CORPORATE NEWS

EARNINGS

PAION AG REPORTS FINANCIAL RESULTS FOR THE FIRST HALF-YEAR 2018

- EU Phase III study started
- Successful pre-NDA meeting held with FDA; remimazolam market approval dossiers in preparation for the U.S. and Japan
- Phase III trial in South Korea started; Phase III trial patient recruitment in Russia completed
- Financial results in line with plan
- EUR 5.2 million raised in private placement with new institutional investor
- Cash and cash equivalents of EUR 23.3 million as of 30 June 2018; cash reach until end of 2019
- Conference call today at 2:00 p.m. CEST (1:00 p.m. BST/8:00 a.m. EDT)

Aachen (Germany), 08 August 2018 – 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 half-year 2018.

Dr. Wolfgang Söhngen, CEO of PAION AG, commented: "*In the first half of 2018, we have made solid progress together with our partners, and we expect the first market approval submission to be completed by the end of this year. We very much appreciate the work our partners are doing in advancing remimazolam towards the market in their territories, as we are able to make full use of all data and insights. Additionally, we are excited to have initiated a Phase III trial in Europe, a major step to support the company's further development.*"

Update on remimazolam development and outlook

U.S.

In the first half of 2018, PAION focused on completing the data package and documentation necessary to enable U.S. license partner Cosmo Pharmaceuticals (Cosmo) to prepare the New Drug Application (NDA) in procedural sedation.

In July 2018, PAION's license partner Cosmo attended a pre-NDA meeting with the FDA together with PAION delegates. Pre-NDA meetings with the FDA represent the final step during drug development before submission of an NDA. These meetings allow companies to discuss with the FDA the appropriateness of the content of their submission package as well as the approval pathway and the preferred label. In preparation for the meeting, the FDA had received a summary

of the application documentation as well as a set of questions, along with company positions and explanatory background.

During the meeting, the main questions raised for discussion following the preliminary assessment of remimazolam by the FDA were clarified. This will allow the process to proceed as planned to file for approval in the fourth quarter 2018/first quarter 2019.

EU
In July 2018, PAION has started an EU Phase III clinical trial with remimazolam 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 in 2019.

The primary objective of the trial is to demonstrate the non-inferiority of remimazolam compared to propofol for the induction and maintenance of general anesthesia during elective surgery. The key secondary objective is to show improved hemodynamic stability (avoidance of intraoperative drop of blood pressure and vasopressor usage) compared to propofol.

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 for filing for market approval for general anesthesia.

Partner activities in other territories
PAION's license partners are extending the data base with clinical studies and are preparing the future filings of remimazolam in their respective territories through regulatory interactions. Highlights include:

Japan: **Mundipharma**, having development and commercialization rights in this territory since the end of 2017, is preparing a market approval dossier with PAION's support and plans to file for market approval in 2018.

Russia: In May 2018, PAION's license partner **R-Pharm** announced the completion of patient recruitment in a Phase III study in general anesthesia. R-Pharm currently plans to file for market approval end of 2018.

South Korea: PAION's license partner **Hana Pharm** started a Phase III study in general anesthesia in March 2018. Completion of the study is expected in 2018.

China: The current development program of PAION's license partner **Yichang Humanwell** with remimazolam amongst others includes a Phase II study in general anesthesia and a Phase III study in procedural sedation.

Other regions: License partners Hana Pharm, Pharmascience (Canada), and TR-Pharm (Turkey, the Middle East and North Africa) plan to file for market approval in their respective territories based on the U.S. or Japanese dossier.

Results of operations, financial position and net assets

Revenues in the first half-year 2018 amounted to EUR 0.5 million compared to EUR 4.1 million in the prior-year period and mainly resulted from the upfront payment received from Mundipharma in January 2018 under the remimazolam license agreement for Japan entered into in 2017. Revenues in the prior-year period primarily resulted from the license agreement with U.S. license partner Cosmo.

Research and development expenses amounted to EUR 6.5 million in the first half-year 2018 and mainly related to expenses in connection with the preparation of the EU Phase III trial in general anesthesia started in July 2018, the validation of commercial scale production as well as preparatory activities for filing for market approval for remimazolam. The decrease of EUR 3.4 million compared to the prior-year period is mainly due to lower costs for Phase III and Phase I studies.

General administrative and selling expenses decreased by EUR 0.2 million to EUR 1.8 million in the first half-year 2018 compared to the prior-year period.

Income taxes amounted to EUR 1.5 million in the first half-year 2018 (prior-year period: EUR 2.0 million) and relate to tax claims for reimbursement of parts of the research and development costs from the British tax authorities. The decrease is primarily attributable to lower research and development costs.

