

PAION HI#2022

Consolidated Financial Interim Report for the First Half-Year 2022

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2022

PAION AG



About PAION AG

PAION AG is a publicly listed specialty pharmaceutical company with innovative drugs to be used in hospital-based sedation, anaesthesia and critical care services. PAION's lead compound is remimazolam, an intravenous, ultra-short-acting and controllable benzodiazepine sedative/anaesthetic. PAION is rolling out remimazolam (Byfavo®) in selected European markets. Remimazolam is partnered in multiple territories outside of Europe. Remimazolam is approved in the U.S., the EU/EEA/UK, China and South Korea for procedural sedation and in Japan and South Korea for general anaesthesia

In addition, PAION markets two intensive care products in selected European countries: Angiotensin II (GIAPREZA®), a vasoconstrictor indicated for the treatment of refractory hypotension in adults with septic or other distributive shock, and eravacycline (XERAVA®), a novel fluorocycline type of antibiotic indicated for the treatment of complicated intra-abdominal infections in adults.

PAION's mission is to be a leading specialty pharmaceutical company in the fields of anaesthesia and critical care by bringing novel products to market to benefit patients, doctors and other stakeholders in healthcare.

PAION is headquartered in Aachen (Germany).

Key Figures

(all figures in KEUR unless otherwise noted)	Q2 2022	Q2 2021	H1 2022	H1 2021
Revenues	3,728	413	25,230	3,617
Cost of Sales	17	0	-655	-466
Research and development expenses	-1,913	-1,575	-3,051	-2,912
General administrative and selling expenses	5,230	-4,875	-10,294	-8,706
Earnings before interest and tax (EBIT)	-3,388	-6,035	11,112	-8,593
Result for the period	-4,196	-6,677	9,659	-10,436
Earnings per share in EUR for the period (basic)	-0.07	-0.09	0.14	-0.15
Earnings per share in EUR for the period (diluted)	-0.07	-0.09	0.14	-0.15

	H1 2022	H1 2021
Cash flows from operating activities	11,979	-6,979
Cash flows from investing activities	-631	-18,742
Cash flows from financing activities	-63	27,209
Change in cash and cash equivalents	11,285	1,495
Average number of group employees	62	47

	30-06-2022	31-12-2021
Intangible assets	19,543	19,653
Cash and cash equivalents	17,690	6,440
Equity	16,824	6,999
Current liabilities	9,742	10,985
Non-current liabilities	18,978	18,801
Balance sheet total	45,544	36,785

Interim Group Management Report for the First Half-Year 2022

The Reporting Period at a Glance

January

PAION assigns chinese remimazolam patents and sells related future royalties for EUR 20.5 million to Humanwell Healthcare Group

PAION AG announces change in Supervisory Board

March

PAION AG announces change in Management Board

April

PAION grants exclusive license to Cristália for development and commercialization of remimazolam in Latin America

May

Annual General Meeting approves all agenda items and elects Michael Schlenk and Gregor Siebert to the Supervisory Board

Juni

PAION reports solid progress with commercial activities in Europe

August (after the reporting period)

PAION launches eravacycline for the treatment of complicated intra-abdominal infections in adults in Germany

Update on business activity in the first half-year 2022

Highlights European product portfolio

PAION has already launched remimazolam (Byfavo®) in UK, Denmark and Netherlands. Remimazolam is planned to be launched for procedural sedation in most key European markets by the end of 2022/beginning of 2023. In Germany, remimazolam will not be available until the first quarter of 2023 at the earliest, once the marketing authorization extension for general anaesthesia has been granted, which is expected in the first quarter of 2023.

The sale of angiotensin II (GIAPREZA®) was expanded from Germany to the Netherlands and Austria in early 2022.

In April 2022, PAION was informed that the Federal Joint Committee (G-BA) voted in favor of PAION's application for eravacycline (XERAVA®) as a reserve antibiotic. This means that eravacycline is considered to provide added benefit to standard of care. PAION is now exempt from providing a full benefit dossier and is only required to provide an

abbreviated dossier by 1st August 2022. Subsequently has been launched and is commercially available in Germany for order and delivery to customers through direct sales.

Initial product use indicates good market acceptance of the products, and PAION has received positive feedback from customers on initial experiences with its products, particularly remimazolam.

Based on the positive results from the EU Phase III trial in general anaesthesia, PAION submitted an extension application to the marketing authorization for remimazolam for general anaesthesia to the European Medicines Agency (EMA) in December 2021. A decision by the EMA is expected in the first quarter of 2023. This application also will be submitted to the MHRA (Medicines and Healthcare products Regulatory Agency) via the ECDRP (European Commission Decision Reliance Procedure) to obtain approval in the UK.

Remimazolam activities in licensed territories in the first half of 2022

Licensees generated remimazolam revenues totalling EUR 2.7 million (without china sales) in the first half of 2022, amounting to royalties for PAION of EUR 0.3 million.

In the U.S., remimazolam (BYFAVO™) has been marketed by Acacia for procedural sedation since the beginning of 2021. Recently, Eagle Pharmaceutical, a well-established U.S. specialty pharma company has acquired Acacia. The license agreement for remimazolam remains unchanged and will be transferred to Eagle Pharmaceutical. Eagle Pharmaceutical is a publicly traded U.S. specialty pharmaceutical company with revenues of over USD 170 million in critical care, oncology and rare diseases. PAION expects, that this transaction will have a positive impact on the sales development of remimazolam in the U.S.

In China, PAION entered into a patent assignment agreement with Humanwell at the beginning of 2022. Under the agreement, PAION assigned all its Chinese remimazolam patents and related future royalties on sales in China under the license agreement with Yichang Humanwell to Humanwell for EUR 20.5 million. EUR 16 million were received in the first quarter of 2022, and the remaining EUR 4.5 million have been paid in June 2022. Yichang Humanwell was released from any future royalty payments to PAION, and the license has been terminated.

In March 2022, PAION terminated the licensing agreement for Russia, Turkey and the Mena region with Russia's R-Pharm after R-Pharm failed to pay outstanding milestones.

In Canada, PAION and Pharmascience Inc. mutually agreed at the beginning of 2022 to terminate their license agreement, which had granted Pharmascience Inc. exclusive rights to develop and commercialize remimazolam in Canada. PAION retains full access to all market data generated by Pharmascience and plans to explore strategic options for the commercialization of remimazolam in Canada.

In February 2022, PAION entered into an exclusive cooperation agreement with Medis, d.o.o. for the supply, distribution, marketing and sale of remimazolam, angiotensin II and eravacycline in Eastern Europe (Estonia, Latvia, Lithuania, Czech Republic, Slovakia, Hungary, Croatia, Slovenia and Bulgaria).

In April 2022, PAION and Cristália signed an exclusive license agreement for the development and commercialization of remimazolam in Latin America. Cristália intends to commercialize remimazolam in procedural sedation and general anaesthesia and expects to obtain marketing authorization for both indications in Brazil in 2024.

Financial Overview

In the first half of 2022, revenues of EUR 25.2 million (prior-year period: EUR 3.6 million) were recognized, primarily resulting from the sale of the Chinese remimazolam patents to Yichang Humanwell for 20.5 million, as well as from milestone payments from remimazolam license agreements, the sale of remimazolam API (active pharmaceutical ingredient) to licensees, and royalties from the commercialization of remimazolam. As planned, research and development expenses stabilised at EUR 3.0 million, the same level as in the same period of the previous year (EUR 2.9 million). General administrative and selling expenses increased as planned from EUR 8.7 million in the prior-year period to EUR 10.3 million in the first half of 2022. Overall, earnings before interest and taxes (EBIT) amounted to EUR 11.1 million in the first half of 2022, compared to an EBIT of EUR -8.6 million in the prior-year period.

