PAION HI#2023

Consolidated Financial Interim Report for the First Half-Year 2023

PAION AG

01.01.
30.06.
2023

Contents

PAION

About PAION AG

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

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 anesthesia 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

(Figures in KEUR unless otherwise stated)	Q2 2023	Q2 2022	H1 2023	H1 2022
Revenues	4.524	3.728	6.790	25.230
Cost of sales	-3.020	16	-3.574	-655
Research and development expenses	-731	-1.913	-1.648	-3.051
General administrative and selling expenses	-4.378	-5.230	-9.350	-10.294
Earnings before interest and taxes (EBIT)	-3.781	-3.389	-7.957	11.112
Result for the period	-4.468	-3.839	-9.622	9.659
Earnings per share for the period (in EUR), basic	-0,63	-0,54	-1,35	1,35
Earnings per share (in EUR), diluted	-0,63	-0,54	-1,35	1,35

	H1 2023	H1 2022
Cash flow from operating activities	-5.883	11.979
Cash flow from investing activities	0	-631
Cash flow from financing activities	-61	-63
Change in cash and cash equivalents (before effect of exchange rate changes)	-5.945	11.285
Average number of employees in the Group	71	62

	30.06.2023	31.12.2022
Intangible assets	18.752	19.585
Cash and cash equivalents	4.647	10.629
Equity	-3.066	6.615
Current liabilities	16.803	12.616
Long-term debt	18.500	18.946
Balance sheet total	32.237	38.177

Interim Group Management Report for the First Half-Year 2023

The reporting period at a glance

January

PAION announces submission of Byfavo® marketing authorization application by its licensee CRISTÁLIA in Brazil

Extraordinary General Meeting approves capital reductions and creates scope for further corporate financing

PAION receives positive CHMP opinion recommending approval of Byfavo® for induction and maintenance of general anesthesia in adults

March

PAION hosts sponsored GIAPREZA®- Symposium at ISECEM in Brussels
TTY Biopharm (Taiwan) submitted a marketing authorization application for Byfavo® in general anesthesia in March 2023

April

PAION receives Byfavo® approval from the European Commission for the induction and maintenance of general anesthesia in adults

May

PAION to host sponsored Byfavo®- symposium at EUROANAESTHESIA 2023 in Glasgow

July (after the reporting period)

Hana Pharm receives marketing authorization for Byfavo® in general anesthesia in the Philippines

August

Tilmann Bur is announced as successor to Gregor Siebert as Chief Executive Officer.
PAION starts marketing Byfavo® in general anesthesia in the first European country
PAION receives marketing authorization for Byfavo® in general anesthesia in the UK

Update on business activities in the first half of 2023

Business performance in the first six months of 2023

PAION continued to expand its commercialization infrastructure for marketing activities in selected target markets in the first half of 2023, including the necessary production, supply and distribution structures as well as the marketing and sales processes for the entire product portfolio.

Feedback on the use of the products continues to indicate good market acceptance. Since the beginning of 2023, PAION has received positive feedback from customers about their experience with PAION's products, which has increasingly been reflected in product sales in recent weeks.

After the European Medicines Agency's Committee for Medicinal Products for Human Use (CHMP; Committee for Medicinal Products for Human Use) adopted a positive opinion on January 27, 2023, recommending approval of Byfavo® for the induction and maintenance of general anesthesia in adults, this was finally followed by approval by the European Commission on April 03, 2023 and the UK Medicines & Healthcare products Regulatory Agency (MHRA) approval for the UK followed end of August 2023.

In August 2023, it was announced that the commercialization of Byfavo® in general anesthesia has started in the EU and is now available for ordering and delivery to customers for use in the Netherlands. PAION has thus reached another important milestone for the commercial distribution of its innovative products in Europe.

Licensees generated product sales of EUR 4.4 million in the first six months of 2023 (H1 2022: EUR 2.7 million), resulting in royalties for PAION of EUR 0.5 million (H1 2022: EUR 0.3 million).

In the U.S., Eagle Pharmaceuticals had announced in early May 2023 that the Centers for Medicare & Medicaid Services ("CMS") has introduced a product-specific billing code for Byfavo® . The introduction of this unique so-called "J-code" (reimbursement code) for Byfavo® in the U.S. is an important step in facilitating reimbursement and expanding patient access to Byfavo® . On August 8, 2023, Eagle reported Q2 2023 numbers, stating that Byfavo® sales in Q1 2023 were up nearly 70% from the previous quarter and then doubled in Q2 2023 compared to Q1 2023.

Furthermore, Taiwanese licensee TTY Biopharm submitted the marketing authorization application for Byfavo® in general anesthesia in March 2023 and expects approval by the end of 2023.

Hana Pharm, licensee of Byfavo® for South Korea and Southeast Asia had received approval from the Philippine FDA in July 2023 for Byfavo™ 50mg for the induction and maintenance of general anesthesia. Hana Pharm plans to launch the product in the Philippines in the fourth quarter of this year.

Financial overview

In the first half of 2023, revenues of EUR 6.8 million (prior-year period: EUR 25.2 million) were recognized, mainly from the sale of Byfavo® to licensees, but also from milestone payments from Byfavo® license agreements and royalties from the commercialization of Byfavo® . Research and development expenses decreased as planned to EUR 1.6 million (prior-year period: EUR 3.0 million). This is mainly the result of proactive cost management. Administrative and selling expenses amounted to EUR 10.0 million in the first half of 2023 and have decreased compared to the prior-year period (EUR 10.3 million). Overall, PAION achieved earnings before interest and taxes (EBIT) of EUR -7.8 million in the first half of 2023 compared to EBIT of EUR 11.1 million in the same period of the previous year.

Cash and cash equivalents decreased by a total of EUR 6.0 million in the first half of 2023 compared with December 31, 2022, and amounted to EUR 4.6 million as of June 30, 2023.

Capital Market Environment and Development of the PAION Share

Developments on the German capital markets in the first six months of 2023 continued to be dominated by geopolitical conflicts. Added to this were global supply chain disruptions, rising inflation and a more restrictive monetary policy. In addition, the ongoing war in Ukraine and the associated sanctions against Russia increased uncertainty about economic developments. The DAXsubsector Biotechnology declined by around 9% in the first six months of 2023, and the NASDAQ Biotechnology Index also fell slightly by around 3%.

The resolutions of the Extraordinary General Meeting of PAION AG on 25 January 2023 regarding the reductions of the share capital were entered into the commercial register at the Local Court of Aachen on 14 March 2023. As of April 12, 2023, the converted shares will be traded under ISIN DE000A3E5EG5. For better comparability, the total values for 2023 are shown in converted form at a ratio of 10:1.

The PAION share started the year 2023 with a price of EUR 5.12 (Xetra closing price). The highest price in the first six months of 2023 was marked on 31 January 2023 with EUR 8.86 based on Xetra closing prices. The lowest price in the first six months of 2023 was marked on May 05, 2023 at EUR 4.35 (Xetra closing price). The closing price on June 30, 2023 was EUR 6.03 (Xetra). This corresponds to an increase of approximately 37% compared with the closing price on December 30, 2022 (EUR 4.40; Xetra).

The average daily trading volume in the first six months of 2023 was 26,091 shares (Xetra+Frankfurt). In 2022 as a whole, the average daily trading volume was 39,370 shares (Xetra+Frankfurt).

