CORPORATE NEWS

EARNINGS

PAION AG PUBLISHES GROUP QUARTERLY STATEMENT FOR THE FIRST NINE MONTHS OF 2021

- Transformation into commercial specialty pharma company following expansion of European product portfolio; angiotensin II (GIAPREZA®) and eravacycline (XERAVA®) successfully launched in Q3 2021
- PAION launches remimazolam (Byfavo®) in the UK and the Netherlands following EU and UK market approvals in procedural sedation
- Remimazolam launched by partners in the U.S. and South Korea
- Financial position strengthened to support product launches: EUR 7.8 million gross proceeds raised in rights issue and EUR 20 million loan fully drawn from EIB
- Combined revenues of EUR 5.5 million for first nine months of 2021 coming increasingly from product sales and royalties as opposed to milestone payments
- Cash and cash equivalents of EUR 13.1 million as of 30 September 2021

Aachen (Germany), 10 November 2021 – The specialty pharmaceutical company PAION AG (ISIN DE000A0B65S3; Frankfurt Stock Exchange, Prime Standard: PA8) today reports its consolidated financial results according to International Financial Reporting Standards (IFRS) for the first nine months of 2021.

"Remimazolam is increasingly available to physicians around the world and sales growth is strong, despite the challenges of the ongoing Covid-19 pandemic. We are now developing this ultrafast-acting anesthetic for pediatric patients, and we hope that children will benefit from sedation with remimazolam soon," said Dr. Jim Phillips, CEO of PAION AG. *"We are also making strong progress in Europe with our direct rollout of remimazolam, as well as our two other promising critical care products – angiotensin II (GIAPREZA®) and eravacycline (XERAVA®). We have already seen our first sales and look forward to growing the sales in these important markets in the months & years ahead."*

Update and outlook

Commercial activities and expansion of product portfolio in Europe

In January 2021, PAION entered into an exclusive license agreement with La Jolla Pharmaceutical Company for the intensive care products angiotensin II (brand name GIAPREZA®) and eravacycline (brand name XERAVA®). The agreement grants PAION an exclusive license for the commercialization of

these two approved products in the European Economic Area (EEA), the United Kingdom and Switzerland. Angiotensin II is a vasoconstrictor indicated for the treatment of refractory hypotension in adults with septic or other distributive shock who remain hypotensive despite other therapeutic measures. Eravacycline is a novel fluorocycline type of antibiotic indicated for the treatment of complicated intra-abdominal infections in adults.

With the addition of angiotensin II and eravacycline to its commercial portfolio, PAION has started to establish its own commercial infrastructure in certain core countries in Western Europe, including Germany, the UK, the Netherlands and Denmark, to market angiotensin II and eravacycline together with remimazolam. PAION launched these three products in the third quarter of 2021 in a staggered manner by country; by the end of 2022, launches are planned to have been conducted in most key European markets. Initial product sales indicate a good market acceptance of the products.

Remimazolam in Europe

Procedural sedation: Remimazolam (brand name Byfavo®) received market approval in the EU (including EEA countries) in March 2021 and in the United Kingdom in June 2021. PAION launched remimazolam in the United Kingdom in August 2021 and signed an exclusive collaboration agreement with Clinigen for the supply and distribution of its products into the UK in September 2021. Also in September 2021, PAION launched remimazolam in the Netherlands.

General anesthesia: Based on the positive results in the Phase III trial in general anesthesia and the approval in procedural sedation, PAION plans to submit an extension of the marketing authorization application (MAA) for remimazolam for general anesthesia by the end of 2021. The approval process for an extension application is generally faster than for an MAA.

Intensive Care Unit (ICU) sedation: In October 2021, the last patient was treated in the Investigator Initiated REHSCU rial[1]. This trial, led by Raphael Cinotti 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.

Pediatric development: In September 2021, PAION and U.S. licensee Acacia Pharma (Acacia) announced the initiation of a pivotal study investigating remimazolam in the mild to moderate 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 patients.

Remimazolam activities in the license territories in the first nine months of 2021

Licensees generated remimazolam revenues totalling EUR 4.4 million in the first nine months of 2021. Based on these, PAION receives royalty payments in varying amounts.

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

In the **U.S.**, remimazolam (brand name BYFAVO™) was launched by Acacia for procedural sedation in January 2021. While Acacia has indicated that initial market response was positive, access to clinics and prescribing doctors has been severely limited due to the COVID-19 pandemic. At the end of September 2021, Acacia reported remimazolam to be on track to meet its full year 2021 formulary acceptance goal. By the end of September, remimazolam had been put on formulary in 95 accounts with a >90% win rate; Acacia expects a total of 150 accounts to put remimazolam on formulary by the end of 2021.

