CORPORATE NEWS

FINANCIAL RESULTS 2017

PAION AG REPORTS ON FISCAL YEAR 2017 AND FINANCIAL RESULTS

- Phase III program for remimazolam in the U.S. completed
- Partnership announced with Mundipharma for Japan
- Strong progress made by remimazolam partners in Canada, Russia and South Korea
- Financial results in line with plan
- Cash and cash equivalents of EUR 24.8 million as of 31 December 2017
- EU Phase III study will start in the second half of 2018
- Conference call (in English) today at 2:00 p.m. CET (1:00 p.m. GMT/9:00 a.m. EDT)

Aachen (Germany), 22 March 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 fiscal year 2017.

Dr. Wolfgang Söhngen, CEO of PAION AG, commented: "*2017 was a very successful year. We achieved all major clinical development goals and announced positive Phase III results from U.S. trials with remimazolam. We were also very pleased to see the substantial progress made by our commercialization and development partners in several territories and were excited to end the year with closing a partnership for remimazolam in Japan. In addition, we strengthened our patent portfolio and completed two successful financings."*

He continued: *"Our key goals for 2018 are the completion and delivery of data and documentation to Cosmo, our partner for the U.S., and the initiation of an EU Phase III study in general anesthesia. We also expect several of our partners to make key clinical and regulatory progress in their respective territories during the year."*

Remimazolam development activities

In 2017, PAION mainly focused on the completion of its Phase III U.S. development program for **remimazolam** in procedural sedation.

U.S.

In June 2017, PAION announced positive headline data from the second pivotal U.S. Phase III clinical trial with remimazolam. The trial was designed to evaluate the efficacy and safety of remimazolam compared to placebo (with midazolam rescue medication) in procedural sedation in patients undergoing

bronchoscopy. The primary endpoint and important secondary endpoints were achieved with high statistical significance.

In March 2017, PAION announced positive headline data from the U.S. clinical safety trial with remimazolam in ASA III/IV patients (American Society of Anesthesiologists classification) undergoing colonoscopy. The trial confirmed remimazolam's safety profile and tolerability shown in all previous studies in a more vulnerable patient population. Efficacy and efficiency improvements in this trial were comparable to the two positive pivotal U.S. Phase III trials in colonoscopy and bronchoscopy patients.

Based on the results of preclinical and Phase I studies and in consultation with the FDA, PAION conducted additional Phase I studies to further assess the abuse potential of remimazolam. Two aspects were studied: if remimazolam could inappropriately be used as a knock-out cocktail in combination with alcohol and if it could be abused intranasally. In November 2017, the FDA informed PAION that it determines the abuse liability program conducted by PAION as sufficient to provide the necessary data regarding the abuse potential of remimazolam in humans. PAION therefore assumes the clinical development program for remimazolam in procedural sedation in the U.S. as completed.

PAION is working intensely to complete and deliver the data packages and documentation from the extensive U.S. clinical development program to U.S. license partner **Cosmo**, which plans to submit for regulatory approval in the U.S. in the fourth quarter 2018/first quarter 2019.

EU

In consultation with key opinion leaders in general anesthesia, PAION has successfully conducted a Phase I trial which served as a means to define key elements and sample size calculation for the planned Phase III trial. Based on the results of this study, subsequent simulations and Scientific Advice obtained from the European authority EMA in January 2018 for defining the new European Phase III program, PAION currently assumes that approximately 450 to 500 patients will be required for the EU Phase III study in general anesthesia.

PAION plans a study design in general surgery close to the successfully completed Phase III program in general anesthesia in Japan, but in sicker patients, where the medical need to reduce hypotensive events is greater. The study is currently planned to start in the second half of 2018.

Partner activities in other territories

All license partners have activities ongoing to support future filings in their respective territories with a focus on clinical studies and regulatory interactions.

In May 2017, PAION's remimazolam license partner for Canada, **Pendopharm**, a division of Pharmascience Inc., together with PAION delegates, had a pre-NDS meeting with Health Canada for the indication conscious sedation. Health Canada is the agency responsible for approving drugs in Canada. During the meeting, the main questions raised for discussion following the preliminary assessment of remimazolam by Health Canada were clarified. Health Canada stated in the meeting that the non-clinical and the clinical data package, including the human abuse liability data available at the time, were regarded as adequate for filing. Currently, PAION expects filing for

market approval in Canada after the market approval dossier in the U.S. has been filed.

