



CORPORATE NEWS

EARNINGS

PAION AG PUBLISHES GROUP QUARTERLY STATEMENT FOR THE FIRST QUARTER OF 2021

- Remimazolam launches in the U.S. and South Korea in the first quarter of 2021
- EU market approval received for remimazolam in procedural sedation in March 2021
- Good progress in commercialization of remimazolam in the U.S., Japan, China and South Korea through our partners
- Expansion of European product portfolio with GIAPREZA® and XERAVA®; PAION further drives specialty pharma transformation
- Successful rights issue of EUR 7.8 million completed in April 2021
- Revenues of EUR 3.2 million
- Cash and cash equivalents of EUR 13.9 million as of 31 March 2021

Aachen (Germany), 12 May 2021 – 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 2021.

Dr. Jim Phillips, CEO of PAION AG, commented: "*The first quarter of 2021 brought important progress in our transformation into a specialty pharma company. Our in-house developed remimazolam was approved in procedural sedation in the EU and successfully launched in other countries around the globe through partners. Another key to our future success has been the addition of GIAPREZA® and XERAVA® to our product portfolio in January, which allows the creation of a more efficient sales and marketing organization. We are now building our commercial organization and preparing launches for all three products in the second half of 2021, addressing important unmet medical needs.*"

Update and outlook on remimazolam

Regulatory activities

In Europe, remimazolam (trade name Byfavo®) is approved in procedural sedation and in addition PAION is seeking approval for general anesthesia.

Procedural sedation: The European Commission approved Byfavo® in the EU (including European Economic Area (EEA) countries) in March 2021. The decision of the UK Medicines & Healthcare products Regulatory Agency (MHRA) on a potential approval in the UK is expected shortly.

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 market approval application (MAA) for remimazolam for general anesthesia until the end of 2021. The approval process for an extension application is generally faster than for an MAA.

Partner activities in the first quarter of 2021

Commercialization activities in **Japan** and **China** were continued successfully. PAION and Mundipharma have agreed on an amendment of the royalty calculation in the first quarter of 2021. A corresponding contract amendment is currently being put in place, based on which remaining EUR 0.2 million royalties from fiscal year 2020 are expected to be additionally recognized as revenue in fiscal year 2021.

In the **U.S.**, the launch of remimazolam (trade name BYFAVO™) by licensee Acacia Pharma (Acacia) was announced in January 2021. Initial feedback from the licensee on market response was very positive.

In **South Korea**, licensee Hana Pharm received market approval for Byfavo™ (remimazolam) in general anesthesia in January 2021 and launched in South Korea at the end of March 2021.

In March 2021, PAION and TTY Biopharm (“TTY”) entered into a license agreement for remimazolam with PAION granting TTY an exclusive license for the development and commercialization of remimazolam in **Taiwan**.

GIAPREZA® and XERAVA®

In January 2021, PAION entered into an exclusive license agreement with La Jolla Pharmaceutical Company for the intensive care products GIAPREZA® (angiotensin II) and XERAVA® (eravacycline). The agreement grants PAION an exclusive license for the commercialization of these two approved products in the European Economic Area, the United Kingdom and Switzerland. GIAPREZA® is a vasoconstrictor indicated for the treatment of refractory hypotension in adults with septic or other distributive shock who remain hypotensive despite adequate volume restitution and application of catecholamines and other available vasopressor therapies. XERAVA® is a novel fluorocycline indicated for the treatment of complicated intra-abdominal infections in adults.

Commercial activities

With the addition of GIAPREZA® and XERAVA® to its commercial portfolio, PAION has started to establish its own commercial structures in certain core countries in Western Europe including Germany, UK, Netherlands, Denmark with more to follow to market GIAPREZA® and XERAVA® together with Byfavo®. PAION plans to launch all three products in a staggered manner by country beginning in the second half of 2021 so that by the end of 2022, launches will have been conducted in all selected European markets.

Financing activities

In June 2019, PAION signed a financing agreement for a loan of up to EUR 20 million with the European Investment Bank (EIB). The first two tranches amounting to EUR 12.5 million in total were drawn down in February. The third tranche in the amount of EUR 7.5 million is available and will be drawn down shortly.