For the indication general anesthesia, the license agreement with Cosmo/Acacia originally provided for an option for the U.S. rights to develop and commercialize remimazolam. As this option was not exercised by the licensee, it has lapsed. An advisory meeting was recently held with the FDA (U.S. Food and Drug Administration) on suitability of the European clinical program for filing of a New Drug Application (NDA) in the U.S. As a positive outcome of the Type B meeting, the FDA stated that a submission would be possible with the current data package consisting of European and Asian general anesthesia data. Submission would require a re-analysis of the current data. Alternatively, an additional clinical trial was recommended. PAION will now use the outcome of the meeting to intensify the discussion with interested parties for the general anesthesia license in the U.S.

For **Japan,** PAION and licensee Mundipharma have agreed on an amendment of the royalty calculation. A corresponding contract amendment has been put in place. Under the terms of the amendment, PAION receives 15.5% royalties on net sales. From mid-2023 onwards, the royalty rate could be reduced in case of (too) high cost of goods in relation to net sales, but not below 5%. Mundipharma initiated a Phase II/III clinical trial in May 2021 to evaluate the efficacy and safety of remimazolam (brand name Anerem®) in Japanese patients undergoing gastrointestinal endoscopy. Following approval in general anesthesia, an additional indication is being developed in Japan.

In **China,** currently the largest market for remimazolam (brand name Ruima®), good sales growth has been seen during the first nine months of 2021. The NDA in general anesthesia was accepted for review by the National Medical Products Administration (NMPA) in July 2021**.** Supported by licensee Yichang Humanwell, Chinese investigators are exploring the use of remimazolam in additional indications, including in the sedation of ICU patients during and after mechanical ventilation and in spinal anesthesia, with a focus on elderly patients. In Shanghai, the first Securities Times journal's "Drug Innovation Award" ceremony was held in June 2021, and Yichang Humanwell won the "Drug Innovation Achievement Award", while remimazolam was selected for the "Annual Pharmaceutical Innovation Achievement Award."

In **South Korea**, licensee Hana Pharm received market approval for remimazolam (brand name Byfavo™) in general anesthesia in January 2021 and launched the product at the end of March. This was followed by market approval in procedural sedation in August 2021. Hana Pharm has reported that its remimazolam domestic landing and market positioning strategy was successful in the first months following launch. Hana Pharm has initiated various academic activities and clinical trial promotion strategies to increase the accessibility of remimazolam, starting with a remimazolam launch symposium held at the end of April 2021.

In March 2021, PAION granted TTY Biopharm (TTY) an exclusive license for the development and commercialization of remimazolam in **Taiwan**.

Financing activities

In February and June 2021, PAION drew down all tranches of the EUR 20 million loan from the European Investment Bank (EIB), for which the agreement was signed in 2019.

In April 2021, a rights issue was completed with gross proceeds of EUR 7.8 million. The subscription rate was over 92%. Thereby, the share capital of PAION AG was increased to EUR 71,336,992.00 by using the Authorized Capital 2020 through the issuance of 5,095,499 new shares.

Results of operations, financial position and net assets

Revenues in the first nine months of 2021 amounted to EUR 5.5 million of which EUR 2.6 million resulted from milestone payments and EUR 2.9 million from remimazolam API sales to licensees (EUR 2.3 million) and royalties (EUR 0.6 million). In the prior-year period, revenues amounted to EUR 19.3 million and mainly resulted from milestone payments.

Cost of sales amounted to EUR 2.0 million in the first nine months of 2021.

Research and development expenses in the first nine months of 2021 amounted to EUR 4.5 million (prior-year period: EUR 8.5 million) and decreased as planned particularly due to the completion of the EU Phase III study in general anesthesia in the previous year.

General administrative and selling expenses increased by EUR 7.9 million to EUR 13.4 million in the first nine months of 2021 compared to the prior-year period. General administrative expenses increased by EUR 1.0 million to EUR 3.4 million, mainly due to financing activities and the expansion of IT systems and infrastructure. Selling expenses increased as planned by EUR 6.9 million to EUR 10.0 million, mainly due to commercialization and supply chain activities for the three products Byfavo®, GIAPREZA® and XERAVA® in Europe.

Earnings before interest and tax amounted to EUR -14.4 million in the first nine months of 2021 and decreased by EUR 19.4 million compared to the prior-year period (earnings before interest and tax in the prior-year period: EUR 5.0 million).

The **financial result** amounted to EUR -2.7 million in the first nine months of 2021 (prior-year period: EUR -0.1 million) and mainly comprises expenses in connection with the EIB loan drawn down in the reporting period totalling EUR 20.0 million. In the prior-year period, the financial result mainly comprised expenses in connection with convertible notes issued in fiscal year 2019.

