



CORPORATE NEWS

EARNINGS

PAION AG REPORTS FINANCIAL RESULTS FOR THE FIRST NINE MONTHS OF 2022

- Combined revenues of EUR 25.6 million
- Cash and cash equivalents of EUR 10.4 million as of 30 September 2022
- PAION raises guidance for 2022 and expects EBITDA in the corridor of EUR -1.5 million to EUR +0.5 million
- Transformation into commercial specialty pharma company progressing well
- Up-front and milestone payments as an important component of financing until planned break-even in 2024; royalty income at previous year's level

Aachen, 16 November 2022 – The specialty pharmaceutical company PAION AG (ISIN DE000A0B65S3; Frankfurt Stock Exchange, Prime Standard: PA8) today announces its consolidated financial results according to International Financial Reporting Standards (IFRS) for the first nine months of 2022.

"Compared to the previous quarters of this year, we achieved a pleasing sales development in important target markets and were able to win new customers for our products. We expect this trend to continue in the current final quarter and beyond. Meanwhile, we will continue to focus on expanding commercial sales for our products in the European markets," said Dr Jim Phillips, CEO of PAION AG.

Business performance in the first nine months of 2022

PAION has already launched **remimazolam** (Byfavo®) in the UK, Denmark and the Netherlands. By the end of 2022/beginning of 2023, remimazolam is expected to be launched for the indication of short sedation in most European core markets. In the German market, remimazolam will not be commercially available until the first quarter of 2023 at the earliest, once the marketing authorization extension for general anaesthesia has been granted, which is expected in the first quarter of 2023.

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

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

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

Continued expansion of remimazolam activities in licensed territories in the first nine months of 2022

In the first nine months of 2022, licensees generated product sales of EUR 4.2 million. On this basis, PAION receives royalty payments in varying amounts.

In **China**, PAION entered into a patent assignment agreement for remimazolam (trade name Ruima®) with Humanwell in early 2022. Under the agreement, PAION transferred all of its Chinese remimazolam patents and sold the related future royalties on sales in China from the licensing agreement with Yichang Humanwell to Humanwell for EUR 20.5m. Of this amount, EUR 16 million was received in the first quarter of 2022; the remaining EUR 4.5 million was paid as scheduled in June 2022. Yichang Humanwell was released from all future royalty payments to PAION and the licence has been terminated.

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

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

In February 2022, PAION entered into an exclusive cooperation agreement with Medis 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).

Results of operations, financial position and net assets

Revenues increased to EUR 25.6 million in the first nine months of 2022 (same period last year: EUR 5.5 million).

Cost of sales amounted to EUR 0.6 million in the first nine months of 2022.

Research and development expenses in the first nine months of 2022 increased to EUR 4.9 million compared to the previous year's figure of EUR 4.5 million.

General administrative and selling expenses increased by EUR 2.0 million to EUR 15.4 million in the first nine months of 2022 compared to the same period of the previous year. The increase in general administrative expenses by EUR 0.5 million to EUR 3.9 million contributed significantly to this. Selling expenses also rose as planned by EUR 1.5 million to EUR 11.5 million. This is due in particular to the commercialisation activities for the three products remimazolam, angiotensin II and eravacycline in Europe.

Earnings before interest and tax amounted to EUR 4.6 million in the first nine months of 2022 and were thus EUR 19.1 million higher than in the same period of the previous year (same period of the previous year: EUR -14.4 million).

The **financial result** amounted to EUR -1.4 million in the first nine months of 2022 (same period of the previous year: EUR -2.7 million) and, as in the same period of the previous year, mainly comprises expenses in connection with the utilised loan from the European Investment Bank (EIB) in the total amount of EUR 20 million. The improvement in the financial result is mainly due to the revaluation of the performance-related interest component of the EIB loan.

Income taxes in the first nine months of 2022 amounted to EUR 0.5 million (same period of the previous year: EUR 0.5 million) and mainly related to the corporate tax liability to the British tax authorities due to the significant increase in milestone payments. In the same period of the previous year, tax incentives through tax credits on parts of the research and development expenses by the British tax authorities had a major impact.