Development of the PAION share price in the first half of 2023

Presentation of the course of business and development activities

The PAION Group's product portfolio mainly consists of Byfavo® (INN: Remimazolam) with its three target indications of procedural sedation, general anesthesia and ICU sedation, as well as the products GIAPREZA® (INN: Angiotensin II) and XERAVA® (INN: Eravacycline).

Byfavo® (remimazolam besilate).

Byfavo® is an ultra-short-acting intravenous benzodiazepine sedative and -anesthetic. In humans, Byfavo® is largely degraded to an inactive metabolite by hepatic esterases, a widely distributed type of enzyme, rather than via cytochrome-dependent degradation pathways in the liver. As with other benzodiazepines, an antidote is available in flumazenil for rapid withdrawal of the patient's sedation or anesthesia if needed. Data show that Byfavo® has a rapid onset of action and a rapid resolution of effect, with a favorable cardiorespiratory safety profile.

Byfavo® is approved in the US, EU/EEA/UK, China, South Korea and Taiwan for procedural sedation and in the EU/EEA, Japan, Philippines and South Korea for general anesthesia.

In addition to procedural sedation and general anesthesia, ICU sedation is another possible indication for Byfavo.®

Byfavo® is partnered in the USA (trade name BYFAVO™) with Eagle Pharmaceutical (Eagle), in Japan (trade name Anerem®) with Mundipharma, in South Korea (trade name Byfavo™) and Southeast Asia with Hana Pharm, in Latin America with Cristália and in Taiwan with TTY Biopharm. In addition, PAION has distribution partnerships with Viatris for Belgium, Poland, France and Romania as well as the Southern European countries Italy, Spain and Greece and in Eastern Europe (Estonia, Latvia and Lithuania, Czech Republic, Slovakia, Hungary, Croatia, Slovenia and Bulgaria) with Medis. These markets are currently not served by PAION itself.

Procedural sedation market (USA + Europe)

The growth of the procedural sedation market in the U.S. has been driven for many years by the increase in procedural sedation medical procedures, such as colonoscopies, as well as increasing overall demand for preventive care.

In Europe, PAION currently estimates a peak sales potential of approximately EUR 40 million to approximately EUR 50 million annually for procedural sedation based on its own projections. In contrast to the U.S. market, which has a large independent infrastructure for outpatient surgical procedures, procedural sedation in Europe is mainly used in hospitals, where anesthesiologists have the overall responsibility for sedating patients. This has a high synergy potential with the planned commercialization of Byfavo® for use in general anesthesia. In addition, the area of day surgery is also growing in Europe, so that PAION expects a steady growth in short-stay sedations there as well. One driver of this development is the establishment and further spread of measures for colorectal cancer screening (diagnostic colonoscopies). However, important users here are also gastroenterologists, for example. Another short- to medium-term factor is the backlog of patients left untreated during the Covid 19 pandemic, which increases the need for a product such as Byfavo® to increase process efficiency.

General anesthesia market (Europe)

Based on publicly available statistics from previous years on procedures and surgeries in Europe as well as market research, PAION estimates that approximately 29 million surgeries are performed under general anesthesia in Europe each year. Of these, approximately 10 million procedures are performed on high-risk patients (American Society of Anesthesiologists- ("ASA") classifications III or higher) who are particularly susceptible to hemodynamic instability. Approximately 55% of all anesthetics are balanced anesthetics, i.e., a combination of intravenous agents and anesthetic gases, approximately 20% are intravenous anesthetics (TIVA) with propofol, and the remaining approximately 25% are regional anesthetics (e.g., epidural anesthetics). According to PAION's market research, the main anesthetics currently used in Europe for general anesthesia are propofol (mainly for induction) and anesthetic gases, mostly in combination with intravenous opioids.

PAION expects the number and complexity of medical procedures involving the induction and maintenance of anesthesia to increase in Europe in the future, driven in particular by the expected continued aging of the population and advances in surgical techniques. General anesthesia is offered more frequently to elderly patients than it was a few years ago, so that the choice of an individual anesthetic is made depending on the type of surgery, the underlying disease and the assessment of the patient's overall physical health, including concomitant diseases.

Accordingly, PAION expects demand for safer agents with low respiratory and cardiovascular depressant effects to increase in Europe in the coming years. This creates promising opportunities for anesthetics with an improved safety profile such as Byfavo® , even at higher prices compared to existing generic compounds. In Europe, PAION currently estimates a peak sales potential of approximately EUR 50 million to approximately EUR 60 million annually for general anesthesia based on its own projections.

In adults, myocardial injury in noncardiac surgery (MINS) is the most common cardiovascular complication associated with such procedures. Previous studies have concluded that intraoperative myocardial injury in noncardiac surgery occurs in approximately 8% of the approximately 200 million patients worldwide each year and results in higher mortality; for example, approximately 10% of patients who suffer such injury die within 30 days of the respective procedure. Among other things, this is thought to be caused by (excessively) low blood pressure and the associated temporary undersupply of oxygen to the heart muscle during the procedure. [1] Based on the safety data available to date, Byfavo® could make a significant contribution to reducing this mortality rate by reducing intraoperative blood pressure drops.

An emerging market driver is the requirement for hospitals to consider their environmental footprint and ecological impact. In this regard, volatile gases used in anesthesia are a major negative factor leading to more frequent use of TIVA and thus an expanded market opportunity for Byfavo® as an intravenous anesthetic.

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[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.

ICU sedation

Based on data published in Critical Care Medicine on the average length of treatment in ICUs in days per year in the U.S. as well as scientific journal articles from Intensive Care Medicine , in which, among other things, the number of admissions to ICUs per year and the number of adult beds in ICUs in various countries in the EU were surveyed, PAION estimates that in Europe and the U.S. together there are currently at least 14 million patient days in ICUs requiring intensive care per year. A recent publication based on eight EU countries estimates 17.5 million patient days (not necessarily sedated) in the EU alone. [2] PAION expects these numbers to increase in the coming years due to the aging population in both the US and Europe and anticipates that demand for safe sedation drugs such as Byfavo® will increase as elderly patients are significantly more likely to be affected by systemic diseases.

Clinical development

Procedural sedation

The clinical development program of Byfavo® in the USA was successfully completed.

Summary of key results from the three Phase III studies:

	Byfavo®	**Placebo**	**Midazolam (Open Label)***
Primary endpoint reached (ITT)	80.6-91.3 %	0.0-4.8 %	12.9-32.9 %
Time from administration to the start of the procedure	4.0-5.0 min	17-19.5 min	15.5-19.0 min
Time from the end of the procedure to full consciousness	3.0-6.0 min	5.3-15.0 min	7.0-13.0 min
Time to reach normal state (median)	192-402 min	348-936 min	366-444 min

* Comparison with midazolam was descriptive (no significance testing).

General anesthesia

A particular focus in the clinical programs was hemodynamic stability, which addresses an important medical need in general anesthesia. Nonclinical data had indicated, and clinical data have confirmed, that better hemodynamic stability can be achieved with Byfavo® than with propofol.

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

In Europe, a randomized, single-blind, propofol-controlled, confirmatory Phase III study was conducted in 425 ASA III/IV patients (American Society of Anesthesiologists classification III-IV) undergoing planned surgery at more than 20 European study sites. The

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

primary study objective was to demonstrate that Byfavo® is non-inferior ("non-inferiority") to propofol in its efficacy for induction and maintenance of general anesthesia during planned surgery. The secondary primary objective was to demonstrate improved hemodynamic stability compared with propofol. In the study, Byfavo® met both the primary and key secondary endpoints.

