to amount to between approx. EUR 13 million and approx. EUR 15 million, depending on the progress of development. Income from tax credits on parts of research and development expenses from British tax authorities is expected to amount to approx. EUR 2 million. General administrative and selling expenses are expected to amount to between approx. EUR 4 million and approx. EUR 5 million depending on the volume of precommercial activities. Net loss is expected to amount to between approx. EUR 7 million and approx. EUR 10 million in 2019.

This outlook assumes that PAION and licensee activities progress as expected. In case of delays, essential cost blocks would shift into 2020 or subsequent periods. Plans are also based on the current status of discussions with regulatory authorities.

Based on current planning, cash and cash equivalents at hand, including expected tax credits from the British tax authorities on parts of research and development expenses, secure a liquidity runway into the second half of 2020. PAION expects to require further funds of approx. EUR 10 million until filing for market approval in general anesthesia in the EU. This cash requirement could partially or completely be covered by the financing agreement with the EIB. In addition, PAION is looking into complementing financing measures as additional funds will be required in the next years for the planned own commercialization in selected European markets as well as the intended development of the indication ICU sedation and for the multi-year PIP. The magnitude of the required funds will be dependent on the actual setup of commercialization and which European countries PAION will initially focus on as well as the timing and the amount of milestone payments and royalties from licensees.

Aachen, Germany, 07 August 2019
PAION AG


Dr. Wolfgang Söhngen Dr. Jürgen Beck Abdelghani Omari

Condensed Consolidated Interim Financial Statements

Consolidated Balance Sheet

ASSETS	30 June 2019 EUR	31 Dec. 2018 EUR
Non-current assets		
Intangible assets	2,118,747.34	2,212,476.80
Equipment	59,486.05	73,569.84
Right-of-use assets	79,638.73	0.00
Other assets	13.93	13.93
	2,257,886.05	**2,286,060.57**
Current assets		
Trade receivables	0.00	1,500,000.00
Prepaid expenses and other assets	4,222,076.70	3,310,694.39
Cash and cash equivalents	19,191,529.76	17,226,658.20
	23,413,606.46	**22,037,352.59**
Total assets	**25,671,492.51**	**24,323,413.16**

EQUITY AND LIABILITIES	30 June 2019 EUR	31 Dec. 2018 EUR
Equity		
Share capital	63,858,143.00	63,858,143.00
Capital reserve	138,946,611.69	138,730,764.25
Translation reserve	-952,317.63	-712,030.72
Loss carryforward	-181,054,833.90	-171,115,423.14
Result for the period	586,174.30	-9,939,410.76
	21,383,777.46	**20,822,042.63**
Non-current liabilities		
Lease liabilities	29,881.51	0.00
Current liabilities		
Trade payables	2,952,803.71	2,217,979.06
Provisions	644,020.28	629,506.26
Lease liabilities	50,464.52	0.00
Other current liabilities	610,545.03	653,885.21
	4,287,715.05	**3,501,370.53**
Total equity and liabilities	**25,671,492.51**	**24,323,413.16**

Consolidated Statement of Comprehensive Income

EUR	1 April – 30 June 2019	1 April – 30 June 2018	1 January – 30 June 2019	1 January – 30 June 2018
Revenues	7,500,000.00	259,784.71	7,500,000.00	517,168.28
Gross profit	7,500,000.00	259,784.71	7,500,000.00	517,168.28
Research and development expenses	-3,109,127.03	-3,184,505.66	-6,172,304.11	-6,544,355.73
General administrative and selling expenses	-1,336,526.45	-965,421.53	-2,321,342.57	-1,760,642.32
Other income (expenses), net	275,037.14	30,441.96	415,037.63	52,353.11
Operating expenses	-4,170,616.34	-4,119,485.23	-8,078,609.05	-8,252,644.94
Operating result	3,329,383.66	-3,859,700.52	-578,609.05	-7,735,476.66
Financial income	100.05	1,832.79	660.51	3,609.82
Financial expenses	-790.36	0.00	-1,699.49	0.00
Financial result	-690.31	1,832.79	-1,038.98	3,609.82
Result for the period before taxes	3,328,693.35	-3,857,867.73	-579,648.03	-7,731,866.84
Income taxes	498,754.09	739,679.90	1,165,822.33	1,488,817.44
Result for the period	3,827,447.44	-3,118,187.83	586,174.30	-6,243,049.40
of which attributable to other shareholders	0.00	0.00	0.00	0.00
of which attributable to shareholders of PAION	3,827,447.44	-3,118,187.83	586,174.30	-6,243,049.40
Foreign currency translation	-387,660.46	-11,429.13	-240,286.91	-18,017.28
Total income and expense recognized directly in equity that will be reclassified to profit or loss when specific conditions are met	-387,660.46	-11,429.13	-240,286.91	-18,017.28
Other comprehensive income	-387,660.46	-11,429.13	-240,286.91	-18,017.28
Total comprehensive income	3,439,786.98	-3,129,616.96	345,887.39	-6,261,066.68
of which attributable to other shareholders	0.00	0.00	0.00	0.00
of which attributable to shareholders of PAION	3,439,786.98	-3,129,616.96	345,887.39	-6,261,066.68
Earnings per share (basic)	0.06	-0.05	0.01	-0.10
Earnings per share (diluted)	0.06	-0.05	0.01	-0.10

