CORPORATE NEWS

EARNINGS

PAION AG PUBLISHES GROUP QUARTERLY STATEMENT FOR THE FIRST NINE MONTHS OF 2020

- Significant progress with remimazolam with marketing approvals in the major markets U.S., Japan and China and launches in Japan and China
- BYFAVO™ designated as a Schedule IV medicine by DEA and now expected to be commercially available in the U.S. towards the end of 2020
- Topline data from EU Phase III trial in general anesthesia expected in the upcoming weeks
- Net profit of EUR 5.7 million for the first nine months of 2020
- Cash and cash equivalents of EUR 24.5 million as of 30 September 2020

Aachen (Germany), 11 November 2020 – 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 2020.

Dr. Jim Phillips, CEO of PAION AG, commented: *"We are proud of the achievements we and our partners have made during these challenging times. With the recent classification by the DEA, the last step for remimazolam before U.S. market launch has been achieved. With the market approval of remimazolam in three major markets – U.S., Japan and China – we have reached important milestones and will be able to close the year with a positive result. In Europe, we have completed patient recruitment for the Phase III study in general anesthesia and expect the analysis of the data to be finished in the next few weeks."*

Update and outlook on remimazolam development and commercialization activities

U.S.

In the U.S., the FDA (Food & Drug Administration) granted market approval of BYFAVO™ (remimazolam) for procedural sedation in July 2020.

In October 2020, the Drug Enforcement Administration (DEA) designated BYFAVO™ as a Schedule IV medicine, which was a prerequisite for launch. This designation is the schedule for drugs with a low potential for abuse and low risk of dependence. Licensee Acacia Pharma (Acacia) plans to launch BYFAVO™ in the U.S. towards the end of 2020. Based on this, no royalties from product sales in the U.S. are expected in 2020.

EU
In Europe, PAION is seeking approval for remimazolam in procedural sedation and in general anesthesia.

Procedural sedation: PAION submitted a Marketing Authorization Application (MAA) for procedural sedation to the European Medicines Agency (EMA) in November 2019. PAION currently expects that the Committee for Medicinal Products for Human Use (CHMP) of the EMA will publish its recommendation on the MAA by the end of January 2021 at the latest. The European Commission will review the CHMP recommendation and a final decision on the MAA is expected in the first half of 2021 accordingly.

General anesthesia: The data from the Phase III study in general anesthesia with ASA III/IV (American Society of Anesthesiologists classification III to IV) patients is currently being analyzed, with topline data expected in the upcoming weeks. The randomized, single-blind, propofol-controlled, confirmatory Phase III trial enrolled 424 ASA III/IV patients. Assuming approval in procedural sedation and positive results in the Phase III study in general anesthesia, PAION plans to submit an extension of the MAA for remimazolam for general anesthesia as soon as the MAA for procedural sedation is approved. The approval process for an extension application is generally faster than for an MAA.

Commercialization plans: PAION continues to conduct pre-commercialization activities. The build-up of its own distribution structure in Europe is dependent on PAION's ability to add more products to its commercial portfolio. Thus, PAION is also considering out-licensing remimazolam for commercialization in Europe alternatively.

Compassionate use: Due to the coronavirus pandemic, shortages of anesthetics have emerged. As a result, PAION had been approached by one of its Phase III study centers – San Raffaele Hospital in Milan, Italy – as well as Belgian authorities regarding the compassionate use of remimazolam. Remimazolam has been approved for compassionate use with certain restrictions at the San Raffaele Hospital as well as in Belgium, and PAION is providing product free of charge under these programs.

Licensee activities in other territories in 2020
In Japan, licensee Mundipharma received market approval for Anerem® (remimazolam) for general anesthesia in January 2020 and has successfully launched Anerem® in mid-2020 with first commercial product sales.

In China, licensee Yichang Humanwell received market approval for Ruima® (remimazolam) in procedural sedation in July 2020 and launched Ruima® in the third quarter 2020 as well.

Revenue data and royalties from the two territories for fiscal year 2020 will be available for the consolidated financial statements for 2020.

In South Korea, licensee Hana Pharm submitted a market approval dossier in general anesthesia in December 2019. A decision on market approval is currently expected still in 2020. In January 2020, PAION and Hana Pharm extended their license agreement for remimazolam to include Southeast Asia (Indonesia, Malaysia, Philippines, Singapore, Thailand, Vietnam).

Supply chain activities

PAION is building up the supply chain in order to be able to regularly provide remimazolam API (active pharmaceutical ingredient) to the licensees as well for PAION's potential own commercialization. Activities include establishing structures and processes and obtaining all necessary pharmaceutical permits.