Sedation in the intensive care unit

In 2021, an IIT (investigator-initiated) REHSCU [3] (IIT: Investigator Initiated Trial) was conducted. This study, conducted at the University of Nantes, evaluated Byfavo® for sedation of patients in the intensive care unit. 30 patients were enrolled in the study. In particular with regard to pharmacokinetics, the study provided further evidence for a successful use of Byfavo® for the sedation of patients in the intensive care unit.

PAION is currently not pursuing further development in this indication.

Pediatric development

PAION submitted a pediatric development plan to the EMA in 2018, which was approved in November 2019. This development plan calls for the conduct of various studies over several years, beginning in the procedural -sedation setting. In September 2021, PAION and Acacia, then Byfavo® licensee for the U.S., announced the initiation of a pivotal study, required for regulatory approval, evaluating Byfavo® in pediatric sedation. The study will enrol approximately 100 children and adolescents, ages up to and including 17 years, at leading facilities in the United States and Denmark. If the program is successful, it is expected that the EU and U.S. approvals of Byfavo® will be expanded to include mild to moderate sedation for procedures in pediatric patients.

Post-approval obligations and life cycle management

PAION is currently working and will continue to work on a number of formulation development activities as well as on the preparation and conduct of non-clinical and clinical studies for Byfavo® , to fulfil post-approval obligations and for life cycle management. Most of these activities are pediatric studies to make these drugs available for use in children.

Regulatory activities of the product portfolio

In Europe, Byfavo® is approved for the indication of procedural sedation and general anesthesia.

After the European Medicines Agency's Committee for Medicinal Products for Human Use (CHMP; Committee for Medicinal Products for Human Use) adopted a positive opinion on 27 January 2023, recommending approval of Byfavo® for the induction and maintenance of general anesthesia in adults, this was finally followed by approval by the European Commission on 03 April 2023 and the UK Medicines & Healthcare products Regulatory Agency (MHRA) approval for the UK followed end of August 2023.

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

The Norwegian Decision Forum (the overarching decision maker in specialist care in Norway) has approved the use of GIAPREZA® for the treatment of refractory hypotension. This means that the use has been approved since 1 July 2023.

Commercial activities of the product portfolio

PAION has established a commercialization infrastructure for its marketing activities in selected target markets, including the necessary production, supply and distribution structures as well as the marketing and sales processes for the entire product portfolio. Nevertheless, PAION follows a business model based on low fixed assets and maintains only centralized functional areas within its own organization in order to be able to focus on its core competencies. Accordingly, Byfavo® or the active pharmaceutical ingredient for Byfavo® is manufactured, packaged and labelled by several external contract manufacturers for PAION and/or its cooperation partners. In addition, PAION has entered into agreements as a one-stop solution for distribution processes. Agreements have also been concluded with vendors for the provision of medical/scientific contacts and key account management services. Currently, PAION sources GIAPREZA® and XERAVA® under a separate supply agreement from La Jolla, a subsidiary of Innoviva.

In the UK, the company has a partnership with Clinigen for the supply of PAION's products. With further successful listings of Byfavo® in National Health Service (NHS) Trust hospitals, PAION expects to see sustained growth in the uptake of its products in the UK going forward. Following receipt of market approval for general anesthesia, the launch in the UK followed early September 2023.

In Scandinavia, Denmark acts as the sales center, with sales activities currently focused on Byfavo®.

In the Netherlands, all three products are listed and available. PAION's sales team is expanding the original target group of anesthesiologists to gastroenterologists and therefore expects strong synergies and a highly efficient use of the sales force by marketing multiple products.

Based on the approval of Byfavo® for the induction and maintenance of general anesthesia in adults by the European Commission, PAION had started commercialization in general anesthesia in Europe in August 2023 and is now available for ordering and delivery to customers in the Netherlands. PAION has thus reached another important milestone for the commercial distribution of its innovative products in Europe.

The market launch of Byfavo® in Germany will continue to be postponed until further study data and experience are available that can prove the additional benefit, as the previous Byfavo® studies against propofol may not be broad enough to prove the required additional benefit in the short term. Therefore, PAION is currently focusing its marketing efforts on countries with low market entry barriers.

PAION has continued to commercialize GIAPREZA® in 2023. It is currently commercially available in Germany, the Netherlands, Austria, UK, Portugal, Denmark, Sweden, Norway and Finland. The commercialization of XERAVA® was also intensified in 2023. It is currently commercially available in the Netherlands, Germany, Austria, UK, Portugal, Denmark, Sweden and Finland.

The build-up of commercial sales with the involvement of experienced distribution partners has successively shown effect in 2023, accompanied by an increase in product sales. Since the beginning of 2023, PAION has received positive feedback from customers about their

experience with PAION's products, which has been increasingly reflected in product sales in recent weeks. Viatris and Medis are also preparing product launches and are subject to pricing and reimbursement approvals in most countries.

To achieve PAION's goal of becoming a leading specialty pharmaceutical company in anesthesia and critical care, the following key elements of the strategy have been identified:

PAION aims to become a recognized market player with innovative products in the field of anesthesia and intensive care medicine in the coming years;

PAION has established its own marketing capabilities combined with distribution partners in Europe. Medis has already started product sales and Viatris is expected to follow in H2 2023.

The staggered rollout of Byfavo®, GIAPREZA® and XERAVA® in the European markets will continue in order to achieve profitability in the medium term; and

PAION intends to continue to explore synergy potentials, in-licensing of additional products and other opportunities to support longer-term growth.

Partner activities in the first half of 2023

Licensees generated product sales of EUR 4.4 million in the first six months of 2023 (H1 2022: EUR 2.7 million), resulting in royalties for PAION of EUR 0.5 million (H1 2022: EUR 0.3 million).

In the **U.S.,** Eagle Pharmaceutical had announced in early May 2023 that the Centers for Medicare & Medicaid Services ("CMS") has implemented a unique, product-specific billing code for Byfavo®. The introduction of a unique so-called "J-code" (reimbursement code) for Byfavo® in the U.S. on July 1, 2023 is an important step in facilitating reimbursement and expanding patient access to Byfavo®. On 8 August 2023, Eagle reported Q2 2023 numbers, reporting that Byfavo® sales in Q1 2023 were up nearly 70% from the previous quarter and then doubled in the final quarter Q2 2023 compared to Q1 2023.

In **Japan,** Mundipharma had successfully completed clinical trials (Investigator Initiated Clinical Trials) in 2022 to evaluate the efficacy and safety of Byfavo® (brand name Anerem®) in Japanese patients undergoing gastrointestinal endoscopy. These studies are a prerequisite for the planned regulatory submission in procedural sedation, which is scheduled for 2023.

In **Taiwan,** TTY Biopharm had submitted the marketing authorization application in general anesthesia in March 2023 and expects approval by the end of 2023.

Hana Pharm, licensee of Byfavo® for **South Korea** and **Southeast Asia** had received approval from the Philippine FDA in July 2023 for Byfavo™ 50mg for the induction and maintenance of general anesthesia. Hana Pharm plans to launch the product in the Philippines in the fourth quarter of this year.