Consolidated Cash Flow Statement

EUR	1 January – 30 June 2019	1 January – 30 June 2018
Cash flows from operating activities:		
Result for the period	586,174.30	-6,243,049.40
Reconciliation of net result for the period to cash flows from operating activities:		
Income taxes	-1,165,822.33	-1,488,817.44
Amortization/depreciation and non-cash changes of fixed assets	111,626.98	107,158.87
Loss/Profits from the disposal of non-current assets	0.00	0.00
Interest expenses and interest income	1,038.98	-3,609.82
Release of deferred income	0.00	-504,827.40
Expenses from stock option plans	215,847.44	157,461.87
Change in assets and liabilities which are not attributable to investing or financing activities:		
Trade receivables	1,500,000.00	37,433.15
Prepaid expenses and other assets	254,440.02	246,138.52
Trade payables	734,824.65	2,943.65
Provisions	14,514.02	97,026.48
Other current liabilities	-43,340.18	10,846.46
Deferred income	0.00	969,317.55
Non-cash exchange losses/gains	-218,576.79	-18,183.45
	1,990,727.09	-6,630,160.96
Paid income taxes	0.00	0.00
Tax payments received	0.00	0.00
Interest paid	-1,699.49	0.00
Interest received	660.51	3,844.70
Cash flows from operating activities	1,989,688.11	-6,626,316.26
Cash flows from investing activities:		
Cash paid for investments in intangible assets and equipment	-3,813.73	-12,164.83
Cash flows from investing activities	-3,813.73	-12,164.83
Cash flows from financing activities:		
Principal portion of lease payments	-24,828.22	0.00
Capital increase	0.00	2,619,440.00
Contributions to the capital reserve	0.00	2,605,054.40
Payments in connection with raising capital	0.00	-157,780.94
Cash flows from financing activities	-24,828.22	5,066,713.46
Change in cash and cash equivalents	1,961,046.16	-1,571,767.63
Effect of exchange rate changes on cash	3,825.40	166.17
Cash and cash equivalents at beginning of the period	17,226,658.20	24,838,652.24
Cash and cash equivalents at end of the period	19,191,529.76	23,267,050.78
Composition of cash and cash equivalents at the end of the period:		
Cash and cash equivalents	19,191,529.76	23,267,050.78

Consolidated Statement of Changes in Equity

EUR	Share capital	Capital reserve	Translation reserve	Loss carryforward	Equity
31 December 2017	61,120,046.00	135,854,744.31	-630,192.60	-171,115,423.14	25,229,174.57
Total comprehensive income	0.00	0.00	-18,017.28	-6,243,049.40	-6,261,066.68
Issue of shares	2,619,440.00	0.00	0.00	0.00	2,619,440.00
Contribution to the capital reserve	0.00	2,605,054.40	0.00	0.00	2,605,054.40
Cost of raising capital	0.00	-157,780.94	0.00	0.00	-157,780.94
Additional contribution to the capital reserve due to the issue of options	0.00	157,461.87	0.00	0.00	157,461.87
30 June 2018	63,739,486.00	138,459,479.64	-648,209.88	-177,358,472.54	24,192,283.22
Total comprehensive income	0.00	0.00	-63,820.84	-3,696,361.36	-3,760,182.20
Issue of shares	118,657.00	0.00	0.00	0.00	118,657.00
Contribution to the capital reserve	0.00	30,850.82	0.00	0.00	30,850.82
Cost of raising capital	0.00	-1,795.50	0.00	0.00	-1,795.50
Additional contribution to the capital reserve due to the issue of options	0.00	242,229.29	0.00	0.00	242,229.29
31 December 2018	63,858,143.00	138,730,764.25	-712,030.72	-181,054,833.90	20,822,042.63
Total comprehensive income	0.00	0.00	-240,286.91	586,174.30	345,887.39
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
Cost of raising capital	0.00	0.00	0.00	0.00	0.00
Additional contribution to the capital reserve due to the issue of options	0.00	215,847.44	0.00	0.00	215,847.44
30 June 2019	63,858,143.00	138,946,611.69	-952,317.63	-180,468,659.60	21,383,777.46