Cash and cash equivalents increased by EUR 11.2 million in the first half-year 2022 compared to 31 December 2021 and amounted to EUR 17.7 million as of 30 June 2022. Based on current planning, cash and cash equivalents secure a liquidity runway into the first half of 2023.

Capital Market Environment and PAION Share Performance

The development of the German capital markets in the first half of 2022 was still impacted by the Covid-19 pandemic. In addition, there are global supply chain disruptions, rising inflation and a more restrictive monetary policy. In addition, the war in Ukraine that broke out in February 2022 and the associated sanctions against Russia increase the uncertainty regarding economic development. The DAXsubsector Biotechnology decreased by about 30 % and the NASDAQ Biotechnology Index also decreased by approx. 21 % in the first six months of 2022.

The PAION share started the year 2022 at a price of EUR 1.25 (Xetra closing price). The peak share price in the first half-year 2022 was marked on 12 January 2021 with EUR 1.64 based on Xetra closing prices. On 21 June 2022, the lowest price in the first half-year 2021 was marked at EUR 0.69 (Xetra closing price). The closing price on 30 June 2021 was EUR 1.94 (Xetra). This corresponds to a decrease of approx. 23 % compared to the closing price on 30 December 2021 (EUR 1.20; Xetra).

The average daily trading volume in the first half of 2022 amounted to 38,370 shares (Xetra) and 71,200 shares (Tradegate). In the full year 2021: 27.26 million shares (Xetra) and 25,88 million shares (Tradegate) were traded.

Development of the PAION Share Price and Volume (Xetra) in the First Half-Year 2022



Presentation of the course of business and development activities

Market opportunities

PAION believes that all products provide a significant market opportunity and address certain unmet needs in their relevant markets. Based on own projections (assuming the successful roll-out of the product offering in all current target markets), PAION estimates that remimazolam has the potential to eventually reach total peak sales of approx. EUR 90 million on an annual basis in the European Union, of which approx. EUR 40 million to EUR 50 million account for sales potential in the indication procedural sedation and approx. EUR 50 million to EUR 60 million account for sales potential in the indication general anaesthesia. In addition, based on own projections, PAION estimates the maximum revenue potential generated from royalties under the collaboration agreements based on peak sales outside Europe to amount to approx. EUR 35 million. Furthermore, PAION currently estimates an annual peak sales potential for angiotensin II and eravacycline in the range of approx. EUR 50 million and of approx. EUR 25 million to approx. EUR 35 million, respectively, based on own projections. Together with the peak sales potential of remimazolam in the amount of EUR 125 million (including own sales as well as milestone payments or royalties resulting from the expected sales of collaboration partners), PAION estimate a total peak sales potential of approx. EUR 200 million.

Byfavo[®] (remimazolam besylate)

Remimazolam is an ultra-short-acting intravenous benzodiazepine sedative/anaesthetic. In humans, remimazolam is rapidly metabolized to an inactive metabolite by liver esterases and is not metabolized by cytochrome-dependent hepatic pathways. Like other benzodiazepines, remimazolam can be reversed with flumazenil to rapidly terminate sedation or anaesthesia if necessary. Data demonstrate that remimazolam has a rapid onset and offset of action combined with a favorable cardio-respiratory safety profile.

Remimazolam is approved in the U.S., the EU/EEA/UK and China for procedural sedation and in Japan and South Korea for general anaesthesia.

In addition to procedural sedation and general anaesthesia, ICU sedation is another possible indication for remimazolam.

Remimazolam is partnered in the U.S. (brand name BYFAVOTM) with Eagle Pharmaceutical (Eagle), in Japan (brand name Anerem[®]) with Mundipharma, in South Korea (brand name ByfavoTM) and Southeast Asia with Hana Pharm, in Latinamerica with Cristália and in Taiwan with TTY Biopharm. For all other markets except European core markets and China, remimazolam is available for licensing.

Market potential

Based on own projections, PAION estimates the maximum annual revenue potential from royalties under the collaboration agreements based on peak sales in territories outside Europe to amount to approx. EUR 35 million, leading to a total annual revenue potential of remimazolam to PAION of EUR 125 million. This total includes the peak sales potential from our own commercialization efforts, of which approx. EUR 40 million to EUR 50 million account for sales potential in the indication procedural sedation and EUR 50 million to EUR 60 million account for sales potential in the indication general anaesthesia.

Procedural Sedation Market (U.S. + Europe)

The growth of the procedural sedation market in the U.S. has been driven for many years by the increase in medical procedures involving procedural sedations, such as colonoscopies, as well as by an increasing general demand for screening. Overall, the estimated total addressable market in procedural sedation is more than USD 400 million per year in the U.S, according to new estimates by Eagle Pharmaceuticals.

In Europe, based on its own projections for procedural sedation, PAION currently estimates an annual peak sales potential of approx. EUR 70 million to approx. EUR 80 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 anaesthesiologists 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 anaesthesia. In addition, the area of day surgery is also growing in Europe, so that PAION expects a steady growth of procedural sedation procedures in Europe as well. One driver of this development is the establishment and further spread of colorectal cancer screening (diagnostic colonoscopies) and so important users here are also proceduralists, e.g. gastroenterologists. Another, short-to-mid-term driver is the backlog of patients being untreated throughout the COVID-19 pandemic causing a need for a product such as remimazolam increasing process efficiency.

General Anaesthesia Market (Europe)

Based on publicly available European procedure statistics and market research, PAION estimates that in Europe, approximately 29 million procedures requiring general anaesthesia 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 anaesthesias are balanced anaesthesia (a combination of intravenous agents for induction and volatile gases for maintenance), approx. 20 % are total intravenous anaesthesias ("TIVA") using propofol, and the remaining approx. 25 % include regional anaesthesia (for example epidural administration). Based on PAION's market research, in Europe, the current standard-of-care drugs for general anaesthesia are propofol (especially for induction) and narcotic gases; mostly used in conjunction with intravenous opioids.

PAION anticipates an increasing number and complexity of medical interventions requiring induction and maintenance of anaesthesia in Europe in the future particularly driven by an ongoing aging of the population and the progress of surgical techniques. General anaesthesia is more frequently offered to elderly patients than in the past, therefore the choice of a tailored anaesthesia 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 Europe the demand for safer agents with low respiratory and cardio-depressive effects will increase over the coming years, creating opportunities for anaesthetics with an enhanced safety profile such as remimazolam, even at higher prices compared to existing generic drugs. In Europe, based on its own projections,

PAION currently estimates an annual peak sales potential of approx. EUR 80 million to approx. EUR 90 million for general anaesthesia.

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 mortality. 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.¹ Based on the safety data available to date, remimazolam could contribute significantly to reducing this mortality rate by reducing intraoperative blood pressure drops.

An emerging market driver is the requirement of hospitals to consider their carbon footprint and ecological impact. To that regards, volatile gases used in anaesthesia are a major negative contributor leading to a more common use of TIVA and hence an enlarged market opportunity for remimazolam as an intravenous anaesthetic

Intensive Care Unit (ICU) Sedation Market

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 at least 14 million ICU patient days requiring ICU sedation in the U.S. and Europe combined per year. A publication published in 2013 on the basis of eight EU countries comes to an extrapolated figure of 17.5 million patient days (not necessarily sedated) for the EU alone.² PAION expects these numbers to increase in the years to come, driven by demand from the aging population both in the USA and in Europe. 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.

Clinical development

Procedural sedation

The first U.S. Phase III trial 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 trial had an open-label midazolam arm.