GIAPREZA® and XERAVA®

PAION AG and PAION Deutschland GmbH have entered into a license agreement for GIAPREZA® and XERAVA® with La Jolla Pharmaceutical Company in January 2021. In addition to a payment of USD 22.5 million already made, La Jolla is entitled to further payments contingent on the achievement of certain commercial milestones. In July 2022, it was announced that Innoviva Inc, a diversified holding company with a portfolio of royalty and

other healthcare assets, planned to acquire La Jolla. The acquisition was completed on 22 August 2022. The existing agreement remains unaffected.
The agreement grants PAION an exclusive license to market these two approved products in the European Economic Area, UK and Switzerland.

GIAPREZA ®

GIAPREZA® for injection is an FDA-approved vasoconstrictor to increase blood pressure in adults with septic or other distributive shock. GIAPREZA® is approved by the European Commission and the United Kingdom Food and Drug Administration for the treatment of refractory hypotension in adults with septic or other distributive shock who remain at low blood pressure despite adequate volume restitution and use of catecholamines and other available vasopressor therapies. GIAPREZA® mimics the endogenous GIAPREZA® peptide, which plays a central role in the renin- GIAPREZA®- aldosterone system, which in turn regulates blood pressure.

GIAPREZA® increases blood pressure by vasoconstriction; the increased release of aldosterone by the direct action of GIAPREZA® on the vessel wall is mediated by binding to the G-protein-coupled GIAPREZA® receptor type 1 on vascular smooth muscle cells, stimulating Ca2+/calmodulin-dependent phosphorylation of myosin and causing smooth muscle contraction.

The European summary of product characteristics is available on the EMA website: www.ema.europa.eu/en/medicines/human/EPAR/giapreza.

PAION has started marketing GIAPREZA® in 2021. Especially in the last months, an increase in product orders could be noted.

Market

Regarding GIAPREZA® , the occurrence of distributive shock due to sepsis remains one of the most important unmet medical needs in healthcare. According to the information available to PAION, the mortality rate of patients with septic shock is higher than for most other acute conditions requiring hospitalization (including pneumonia, acute myocardial infarction and heart failure). A relatively high mortality rate is seen in shock patients who do not respond to existing treatment options. Globally, an estimated 47 to 50 million sepsis cases and at least 11 million sepsis-related deaths occur each year, accounting for approximately 20% of all deaths worldwide. Sepsis mortality rates vary from 15% to more than 50% depending on the [4] . The first line of therapy in septic shock is catecholamines (such as dopamine, epinephrine or norepinephrine) and the second line of therapy consists of vasopressors (alternative drugs that constrict blood vessels, such as argipressin or vasopressin), while the prioritization of GIAPREZA® varies from market to market. PAION estimates that approximately 100,000 to 150,000 patients with septic shock would not respond adequately to first- and second-line treatment and would be eligible for treatment with GIAPREZA® . In addition, certain existing second-line drugs are not reimbursed in certain European countries due to their lack of efficacy

[4] World Sepsis Day, What is sepsis? September 2020 (https://www.worldsepsisday.org/sepsis)

in catecholamine-resistant septic shock, which may provide an opportunity to establish GIAPREZA® as a second-line drug in the relevant markets.

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

XERAVA®

XERAVA® for injection is a novel fluorocycline from the tetracycline class. XERAVA® is an antibiotic used to treat complicated intra-abdominal (affecting the abdomen) infections (cIAI) in adults. According to the Infectious Diseases Society of America (IDSA), a cIAI is defined as an infection that spreads beyond the wall of a hollow viteum of origin into the abdominal cavity and is associated with an abscess or peritonitis. [5]

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

XERAVA® is approved by the FDA for the treatment of complicated abdominal infections in patients 18 years of age and older. XERAVA® is approved by the European Commission and the UK Medicines Agency for the treatment of abdominal infections in adults. Official guidelines for the appropriate use of antibacterial medicinal products should be taken into account.

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 has started marketing XERAVA® in 2021. In April 2022, PAION was informed that the Federal Joint Committee (G-BA) has endorsed PAION's application for XERAVA® as a reserve antibiotic. Thus, XERAVA® is granted an additional benefit compared to standard care. The price negotiations with the G-BA in Germany were recently successfully concluded. Product sales of XERAVA® have also increased in recent months.

Market

XERAVA® competes with several established antibiotics on the market for complicated intra-abdominal infections. In particular, established generic antibiotic classes, including the carbapenem class, the cephalosporin class or fluoroquinolones, form the first line of therapy, while established non-generic antibiotics such as avibactam, ceftazidime and ceftolozane-tazobactam typically form the second line of therapy in the relevant markets. Clinical studies have shown that XERAVA® has favorable specifications and comparable activity to ertapenem and meropenem, two widely used carbapenem-class antibiotics that have been on the market for decades. Due to the steadily increasing use of carbapenems, resistance to carbapenems has also increased, particularly in Europe, and strains of pathogens that are particularly difficult to treat have been identified in several European markets [6]. PAION available information indicates

[5] 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.

[6] Magiorakos, A. P., Suetens, C., Monnet, D.L. et al. (2013), The rise of carbapenem resistance in Europe: just the tip of the iceberg?, Antimicrob Resist Infect Control 2, 6 (2013) (https://aricjournal.biomedcentral.com/articles/10.1186/2047-2994-2-6).

that a large number of infections occur in Europe each year, resulting in a significant number of deaths due to bacteria that are resistant to antibiotics. This in turn leads to significant costs for healthcare systems. XERAVA® offers several advantages over carbapenems. First, XERAVA® demonstrates significantly higher efficacy against a broad spectrum of typically multidrug-resistant pathogens. In addition, XERAVA® can be prescribed even if the causative agent of the infection has not yet been identified. In addition, XERAVA® does not need to be adjusted in patients with impaired renal function.

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 2023 KEUR	Q2 2022 KEUR	H1 2023 KEUR	H1 2022 KEUR
Revenues	4,524	3,728	6,790	25,230
Cost of sales	-3,020	16	-3,574	-655
Gross profit	1,504	3,744	3,217	24,575
Research and development expenses	-731	-1,913	-1,648	-3,051
General administration and selling expenses	-4,378	-5,230	-9,350	-10,294
Other income (expenses)	-177	11	-177	-119
Operating expenses	-5,286	-7,132	-11,174	-13,463
Operating result	-3.781	-3,389	-7,957	11,112
Financial result	-687	-357	-1,664	-958
Income taxes	0	-93	0	-494
Net result for the period	-4,468	-3,839	-9,622	9,659

Revenues amounted to KEUR 6,790 in the first half of 2023, of which KEUR 1,014 was attributable to milestone payments and KEUR 4,701 to Remimazolam drug sales to licensees (H1 2022: KEUR 1,050), KEUR 480 to royalties (H1 2022: KEUR 311) and KEUR 595 (H1 2022: KEUR 84) to commercial product sales to wholesalers and hospitals in selected European markets. In the prior-year period, revenues amounted to KEUR 25,230 and mainly resulted from milestone payments or from the sale of licenses.

Cost of sales amounted to KEUR 3, in the first half of 2023.

Research and development expenses in the first half of 2023 amounted to KEUR 1,648 (prior-year period: KEUR 3,051) and were reduced as planned compared with the prior-year period due to strict cost control.

General and administrative expenses decreased by KEUR 944 to KEUR 9,350 in the first half of 2023 compared to the prior-year period, with general and administrative expenses increasing by KEUR 458 to KEUR 3,038 and selling expenses decreasing by KEUR 1,403 to KEUR 6,311.

Earnings before interest and taxes in the first half of 2023 amounted to KEUR -7,957 and decreased by KEUR 19,069 compared with the prior-year period (earnings before interest and taxes in the prior-year period: KEUR 11,112).

