CORPORATE NEWS

EARNINGS

PAION AG PUBLISHES GROUP QUARTERLY STATEMENT FOR THE FIRST QUARTER OF 2020

- Market approval granted for remimazolam in Japan
- Remimazolam license for Southeast Asia granted to Hana Pharm
- Extension of review period for remimazolam in the U.S – New PDUFA date set for 05 July 2020
- Patient recruitment completed in EU Phase III trial
- Cash and cash equivalents of EUR 18.0 million as of 31 March 2020

Aachen (Germany), 13 May 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 quarter of 2020.

Dr. Jim Phillips, CEO of PAION AG, commented: "*We have been managing the company efficiently through the coronavirus pandemic so far, while making the health and safety of our employees, and the participants in the EU Phase III clinical trial our top priority. The company's financial position remains strong and we are looking very closely at opportunities currently available to accelerate our growth as a business.*

We are conducting the data analysis of the recently completed European Phase III study in general anesthesia, and expect topline results in the second half of the year. We are working closely with regulatory authorities and our partners to ensure we are supporting submissions, pre-commercial and commercial remimazolam activities globally."

Update and outlook on remimazolam development and commercialization activities

U.S.

The New Drug Application (NDA) in procedural sedation was prepared together with licensee Cosmo Pharmaceuticals (Cosmo) and submitted to the FDA (U.S. Food and Drug Administration) by Cosmo in April 2019. The filing was accepted by the FDA in June 2019. In March 2020, Cosmo announced an extension of the review period by the FDA of up to three months for the evaluation of additional data with a new target date for completion of the review under the Prescription Drug User Fee Act (PDUFA date) of 05 July 2020 (previously 05 April 2020).

In January 2020, Cosmo announced that it had sublicensed remimazolam (ByFavo™) U.S. rights to Acacia Pharma (Acacia). Going forward, Acacia will be responsible for the commercialization of remimazolam in the U.S. In 2016,

PAION entered into a U.S. license agreement for remimazolam with Cosmo, which remains unchanged. Acacia has indicated that the company expects to launch remimazolam in the U.S. in the second half of 2020.

EU

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

Procedural sedation: PAION submitted a Marketing Authorization Application (MAA) for procedural sedation to the European Medicines Agency (EMA) in November 2019. A decision on market approval is currently expected in the beginning of 2021 at the earliest.

General anesthesia: PAION is currently evaluating the data from a Phase III study in general anesthesia evaluating ASA III/IV (American Society of Anesthesiologists classification III to IV) patients. The randomized, single-blind, propofol-controlled, confirmatory Phase III trial was expected to enroll approximately 500 ASA III/IV patients undergoing planned surgery. Due to the coronavirus pandemic, patient recruitment was completed in April 2020 with 424 patients enrolled, as agreed by the Data Monitoring Committee. PAION believes that these data will provide sufficient statistical power to conduct analyses of the primary and secondary endpoints.

Assuming approval in procedural sedation and positive results in the Phase III trial in general anesthesia, PAION plans to submit an extension of the MAA for remimazolam for general anesthesia. The earliest this submission could occur would be following an approval decision in procedural sedation. The review 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 outlicensing remimazolam for commercialization in Europe.

Licensee activities in other territories

In Japan, licensee **Mundipharma** received market approval for remimazolam (Anerem®) for general anesthesia in January 2020. Mundipharma currently plans to launch remimazolam in mid-2020.

In China, licensee **Yichang Humanwell** submitted a market approval dossier for procedural sedation to the Chinese National Medical Products Administration (NMPA) in November 2018. Market approval is expected in 2020.

In South Korea, licensee **Hana Pharm** submitted a market approval dossier in general anesthesia in December 2019. Market approval is currently expected in the second half of 2020. In January 2020, PAION and Hana Pharm extended their license agreement for remimazolam to include Southeast Asia (Indonesia, Malaysia, Philippines, Singapore, Thailand, Vietnam); Hana Pharm is responsible for development and the market approval process in these territories.

In Russia, licensee **R-Pharm** announced the successful completion of a Phase III trial in general anesthesia in November 2018. R-Pharm is currently preparing first market approval dossiers for the licensed territories.

In Canada, PAION expects its licensee **Pharmascience** to use the U.S. market approval dossier as the basis for filing for market approval for remimazolam.

