CORPORATE NEWS

FINANCIAL RESULTS 2018

PAION AG REPORTS ON SUCCESSFUL FISCAL YEAR 2018

- Remimazolam filings for market approval in China and Japan; U.S. will follow shortly
- EU Phase III trial in general anesthesia started in July 2018
- Successful pre-submission meeting with EMA for the indication procedural sedation
- Phase III trials in Russia and South Korea successfully completed
- Cash and cash equivalents of EUR 17.2 million as of 31 December 2018
- Conference call (in English) today at 2:00 p.m. CET (1:00 p.m. GMT/9:00 a.m. EDT)

Aachen (Germany), 20 March 2019 – 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 fiscal year 2018.

Dr. Wolfgang Söhngen, CEO of PAION AG, commented: "*2018 was again a very successful year for us. We were pleased to see the substantial progress made by our licensees, including regulatory filings for approval in China and Japan. We look forward to another productive year in 2019. We expect to complete recruitment for our EU Phase III study in general anesthesia, and we also anticipate further regulatory filings by our licensees in the different territories, particularly in the U.S. as an important market. The positive signal from the EMA with regard to a possible filing for procedural sedation without a further study creates the opportunity for PAION to accelerate market entry in Europe."*

Update on remimazolam development activities and outlook

U.S.

Together with Cosmo Pharmaceuticals (Cosmo), PAION has prepared the New Drug Application (NDA) in procedural sedation to a degree that allows for filing for market approval with the Food & Drug Administration (FDA) shortly as planned. In that regard, a pre-NDA meeting was held in July 2018 for coordination between the FDA, Cosmo and PAION.

With a regular course of the approval process, the U.S. market launch of remimazolam can be expected in 2020.

EU

In July 2018, PAION started an EU Phase III clinical trial for the induction and maintenance of general anesthesia. The randomized, single-blind, propofol-controlled, confirmatory Phase III trial is expected to enroll approximately 500 ASA III/IV patients (American Society of Anesthesiologists classification III to IV) undergoing elective surgery at more than 20 European trial centers. Patient recruitment is expected to be completed by the end of 2019.

The trial was designed in consultation with EU key opinion leaders in general anesthesia. Based on Scientific Advice obtained from the European Medicines Agency (EMA) in January 2018, PAION expects that a positive Phase III trial in combination with previously completed clinical studies in Europe and Japan should be sufficient to file for market approval for general anesthesia.

Additionally, PAION is currently evaluating the possibility of submitting a Marketing Authorization Application (MAA) for remimazolam in procedural sedation with the EMA based on the completed U.S. development program. At a pre-submission meeting with the EMA held in February 2019, the U.S. Phase III clinical development program, including key safety data and efficacy results, was discussed in relation to a potential regulatory filing in the EU. Based on this pre-submission meeting, PAION assumes that the existing data package is sufficient to be able to submit the MAA for procedural sedation in the EU.

Licensee activities in other territories

PAION's licensees are preparing the future filings of remimazolam in their respective territories through regulatory interactions.

Highlights include:

Chinese remimazolam licensee Yichang Humanwell submitted a market approval dossier to the Chinese National Medical Products Administration (NMPA) for remimazolam in the indication procedural sedation in November 2018. A potential market approval could happen end of 2019 at the earliest.

Japanese remimazolam licensee Mundipharma submitted a market approval dossier to the Japanese Pharmaceuticals and Medical Devices Agency (PMDA) for remimazolam in the indication general anesthesia in December 2018. Market approval could be granted end of 2019 at the earliest.

In November 2018, **Russian** remimazolam licensee R-Pharm announced the successful completion of a Phase III trial in general anesthesia. R-Pharm currently plans to file for market approval in Russia by the end of 2019.

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

PAION’s remimazolam licensee TR-Pharm (**Turkey, the Middle East** and **North Africa**) plans to file for market approval in Turkey based on the U.S. or Japanese dossier.

PAION’s remimazolam licensee Hana Pharm successfully completed patient recruitment of a Phase III trial in general anesthesia in October 2018. Before filing for market approval, the production process for remimazolam needs to

be established in **South Korea**. Accordingly, Hana Pharm plans to file for market approval in 2020.

Results of operations, net assets and financial position for 2018

Revenues recognized in the reporting period amounted to EUR 2.8 million and resulted from the remimazolam license agreement with Mundipharma in the amount of about EUR 2.0 million, thereof EUR 1 million from the filing of the market approval dossier in Japan and almost EUR 1 million from the recognition of the remaining part of the upfront payment of EUR 1 million received in January 2018. Additionally, EUR 0.5 million related to the remimazolam license agreement with Hana Pharm resulting from the filing for market approval in Japan, and EUR 0.3 million related to the remimazolam license agreement with Yichang Humanwell resulting from the filing for market approval in China.

Research and development expenses amounted to EUR 12.2 million and mainly related to expenses in connection with the EU Phase III trial in general anesthesia started in July 2018, the validation of commercial-scale production, as well as activities related to filings for market approval for remimazolam. The decrease of EUR 5.7 million compared to the prior year was mainly due to lower costs for Phase III and particularly Phase I studies, which had been incurred to a significant extent in the prior year, especially in connection with the U.S. development program.

General administrative and selling expenses amounted to EUR 3.4 million and decreased by EUR 0.4 million compared to the previous year. This change mainly stems from a decrease of selling expenses due to lower expenses for market research activities in the reporting period.

