CORPORATE NEWS

EARNINGS

PAION AG PUBLISHES GROUP QUARTERLY STATEMENT FOR THE FIRST QUARTER OF 2022

- Transformation into commercial specialty pharma company continues
- Financial position strengthened to support commercial activities in Europe by sale of Chinese remimazolam patents and future royalties to Humanwell for EUR 20.5 million
- Expansion of partner networks through licensing and cooperation agreements for Latin America and Eastern Europe
- Cash and cash equivalents of EUR 15.9 million as of 31 March 2022

Aachen (Germany), 18 May 2022 – The specialty pharmaceutical company PAION AG (PA8; ISIN DE000A0B65S3; Frankfurt Stock Exchange, Prime Standard) today reports its consolidated financial results according to International Financial Reporting Standards (IFRS) for the first quarter of 2022.

Dr. Jim Phillips, CEO of PAION AG, commented: "*The first quarter of 2022 has brought further progress in our transformation into a specialty pharma company. The recent agreement with Humanwell for the sale of the remimazolam patents in China is enabling us to further expand our commercial organization in Europe. During 2022, we will launch our three products in further European countries to provide new options to address the increasing unmet medical needs in anesthesia and critical care*."

Update and outlook

Highlights European product portfolio

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

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

In April 2022, PAION was informed that the Federal Joint Committee (G-BA) voted in favor of PAION's application for **eravacycline (XERAVA®)** as a reserve antibiotic. This means that eravacycline is considered to provide added benefit to standard of care. PAION is now exempt from providing a full benefit dossier and is only required to provide an abbreviated dossier, which is due by 1st August 2022.

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

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

Remimazolam activities in licensed territories in the first quarter of 2022

Licensees generated remimazolam revenues totalling EUR 0.9 million in the first quarter of 2022, amounting to royalties for PAION of EUR 0.1 million.

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

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

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

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

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

In April 2022, PAION and Cristália signed an exclusive license agreement for the development and commercialization of remimazolam in **Latin America**. Cristália intends to commercialize remimazolam in procedural sedation and

general anesthesia and expects to obtain marketing authorization for both indications in Brazil in 2024.

Financial key figures

Revenues of EUR 21.5 million were recognized in the first quarter of 2022. Of this, EUR 20.5 million related to the agreement with Humanwell, EUR 0.8 million related to the sale of remimazolam API (active pharmaceutical ingredient) to licensees as well as royalties, EUR 0.2 million related to milestone payments, and EUR 0.1 million related to own product sales. In the prior-year period, revenues amounted to EUR 3.2 million and resulted mainly from milestone payments (EUR 2.6 million) and the sale of remimazolam API to licensees as well as royalties (EUR 0.6 million).

Cost of sales in the first quarter of 2022 amounted to EUR 0.7 million.

Research and development expenses in the first quarter of 2022 amounted to EUR 1.1 million (prior-year period: EUR 1.3 million).

Compared to the prior-year period, **general administrative and selling expenses** increased by EUR 1.2 million to EUR 5.1 million in the first quarter of 2022. General and administrative expenses amounted to EUR 1.4 million and were unchanged compared to the prior-year period, and selling expenses increased by EUR 1.2 million to EUR 3.7 million. Selling expenses increased as planned, particularly due to commercialization and supply chain activities for remimazolam, angiotensin II and eravacycline in Europe.

Earnings before interest, taxes, depreciation and amortization (EBITDA) in the first quarter of 2022 amounted to EUR 15.0 million and increased by EUR 17.2 million compared to the prior-year period (EBITDA in the prior-year period: EUR -2.2 million).

Cash and cash equivalents increased by EUR 9.5 million in the first quarter of 2022. PAION had cash and cash equivalents of EUR 15.9 million as of 31 March 2022. As of that date, EUR 16 million related to the agreement with Humanwell had been received, with the remaining EUR 4.5 million due in June 2022. The remimazolam license agreement for Latin America with Cristália was signed in April 2022, and so the related EUR 3.5 million upfront payment was not reflected in the cash position as of 31 March 2022.

Risks and opportunities

The main risks and opportunities of future development are presented in detail in the Group management report for fiscal year 2021. In the first quarter of 2022, the risks and opportunities did not change significantly.

Outlook 2022

PAION confirms its outlook for the current fiscal year given in March 2022 with the publication of the 2021 consolidated financial statements and group management report. PAION's focus in 2022 will be on the commercialization of its approved products - remimazolam, angiotensin II and eravacycline - and the further build-up of a sales infrastructure in select European countries. Launches are expected in these countries by the end of 2022/early 2023. In addition, PAION expects a decision from the EMA on the extension application to the marketing authorization of remimazolam for general anesthesia in the first quarter of 2023.

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Key consolidated financial figures, IFRS (unaudited)

(all figures in KEUR unless otherwise noted)	Q1 2022	Q1 2021
Revenues	21,502	3,204
Cost of sales	-672	-466
Research and development expenses	-1,138	-1,337
General administrative and selling expenses	-5,064	-3,831
Earnings before interest, taxes, depreciation and amortization (EBITDA)	15,006	-2,156
Change in cash and cash equivalents (incl. exchange rate differences)	9,468	-5,762
Average number of group employees	58	44

	31 Mar. 2022	31 Dec. 2021
Cash and cash equivalents	15,908	6,440

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 is rolling out remimazolam (Byfavo®) in selected European markets. Remimazolam is partnered in multiple territories outside of Europe. Remimazolam is approved in the U.S., the EU/EEA/UK, China and South Korea for procedural sedation and in Japan and South Korea for general 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).

Contact

Ralf Penner
Vice President Investor Relations/Public Relations
PAION AG
Heussstrasse 25
52078 Aachen – Germany
Phone +49 241 4453-152
E-mail r.penner@paion.com
www.paion.com

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