The **financial result** amounted to KEUR -1,664 in the first half of 2023 (prior-year period: KEUR -959) and mainly comprises expenses in connection with the EIB loan from the previous year. The deterioration of the financial result mainly results from the revaluation of the performance-based interest component of the EIB loan.

Income taxes in the first half of 2023 amounted to KEUR 0 (prior-year period: KEUR -494) due to the losses. In the prior-year period, it was mainly corporate income tax liability to the UK tax authorities due to the significantly increased milestone payments and license sales.

The **result for the period** in the first half of 2023 amounted to KEUR -9,622 compared with a result for the period of KEUR 9,659 in the prior-year period. This corresponds to a decrease in the net result for the period of KEUR 19,281 compared to the first half of 2022. The reduction in the result for the period is mainly due to the patent sales to Humanwell in the previous year. These led to extraordinary sales in the previous year.

Net assets

	30/06/2023 KEUR	31/12/2022 KEUR	Change KEUR
Non-current assets	19,421	20,344	-923
Current assets	12,816	17,833	-5,017
Total Assets	32,237	38,177	-5,940
Equity	-3,066	6,615	-9,681
Non-current liabilities	18,500	18,946	-446
Current liabilities	16,803	12,616	4,187
Total Equity and liabilities	32,237	38,177	-5,940

Non-current assets mainly comprise the carrying amount of GIAPREZA® (KEUR 12,151) and XERAVA® (KEUR 2,973), which have been in-licensed for marketing in the European Economic Area, the United Kingdom and Switzerland and have already been approved in Europe, as well as the carrying amount of the ERP system capitalized as of January 1, 2023 (KEUR 2,186).The carrying amount of the ERP system capitalized as of January 1, 2023 (KEUR 2,186) and the carrying amount of the Byfavo® development project capitalized as part of the CeNeS acquisition in 2008 (KEUR 1,442), less scheduled amortization, as well as rights to use office space (KEUR 526).

Current assets comprise cash and cash equivalents (KEUR 4,647), inventories (KEUR 4,284), other assets and prepaid expenses (KEUR 2,030) and trade receivables (KEUR 1,854). The decrease of KEUR 5,017 compared with December 31, 2022 is due on the one hand to a decrease in cash and cash equivalents of KEUR 5,982, and on the other hand to an increase in inventories of KEUR 564, a decrease in trade receivables of KEUR 374 and an increase in other assets and prepaid expenses of KEUR 775. The increase in other assets and prepaid expenses is mainly due to the deferral of the costs of the capital increase that have not yet been offset against equity.

The decrease in **equity** by KEUR 9,681 compared to December 31, 2022 is mainly due to the net loss for the first half of 2023 in the amount of KEUR -9,622. The equity ratio as of June 30, 2023 is -9.5% (December 31, 2022: 17.3%).

Non-current liabilities mainly relate to the carrying amount of the non-current portion of the EIB loan (KEUR 18,071 including the performance-related, bullet payment component) and to liabilities under leases (KEUR 406).

Current liabilities increased by a total of KEUR 4,187 compared to December 31, 2022, mainly due to an increase in trade payables of KEUR 2,815 and the current portion of the EIB loan of KEUR 1,357.

Financial position

Cash and cash equivalents decreased by KEUR 5,982 compared to December 31, 2022 to KEUR 4,647 at the end of the current reporting period. The change in cash and cash equivalents results from the following areas:

	H1 2023 KEUR	H1 2022 KEUR
Cash flow from operating activities	-5,883	11,979
Cash flow from investing activities	0	-631
Cash flow from financing activities	-62	-63
Effects of course changes	-37	-35
Change in cash and cash equivalents	-5,982	11,250

Cash flow from operating activities in the first half of 2023 amounted to KEUR -5,883 and resulted mainly from the profit for the period, adjusted for non-cash expenses and income, and changes in working capital.

Cash flow from investing activities amounted to KEUR 0 in the first half of 2023. In the previous year, this was mainly attributable to an ERP system under development (KEUR 591).

The **cash flow from financing activities** results from the repayment portion of lease payments (KEUR -62).

Personnel Development

In the first six months of 2023, PAION employed an average of 71 employees (fiscal year 2022: 62 employees). As of June 30, 2023, PAION had a total of 64 employees.

Impact of the Covid 19 pandemic on the PAION Group

Since the beginning of 2020, a new form of the coronavirus (SARS-CoV-2), which causes the respiratory disease Covid-19, had spread internationally. The pandemic had led to sometimes massive restrictions on public life worldwide, as well as significant declines in economic

output. The success of containment measures, the resulting rate of spread of the virus, and the resulting restrictions in place, particularly in public areas, varied greatly from region to region and also varied significantly depending on the infection. At the time of this writing, most of the measures have been lifted and the transition from pandemic to endemic is underway.

In the past fiscal year, the Covid 19 pandemic again severely restricted market access in some countries such as the USA.

To date, the pandemic has had a moderate direct impact on the PAION Group. On the one hand, PAION currently still realizes a significant portion of its revenues from milestone payments. The underlying milestones are largely independent of the general economic development. On the other hand, PAION was able to continue its business activities almost unchanged even under significant restrictions in public life, as the presence of employees in the business premises was in most cases not mandatory for the normal continuation of operations. On the other hand, however, access to clinics and prescribers has been limited due to the impact of Covid-19 on the healthcare system, resulting in moderate product sales in some cases. PAION hopes to accelerate growth in 2023.

Overall, there has been a moderate direct impact of the pandemic on the PAION Group's net assets, financial position and results of operations to date. Due to limited access to hospitals and prescribers, PAION had a moderate negative impact of the pandemic on its own marketing of the products Byfavo® , GIAPREZA® and XERAVA® . A positive impact could be the backlog of patients left untreated during the Covid 19 pandemic, increasing the need for a product such as Byfavo® to increase process efficiency.

Impact of the Ukraine War on the PAION Group

The Ukraine war, which started on February 24, 2022, has so far not had a significant impact on the PAION Group's business. 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.

Risk and Opportunities

Indication of the existence of a going concern risk

As a precautionary measure, it is pointed out that PAION AG continues to rely on the injection of additional funds to ensure its ability to continue as a going concern and to secure its future solvency. The ability
to continue as a going concern is subject to significant uncertainties, as the negotiations on the granting of additional financial resources are well advanced, but at the time of reporting no legally binding commitments have been made The initiated financing measures mainly comprise further outlicensing, capital measures and debt financing. In the event of failure of the initiated financing measures, there is a high probability that the current corporate strategy cannot be continued. With regard to the need for future financing measures, reference is also made to the statements in the sections "Financing risks" " in the Group management report for the financial year 2022 and "Financial outlook 2023. These events and circumstances indicate the existence of a material uncertainty that may cast significant doubt about the Company's ability to continue as a going concern and represents a going concern risk.

General note

The main risks and opportunities of future development are presented in detail in the Group management report for fiscal 2022. The overall picture of opportunities and risks has not changed significantly in the first half of 2023.

Significant events after the balance sheet date

On July 17, 2023, PAION announced that Hana Pharm has received marketing authorization for Byfavo® in general anesthesia in the Philippines.

On August 14, 2023, Tilmann Bur is announced as successor to Gregor Siebert as Chief Executive Officer.

On August 22, 2023, PAION announced that marketing of Byfavo® in general anesthesia has started in the first European country.

