



CORPORATE NEWS

FINANCIAL RESULTS

PAION AG PUBLISHES GROUP QUARTERLY STATEMENT FOR THE FIRST QUARTER OF 2023

- EU marketing authorization for remimazolam in general anesthesia in April 2023 opens up new growth opportunities
- Capital reduction implemented in the first quarter of 2023
- Initiatives to expand commercial sales continued
- Sales revenues in the amount of EUR 2.3 million.
- Cash and cash equivalents of EUR 7.2 million as of March 31, 2023
- Q1 2023 Webcast (English) today at 2:00 p.m. CEST (1:00 p.m. BST/8:00 a.m. EDT)

Aachen (Germany), May 17, 2023 - The specialty pharmaceutical company PAION AG (ISIN DE000A3E5EG5; Frankfurt Stock Exchange, Prime Standard: PA8K) today reports its consolidated financial results according to International Financial Reporting Standards (IFRS) for the first quarter of 2023.

Gregor Siebert, CEO of PAION AG, commented: *"At the beginning of April 2023, we were able to reach an important milestone in the company's history. Our lead compound remimazolam was approved for general anesthesia and opens up new growth opportunities for PAION. Currently, preparations are underway for the marketing launch in Europe, which we have planned for the beginning of the second half of 2023. Thus, we continued the commercialization of our products in the first quarter of 2023 and will launch them in additional European countries to offer innovative treatment options for the still unmet and growing medical need in anesthesia and intensive care."*

Business performance in the first three months of 2023

PAION continued to expand its commercialization infrastructure for the marketing activities in selected target markets in the first quarter 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. At the beginning of 2023, PAION again received positive feedback from customers about their experience with remimazolam in particular.

Based on the positive results of the European Phase III study in general anesthesia, PAION submitted an extension application of the marketing authorization for remimazolam for the indication general anesthesia to the EMA in December 2021. The European Medicines Agency's Committee for Medicinal Products for Human Use (CHMP) adopted a positive opinion on January 27, 2023, recommending approval of remimazolam for the induction and

maintenance of general anesthesia in adults. This was finally followed by approval by the European Commission on April 03, 2023.

In addition, the UK Medicines & Healthcare products Regulatory Agency (MHRA) will also review a possible approval in the UK.

Licensees generated product sales of EUR 2.4 million in the first three months of 2023 (Q1 2022: EUR 0.9 million); this results in royalties for PAION of EUR 0.3 million (Q1 2022: EUR 0.1 million).

In the **U.S.**, Pharmaceuticals had announced in early May 2023 that the Centers for Medicare & Medicaid Services ("CMS") has implemented a product-specific billing code for remimazolam. The introduction of this unique so-called "J-code" (reimbursement code) for remimazolam in the U.S. is an important step to facilitate reimbursement and expand patient access to remimazolam.

Furthermore, **Taiwanese** licensee TTY Biopharm has submitted the marketing authorization application for remimazolam in general anesthesia in March 2023.

Key financial figures

In the first quarter of 2023, **revenues** of EUR 2.3 million were realised. Of this amount, EUR 1.0 million is attributable to milestone payments and EUR 1.3 million to revenue from operating activities. In the same period of the previous year, revenues amounted to EUR 21.5 million, of which EUR 20.7 million resulted from patent sales and milestone payments and EUR 0.8 million from operating activities.

Research and development expenses in the first quarter of 2023 amounted to EUR 0.9 million (prior-year period: EUR 1.1 million).

Consistent cost management reduced **general and administrative expenses** by EUR 0.6 million to EUR 4.5 million in the first quarter of 2023 compared to the same period of the previous year.

Earnings before interest, taxes, depreciation and amortization (EBITDA) in the first quarter of 2023 amounted to EUR -3.7 million and decreased by EUR 18.7 million compared to the prior-year period (EBITDA in the prior-year period: EUR 15.0 million). The result in the previous year was positively influenced in particular by the special effect of EUR 20.5 million from the Humanwell agreement.

Cash and cash equivalents decreased by EUR 3.5 million in the first quarter 2023 compared to the balance sheet date December 31, 2022. PAION had cash and cash equivalents of EUR 7.1 million as of March 31, 2023.

Risks and opportunities

The main risks and opportunities of future development are presented in detail in the Group management report for fiscal 2022. In the first quarter of 2023, the risks and opportunities have not changed significantly.

Forecast 2023

Business Outlook

PAION continues to focus on the commercialization of its product portfolio in 2023, consisting of the approved products remimazolam (Byfavo®), angiotensin II (GIAPREZA®) and eravacycline (XERAVA®). By the end of 2023, the launch

of remimazolam for the indication of procedural sedation should also have taken place in Germany, Portugal and Austria. Following remimazolam approval by the European Medicines Commission for the induction and maintenance of general anesthesia in adults on 03 April 2023, PAION plans to launch remimazolam in general anesthesia in Europe early in the second half of 2023. In addition, the research and development activities are mainly focused on the pediatric development as well as the processing of so-called "post-approval-commitments" and the Life-Cycle-Management for remimazolam, angiotensin II and eravacycline. In addition, PAION continues its activities in the area of production development to further improve the manufacturing processes. With remimazolam marketed in the U.S., Japan, South Korea and much of Europe, PAION expects product sales and revenues from licensees and distributors to increase in the coming years, resulting in an increase in license revenues.

Financial outlook 2023

PAION expects revenues from operating activities of approximately EUR 13 million to approximately EUR 19 million in 2023.

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.

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 2024 or beyond.

PAION expects increasing revenues in the coming years, both from licensing agreements and from commercialization in 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 as well as additional partnerships. Based on cash on hand, expected payments from revenues as well as 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.

###

Key consolidated financial figures, IFRS (unaudited)

(Figures in EUR thousand unless otherwise stated)	Q1 2023	Q1 2022
Revenues	2,266	21,502
Cost of sales	-553	-672
Research and development expenses	-916	-1,138
General administrative and selling expenses	-4,511	-5,064
Earnings before interest, taxes, depreciation and amortization (EBITDA)	-3,714	15,006

Change in cash and cash equivalents (incl. exchange rate changes)	3,486	9,468
---	-------	-------

	31/03/2023	31/12/2022
Cash and cash equivalents	7,144	10,629

	31/03/2023	31/12/2022
Number of employees in the Group (reporting date)	68	72

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 17 May 2023 at 2:00 p.m. CEST to present the financial results of the first three months of 2023 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, 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 the EU/EEA, 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
Senior Vice President Investor Relations & Corporate Communications
PAION AG
Heussstrasse 25
52078 Aachen – Germany
Phone +49 241 4453-152
E-mail r.penner@paion.com
www.paion.com

Disclaimer:

This release contains certain forward-looking statements concerning the future business of PAION AG. These forward-looking statements contained herein are based on the current expectations, estimates and projections of PAION AG's management as of the date of this release. They are subject to a number of assumptions and involve known and unknown risks, uncertainties and other factors. Should actual conditions differ from PAION AG's assumptions, actual results and actions may differ materially from any future results and developments expressed or implied by such forward-looking statements. Considering the risks, uncertainties and other factors involved, recipients should not rely unreasonably upon these forward-looking statements. PAION AG has no obligation to periodically update any such forward-looking statements to reflect future events or developments.