Selected Explanatory Notes to the Consolidated Interim Financial Statements as of 30 June 2019

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. 115 (2) WpHG ["Wertpapierhandelsgesetz": German Securities Trading Act] in conjunction with Sec. 117 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
- TheraSci Limited, Cambridge/UK

Basis of Accounting

The interim consolidated financial statements have been prepared in accordance with Sec. 315e (1) 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 2018, except for the adoption of the following new or revised standards effective for the current reporting period:

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

The application of these new and/or revised standards may, in some cases, result in additional disclosure obligations in future consolidated financial statements. All disclosure obligations in interim consolidated financial statements resulting from first-time adoption of new standards in the current reporting period have been met accordingly. Of these amendments, only the first-time adoption of IFRS 16 had effects on the Group's net assets, financial position and results of operations. In this context, IFRS 16.C5 b) and the practical expedients according to IFRS 16.C10 a) and c) were applied; there was no cumulative effect to be recognized in equity.

The provisions of IAS 34, "Interim Financial Reporting", have been applied. The interim financial statements as of 30 June 2019 should be read in conjunction with the consolidated financial statements as of 31 December 2018.

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 Pound Sterling for the UK-based companies. 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.

Revenues

Revenues recognized in the first half-year 2019 amounting to KEUR 7,500 entirely related to the region U.S.

Stock options

In connection with the stock options granted from Stock Option Plan 2014 in 2015, 2016 and 2018 and in connection with the stock options granted from Stock Option Plan 2016 in 2017 and 2018, personnel expenses in the amount of KEUR 216 were recognized in the first half-year 2019.

Leases

In the course of first-time adoption of IFRS 16 under application of IFRS 16.C5 b) and the practical expedients according to IFRS 16.C10 a) and c), lease liabilities amounting to KEUR 108 and right-of-use assets in the same amount were recognized on the balance sheet as of 1 January 2019. The weighted average incremental borrowing rate underlying the calculation of the lease liabilities is approx. 3.7%.

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 2019 and as of 31 December 2018, the fair value of financial assets and liabilities was identical to the respective book value.

		Book value		Fair Value	
in KEUR		30 June 2019	31 Dec. 2018	30 June 2019	31 Dec. 2018
Financial assets					
Cash and cash equivalents		19,192	17,227	19,192	17,227
Trade receivables	(1)	0	1,500	0	1,500
Other assets	(1)	163	369	163	369
Financial liabilities					
Provisions	(1)	644	630	644	630
Trade payables	(1)	2,953	2,218	2,953	2,218
Lease liabilities		80	0	80	0
Other liabilities	(1)	492	434	492	434

Measurement category according to IFRS 9:

(1) Recognized at amortized cost

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 2019, there were no movements between the hierarchy levels.

Recoverability of financial assets was assessed based on historical and expected payment defaults. No default risks were identified and no impairment was recognized.

Related Parties

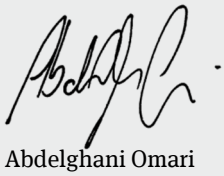
The relationships with related parties have not changed in comparison to those applied in the consolidated financial statements as of 31 December 2018.

Declaration of the Management Board pursuant Secs. 264 para. 2 sentence 3 and 289 para.I 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, 07 August 2019
PAION AG

Dr. Wolfgang Söhngen



Abdelghani Omari

Dr. Jürgen Beck

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, 2019, part of the six-monthly financial report pursuant to § (Article) 115 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 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 7, 2019
Ernst & Young GmbH
Wirtschaftsprüfungsgesellschaft

(s) Zwirner	(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 2019	2018
Numbers of shares at the end of the period	63,858,143	63,858,143
Average daily trading volume (Xetra, FSE, in shares)	68,328	60,451
Year high (Xetra closing price)	EUR 2.48 (10 Jan 2019)	EUR 2.70 (02 Jan 2018)
Year low (Xetra closing price)	EUR 2.06 (25 Jun 2019)	EUR 2.01 (25 Oct 2018)
Share price at the end of the period	EUR 2.16	EUR 2.19
Market capitalization at the end of the period (Xetra)	EUR 138 m	EUR 140 m

Corporate Calendar

20 March 2019	Publication of the financial results 2018
08 May 2019	Publication of the financial results of the first quarter 2019
22 May 2019	Annual General Meeting, Aachen
07 August 2019	Publication of the financial results for the first half-year 2019
06 November 2019	Publication of the financial results for the third quarter and the first nine months of 2019

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