The **net result** increased to EUR 2.7 million in the first nine months of 2022, compared to EUR -16.6 million in the same period of the previous year. This corresponds to an increase of EUR 19.3 million in the profit for the period compared to the first nine months of 2021, which is mainly due to the increased milestone payments.

Cash and cash equivalents increased by EUR 3.9 million compared to 31 December 2021 to EUR 10.4 million at the end of the current reporting period. The increase in cash and cash equivalents consists of the **cash flow from operating activities** of EUR 4.8 million, which mainly results from the profit for the period, the **cash flow from investing activities** of EUR -0.7 million, which is primarily due to the ERP system under development, and the **cash flow from financing activities** of EUR -0.1 million, which results from the repayment portion of the lease payments.

Intangible assets decreased slightly by EUR -0.1 million compared to 31 December 2021 to EUR 19.5 million as at 30 September 2022. In the previous year, the marketing rights for the products angiotensin II and eravacycline in Europe were capitalised with acquisition costs of kEUR 18,493 as part of the licence agreement concluded with La Jolla Pharmaceutical. Both assets are amortised over the expected useful economic life until the end of 2034 for angiotensin II and mid-2033 for eravacycline, which is based on the currently expected period of the respective patent protection.

Equity increased to EUR 9.8 million as of 30 September 2022 (31 December 2021: EUR 6.9 million). The increase in equity by EUR 2.8 million compared to 31 December 2021 is mainly due to the profit for the period of EUR 2.7 million.

Accordingly, the equity ratio improved to 25% as at 30 September 2022 (31 December 2021: 19.0%).

Risks and opportunities

The main risks and opportunities of future development are described in detail in the Group management report for the 2021 financial year. The overall picture of opportunities and risks has not changed significantly in the first nine months of 2022.

Outlook 2022

Based on the results for the first nine months of 2022, PAION raises the outlook for the full year 2022 announced with the Annual Report 2021. In contrast to the previously expected negative EBITDA (EUR -9.0 million to EUR -2.5 million), PAION now expects EBITDA for the financial year 2022 to be in the corridor of EUR -1.5 million to EUR +0.5 million. In the final quarter, PAION will continue to focus on the commercialisation of remimazolam, angiotensin II and eravacycline and the necessary further build-up of a sales infrastructure in selected European countries. Commercialisation is expected to start in these countries by the end of 2022/early 2023. In addition, PAION expects a decision from the EMA on the extension application for remimazolam for general anaesthesia in the first quarter of 2023.

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Key Consolidated Financial Figures, IFRS (unaudited)

(all figures in KEUR unless otherwise noted)	Q3 2022	Q3 2021	Q1–Q3 2022	Q1–Q3 2021
Revenues	371	1,883	25,602	5,500
Research and development expenses	-1,913	-1,555	-4,964	-4,467
General administrative and selling expenses	-5,097	-4,694	-15,390	-13,400
Earnings before interest and tax (EBIT)	-6,470	-5,857	4,642	-14,450
Result for the period	-6,986	-6,144	2,674	-16,580
Earnings per share in EUR for the period (basic)	-0.10	-0.09	0.04	-0.24
Earnings per share in EUR for the period (diluted)	-0.10	-0.09	0.04	-0.24

	Q1–Q3 2022	Q1–Q3 2021
Cash flow from operating activities	4,764	-14,795
Cash flow from investing activities	-741	-18,912
Cash flow from financing activities	-95	27,179
Change in cash and cash equivalents	3,928	-6,524
Average number of employees in the Group	62	50

	30 Sept. 2022	31 Dec. 2021
Intangible assets	19,520	19,653
Cash and cash equivalents	10,367	6,440
Equity	9,824	6,999
Current liabilities	10,443	10,985
Non-current liabilities	19,074	18,801
Balance sheet total	39,340	36,785

Conference call and webcast

In addition to the publication of results, the Management Board of PAION AG will host a conference call (conducted in English) on 16 November 2022 at 2:00 p.m. CET to present the financial results of the first nine months of 2022 and provide a pipeline and strategy update and financial outlook.

A registration for the conference call is available [here](#).

About PAION

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

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

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

PAION is headquartered in Aachen (Germany).

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