On August 31, 2023, PAION receives MHRA approval for Byfavo® for the induction and maintenance of general anesthesia in adults in the United Kingdom.

Report on expected developments

Business Outlook

PAION confirms the business outlook for the full year 2023 announced with the Annual Financial Report 2022. PAION continues to focus on the commercialization of its product portfolio in 2023, consisting of the approved products Byfavo® , GIAPREZA® and XERAVA® . By the end of 2023, the commercialization launch of Byfavo® for the indication of procedural sedation and for general anesthesia should also have taken place in other European markets.

In addition, research and development activities are mainly focused on the pediatric development as well as the processing of so-called "post-approval-commitments" and "life-cycle management" for Byfavo® , GIAPREZA® and XERAVA® . In addition, PAION continues its activities in the area of production development in order to further improve the manufacturing processes.

With Byfavo® being marketed in the U.S., Japan, South Korea and large parts of Europe, PAION expects increasing product sales and revenues from licensees and distributors in the coming years, resulting in an increase in royalty income.

Financial outlook 2023

PAION confirms the financial outlook for the full year 2023 announced with the Annual Financial Report 2022. PAION expects revenues of approximately EUR 13 million to approximately EUR 19 million in 2023. Approximately EUR 1 million of revenues are expected from existing licensees and approximately EUR 12 million from sales of Remimazolam active ingredient. Revenues from distribution partners in Europe and revenues from own sales of Byfavo® , GIAPREZA® and XERAVA® are expected to range from approximately EUR 2 million to approximately EUR 4 million.

The cost of sales will amount to approximately EUR 11 million to approximately EUR 15 million.

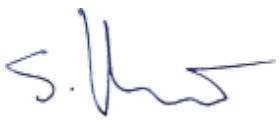
The focus of activities in 2023 will continue to be on marketing and sales, so that administrative and selling expenses of approximately EUR 10 million to approximately EUR 13 million are expected, depending on the progress of commercial activities. Research and development expenses are budgeted between approximately EUR 4 million and approximately EUR 6 million. Earnings before interest, taxes, depreciation and amortization (EBITDA) of approximately EUR -15 million to approximately EUR -13 million are forecast for 2023.

PAION expects the number of employees to remain stable at the previous year's level in 2023.

The key assumption for the outlook is that the activities of PAION and the licensees will continue 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 2023. Delays would lead to a postponement of significant cost blocks and/or revenues into the year 2024 or beyond.

PAION expects increasing revenues in the coming years, both from licensing agreements and from its own commercialization in parts of Europe. The Management Board of PAION AG is working at full speed to establish a solid financing concept. In particular, additional funding will be required for the further expansion of the sales infrastructure, the ongoing sales activities in Europe as well as so-called "post-approval commitments" towards the respective regulatory authorities, e.g. possible Phase IV studies after approval or market launch of the products. According to current planning, there is a financing requirement of approximately EUR 30 million in the coming years until break-even, which could be raised through various financing measures and further partnerships. Based on cash on hand, expected payments from revenues and potential financing and/or out-licensing, PAION expects to have sufficient cash and cash equivalents for the next 12 months, taking into account the current planning.

Aachen, 29 September 2023
PAION AG



Gregor Siebert Sebastian Werner

Tilmann Bur

Condensed Consolidated Interim Financial Statements

Consolidated balance sheet

ASSETS	June 30, 2023 KEUR	Dec. 31, 2022 KEUR
Non-current assets		
Intangible assets	18,752	19,585
Property, plant and equipment	143	168
Rights of use	526	591
Other assets		0
	19,421	**20,344**
Current assets		
Trade receivables	1,854	2,228
Inventories	4,284	3,720
Receivables from affiliated companies		0,00
Prepaid expenses and other assets	2,031	1,256
Cash and cash equivalents	4,647	10,629
	12,816	**17,833**
Total assets	**32,237**	**38,177**

EQUITY AND LIABILITIES	June 30, 2023 KEUR	Dec. 31, 2022 KEUR
Equity		
Share capital	7,134	71,337
Capital reserve	208,750	144,539
Translation reserve	-1,115	-1,048
Loss carryforward	-208,213	-207,634
Result for the period	-9,622	-579
	-3,066	**6,615**
Non-current liabilities		
Financial debt	18,071	18,468
Lease liabilities	406	452
Provisions	23	26
	18,500	**18,946**
Current liabilities		
Trade payables	10,874	8,005
Provisions	417	845
Financial debt	2,641	1,285
Lease liabilities	132	147
Tax liabilities	0	98
Other current liabilities	2,739	2,236
	16,803	**12,616**
Total equity and liabilities	**32,237**	**38,177**

Consolidated Statement of Comprehensive Income

KEUR	April 1 - June 30, 2023	April 1 - June 30, 2022	January 1 - June 30, 2023	January 1 - June 30, 2022
Revenues	4,524	3,728	6,790	25,230
Cost of sales	-3,020	16	-3,574	-655
Gross profit	1,504	3,744	3,217	24,575
Research and development expenses	-731	-1,913	-1,648	-3,051
General administrative and selling expenses	-4,378	-5,230	-9,350	-10,294
Other income (expense), net	-177	10	-177	-119
Operating expenses	-5,286	-7,133	-11,174	-13,463
Operating result	-3781	-3,389	-7,957	11,112
Financial income		4	0	11
Financial expenses	-687	-362	-1,664	-969
Financial result	-687	-357	-1,664	-958
Result for the period before taxes	-4,468	-3,746	-9,622	10,153
Income taxes	0	93	0	494
Result for the period	-4,468	-3,839	-9,622	9,659
of which attributable to minority interests	0	0	0	0
thereof attributable to shareholders of PAION AG	-4,468	-3,839	-9,622	9,659
Foreign currency translation	0	42	67	-75
Change in amounts recognized in equity that are reclassified to profit or loss under certain conditions	0	42	67	-75
Changes recognized directly in equity	0	42	67	-75
Other comprehensive income	-4,468	-3,797	-9,555	9,584
of which attributable to minority interests	0	0	0	0
thereof attributable to shareholders of PAION AG	-4,468	-3,797	-9,555	9,584
Earnings per share (undiluted)	-0.63	-0.53	-1.35	1.35
Earnings per share (diluted)	-0.63	-0.53	-1.35	1.35

Consolidated Cash Flow Statement

KEUR	January 1 - June 30, 2023	January 1 - June 30, 2022
Cash flow from operating activities:		
Result for the period	-9,622	9,659
Reconciliation of net profit/loss for the period to cash flow from operating activities		
Income taxes	0	494
Depreciation, amortization and non-cash changes in non-current assets	969	965
Interest expenses and income	1,451	958
Expenses from stock option plans	8	90
Transaction costs and fair value adjustments relating to financing activities	213	0
Changes in assets and liabilities that are not attributable to investing or financing activities:		
Trade receivables	374	1,676
Receivables from affiliated companies	0	-66
Inventories	-564	589
Prepaid expenses and other assets	-775	-360
Trade payables	2,870	-1,899
Provisions	-430	-1,866
Other current liabilities	404	2,310
Non-cash currency gain/loss	-76	150
Other non-cash expenses / income	-11	0
	5,189	12,701
Interest paid	-694	-732
Interest received	0	11
Cash flow from operating activities	-5,883	11,979
Cash flow from investing activities:		
Payments for investments in intangible assets and property, plant and equipment	0	-631
Cash flow from investing activities	0	-631
Cash flow from financing activities:		
Repayment portion of lease payments	-61	-63
Cash flow from financing activities	-61	-63
Cash-effective changes in cash and cash equivalents	-5,945	11,284
Effects of exchange rate changes on cash and cash equivalents	-37	-34
Cash and cash equivalents at the beginning of the fiscal year	10,629	6,440
Cash and cash equivalents at the end of the period	4,647	17,690
Composition of cash and cash equivalents at the end of the period:		
Cash and cash equivalents	4,647	17,690