The **net loss** for the first half-year 2018 amounted to EUR 6.2 million compared to a net loss of EUR 5.8 million in the prior-year period. This means an increase of the net loss in the amount of EUR 0.4 million compared to the first half-year 2017 which is mainly attributable to lower revenues and lower research and development expenses than in the prior-year period.

Cash and cash equivalents decreased by EUR 1.6 million in the first half-year 2018. As of 30 June 2018, PAION's cash and cash equivalents amounted to EUR 23.3 million.

The decrease of cash and cash equivalents particularly stems from negative **cash flows from operating activities** on the one hand and positive **cash flows from financing activities** on the other hand. Cash flows from operating activities amounted to EUR -6.6 million in the first half-year 2018 and primarily result from the net loss and changes in the working capital, adjusted for the current tax credit claim towards the British tax authorities which has not had a cash effect yet as well as adjusted for the part of the upfront payment received from Mundipharma in January 2018 which has had a cash effect already but has not been recognized as revenues yet. Cash flows from financing activities amounted to EUR 5.1 million in the first half-year 2018 and mainly relate to the net proceeds of the capital increase conducted in June 2018.

Outlook 2018

PAION's major goals for the remainder of 2018 are the completion and transfer of all data and documents in the U.S. to Cosmo and the conduct of the EU Phase III study in general anesthesia. In addition, PAION continues to work on the validation of commercial scale production of remimazolam.

Financial outlook 2018

PAION expects revenues of about EUR 3 million in 2018, thereof EUR 2 million in connection with the planned regulatory filing for remimazolam in Japan by Mundipharma. Moreover, approx. EUR 1 million are related to the upfront payment received from Mundipharma in January 2018 in course of the remimazolam license agreement for Japan. In case of regulatory filing in the U.S. in the fourth quarter 2018, revenues would increase by EUR 7.5 million in 2018.

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 15 million and approx. EUR 17 million, depending on the progress of development. Income from tax credits on parts of research and development expenses from British tax authorities is expected to amount to approx. EUR 3 million. General administrative and selling expenses are expected to amount to between approx. EUR 3.5 million and approx. EUR 4 million. Net loss is expected to amount to between approx. EUR 12.5 million and approx. EUR 15 million in 2018. Should filing for market approval in Japan be delayed to 2019, revenues and net result would decrease by EUR 2 million.

This outlook assumes that PAION and partner activities progress as expected. Delays would result in related costs and/or revenues shifting into 2019. 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 regulatory decisions.

Based on current plans, PAION expects to have sufficient funds until the end of 2019. This includes completing all activities related to the NDA submission for remimazolam in procedural sedation in the U.S., as well as completing the ongoing EU Phase III study.

PAION expects to require additional funds of approximately EUR 10 million until filing for regulatory approval of remimazolam in the EU based on current planning. This funding requirement may partly be covered by potential further milestone payments from existing license agreements.

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Key Consolidated Financial Figures, IFRS

(all figures in KEUR unless otherwise noted)	Q2 2018	Q2 2017	H1 2018	H1 2017
Revenues	260	2,032	517	4,083
Research and development expenses	-3,184	-5,851	-6,544	-9,930
General administrative and selling expenses	-966	-980	-1,761	-1,983
Result for the period	-3,118	-3,553	-6,243	-5,771
Earnings per share in EUR for the period (basic)	-0.05	-0.06	-0.10	-0.10
Earnings per share in EUR for the period (diluted)	-0.05	-0.06	-0.10	-0.10

	H1 2018	H1 2017
Cash flow from operating activities	-6,626	-7,634
Cash flow from investing activities	-12	-17
Cash flow from financing activities	5,067	4,678
Change in cash and cash equivalents (incl. exchange rate differences)	-1,572	-2,991
Average number of employees in the Group	38	31

	30 June 2018	31 Dec. 2017
Intangible assets	2,340	2,415
Cash and cash equivalents	23,267	24,839
Equity	24,192	25,229
Current liabilities	7,232	6,656
Balance sheet total	31,424	31,885

The full half-year financial report will be available as of 08 August 2018 on PAION's website at 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 conference call (conducted in English) on 08 August 2018 at 2 p.m. CEST (1 p.m. BST, 8 a.m. EDT) to present the financial results of the first six months of 2018 and provide a pipeline and strategy update and financial outlook.

To access the call, please dial:

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

When prompted, please provide the password "PAION". The conference call will be supplemented by a webcast presentation which can be accessed during the call at the following link: https://paion-events.webex.com/paion-events/j.php?MTID=m093965a0263d179cddcd1eaab8686398.

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. A full clinical development program for general anesthesia has been completed in Japan. In the EU, PAION initiated a Phase III trial in July 2018. 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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