Results of operations, financial position and net assets

Revenues in the first nine months of 2020 amounted to KEUR 19,270 (prior-year period: KEUR 7,500) and mainly resulted from milestone payments in connection with the market approvals of remimazolam in the U.S., Japan and China, as well as the license extension for remimazolam signed with Hana Pharm in January 2020 to include six additional countries in Southeast Asia. Revenues in the prior-year period entirely resulted from a milestone payment in connection with the submission of the market approval dossier for remimazolam in the U.S.

Research and development expenses amounted to KEUR 8,493 in the first nine months of 2020 (prior-year period: KEUR 9,686) and mainly related to the EU Phase III study in general anesthesia.

General administrative and selling expenses increased by KEUR 1,908 to KEUR 5,539 in the first nine months of 2020 compared to the prior-year period. General administrative expenses decreased by KEUR 323 to KEUR 2,398 while selling expenses increased by KEUR 2,231 to KEUR 3,141. The increase in selling expenses mainly related to pre-commercial activities and the set-up of a supply chain for remimazolam.

The **financial result** of KEUR -126 in the first nine months of 2020 (prior-year period: KEUR -24) mainly included expenses in connection with convertible notes issued in the prior year as well as interest expense on cash and cash equivalents held at banks.

Research & development tax credit income amounted to KEUR 804 in the first nine months of 2020 (prior-year period: KEUR 1,995) and related to tax claims for reimbursement of parts of the research and development expenses from the British tax authorities. The decrease compared to the prior-year period was mainly due to a cap of the claim based on the net result of PAION UK Ltd.

Net income for the first nine months of 2020 amounted to KEUR 5,686 compared to a net loss of KEUR 3,380 in the prior-year period. This means an increase of the net result in the amount of KEUR 9,066 compared to the prior-year period which is mainly attributable to higher revenues partly offset by higher selling expenses than in the prior-year period.

Cash and cash equivalents amounted to KEUR 24,514 as of 30 September 2020, an increase of KEUR 5,727 compared to 31 December 2019.

The increase of cash and cash equivalents primarily stems from **cash flows from operating activities** of KEUR 5,746.

Impact of the Coronavirus pandemic on the PAION Group

Overall, the pandemic has only had minor direct effects on the results of operations, net assets and the financial position of the PAION group. Based on the situation at the date of this statement, also only a minor direct impact is

expected in the future. However, it is currently unknown in how far our own and our licensees' business activities will be restrained by the pandemic in the future.

Risks and Opportunities

Material risks and opportunities relating to future development are presented in detail in the group management report for the fiscal year 2019. The overall evaluation of opportunities and risks has not changed significantly in the first nine months of 2020.

Outlook 2020

PAION confirms its financial outlook for the current fiscal year announced on 12 August 2020 with the publication of the half-year results for 2020. PAION's focus for the remainder of 2020 is on the analysis of the European Phase III study data in general anesthesia, market approval processes in Europe and other regions, the build-up of the supply chain and commercial manufacture of remimazolam, as well as market preparation activities and the launch of remimazolam in various territories.

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Key consolidated financial figures, IFRS (unaudited)

(all figures in EUR thousand unless otherwise noted)	Q3 2020	Q3 2019	Q1-Q3 2020	Q1-Q3 2019
Revenues	15,750	0	19,270	7,500
Research and development expenses	-2,094	-3,513	-8,493	-9,686
General administrative and selling expenses	-1,929	-1,310	-5,539	-3,631
Research & development tax credit income	64	829	804	1,995
Net result for the period	11,738	-3,966	5,686	-3,380
Earnings per share in EUR for the period (basic)	0.18	-0.06	0.09	-0.05
Earnings per share in EUR for the period (diluted)	0.18	-0.06	0.09	-0.05

	Q1–Q3 2020	Q1–Q3 2019
Cash flows from operating activities	5,746	1,141
Cash flows from investing activities	-14	-4
Cash flows from financing activities	-16	4,428
Change in cash and cash equivalents (incl. exchange rate differences)	5,727	5,569
Average number of employees	43	43

	30-09-2020	31-12-2019
Intangible assets	1,860	2,137
Cash and cash equivalents	24,514	18,787
Equity	24,727	14,732
Current liabilities	7,865	10,154
Total assets	32,610	24,912

About PAION

PAION AG is a publicly listed specialty pharmaceutical company focused on developing and commercializing innovative drugs for out-patient and 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 was approved in the U.S. and China for procedural sedation in July 2020 and in Japan for general anesthesia in January 2020. In South Korea, a market application for remimazolam in general anesthesia was filed in December 2019.

In Europe, PAION is seeking approval of remimazolam for general anesthesia and for procedural sedation. PAION submitted a Marketing Authorization Application (MAA) for procedural sedation in November 2019. Topline data from a Phase III trial in general anesthesia are expected still in 2020.

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 & other stakeholders in healthcare.

PAION is headquartered in Aachen (Germany) with an additional site in Cambridge (United Kingdom).

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