In August 2017, PAION's remimazolam license partner for Russia, **R-Pharm,** announced the start of a Phase III study in general anesthesia in Russia. Completion of the study is expected still in the first half of 2018. Subsequently, R-Pharm plans filing for market approval which is currently planned end of 2018.

In December 2017, PAION entered into a remimazolam license agreement with **Mundipharma** in course of which PAION has granted Mundipharma an exclusive license for the development and commercialization of remimazolam in Japan. Under the terms of the agreement, Mundipharma has the right and obligation to further develop remimazolam in all indications in Japan with PAION's support. Mundipharma will bear all cost for market authorization and distribution. PAION receives a EUR 1 million upfront payment (received in January 2018). PAION is also entitled to receive additional payments totaling up to EUR 25 million depending on the achievement of certain regulatory and commercial milestones in the three indications procedural sedation, general anesthesia and Intensive Care Unit (ICU) sedation. PAION is also entitled to receive tiered royalties starting in the low double-digits to over 20% of net sales, depending on sales levels and sales price (National Health Insurance (NHI) price), which will be determined by the Japanese government. Based on the positive pre-NDA meeting with the Japanese authority, PAION had started preparations for a market approval dossier for remimazolam. Mundipharma has now taken over these tasks with PAION's support. Mundipharma currently plans filing for market approval in Japan in 2018.

PAION's South Korean remimazolam license partner **Hana Pharm** is going to conduct a Phase III study with remimazolam in general anesthesia in South Korea. Completion of the study is expected in 2018.

PAION's Chinese remimazolam license partner Yichang Humanwell is going to conduct a Phase II study with remimazolam in general anesthesia and a Phase III study with remimazolam in procedural sedation in China.

Results of operations, net assets and financial position for 2017

Revenues amounted to EUR 5.8 million in the reporting period, an increase of EUR 1.5 million compared to the previous year. Revenues included an amount of EUR 5.7 million from the upfront payment of EUR 10 million received from Cosmo in 2016. Recognition of the upfront payment was dependent on the progress of certain development components.

Research and development expenses amounted to EUR 17.9 million and were mainly related to the U.S. clinical development program for remimazolam in procedural sedation. The decrease of EUR 5.6 million compared to the prior year was mainly due to lower costs for Phase III studies which were partially offset by higher costs for Phase I studies.

General administrative and selling expenses amounted to EUR 3.8 million, a decrease of EUR 1.3 million compared to the previous year. Administrative expenses decreased by EUR 0.7 million to EUR 3.1 million and selling expenses decreased by EUR 0.6 million to EUR 0.7 million. Higher general and administrative expenses incurred in the prior-year period were mainly due to preparations for potential capital measures that were ultimately not

conducted while selling expenses recognized in the prior-year period comprised essential costs related to the initiation and preparation of license agreements which have only been incurred to a lesser extent in the reporting period.

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

Net loss was EUR 12.1 million, significantly lower than the prior year figure of EUR 20.1 million and at the lower end of the forecast range of approx. EUR 12 million to approx. EUR 14 million.

Cash and cash equivalents as of 31 December 2017 amounted to EUR 24.8 million**,** a decrease of EUR 5.3 million compared to the prior year.

Cash flow from operating activities of EUR -17.7 million mainly results from the net loss of EUR 12.1 million adjusted for non-cash revenues of EUR 5.8 million.

Cash flow from financing activities results from gross proceeds from the capital increase with subscription rights in February 2017 (EUR 5 million) and the capital increase excluding subscription rights in July 2017 (EUR 8 million), the cost of funds related to these capital increases (EUR 0.7 million) as well as the exercise of stock options (EUR 0.1 million).

Outlook

Development and commercialization

PAION's major goals for 2018 are the completion and transfer of all data and documentation related to the U.S. remimazolam development program to Cosmo and the start of a new EU Phase III study in general anesthesia. In addition, PAION continues to work on production development for remimazolam.

For the U.S. PAION is focussing on the integrated analysis of all clinical studies with remimazolam, which is necessary for preparing and filing for marketing approval in the U.S. Before filing, a pre-NDA meeting with the FDA is usually held, which Cosmo currently plans shortly before filing for approval. The necessary coordination and preparatory work are currently being conducted together with Cosmo, U.S. key opinion leaders and regulatory experts. Filing for market approval is Cosmo's responsibility. Cosmo currently expects to file for approval in the fourth quarter 2018/first quarter 2019.