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

¹ 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.

² Bittner et al. (2013): How is intensive care reimbursed? A review of eight European countries; *Annals of Intensive Care*, 3:37.

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

As part of the U.S. development program, also a safety trial in ASA III/IV (American Society of Anaesthesiologists 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 safety and efficacy of remimazolam compared to placebo (with midazolam rescue sedation) in patients undergoing proceduralist-supervised sedation for colonoscopy.

Summary of key results from the three Phase III trials:

	Remimazolam	Placebo	Midazolam (Open Label) *
Primary endpoint achieved (ITT)	80.6–91.3%	0.0–4.8%	12.9–32.9%
Time from start of medication to start of procedure	4.0–5.0 min	17–19.5 min	15.5–19.0 min
Time from end of procedure to fully alert	3.0–6.0 min	5.3–15.0 min	7.0–13.0 min
Time to back to normal	192–402 min	348–936 min	366–444 min

* Only partially relevant for the label claim

General Anaesthesia

In the clinical program, specific attention was paid to hemodynamic stability, which addresses a current need in general anaesthesia. Nonclinical data had suggested and clinical data confirmed that a better hemodynamic stability can be reached with remimazolam than with propofol.

The clinical development program in Europe and Japan demonstrated safety and efficacy as an anaesthetic as well as an improved hemodynamic profile compared to propofol.

In Europe, a randomized, single-blind, propofol-controlled, confirmatory Phase III trial enrolled 425 ASA III/IV patients (American Society of Anesthesiologists classification III to IV) undergoing planned surgery at more than 20 European sites. The primary objective of the trial was to demonstrate non-inferiority of remimazolam compared to propofol for the induction and maintenance of general anaesthesia during elective surgery. The key secondary objective was to show improved hemodynamic stability compared to propofol. In the trial, remimazolam met both the primary and key secondary endpoints.

ICU sedation

PAION's former licensee in Japan, Ono, independently initiated a Phase II trial for sedation in ICUs. Higher than expected plasma concentrations by pure calculation 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 nonclinical 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.

In October 2021, the last patient was treated in the Investigator Initiated REHSCU trial³. This trial, performed at the University of Nantes, is evaluating remimazolam for the sedation of patients on ICUs. Thirty patients were enrolled in the study. The results should provide further evidence for a successful use of remimazolam in this patient group.

Further development in this indication is currently not being conducted by PAION.

Pediatric development

In 2018, PAION submitted a PIP (Pediatric Investigation Plan) to the EMA which was approved in November 2019. In this development plan, various trials are planned to be carried out over several years, starting with procedural sedation. The clinical trials will initially be conducted with adolescents and increasingly younger children being enrolled in a stepwise approach. In September 2021, PAION and U.S. licensee Acacia Pharma (Acacia) announced the initiation of a pivotal study investigating remimazolam for sedation of pediatric patients. The study will enrol approximately 100 children and adolescents aged up to and including 17 years at leading institutions across the United States and Denmark. Upon successful completion of the pediatric development plans, it is expected that the EU and U.S. label of remimazolam will be expanded to include mild to moderate sedation for procedures in pediatric patient.

Postapproval commitments and life-cycle management

In 2022 and the following years, PAION will conduct a number of formulation development, non-clinical and clinical studies for remimazolam, angiotensin II and eravacycline to fulfil postapproval commitments and for life-cycle management. The majority of these activities are mandatory pediatric studies in order to make these medicinal products available for use in children.

Regulatory activities

In Europe, remimazolam (trade name Byfavo®) is approved in procedural sedation and in addition PAION is seeking approval for general anaesthesia.

Procedural sedation: The European Commission approved remimazolam in the EU (including EEA countries) in March 2021. The decision of the MHRA for approval in the United Kingdom followed in June 2021.

General anaesthesia: Based on the positive results of the EU Phase III trial in general anaesthesia, PAION has now submitted an extension application to the marketing authorization for remimazolam in the indication of general anaesthesia to the EMA. A decision by the EMA is expected in the first quarter of 2023. This application will be also submitted to the MHRA via the ECD RP route (European Commission Decision Reliance Procedure) to obtain approval in the UK as well.

³ Remimazolam Infusion in the Context of Hypnotic Shortage in the Critical Care Unit During the Pandemic of COVID-19, the REHSCU Study (REHSCU)

Commercial activities

PAION has recently built up its own commercialization infrastructure for its own marketing efforts in the first target markets, including the required production, supply and distribution structures as well as marketing and sales processes, with respect to a full product portfolio and has started a staggered roll-outs of our commercialization set-up and product offering in all our European target markets until 2023. However, PAION follows an asset-light business approach and only maintain core functions in the organization in order to be able to focus on the key competencies. This means that remimazolam or the active pharmaceutical ingredient for remimazolam is being manufactured, packaged and labeled by several third-party contract manufacturing organizations for PAION and/or its collaboration partners. In addition, PAION has entered into an agreement with the Dutch branch of the logistics services provider Movianto GmbH as a one-stop-shop solution for our distribution processes. Furthermore, PAION has entered into an agreement with Syneos Health Inc. as a global provider of marketing and selling solutions for the provision of medical science liaison and key account management services. PAION currently indirectly source angiotensin II and eravacycline from La Jolla under a separate supply agreement but is considering setting up direct supply chains for these two products as well.

PAION has started the commercialization of remimazolam, eravacycline and angiotensin II in the second half of 2021 in a staggered manner by country.

Commercialization of remimazolam started in the UK in August 2021. In the UK, the Company has a partnership with Clinigen for the supply of PAION's products. With successful first formulary approvals of remimazolam in National Health Service (NHS) Trust hospitals, PAION expects to see an increased and steadier uptake of its products in the UK going forward.

For Scandinavia, Denmark is serving as the commercial operating hub, with activities currently focused on remimazolam. Discussions with the Danish Medicines Council (DMC) regarding reimbursement have been completed. As purchasing and pricing decisions will not be dictated nationally, PAION has more freedom in the other countries in Scandinavia. Rollouts started in Denmark in the fourth quarter of 2021; rollouts in other countries in the region are underway.

In the Netherlands, all three products are now listed and available. PAION's commercial team is expanding the initial target group of anaesthesiologists to include gastroenterologists and expects strong synergies and highly efficient deployment of the sales force due to marketing of several products.

By the end of 2022/beginning of 2023, launches are planned to have been conducted in most key European markets. In the German market, remimazolam will not be available until the first quarter of 2023 at the earliest. In connection with the German benefit assessment process, PAION has decided to wait for a marketing authorisation extension for general anaesthesia before the product will be commercially available in Germany.

PAION launched angiotensin II in Germany in July 2021 and in the Netherlands in January 2022. In Austria it is commercially available since February 2022. PAION launched eravacycline in the Netherlands in September 2021. In Germany it is commercially available since August 2022.

Initial product use indicates a good market acceptance of the products and there is positive feedback from customers on initial experience especially with remimazolam.

To achieve PAION's mission to become a leading specialty pharmaceutical company in the fields of anaesthesia and critical care services, PAION identified the following key elements of the strategy:

PAION aims to become a recognized innovative leader in anaesthesia and critical care services within three years;

PAION intends to implement and execute leading commercial capabilities in Europe;

PAION plans to continue staggered product roll-outs of remimazolam, angiotensin II and eravacycline across our European target markets and drive rapid revenue growth to reach profitability at the end of 2023 or the beginning of 2024; and

PAION also intends to continue to explore synergistic potential, the in-licensing of additional products and other opportunities to drive longer-term growth.