Income taxes for the fiscal year related to tax claims for reimbursement of parts of the research and development expenses from the British tax authorities. The change compared to the prior year was mainly associated with the decrease in research and development expenses for remimazolam in the reporting period.

Net loss decreased from EUR 12.1 million in the previous year to EUR 9.9 million in fiscal year 2018.

Compared to 31 December 2017, **cash and cash equivalents** decreased by EUR 7.6 million to EUR 17.2 million as of 31 December 2018. The change in cash and cash equivalents stems from the following areas:

Cash flows from operating activities amounted to EUR -12.8 million and primarily resulted from the net loss for the year in the amount of EUR 9.9 million, changes in working capital, particularly the decrease in trade payables of EUR 3.7 million, as well as the tax credit payment from the British tax authorities in the amount of EUR 3.7 million received in September 2018, adjusted for the current tax credit claim towards the British tax authorities (EUR 2.5 million), which has not yet had a cash effect.

Cash flows from financing activities amounted to EUR 5.2 million and resulted from the gross proceeds from the capital increase excluding subscription rights conducted in June 2018 (EUR 5.2 million), the cost of funds for this capital increase (EUR 0.2 million) and the exercise of stock options (EUR 0.2 million).

Outlook

PAION's focus for 2019 is on the development program in Europe, approval processes in the U.S. and other regions, manufacture of and supply chain for remimazolam. In addition, it is expected that further development and approval activities in the various territories will also promote the other indications.

PAION also plans small-scale pre-marketing activities for the preparation of an own commercialization subject to possible dates for filing its own market approval dossiers for remimazolam in Europe.

Financial outlook 2019

PAION expects revenues of about EUR 8 million in 2019, thereof EUR 7.5 million in connection with the planned regulatory filing for remimazolam in the U.S. by Cosmo. Moreover, EUR 0.5 million are expected related to revenues from TR-Pharm in connection with the transfer of the Japanese filing dossier translated into English or transfer of the U.S. filing dossier.

Due to the ongoing investment in the development of remimazolam including the EU Phase III study, PAION expects research and development expenses to amount to between approx. EUR 13 million and approx. EUR 15 million, depending on the progress of development. Income from tax credits is expected to amount to approx. EUR 2 million. General administrative and selling expenses are expected to amount to between approx. EUR 4 million and approx. EUR 5 million depending on the volume of pre-commercial activities. Net loss is expected to amount to between approx. EUR 7 million and approx. EUR 10 million in 2019.

This outlook assumes that PAION and licensee activities progress as expected. In case of delays, major costs and/or revenues would shift into 2020 or subsequent periods. Plans are also based on the current status of discussions with regulatory authorities. Additional unexpected requirements by regulatory authorities could lead to higher costs than planned and to delays in approvals and related revenues.

Based on current planning, cash and cash equivalents on hand, including expected tax credits from the British tax authorities on parts of research and development expenses and the expected milestone payment in connection with filing for market approval in the U.S., secure a liquidity runway until approx. mid-2020. Based on current planning, PAION expects to require additional funds of approximately EUR 10 million until filing for market approval in general anesthesia in the EU.

Additional funds will also be required in the coming years for the planned own commercialization in selected European markets. The magnitude of the required funds will depend on the actual setup of commercialization and which European countries PAION will initially focus on. Also, additional funds will be required for the planned development of the indication ICU sedation as well as for the multi-year pediatric development plan. PAION expects that the total requirement for funds can be partially covered by potential future milestone payments and royalties.

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Key consolidated financial figures, IFRS

(all figures in KEUR unless otherwise noted)	2018	2017
Revenues	2,766	5,811
Research and development expenses	-12,167	-17,853
General administrative and selling expenses	-3,408	-3,828
Income taxes	2,510	3,759
Net result	-9,939	-12,093
Earnings per share in EUR (basic)	-0.16	-0.20
Earnings per share in EUR (diluted)	-0.16	-0.20
Cash flows from operating activities	-12,813	-17,720
Cash flows from investing activities	-13	-25
Cash flows from financing activities	5,214	12,494
Intangible assets	2,212	2,415
Cash and cash equivalents	17,227	24,839
Equity	20,822	25,229
Current liabilities	3,501	6,656
Balance sheet total	24,323	31,885
Average number of group employees	39	33

The full annual financial report will be available on 20 March 2019 on PAION's corporate website: http://www.paion.com/media-and-investors/investorcenter/financial-reports.

Conference call and webcast

In addition to the publication of results, the Management Board of PAION AG will host a public conference call (conducted in English) on 20 March 2019 at 2 p.m. CET (1 p.m. GMT, 9 a.m. EDT) to present the 2018 financial results, highlight key events and provide a pipeline and strategy update and financial outlook.

To access the call, participants may dial from

- Germany +49 (0) 69 7104 45598
- UK +44 (0) 20 3003 2666
- U.S. +1 212 999 6659
- Other countries: please use the UK number

When prompted, please give the password "PAION". The conference call will include a webcast presentation, which can be accessed during the call using the following link: https://paion-events.webex.com/paion-events/j.php?MTID=md81282726f596886df549ea76529fa7c

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 drug candidate for which PAION has completed the clinical development for use in procedural sedation in the U.S. Outside the U.S., PAION is currently focused on the development of remimazolam for general anesthesia. Development of remimazolam for

intensive care unit (ICU) sedation is also part of the longer-term life-cycle plan for remimazolam.

PAION's vision is to become an acknowledged “PAIONeer” in sedation and anesthesia. PAION is headquartered in Aachen (Germany) with an additional site in Cambridge (United Kingdom).

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