Consolidated Statement of Changes in Equity

On January 25, 2023, the Extraordinary General Meeting approved a capital reduction. The current share capital of the Company of EUR 71,336,992.00 will therefore be reduced to EUR 7,133,699.00 by way of an ordinary capital reduction through the consolidation of shares at a ratio of 10:1. The capital reduction was entered in the commercial register on March 14, 2

KEUR	Share capital	Capital reserve	Translation reserve	Loss carryforward	Equity
December 31, 2021	71,337	144,414	-1,118	-207,634	6,999
Total comprehensive income	0	0	75	9,659	9,734
Issuance of shares	0	0	0	0	0
Allocations to additional paid-in capital	0	0	0	0	0
Cost of raising capital	0	0	0	0	0
Additional capital reserve due to the issue of options	0	90	0	0	90
June 30, 2022	71,337	144,504	-1,043	-197,975	16,824
Total comprehensive income	0	0	-5	-10,238	-10,243
Issuance of shares	0	0	0	0	0
Allocations to additional paid-in capital	0	0	0	0	0
Cost of raising capital	0	0	0	0	0
Additional capital reserve due to the issue of options	0	35	0	0	35
December 31, 2022	71,337	144,539	-1,048	-208,213	6,615
Total comprehensive income	0	0	-67	-9,622	-9,689
Issuance of shares	0	0	0	0	0
Allocations to additional paid-in capital	0	0	0	0	0
Cost of raising capital	0	0	0	0	0
Capital reduction through reverse stock split	-64,203	64,203	0	0	0
Additional capital reserve due to the issue of options	0	8	0	0	8
June 30, 2023	7,134	208,750	-1,115	-217,835	-3,066

Selected Explanatory Notes to the Consolidated Interim Financial Statements as of 30 June 2023

General information

In accordance with the provisions of Sec. 115 (2) of the German Securities Trading Act (Wertpapier handelsgesetz, WpHG) in conjunction with Sec. 117 WpHG, the half-year financial report of PAION AG contains consolidated interim financial statements, a consolidated interim management report and a declaration of the Management Board pursuant to Sec. 264 (2) sentence 3 and Sec. 289 (1) sentence 5 of the German Commercial Code (Handelsgesetzbuch, HGB). The consolidated interim financial statements have been prepared in accordance with International Financial Reporting Standards (IFRS) for interim reporting. The Group interim management report has been prepared in accordance with the applicable provisions of the German Securities Trading Act (WpHG) .

The consolidated financial statements include PAION AG as the parent company with its registered office at Heussstrasse 25, 52078 Aachen, Germany, and the wholly-owned subsidiaries included by way of full consolidation:

- PAION Deutschland GmbH, Aachen/Germany
- PAION Holdings UK Ltd, Cambridge/UK
- PAION UK Ltd, Cambridge/UK
- PAION Netherlands B.V., Heerlen/Netherlands
- PAION Scandic ApS, Odense/Denmark
- TheraSci Limited, Cambridge/UK
- PAION Farmaceutica Unipessoal, Lissabon/Llda

Basis of accounting

The interim consolidated financial statements have been prepared in accordance with Section 315e of the German Commercial Code (HGB) and IFRSs as adopted by the European Union (EU) and the interpretations of the International Financial Reporting Interpretations Committee (IFRIC). For the preparation of the interim consolidated financial statements, the consolidation principles and accounting policies applied for the preparation of the consolidated financial statements as of December 31, 2022 have been adopted unchanged. The following new or amended standards to be applied for the first time in the reporting period were an exception to this principle:

- 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,
- Fulfilment costs of contracts)
- Annual Improvements to IFRSs 2018-2020 Amendments to IFRS 1 (Subsidiaries as First-time Adopters), IFRS 9 (Fees in the "10% Test" in Relation to the, Derecognition of Financial Liabilities), IFRS 16 (Lease Incentives), IAS 41 (Taxation on Fair Value Measurements).

The application of these standards, amendments and interpretations, which are applicable for the first time, did not result in any additional disclosures or impact 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 consolidated financial statements as of June 30, 2023 should be read in conjunction with the consolidated financial statements as of December 31, 2022.

The preparation of the interim consolidated financial statements in conformity with IFRS requires the use of estimates and assumptions that affect the reported amounts of assets and liabilities, income and expenses, and contingent liabilities. The actual values may differ from the estimates.

Segment reporting in the interim consolidated financial statements has been dispensed with, as no significant reportable operating segments could be identified.

Foreign currency translation

The consolidated financial statements are presented in euros, which is the functional currency of PAION AG and the presentation currency of the Group. Each entity within the Group determines its own functional currency. This is the euro for the German companies and the Dutch company, the British pound for the UK-based companies and the Danish

krone for the Danish company. Items included in the financial statements of each entity are initially translated into the functional currency using the exchange rate prevailing at the date of the transaction. Monetary assets and liabilities denominated in a foreign currency are translated into the functional currency at each reporting date using the closing rate. All resulting exchange differences are recognized in profit or loss, with the exception that exchange rate gains and losses on intragroup loans are classified as a net investment in a foreign operation and recognized directly in equity if the conditions of IAS 21 are met.

Assets and liabilities of foreign entities are translated into euros at the balance sheet date using the closing rate. This also includes any goodwill arising on the acquisition of a foreign entity and any fair value adjustments to the carrying amounts of assets and liabilities. Equity components are translated at historical rates. Income and expenses are translated into euros using average monthly exchange rates. The resulting translation differences are recognized as a separate component of equity.

Intangible assets

Intangible assets amount to KEUR 18,752 as of June 30, 2023 (December 31, 2022: KEUR 19,585). The marketing rights for the products GIAPREZA® and XERAVA® in Europe have a residual carrying amount of KEUR 15,123. Both assets are amortized over their expected useful lives until the end of 2034 for GIAPREZA® and mid-2033 for XERAVA® , respectively, based on the currently expected period of the respective patent protection.

As of June 30, 2023, KEUR 2,185 of the intangible assets relate to the ERP software capitalized as of January 1, 2023 (December 31, 2022: KEUR 2,301).

Inventories

Inventories amounted to KEUR 4,284 as of June 30, 2023 (December 31, 2022: KEUR 3,720) and comprise work in progress of KEUR 2,194 and advance payments on inventories (remimazolam active ingredient) of KEUR 2,090. No write-downs on inventories were recognized in the reporting period.

Financial debt

PAION AG has drawn down the first two tranches of the loan totaling KEUR 12,500 in February 2021 and the third and final tranche of the loan totaling KEUR 7,500 in June 2021 under the KEUR 20,000 loan agreement entered into with the European Investment Bank (EIB) in the fiscal 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 compensation component as a derivative subject to separation on the other. The basic liability including the current and bullet interest components is measured at amortized cost using the effective interest method. The performance-based remuneration component is a payment obligation that depends on the share price of PAION AG at the time of repayment of the final portion 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 bullet interest component amounts to KEUR 19,875 as of June 30, 2023, and the carrying amount of the bullet performance-based compensation component amounts to KEUR 837 as of June 30, 2023.