Partner activities

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In the U.S., remimazolam (BYFAVO™) has been marketed by Acacia for procedural sedation since the beginning of 2021. Recently, Eagle Pharmaceutical, a well-established U.S. specialty pharma company has acquired Acacia. The license agreement for remimazolam remains unchanged and will be transferred to Eagle Pharmaceutical. Eagle Pharmaceutical is a publicly traded U.S. specialty pharmaceutical company with revenues of over USD 170 million in critical care, oncology and rare diseases. PAION expects, that this proposed transaction would have a positive impact on the sales development of remimazolam in the U.S.

In China, PAION entered into a patent assignment agreement with Humanwell at the beginning of 2022. Under the agreement, PAION assigned all its Chinese remimazolam patents and related future royalties on sales in China under the license agreement with Yichang Humanwell to Humanwell for EUR 20.5 million. EUR 16 million were received in the first quarter of 2022, and the remaining EUR 4.5 million are due and expected in June 2022. Yichang Humanwell was released from any future royalty payments to PAION, and the license has been terminated.

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In Canada, PAION and Pharmascience Inc. mutually agreed at the beginning of 2022 to terminate their license agreement, which had granted Pharmascience Inc. exclusive rights to develop and commercialize remimazolam in Canada. PAION retains full access to all market data generated by Pharmascience and plans to explore strategic options for the commercialization of remimazolam in Canada.

In February 2022, PAION entered into an exclusive cooperation agreement with Medis, d.o.o. for the supply, distribution, marketing and sale of remimazolam, angiotensin II and eravacycline in Eastern Europe (Estonia, Latvia, Lithuania, Czech Republic, Slovakia, Hungary, Croatia, Slovenia and Bulgaria).

In April 2022, PAION and Cristália signed an exclusive license agreement for the development and commercialization of remimazolam in Latin America. Cristália intends to commercialize remimazolam in procedural sedation and general anaesthesia and expects to obtain marketing authorization for both indications in Brazil in 2024.

Angiotensin II and Eravacycline

In January 2021, PAION AG and PAION Deutschland GmbH entered into an exclusive license agreement with La Jolla Pharmaceutical Company, San Diego, U.S., and certain of its wholly-owned subsidiaries (collectively La Jolla) for angiotensin II (GIAPREZA®) and eravacycline (XERAVA®). The agreement grants PAION an exclusive license for the commercialization of these two approved products in the European Economic Area, the United Kingdom and Switzerland.

In July 2022 it has been announced that Innoviva, a diversified holding company with a portfolio of royalties and other healthcare assets, plans to acquire La Jolla. The acquisition was completed on 22 August 2022. The existing agreement remains unaffected.

In addition to an upfront payment in the amount of USD 22.5 million, La Jolla is entitled to receive additional payments of up to USD 109.5 million contingent upon the achievement of certain commercial milestones of which the majority are dependent on the respective first achievement of significant sales revenues.

La Jolla is also entitled to royalties on PAION's own net sales in Europe and a share of revenues from indirect sales.

La Jolla had agreed with the EMA to conduct pediatric trials for eravacycline and for angiotensin II and a Phase IV trial for angiotensin II. For the Phase IV trial, a protocol approved by the EMA already exists. PAION is examining the specifics of the study and will coordinate these in discussion with the EMA.

Angiotensin II (GIAPREZA®)

Angiotensin II for injection is an FDA-approved vasoconstrictor to increase blood pressure in adults with septic or other distributive shock. Angiotensin II is approved by the European Commission and the UK Medicines Agency for the treatment of refractory hypotension in adults with septic or other distributive shock who remain hypotensive despite adequate volume restitution and application of catecholamines and other available vasopressor therapies. Angiotensin II mimics the body's endogenous angiotensin II peptide, which is central to the renin-angiotensin-aldosterone system, which in turn regulates blood pressure.

Angiotensin II raises blood pressure by vasoconstriction; increased aldosterone release via direct action of angiotensin II on the vessel wall is mediated by binding to the G-protein-coupled angiotensin II receptor type 1 on vascular smooth muscle cells which stimulates Ca²⁺/calmodulin dependent phosphorylation of myosin and causes smooth muscle contraction.

The pivotal phase III trial of angiotensin II for the treatment of high-output shock (ATHOS-3) was a randomized, placebo-controlled, double-blind, international, multicenter Phase III safety and efficacy trial in which 321 adults with septic shock or other distributive shock who had hypotension despite fluid and vasopressor therapy were randomized 1:1 to angiotensin II or placebo. The primary efficacy endpoint, an increase in blood pressure, was achieved by 70 % of patients randomized to angiotensin II compared with 23 % of patients treated with placebo; $p < 0.0001$ (a treatment effect of 47 %).

The European Summary of Product Characteristics is available on the EMA website: www.ema.europa.eu/en/medicines/human/EPAR/giapreza.

In 2021, a benefit assessment was conducted by the Federal Joint Committee (G-BA), which was completed at the beginning of 2022. The G-BA commissioned the Institute for Quality and Efficiency in Health Care (IQWiG) with the benefit assessment of the active substance angiotensin II in accordance with Section 35a of the German Social Code (SGB V). The assessment is based on a dossier submitted by PAION to IQWiG on 15 July 2021. The G-BA came to the conclusion that there is no evidence of an additional benefit. However, following discussions with the Federal Institute for Drugs and Medical Devices (BfArM) and on the basis of the European public assessment report (EPAR), the G-BA also came to the conclusion that the indication can be interpreted as second- and third-line therapy. Following the public hearing, IQWiG was asked to assess the third-line subpopulation. This showed an additional benefit in terms of mortality and was published as an addendum to the decision. PAION then entered into price negotiations with the umbrella organisation of the statutory health insurance funds to determine the maximum reimbursable price for the product. This should come to a conclusion in 2022.

PAION launched angiotensin II in Germany in July 2021 and in the Netherlands in January 2022. In Austria it is commercially available since February 2022.

In Europe, PAION currently estimates a peak sales potential of approximately EUR 50 million per year based on its own projections.

Eravacycline (XERAVA®)

Eravacycline for injection is a novel fluorocycline of the tetracycline class. Eravacycline is an antibiotic used to treat complicated intra-abdominal infections (cIAI) in adults. According to the Infectious Diseases Society of America (IDSA), cIAI is defined as an infection that extends beyond the wall of a hollow viscus of origin into the abdominal cavity while being associated with an abscess or peritonitis.⁴

The mechanism of action of eravacycline is to interfere with bacterial protein synthesis by binding to the ribosomal subunit 30S, thereby preventing the incorporation of amino acid residues into extended peptide chains.

Eravacycline has been shown to be as effective as alternative antibiotics in two main trials in adults with cIAI. The main indicator of efficacy in both trials was the cure rate of infections. In the first trial, involving 538 patients, eravacycline was compared with ertapenem (another antibiotic). After about one month, 87 % of patients treated with eravacycline were cured of their infection, compared with 89 % of patients treated with ertapenem. In the second trial, involving 499 patients, eravacycline was compared with meropenem (a carbapenem antibiotic commonly used in Europe in this indication). After about one month, 92 % of patients treated with eravacycline and 92 % of patients treated with meropenem were cured of their infection.

Eravacycline is FDA-approved for the treatment of complicated abdominal infections in patients 18 years of age and older. Eravacycline is approved by the European Commission and the UK Medicines Agency for the treatment of abdominal infections in adults. Consideration should be given to official guidance on the appropriate use of antibacterial agents.

⁴ Solomkin JS, Mazuski JE, Bradley JS: Diagnosis and management of complicated intra-abdominal infection in adults and children: guidelines by the Surgical Infection Society and the Infectious Diseases Society of America. Clin Infect Dis. 2010;50:133-164.