In April 2021, a rights issue was successfully 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 of EUR 3.2 million were recognized in the first quarter of 2021. Of this amount, EUR 2.6 million relate to milestone payments, and EUR 0.6 million relate to the sale of remimazolam API (active pharmaceutical ingredient) to licensees as well as royalties. Royalties from Japan for the first quarter of 2021 are not included in this amount since due to the amendment of the license agreement currently taking place, no corresponding calculation of royalties has been conducted yet by Mundipharma. The royalties from Japan for fiscal year 2020 in the amount of EUR 0.2 million, which are still to be recognized, are also not yet included in the revenues, as the contract amendment with Mundipharma was not yet signed as of the reporting date. In the prior-year period, revenues amounted to EUR 3.5 million and resulted entirely from milestone payments.

Cost of sales in the first quarter of 2021 amounted to EUR 0.5 million.

Research and development expenses in the first quarter of 2021 amounted to EUR 1.3 million (prior-year period: EUR 3.7 million) and decreased as planned, in particular against the background of the EU Phase III study in general anesthesia, which was successfully completed in the previous year.

Compared to the prior-year period, **general administrative and selling expenses** increased by EUR 2.0 million to EUR 3.8 million in the first quarter of 2021. General and administrative expenses increased by EUR 0.5 million to EUR 1.4 million and selling expenses increased by EUR 1.5 million to EUR 2.4 million. The increase in general and administrative expenses is mainly related to financing activities and the expansion of IT systems and infrastructure. Selling expenses increased as planned, particularly due to commercialization and supply chain activities for the three products Byfavo[®], GIAPREZA[®] and XERAVA[®] in Europe.

Earnings before interest and tax in the first quarter of 2021 amounted to EUR -2.6 million and decreased by EUR 0.5 million compared to the prior-year period (earnings before interest and tax in the prior-year period: EUR -2.1 million).

Cash and cash equivalents decreased by EUR 5.8 million in the first quarter of 2021. PAION had cash and cash equivalents of EUR 13.9 million as of 31 March 2021.

The decrease in cash and cash equivalents is mainly due to the **cash flow from investing activities** of EUR -18.6 million, which is mainly related to the licensing of the new products GIAPREZA[®] and XERAVA[®] in January 2021. This is partly offset by a positive **cash flow from financing activities** in the amount of EUR 12.5 million, mainly resulting from the draw-down of the first two tranches of the loan agreement with the EIB in the amount of EUR 12.5 million. The **cash flow from operating activities** amounted to EUR 0.3 million in the first quarter of 2021.

Equity decreased by EUR 3.7 million in the first quarter of 2021 to EUR 17.6 million as of 31 March 2021. The change is mainly due to the net loss for the period.

Risks and opportunities

The main risks and opportunities of future development are presented in detail in the Group management report for fiscal year 2020. In the first quarter of 2021, the risks and opportunities have not changed significantly.

Outlook 2021

PAION confirms its outlook for the current fiscal year given in March 2021 with the publication of the 2020 consolidated financial statements and group management report. PAION's focus in 2021 is on preparing the commercialization of its product portfolio, comprising its approved products Byfavo® (remimazolam), GIAPREZA® and XERAVA®, and on building a distribution infrastructure in selected European countries.

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Key consolidated financial figures, IFRS (unaudited)

(all figures in KEUR unless otherwise noted)	Q1 2021	Q1 2020
Revenues	3,204	3,500
Cost of sales	-466	0
Research and development expenses	-1,337	-3,730
General administrative and selling expenses	-3,831	-1,864
Earnings before interest and tax (EBIT)	-2,558	-2,090

Cash flows from operating activities	321	-809
Cash flows from investing activities	-18,577	0
Cash flows from financing activities	12,488	-14
Change in cash and cash equivalents (incl. exchange rate differences)	-5,762	-815
Average number of group employees	44	44

	31 Mar. 2021	31 Dec. 2020
Intangible assets	20,036	1,829
Cash and cash equivalents	13,904	19,666
Equity	17,555	21,290
Current liabilities	10,754	6,845
Non-current liabilities	13,535	15
Balance sheet total	41,844	28,150

About PAION

PAION AG is a publicly listed specialty pharmaceutical 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. Remimazolam is partnered in multiple territories outside of Europe. Remimazolam is approved in the U.S., the EU/EEA and China for procedural sedation and in Japan and South Korea for general anesthesia.

In addition to Byfavo® (remimazolam), PAION is preparing to launch the two products GIAPREZA® (Angiotensin II) and XERAVA® (Eravacycline) in Europe. GIAPREZA® is a vasoconstrictor indicated for the treatment of refractory hypotension in adults with septic or other distributive shock who remain hypotensive despite adequate volume restitution and application of catecholamines and other available vasopressor therapies. XERAVA® is a novel fluorocycline 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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