Revenues

Revenue recognized in the first half of 2023 is attributable to the following categories:

- Royalties: KEUR 480
- Sales of active ingredients: KEUR 4,701
- Milestones: KEUR 1,014
- Product sales: KEUR 595

Stock options

In connection with the stock options issued under the 2016, 2018 and 2020 stock option programs, a personnel expense of KEUR 8 was recognized in the first half of 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

The fair value of the financial assets and liabilities was identical to the carrying amount at both June 30, 2023 and December 31, 2022.

		Book value		Fair value	
in KEUR		June 30, 2023	Dec. 31, 2022	June 30, 2023	Dec. 31, 2022
Financial assets					
Cash and cash equivalents	(1)	4,647	10,629	4,647	10,629
Trade receivables	(1)	1,854	2,228	1,854	2,228
Other assets	(1)	2,030	138	2,030	138
Financial liabilities					
Financial debt (underlying liability EIB loan)	(1)	19,875	19,129	19,875	19,129
Trade payables	(1)	10,874	8,005	10,874	8,005
Provisions	(1)	440	871	440	871
Financial debt (performance-related compensation component EIB loan)	(2)	836	624	836	624
Lease liabilities		538	599	538	599
Other liabilities	(1)	2,739	2,019	2,739	2,019

Measurement categories according to IFRS 9:
(1) Accounted for 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 remaining terms to maturity and their carrying amounts at the balance sheet date correspond to their fair values. The fair values of these financial instruments were determined on the basis of unobservable inputs (Level 3 inputs under IFRS 13). Financial debt includes, on the one hand, the underlying liability of the EIB loan, which, taking into account the current and bullet interest components, is measured at amortized cost using the effective interest method.

The carrying amount corresponds to fair value; the fair value was determined on the basis of unobservable inputs (level 3 inputs under IFRS 13) using discounted future cash flows. The carrying amount corresponds to the fair value; the fair value was determined on the basis of unobservable inputs (Level 3 inputs under IFRS 13) using discounted future cash flows. On the other hand, financial debt includes the bullet success component of the EIB loan, which is recognized 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 hierarchy levels in the first half of 2023. The recoverability of the financial assets was tested on the basis of historical and expected

payment defaults. No default risks were identified and no impairment losses were recognized.

Related Parties

There have been no changes in related party transactions compared to the consolidated financial statements as of December 31, 2022. There have been no material transactions with persons having a significant influence on the net assets and results of operations of the Company.

Indication of the existence of a going-concern risk

With regard to going concern risks to which the Group is exposed, we refer to the section "Risk and opportunities report" of the group management report. PAION continues to be dependent on the injection of additional funds. In this respect, there is a material uncertainty with regard to the going concern of the Company, as the negotiations on the granting of additional financial resources are well advanced, but at the time of reporting no legally binding commitments have been made.

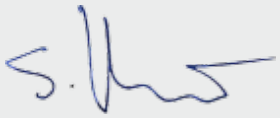
Declaration of the Management Board pursuant Secs. 264 para. 2 sentence 3 and 289 para.I sentence 5 HGB [German Commercial Code]

"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, 29 September 2023

PAION AG

Gregor Siebert



Sebastian Werner

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Review Report

To PAION AG:

We have reviewed the condensed interim consolidated financial statements - comprising the consolidated income statement and other comprehensive income, the consolidated statement of financial position, the consolidated statement of cash flows, the consolidated statement of changes in equity and selected explanatory notes - and the interim group management report of PAION AG, Aachen, for the period from January 1, 2023 to June 30, 2023 which are part of the half-year financial report pursuant to § 115 WpHG ("Wertpapierhandelsgesetz": German Securities Trading Act). The preparation of the condensed interim consolidated financial statements in accordance with those IFRS applicable to interim financial reporting as adopted by the EU, and of the interim group management report in accordance with the requirements of the WpHG applicable to interim group management reports, is the responsibility of the Company's management. Our responsibility is to issue a review report on the condensed interim consolidated financial statements and on 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 German generally accepted standards for the review of financial statements promulgated by the Institut der Wirtschaftsprüfer (IDW). Those standards require that we plan and perform the review so that we can preclude through critical evaluation, with moderate assurance, that the condensed interim consolidated financial statements have not been prepared, in material respects, in accordance with the IFRS applicable to interim financial reporting as adopted by the EU, and that the interim group management report has not been prepared, in material respects, in accordance with the requirements of the WpHG applicable to interim group management reports. A review is limited primarily to inquiries of company personnel and analytical procedures and therefore does not provide the assurance attainable in a financial statement audit. Since, in accordance with our engagement, we have not performed a financial statement audit, we cannot express an audit opinion.

Material uncertainty in connection with the continuation of the company's operations

We refer to the disclosures in the interim group management report in the section "Indication of the existence of a going concern risk" of the risk and opportunity report, in which the legal representatives describe that PAION AG is dependent on the injection of additional funds to ensure its ability to continue as a going concern and to secure its future solvency. The ability to continue as a going concern is subject to material uncertainties, as negotiations on the provision of additional financial resources are at an advanced stage, but no legally binding commitments have been made at the time of reporting. The initiated financing measures mainly comprise further outlicensing, capital measures and debt financing. In the event of failure of the initiated financing measures, there is a high probability that the company will not be able to continue as a going concern. With regard to the necessity of future financing measures, reference is also made to the statements in the sections "Financing risks" in the Group management report for the financial year 2022 and "Financial outlook 2023".

As stated in the aforementioned section of the interim group management report, these events and circumstances indicate that a material uncertainty exists that may cast significant doubt about the Company's ability to continue as a going concern and that represents a going concern risk within the meaning of Section 322 (2) sentence 3 HGB.

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

Munich, Germany, October 19, 2023

Baker Tilly GmbH & Co. KG
Wirtschaftsprüfungsgesellschaft
(Düsseldorf)

(s) Hanfland	(s) Ninnemann
Wirtschaftsprüfer	Wirtschaftsprüfer
[German Public Auditor]	[German Public Auditor]

PAION share data

Market segment	Regulated market - Prime Standard of the Frankfurt Stock Exchange
Stock exchange symbol	PA8
Reuters abbreviation	PA8G.DE (Xetra)
Bloomberg	PA8 GR (Xetra)
ISIN	DE000A3E5EG5
First trading day	February 11, 2005
Designated Sponsor	Oddo BHF

Key figures	H1 2023[1]	FY 2022
Number of shares at the reporting date	7.133.699[1]	71.336.992
Average daily trading volume (Xetra, Frankfurt, in shares)	26.091	39.370
Annual high (Xetra closing price)	EUR 8.86[1] (01/30/2023)	EUR 1.54 (01/13/2022)
Annual low (closing price Xetra)	EUR 4.35[1] (06/21/2023)	EUR 0.44 (12/28/2022)
Share price on reporting date (Xetra)	EUR 6.03[1]	EUR 0.44
Market capitalization at reporting date (Xetra)	EUR 43 million	EUR 31 million

[1] Figures are adjusted for stock split (10:1)

Financial calendar

30 March 2023	Publication of the financial results 2022
17 May 2023	Publication of the financial results of the first quarter 2023
12 July 2023	Annual General Meeting
30 August 2023	Publication of the financial results for the first half-year 2023
15 November 2023	Publication of the financial results for the third quarter and the first nine months of 2023

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