The European Summary of Product Characteristics is available on the EMA website: https://www.ema.europa.eu/en/documents/product-information/xerava-epar-product-information_en-0.pdf.

PAION launched eravacycline in the Netherlands in September 2021. In April 2022, PAION was informed that the Federal Joint Committee (G-BA) voted in favor of PAION's application for eravacycline as a reserve antibiotic. This means that eravacycline is considered to provide added benefit to standard of care. PAION is now exempt from providing a full benefit dossier and is only required to provide an abbreviated dossier by 1 August 2022. Subsequently has been launched and is commercially available in Germany for order and delivery to customers through direct sales.

In Europe, PAION currently estimates a peak sales potential of approximately EUR 25 million to approximately EUR 35 million annually based on its own projections.

Net Assets, Financial Position, and Results of Operations

Results of Operations

	Q2 2022	Q2 2021	H1 2022	H1 2021
	KEUR	KEUR	KEUR	KEUR
Revenues	3,728	413	25,230	3,617
Cost of sales	17	0	-655	-466
Gross profit	3,745	413	24,575	3,151
Research and development expenses	-1,913	-1,575	-3,051	-2,912
General administrative and selling expenses	-5,230	-4,875	-10,294	-8,706
Other income (expenses)	11	2	-118	-126
Operating expenses	-7,132	-6,448	-13,463	-11,744
Operating result	-3,388	-6,035	11,112	-8,593
Financial result	-341	-961	-959	-2,242
Income taxes	-494	319	-494	399
Net result for the period	-4,196	-6,677	9,659	-10,436

Revenues in the first half-year 2022 amounted to KEUR 25,230 of which KEUR 24,180 resulted from milestone payments and KEUR 1,050 from remimazolam API sales to licensees (KEUR 655) and royalties (KEUR 311), and in the amount of KEUR 84 (Q1 2022 KEUR 57) from commercial product sales to wholesalers and hospitals in selected European markets. In the prior-year period, revenues amounted to KEUR 3,617 and mainly resulted from milestone payments.

Cost of sales amounted to KEUR 655 in the first half-year 2022.

Research and development expenses in the first half-year 2022 amounted to KEUR 3,051 (prior-year period: KEUR 2,912) and have stabilised as planned at the level of the previous year's period.

General administrative and selling expenses increased by KEUR 1,588 to KEUR 10,294 in the first half-year 2022 compared to the prior-year period. General administrative expenses increased by KEUR 32 to KEUR 2,580 and selling expenses increased by KEUR 1,556 to KEUR 7,714. Selling expenses increased as planned particularly due to commercialization activities for the three products remimazolam, angiotensin II and eravacycline in Europe.

Earnings before interest and tax amounted to KEUR 11,112 in the first half-year 2022 and increased by KEUR 19,705 compared to the prior-year period (earnings before interest and tax in the prior-year period: KEUR -8,593).

The **financial result** amounted to KEUR -959 in the first half of 2022 (prior-year period: KEUR -2,242) and mainly comprises expenses in connection with the EIB loan drawn down in the prior-year period. The improvement in the financial result is mainly due to the revaluation of the performance-related interest component of the EIB loan.

Income taxes amounted to KEUR -494 in the first half-year 2022 (prior-year period: KEUR 399) and mainly relate to corporate tax liability to the British tax authorities due to the significant increase in milestone payments. In the prior-year period it was mainly tax claims for reimbursement of parts of the research and development expenses from the British tax authorities.

The **net result** for the first half-year 2022 amounted to KEUR 9,659 compared to a net result of KEUR -10,436 in the prior-year period. This corresponds to an increase of the net result in the amount of KEUR 20,095 compared to the first half-year 2021. The increase in the result for the period is due to the increased milestone payments.

Net Assets

	30-06-2022	31-12-2021	Change
	KEUR	KEUR	KEUR
Non-current assets	20,393	20,551	-158
Current assets	25,151	16,234	8,917
Total Assets	45,544	36,785	8,759
Equity	16,824	6,999	9,825
Non-current liabilities	18,978	18,801	177
Current liabilities	9,742	10,985	-1,243
Total Equity and liabilities	45,544	36,785	8,759

Non-current assets primarily include the balance sheet value of the products angiotensin II (KEUR 13,119) and eravacycline (KEUR 3,239), which were in-licensed in the reporting year for marketing in the European Economic Area, the United Kingdom and Switzerland and already approved in Europe, as well as the book value of the value of the development project remimazolam (KEUR 1,620) reduced by scheduled amortisation, capitalised from the purchase price allocation as part of the CeNeS acquisition in 2008, as well as right-of-use assets for office space (KEUR 648).

Current assets comprise cash and cash equivalents (KEUR 17,690), inventories (KEUR 4,233), other assets and prepaid expenses (KEUR 3,121) as well as trade receivables (KEUR 41). The increase of KEUR 8,917 compared to 31 December 2021 is due to an increase in cash and cash equivalents of KEUR 11,250 on the one hand and a decrease in inventories of KEUR 590, in trade receivables of KEUR 1,676 and other assets and prepaid expenses of KEUR 133 on the other hand. The decrease in other assets and prepaid expenses is mainly due to a lower tax claim for reimbursement of parts of the research and development expenses from the British tax authorities.

The increase in **equity** of KEUR 9,825 compared to 31 December 2021 mainly results from the net result of the first half-year 2022 in the amount of KEUR 9,659. As of 30 June 2022, the equity ratio was 36.9 % (31 December 2021: 19.0 %).

Non-current mainly relate to the carrying amount of the non-current portion of the EIB loan drawn down in the reporting year (KEUR 18,435 including the performance-based, bullet payment component) and liabilities from leases (KEUR 508).

Current liabilities decreased by KEUR 1,243 compared to 31 December 2021. This decrease mainly results from a decrease of trade payables by KEUR 1,937, of accruals by KEUR 1,583 as well as an increase in other liabilities by KEUR 2,283 (incl. Yichang refund liability KEUR 1,800).

Financial Position

Compared to 31 December 2021, **cash and cash equivalents** increased by KEUR 11,250 to KEUR 17,690 at the end of the current reporting period. The change in cash and cash equivalents stems from the following areas:

	H1 2022 KEUR	H1 2021 KEUR
Cash flows from operating activities	11,979	-6,979
Cash flows from investing activities	-631	-18,742
Cash flows from financing activities	-63	27,209
Effects of exchange rate changes	-35	7
Change in cash and cash equivalents	11,250	1,495

The **cash flows from operating activities** in the first half-year 2022 were KEUR 11,979 and primarily resulted from the net result for the period, adjusted for non-cash items, as well as changes of the working capital.

The **cash flows from investing activities** amounted to KEUR -631 in the first half-year 2022 and mainly resulted from an ERP system under development (KEUR 591).

The **cash flows from financing activities** of KEUR -63 resulted from the redemption portion of the lease payments.

Personnel Development

On average, PAION employed 62 employees in the first six months of 2022 (fiscal year 2021: 47 employees). As of 30 June 2022, the headcount was 64.

Impact of the Covid-19 pandemic on the PAION Group

At the time of this report, there is still uncertainty about the further course of the Covid-19 pandemic. In light of this, it is currently not possible to accurately assess the short- and medium-term consequences for the economic development.

The Covid-19 pandemic is severely restricting access to the market in some territories like the U.S., whilst in others like China the effects are not significant. This remains a key commercial risk as healthcare systems globally struggle to cope with both the pandemic and the extra healthcare costs it has brought, as well as the back-log of work. PAION will continue to as far as possible work to mitigate these risks with our global partners.