Supply chain activities

PAION is building up the supply chain in order to be able to provide remimazolam product to the licensees in time for market launches as well for PAION's potential own launch. Activities include establishing structures and processes and obtaining all necessary pharmaceutical permits.

Results of operations, financial position and net assets

In the first quarter of 2020, **revenues** of KEUR 3,500 were realized. These result from the license extension signed with Hana Pharm to include six additional countries in Southeast Asia as well as from market approval in general anesthesia in Japan. In the prior-year period, no revenues were recognized.

Research and development expenses amounted to KEUR 3,730 in the first quarter of 2020 (prior-year period: KEUR 3,063) and mainly relate to the EU Phase III study in general anesthesia for which patient recruitment was completed in April 2020.

General administrative and selling expenses increased by KEUR 879 to KEUR 1,864 in the first quarter of 2020 compared to the prior-year period. General administrative expenses increased by KEUR 127 to KEUR 916 and selling expenses increased by KEUR 752 to KEUR 948. The increase in selling expenses particularly stems from pre-commercial activities and the build-up of a supply chain for remimazolam.

Tax income amounted to KEUR 441 in the first quarter of 2020 (prior-year period: KEUR 667) and relates to tax claims for reimbursement of a portion of research and development expenses from the British tax authorities. The decrease despite increased research and development expenses compared to the prior-year period is mainly due to a cap of the claim based on the net result of the period of PAION UK Ltd.

Net loss for the first quarter of 2020 amounted to KEUR 1,711 and decreased by KEUR 1,530 compared to the prior-year period (net loss in the prior-year period: KEUR 3,241).

Cash and cash equivalents decreased by KEUR 815 in the first quarter of 2020. As of 31 March 2020, PAION's cash and cash equivalents amounted to KEUR 17,972.

The decrease of cash and cash equivalents nearly entirely stems from **cash flows from operating activities** of KEUR -809. These primarily result from the net loss, adjusted for the current tax credit claim towards the British tax authorities which has not had a cash effect yet, as well as changes of the working capital, particularly an increase of trade payables.

Equity increased by KEUR 294 in the first quarter of 2020 and amounted to KEUR 15,026 as of 31 March 2020. The change primarily results from the net

loss for the period on the one hand and capital increases from the conversion of convertible debt on the other hand.

Risks and opportunities

Material risks and opportunities relating to future development were presented in detail in the group management report for fiscal year 2019. Risks and opportunities have not changed significantly in the first quarter of 2020.

Outlook 2020

PAION confirms its outlook for the current fiscal year given in March 2020 with the publication of the 2019 consolidated financial statements and group management report. PAION's focus for 2020 is on the evaluation of the European Phase III study in general anesthesia, market approval processes in the U.S., Europe and other regions, the build-up of the supply chain and commercial manufacture of remimazolam as well as the market preparation for and commercial launch of remimazolam in different territories.

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Key consolidated financial figures, IFRS (unaudited)

(all figures in KEUR unless otherwise noted)	Q1 2020	Q1 2019
Revenues	3,500	0
Research and development expenses	-3,730	-3,063
General administrative and selling expenses	-1,864	-985
Tax income	441	667
Net result for the period	-1,711	-3,241
Earnings per share in EUR for the period (basic)	-0.03	-0.05
Earnings per share in EUR for the period (diluted)	-0.03	-0.05

Cash flows from operating activities	-809	-1,611
Cash flows from investing activities	0	0
Cash flows from financing activities	-14	-12
Change in cash and cash equivalents (incl. exchange rate differences)	-815	-1,615
Average number of group employees	44	42

	31 Mar. 2020	31 Dec. 2019
Intangible assets	2,006	2,137
Cash and cash equivalents	17,972	18,787
Equity	15,026	14,732
Current liabilities	9,289	10,154
Balance sheet total	24,338	24,912

About PAION

PAION AG is a publicly listed specialty pharmaceutical company developing and aiming to commercialize 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. In Japan, remimazolam was approved for general anesthesia in January 2020. In the U.S., a New Drug Application

(NDA) for procedural sedation is under review, with a PDUFA date of 5 July 2020. In China, licensee Yichang Humanwell filed for market approval for remimazolam in procedural sedation in November 2018 and in South Korea, licensee Hana Pharm filed for market approval for remimazolam in general anesthesia 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. Results of a Phase III trial in general anesthesia are expected in the second half of 2020.

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

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

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