Tax income amounted to EUR 0.5 million in the first nine months of 2021 (prior-year period: EUR 0.8 million) and mainly relates to tax claims for reimbursement of parts of the research and development expenses from the British tax authorities. The decrease in comparison to the prior-year period is mainly due to lower research and development expenses.

The **net result** for the first nine months of 2021 amounted to EUR -16.6 million compared to a net result of EUR 5.7 million in the prior-year period. This

corresponds to a decrease of the net result in the amount of EUR 22.3 million compared to the first nine months of 2020 which is mainly attributable to lower revenues and lower expenses for research and development on the one hand and higher financial expenses as well as general administrative and selling expenses than in the prior-year period on the other hand.

Compared to 31 December 2020, **cash and cash equivalents** decreased by EUR 6.5 million to EUR 13.1 million at the end of the current reporting period. The decrease of cash and cash equivalents stems from **cash flows from operating activities** of EUR -14.8 million mainly resulting from the net result of the period and working capital changes, **cash flows from investing activities** of EUR -18.9 million primarily in connection with the acquisition of the commercialization rights for the products GIAPREZA® und XERAVA® in Europe and **cash flows from financing activities** of EUR 27.2 million which mainly resulted from the complete draw-down of the loan from the EIB as well as the net proceeds from the rights issue completed in April 2021.

Intangible assets increased by EUR 17.9 million compared to 31 December 2020 to EUR 19.8 million as of 30 September 2021. Thise increase primarily stems from the commercialization rights for the products GIAPREZA® and XERAVA® in Europe amounting to EUR 17.5 million as of 30 September 2021 which were acquired in the reporting period under the license agreement concluded with La Jolla Pharmaceutical.

Equity amounted to EUR 12.1 million as of 30 September 2021 (31 December 2020: EUR 21.3 million). The decrease of EUR 9.2 million mainly results from the negative net result of the first nine months of 2021 on the one hand, and the proceeds from the issue of new shares in the course of a rights issue completed in April 2021 on the other hand. As of 30 September 2021, the equity ratio was 28.1% (31 December 2020: 75.6%).

Impact of the Covid-19 pandemic on the PAION Group

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. Based on the factual situation at the time of this statement, 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. Any impact of the pandemic on the general financing environment could limit PAION's ability to obtain necessary financing.

Risks and Opportunities

Material risks and opportunities relating to future development are presented in detail in the group management report for the fiscal year 2020. The overall evaluation of opportunities and risks has not changed significantly in the first nine months of 2021.

Outlook 2021

PAION confirms its financial outlook for the current fiscal year announced on 23 August 2021 with the publication of the half-year results for 2021. PAION's focus in 2021 remains on preparing and starting the commercialization of its product portfolio, consisting of remimazolam, angiotensin II and eravacycline, and on further building a distribution infrastructure in selected European

countries. In addition, PAION plans to submit the MAA for remimazolam for general anesthesia in Europe by the end of 2021. PAION has started launching its products in a staggered manner by country beginning in the second half of 2021 so that by the end of 2022, launches are planned to have been conducted in most key European markets.

It is planned to grant the commercialization rights for remimazolam, angiotensin II and eravacycline to licensees in selected territories in Europe where no own commercialization is planned, and to also out-license remimazolam for additional markets outside Europe as well.

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Key consolidated financial figures, IFRS (unaudited)

(all figures in EUR thousand unless otherwise noted)	Q3 2021	Q3 2020	Q1-Q3 2021	Q1-Q3 2020
Revenues	1,883	15,750	5,500	19,270
Research and development expenses	-1,555	-2,094	-4,467	-8,493
General administrative and selling expenses	-4,694	-1,929	-13,400	-5,539
Earnings before interest and tax (EBIT)	-5,857	11,690	-14,450	5,008
Net result for the period	-6,144	11,738	-16,580	5,686
Earnings per share in EUR for the period (basic)	-0.09	0.18	-0.24	0.09
Earnings per share in EUR for the period (diluted)	-0.09	0.18	-0.24	0.09

	Q1–Q3 2021	Q1–Q3 2020
Cash flows from operating activities	-14,795	5,746
Cash flows from investing activities	-18,912	-14
Cash flows from financing activities	27,179	-16
Change in cash and cash equivalents	-6,524	5,727
Average number of employees	50	43

	30-09-2021	31-12-2020
Intangible assets	19,775	1,829
Cash and cash equivalents	13,142	19,666
Equity	12,132	21,290
Current liabilities	9,735	6,845
Non-current liabilities	21,287	15
Total assets	43,154	28,150

About PAION

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 remimazolam, an intravenous, ultra-short-acting and controllable benzodiazepine sedative/anesthetic. PAION has started to launch 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 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).

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