To date, the pandemic has had a modest direct impact on the PAION Group. On the one hand, PAION currently still recognizes a significant portion of its revenues from milestone payments. The underlying milestones are largely independent from the general economic development. On the other hand, PAION was and is able to continue its business activity also under significant restrictions in public life with barely any changes since office presence of employees is not necessary for the normal continuation of the business in the vast majority of time. In addition, PAION is largely independent from the general economic development in the short- to medium-term, since in the worst case, development and commercial activities could be reduced in order to increase the cash reach. As PAION has only started commercializing its own products and therefore only a small amount of supplies of commercially manufactured product has occurred yet, the pandemic has not had a major impact in this respect either. However, a lack of production capacities at Contract Manufacturing Organizations (CMOs) and very long order times for certain materials (e.g. glass vials) can be observed and have partially impacted the business of our licensees. Furthermore, access to clinics and prescribers has been limited by Covid-19 effects on the healthcare system, leading to partially moderate product sales. PAION is hoping to see growth accelerating in the second half of 2022.

Overall, the direct impact of the pandemic on the PAION Group's net assets, financial position and results of operations has been moderate to date. Due to the limited access to clinics and prescribers, PAION currently expects a moderate negative impact of the pandemic on the own commercialization of remimazolam, angiotensin II and eravacycline. As such, based on the factual situation at the time of this report, moderate direct effects on the own operating business are assumed for the future. It is currently unknown in how far particularly our licensees' business activities will be (further) restrained by the pandemic potentially leading to revenues from milestones or royalties being recognized not at all, in a lower amount or delayed. However, PAION currently expects a moderate impact on its licensees' business overall as well leading to moderate planning adjustments due to the Covid-19 pandemic at the present time. Any impact of the pandemic on the general financing environment could limit PAION's ability to obtain necessary financing.

Effects of the Ukraine War on the PAION Group

The Ukraine war that began on 24 February 2022 has not had any significant impact on the business activities of the Paion Group so far. PAION terminated the license agreement for Russia, Turkey and the Mena region with the Russian R-Pharm in March 2022 after R-Pharm failed to pay outstanding milestones.

Risks and Opportunities

Material risks and opportunities relating to future development are presented in detail in the group management report for the fiscal year 2021. The overall evaluation of opportunities and risks has not changed significantly in the first half-year 2022.

Significant Events Occurring After the Balance Sheet Date

There were no significant events in the period between the reporting date, 30 June 2022, and the preparation of this report.

Report on expected developments

Business Outlook

PAION's focus in 2022 will be on the commercialisation of its approved products - remimazolam, angiotensin II and eravacycline - and the necessary further build-up of a sales infrastructure in select European countries. Launches are expected to have taken place in these countries by the end of 2022/early 2023. In addition, PAION expects a decision from the EMA on the extension application to the marketing authorisation for remimazolam for general anaesthesia in late 2022/early 2023.

Furthermore, during 2022, PAION plans to grant commercialisation rights for remimazolam, angiotensin II and eravacycline to licensees in select territories in Europe where the Company is not building its own distribution capabilities and to out-license remimazolam for additional markets outside of Europe.

Planned research and development activities mainly relate to paediatric development and carrying out post-approval commitments and life-cycle management for remimazolam. In addition, limited activities related to product development are ongoing. Following the launch of remimazolam by marketing partners in the U.S., Japan and South Korea, PAION expects product sales and revenues from licensees to increase, resulting in an increase in royalties for PAION.

Financial outlook 2022

PAION confirms the outlook for the full year 2022 announced with the Annual Report 2021.

PAION expects revenues of approximately EUR 32 million to approximately EUR 35 million in 2022. Existing licensees are expected to contribute approximately EUR 25 million to approximately EUR 27 million in revenue, thereof EUR 20.5 million from the January 2022 sale of the Chinese remimazolam patents and future royalties in China to Humanwell, and approximately EUR 4.5 million to approximately EUR 6.5 million from the sale of remimazolam active ingredient and royalties from the commercialisation of remimazolam outside of Europe. Revenues from the sale of remimazolam, angiotensin II and eravacycline in Europe are expected to be approximately EUR 2 million to approximately EUR 3 million in the first year after market launch. Revenues from out-licensing (royalties) of remimazolam, angiotensin II and eravacycline in select European countries and out-licensing of remimazolam outside of Europe are expected to total approximately EUR 5 million.

Cost of sales is expected to be approximately EUR 5 million to approximately EUR 6 million.

The focus of activities in 2022 will continue to be on marketing and sales, with administrative and selling expenses expected to be approximately EUR 26 million to approximately EUR 29 million, depending on the progress of commercial activities. Research and development expenses are budgeted between approximately EUR 7 million and approximately EUR 9 million. Depreciation will amount to between approximately EUR 1.5 million and EUR 2 million. Earnings before interest, taxes, depreciation and amortisation (EBITDA) is forecasted to be between approximately EUR -9 million and approximately EUR -2.5 million for 2022.

As part of the further development of the commercial infrastructure, the number of employees is expected to increase to approximately 70 to 80.

Overall, PAION expects a significant increase in revenues compared to 2021, as well as an increase in operating expenses. Overall, however, EBITDA in 2022 is expected to improve compared to 2021.

The key assumption for the outlook is that the activities of PAION and its licensees will progress as planned. Furthermore, the planning is based on the assumption that the further funding requirements can be at least partially covered by financing measures in the course of the fiscal year 2022. Delays would lead to a deferral of significant cost blocks and/or revenue into 2023 or beyond. Possible effects of the COVID-19 pandemic on PAION's business activities and those of its partners could also lead to delays and deferral of revenues and/or costs.

PAION expects increasing revenues in the coming years, both from licensing agreements and from its own commercialisation activities in parts of Europe, and, based on current planning, expects to achieve break-even in 2024. Until break even, according to current planning, the Company will need additional financing of approximately EUR 30 million, particularly for the further development of the sales infrastructure and the planned staggered country-by-country product launches in Europe, as well as post-approval commitments such as possible Phase IV studies. These funds could be raised through various financing measures and further partnerships. Based on cash at hand, cash from the sale of the Chinese remimazolam patents and future royalties in China to Humanwell in January 2022, expected sales and royalty revenues as well as revenue from potential financing and/or out-licensing activities, PAION expects to have sufficient cash for the next 12 months, based on current planning. If planned cash inflows are delayed or lower than projected, PAION could reduce costs during fiscal year 2022 to ensure sufficient cash for the next 12 months.

Aachen, Germany, 31 August 2022

PAION AG



Dr. James Phillips



Sebastian Werner

Condensed Consolidated Interim Financial Statements

Consolidated Balance Sheet

ASSETS	30 June 2022	31 Dec. 2021
	EUR	EUR
Non-current assets		
Intangible assets	19,542,982.66	19,652,677.93
Equipment	194,504.35	178,318.43
Right-of-use assets	655,488.92	719,781.33
Other assets	14.02	14.08
	20,392,989.95	20,550,791.77
Current assets		
Trade receivables	41,160.95	1,717,174.11
Inventories	4,233,273.32	4,822,715.55
Receivables from affiliated companies	66,307.68	0.00
Prepaid expenses and other assets	3,120,617.51	3,254,463.08
Cash and cash equivalents	17,689,676.49	6,439,521.59
	25,151,035.95	16,233,874.33
Total assets	45,544,025.90	36,784,666.10

EQUITY AND LIABILITIES	30 June 2022	31 Dec. 2021
	EUR	EUR
Equity		
Share capital	71,336,992.00	71,336,992.00
Capital reserve	144,504,207.10	144,413,862.19
Translation reserve	-1,042,662.55	-1,117,673.47
Loss carryforward	-207,634,093.75	-185,848,505.42
Result for the period	9,659,189.11	-21,785,588.36
	16,823,631.88	6,999,086.94
Non-current liabilities		
Financial debt	18,434,725.52	18,199,488.42
Lease liabilities	507,942.58	566,381.84
Provisions	35,000.00	35,000.00
	18,977,668.10	18,800,870.26
Current liabilities		
Trade payables	4,648,093.89	6,584,949.14
Provisions	721,187.43	2,304,416.11
Financial debt	1,283,712.86	1,284,509.44
Lease liabilities	153,227.94	158,177.76
Tax liabilities	156,976.49	51,459.41
Other current liabilities	2,779,527.31	601,197.04
	9,742,725.92	10,984,708.90
Total equity and liabilities	45,544,025.90	36,784,666.10

Consolidated Statement of Comprehensive Income

EUR	1 April – 30 June 2022	1 April – 30 June 2021	1 January – 30 June 2022	1 January – 30 June 2021
Revenues	3,728,039.05	412,634.15	25,230,326.13	3,616,918.33
Cost of sales	16,364.68	0.00	-655,246.37	-466,349.91
Gross profit	3,744,403.73	412,634.15	24,575,079.76	3,150,568.42
Research and development expenses	-1,912,831.91	-1,575,112.76	-3,050,800.66	-2,912,103.49
General administrative and selling expenses	-5,229,849.78	-4,875,574.48	-10,293,864.95	-8,706,108.97
Other income (expenses), net	9,691.46	2,930.07	-118,728.62	-125,825.50
Operating expenses	-7,132,990.23	-6,447,757.17	-13,463,394.23	-11,744,037.96
Operating result	-3,388,586.50	-6,035,123.02	11,111,685.53	-8,593,469.54
Financial income	4,495.03	0.00	10,542.74	141.70
Financial expenses	-361,726.27	-960,757.97	-968,910.17	-2,242,521.58
Financial result	-357,231.24	-960,757.97	-958,367.43	-2,242,379.88
Result for the period before taxes	-4,196,145.49	-6,995,880.99	10,153,318.10	-10,835,849.42
Income taxes	-93,096.51	318,800.24	-494,128.99	399,761.45
Result for the period	-4,196,145.49	-6,677,080.75	9,659,189.11	-10,436,087.97
of which attributable to other shareholders	0.00	0.00	0.00	0.00
of which attributable to shareholders of PAION	-4,196,145.49	-6,677,080.75	9,659,189.11	-10,436,087.97
Foreign currency translation	41,802.14	-3,854.64	-75,010.92	-59,230.58
Total income and expense recognized directly in equity that will be reclassified to profit or loss when specific conditions are met	41,802.14	-3,854.64	-75,010.92	-59,230.58
Other comprehensive income	41,802.14	-3,854.64	-75,010.92	-59,230.58
Total comprehensive income	-4,154,343.35	-6,680,935.39	9,584,178.19	-10,495,318.55
of which attributable to other shareholders	0.00	0.00	0.00	0.00
of which attributable to shareholders of PAION	-4,154,343.35	-6,680,935.39	9,584,178.19	-10,495,318.55
Earnings per share (basic)	0.07	-0.09	0.13	-0.15
Earnings per share (diluted)	0,07	-0.09	0.13	-0.15

Consolidated Cash Flow Statement

EUR	1 January – 30 June 2022	1 January – 30 June 2021
Cash flows from operating activities:		
Result for the period	9,659,189.11	-10,436,087.97
Reconciliation of result for the period to cash flows from operating activities:		
Income taxes	494,128.99	-399,761.45
Amortization/depreciation and non-cash changes of fixed assets	965,051.11	642,771.93
Interest expenses and interest income	958,367.43	2,242,379.88
Expenses from stock option plans	90,344.91	158,605.00
Gain/loss on disposal of assets	0.00	7,518.66
Change in assets and liabilities which are not attributable to investing or financing activities:		
Trade receivables	1,676,013.16	-658,195.68
Receivables from affiliated companies	-66,307.68	
Inventories	589,442.23	-1,250,362.10
Prepaid expenses and other assets	-360,283.42	-120,756.10
Trade payables	-1,899,021.51	990,381.42
Provisions	-1,865,996.78	-345,376.95
Other current liabilities	2,309,772.08	117,090.60
Non-cash exchange losses/gains	149,968.83	38,100.43
	12,700,668.46	-9,013,692.33
Tax payments received	0.00	2,315,229.25
Interest paid	-732,307.35	-280,753.48
Interest received	10,542.74	141.70
Cash flows from operating activities	11,978,903.85	-6,979,074.86
Cash flows from investing activities:		
Cash paid for investments in intangible assets and equipment	-630,991.63	-18,742,141.79
Cash flows from investing activities	-630,991.63	-18,742,141.79
Cash flows from financing activities:		
Capital increase	0.00	5,095,499.00
Contributions to the capital reserve	0.00	2,751,569.46
Payments in connection with raising capital	0.00	-586,055.40
Drawdown of loans	0.00	20,000,000.00
Principal portion of lease payments	-63,389.07	-51,530.77
Cash flows from financing activities	-63,389.07	27,209,482.29
Change in cash and cash equivalents	11,284,523.15	1,488,265.64
Effect of exchange rate changes on cash	-34,368.25	5,962.54
Cash and cash equivalents at beginning of the period	6,439,521.59	19,666,309.58
Cash and cash equivalents at end of the period	17,689,676.49	21,160,537.76
Composition of cash and cash equivalents at the end of the period:		
Cash and cash equivalents	17,689,676.49	21,160,537.76

Consolidated Statement of Changes in Equity

EUR	Share capital	Capital reserve	Translation reserve	Loss carryforward	Equity
31 December 2020	66,241,493.00	141,906,632.49	-1,009,793.75	-185,848,505.42	21,289,826.32
Total comprehensive income	0.00	0.00	-59,230.58	-10,436,087.97	-10,495,318.55
Issue of shares	5,095,499.00	0.00	0.00	0.00	5,095,499.00
Contribution to the capital reserve	0.00	2,751,569.46	0.00	0.00	2,751,569.46
Cost of raising capital	0.00	-586,055.40	0.00	0.00	-586,055.40
Additional contribution to the capital reserve due to the issue of options	0.00	158,605.00	0.00	0.00	158,605.00
30 June 2021	71,336,992.00	144,230,751.55	-1,069,024.33	-196,284,593.39	18,214,125.83
Total comprehensive income	0.00	0.00	-48,649.14	-11,349,500.39	-11,398,149.53
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	183,110.64	0.00	0.00	183,110.64
31 December 2021	71,336,992.00	144,413,862.19	-1,117,673.47	-207,634,093.78	6,999,086.94
Total comprehensive income	0.00	0.00	75,010.92	9,659,189.11	9,734,200.03
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	90,344.91	0.00	0.00	90,344.91
30 June 2022	71,336,992.00	144,504,207.10	-1,042,662.55	-197,974,904.67	16,823,631.88

Selected Explanatory Notes to the Consolidated Interim Financial Statements as of 30 June 2022

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 Heussstrasse 25, 52078 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 Netherlands B.V., Heerlen/The Netherlands
- PAION Scandic ApS, Odense/Denmark
- 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 2021, except for the adoption of

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

- IFRS 3 “Business Combinations” (Amendment of References to the Framework)
- Amendments to IAS 16 “Property, Plant and Equipment” (Revenue before Intended Use)
- Amendments to IAS 37 “Provisions, Contingent Liabilities and Contingent Assets” (Onerous Contracts, Settlement Costs of Contracts)
- Annual Improvements to IFRS 2018-2020 Amendments to IFRS 1 (Subsidiaries as First-time Adopters), IFRS 9 (Charges in the “10% Test” in Relation to, Derecognition of Financial Liabilities), IFRS 16 (Lease Incentives), IAS 41 (Taxation on Fair Value Measurements)

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. 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 2022 should be read in conjunction with the consolidated financial statements as of 31 December 2021.

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 Dutch company, Pound Sterling for the UK-based companies and Danish Kroner for the Danish entity. 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.

Intangible assets

Intangible assets amount to KEUR 19,543 as of 30 June 2022 (31 December 2021: KEUR 19,653). In the prior-year period, the commercialization rights for the products angiotensin II and eravacycline in Europe were capitalized with acquisition costs of KEUR 18,493 under the license agreement concluded with La Jolla Pharmaceutical. Both assets are amortized over their expected useful lives until the end of 2034 for angiotensin II and mid-2033 for eravacycline, respectively, based on the currently expected period of the respective patent protection.

Intangible assets relate to assets in development in the amount of KEUR 1.560 as of 30 June 2022 (31 December 2021: KEUR 50).

Inventories

Inventories amount to KEUR 4,233 (31 December 2021: KEUR 4,823) as of 30 June 2022 and comprise finished goods in the amount of KEUR 2,155 as well as advance payments on inventories (remimazolam API) in the amount of KEUR 2,078. No allowance on inventories was recognized in the reporting period.

Financial debt

PAION AG has drawn down the first two tranches of the loan totalling KEUR 12,500 in February 2021 and the third and final tranche of the loan totalling KEUR 7,500 in June 2021 under the KEUR 20,000 loan agreement entered into with the European Investment Bank (EIB) in the financial year 2019. Each tranche has a term of five years and is repaid from the 39th month after disbursement. The interest rate consists of a current cash interest component of 6 % (tranche 3) and 7.5 % (tranches 1 and 2), a deferred bullet interest component of 3 % (tranche 3) and 5 % (tranches 1 and 2) and a performance-based bullet component. At the time of initial recognition, the payment amount of the respective tranches was divided between the basic liability on the one hand and the performance-based remuneration component as a derivative subject to separation on the other. The basic liability, including the current and bullet interest components, is measured at amortised cost using the effective interest method. The performance-related remuneration component is a payment obligation that depends on the share price of PAION AG at the time of repayment of the last part of the respective tranche of the loan and is due at that time; as an embedded derivative, it is required to be separated and is subsequently measured at fair value on the basis of the Black/Scholes model. The carrying amount of the base component, including the current and final interest component, amounts to KEUR 18,414 as at 30 June 2022. The carrying amount of the final performance-based remuneration component amounts to KEUR 1,304 as at 30 June 2022.

Revenues

Revenues recognized in the first half-year 2022 relate to following categories:

- Royalties: KEUR 311
- API sales: KEUR 739

- Milestones: KEUR 24,180

Stock options

In connection with the stock options granted from Stock Option Plans 2016, 2018 and 2020 personnel expenses in the amount of KEUR 90 were recognized in the first half-year 2022.

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.

Financial instruments

As of 30 June 2022 and as of 31 December 2021, the fair value of financial assets and liabilities was identical to the respective book value.

in KEUR	Book value		Fair Value		
	30 June 2022	31 Dec. 2021	30 June 2022	31 Dec. 2021	
Financial assets					
Cash and cash equivalents	(1)	17,690	6,440	17,690	6,440
Trade receivables	(1)	41	1,717	41	1,717
Other assets	(1)	661	181	661	181
Financial liabilities					
Financial debt (underlying liability EIB loan)	(1)	18,414	17,773	18,414	17,773
Trade payables	(1)	14,648	6,585	14,648	6,585
Provisions	(1)	756	2,339	756	2,339
Financial debt (performance-related remuneration component EIB loan)	(2)	1,304	1,711	1,304	1,711
Lease liabilities		661	725	661	725
Other liabilities	(1)	2,136	401	2,136	401

Measurement categories according to IFRS 9:

- (1) Recognized at amortized cost
- (2) Recognized at fair value through profit or loss

Cash and cash equivalents, trade receivables, other assets, trade payables, provisions and other liabilities almost exclusively have short residual terms and the carrying amounts correspond to the fair value on the balance sheet date. The fair values for these financial instruments were determined on the basis of non-observable input factors (level 3 input factors according to IFRS 13). The financial liabilities include, on the one hand, the basic liability of the EIB loan, which is subsequently measured using the effective interest method, taking into account the current and bullet interest components. The carrying amount corresponds to the The fair value was determined on the basis of unobservable input factors (level 3 input factors according to IFRS 13) using discounted future cash flows. On the other hand, the financial liabilities include the bullet component of the EIB loan, which is recognised at fair value. This was calculated on the basis of market prices in an active market (level 2 input factor under IFRS 13) using the Black/Scholes model.

There were no changes between the hierarchy levels in the first half year 2022. The recoverability of the financial assets was reviewed on the basis of 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 2021.

**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, 31 August 2022

PAION AG



Dr. James Phillips



Sebastian Werner

Review Report

To PAION AG:

We have prepared the condensed consolidated interim financial statements – comprising the consolidated income statement and other comprehensive income, consolidated balance sheet, condensed statement of cash flows, condensed statement of changes in equity and selected explanatory notes – and the consolidated interim management report of PAION AG, Aachen, for the period from January 1 to June 30, 2022, 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 for interim reporting, as applicable in the EU, and the group interim management report in accordance with the provisions of the WpHG applicable to group interim management reports are the responsibility of the legal representatives of the company. Our responsibility is to issue a certificate on the condensed interim consolidated financial statements and the interim group management report based on our review.

We conducted our review of the condensed interim consolidated financial statements and the interim group management report in accordance with the German principles for the review of financial statements established by the Institute of Public Auditors in Germany (IDW). According to this, the auditor's review is to be planned and carried out in such a way that, after a critical appraisal, we can rule out with a certain certainty that the condensed consolidated interim financial statements are not in accordance with the IFRS for interim reporting in material respects as they are to be applied in the EU, and the interim group management report have not been prepared in material respects in accordance with the provisions of the WpHG applicable to interim group management reports. An auditor's review is primarily limited to surveys of the company's employees and to analytical assessments and therefore does not offer the security that can be achieved by an audit of the financial statements. Since we did not carry out an audit as ordered, we cannot issue an auditor's report.

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

Munich, Germany, August 31, 2022

Baker Tilly GmbH & Co. KG
Wirtschaftsprüfungsgesellschaft
(Düsseldorf)

(s) Weissinger	(s) Hanfland
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 BHF

Key figures	H1 2022	2021
Numbers of shares at the end of the period	71,336,992	71,336,992
Average daily trading volume (Xetra, Tradegate, in shares)	41,289	113,325
Year high (Xetra closing price)	EUR 1.64 (12 Jan. 2022)	EUR 2.55 (11 Jan 2021)
Year low (Xetra closing price)	EUR 0.69 (21 Jun 2022)	EUR 1.20 (29 Dec 2021)
Share price at the end of the period (Xetra)	EUR 0.92	EUR 1,20
Market capitalization at the end of the period (Xetra)	EUR 66 million	EUR 86 Mio.

Corporate Calendar

30 March 2022	Publication of the financial results 2021
18 May 2022	Publication of the financial results of the first quarter 2022
25 May 2022	Annual General Meeting
31 August 2022	Publication of the financial results for the first half-year 2022
16 November 2022	Publication of the financial results for the third quarter and the first nine months of 2022

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