For the EU, PAION is preparing a Phase III trial in general anesthesia using a study design comparable to the successfully completed Phase III program in general anesthesia in Japan. Following the receipt of Scientific Advice from the EMA in January 2018 which served to outline the new European Phase III program, the study is planned to start in the second half of 2018.

PAION expects its other regional remimazolam partners to continue their development activities towards filing. Mundipharma plans to file for market approval in Japan in 2018. R-Pharm is currently conducting a Phase III study in Russia, and recruitment is expected to complete in the first half of 2018.

Subsequently, R-Pharm plans to file for market approval currently anticipated for end of 2018. Yichang Humanwell will conduct two clinical studies with remimazolam in China; one Phase III study in procedural sedation and one Phase II study in general anesthesia. PAION's partner Hana Pharm is going to conduct a Phase III study with remimazolam in general anesthesia in South Korea. Pharmascience, Hana Pharm and TR-Pharm plan to file for market approval in their respective territories based on the U.S. or Japanese dossier.

Financial outlook

PAION expects revenues of approx. 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.

Due to the ongoing investment in the development of remimazolam including the EU Phase III study, PAION expects research and development expenses to be between approx. EUR 15 million and approx. EUR 17 million, depending on the progress of development. Income from tax credits on portions of research and development expenses from British tax authorities is expected to be approx. EUR 3 million. General administrative and selling expenses are expected to be between approx. EUR 3.5 million and approx. EUR 4 million. Net loss is expected to be 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. In case of regulatory filing in the U.S. in the fourth quarter 2018, revenues as well as net result would increase in 2018.

This outlook assumes that PAION and partner activities progress as expected. Otherwise, essential cost blocks would shift into 2019. Plans are also based on the current status of discussions with regulatory authorities. Additional requirements by regulatory authorities could lead to higher costs than planned and to delays in approvals.

Based on current plans, PAION believes that cash and cash equivalents of EUR 24.8 million as of 31 December 2017 enable PAION to complete all activities for preparation of the filing dossier in procedural sedation in the U.S. PAION expects to receive payments from its license partners, subject to the achievement of certain regulatory milestones, and, once remimazolam is approved, royalties on net sales. Should development, filing and approval go according to plan, PAION will not need additional funding to bring remimazolam to the U.S. market.

For the planned EU Phase III study, no further funding will be required based on current planning allowing for the planned study start in the second half of 2018. Cash and cash equivalents, including expected tax credits from the British tax authorities on parts of research and development expenses and expected potential milestone payments in connection with filings for market approval in the U.S. and Japan, secure the conduct of the targeted Phase III study in the EU based on current cost planning. Overall, this ensures a cash reach into the second half of 2019. Until filing for market approval in the EU, further funds of approx. EUR 15 million are required based on current planning. This funding requirement may partly be covered by potential further milestone payments.

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Key consolidated financial figures, IFRS

(all figures in KEUR unless otherwise noted)	**2017**	**2016**
Revenues	5,811	4,262
Research and development expenses	-17,853	-23,408
General administrative and selling expenses	-3,828	-5,129
Income taxes	3,759	4,943
Net result	-12,093	-20,118
Earnings per share in EUR (basic)	-0.20	-0.38
Earnings per share in EUR (diluted)	-0.20	-0.38
Cash flow from operating activities	-17,720	-11,586
Cash flow from investing activities	-25	-192
Cash flow from financing activities	12,494	9,212
Intangible assets	2,415	2,688
Cash and cash equivalents	24,839	30,111
Equity	25,229	24,943
Current liabilities	6,656	13,040
Balance sheet total	31,885	37,983
Average number of group employees	33	36

The full annual financial report will be available on 22 March 2018 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 22 March 2018 at 2 p.m. CET (1 p.m. GMT, 9 a.m. EDT) to present the 2017 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=m29353e1c69b51b6cdcf4eb74b220c512

About PAION
PAION AG is a publicly listed specialty pharmaceutical company developing and aiming to commercialize innovative drugs to be used in 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 which is in the final stage of clinical development for use in procedural sedation in the U.S. Currently,

PAION is mainly focusing its business and financial resources on successfully completing its development program in procedural sedation in the U.S. Outside the U.S., PAION has so far focused on the development of remimazolam in the indication general anesthesia. A full clinical development program for general anesthesia was completed in Japan. In the EU, PAION is currently planning to continue the clinical development program by starting a Phase III trial in the second half of 2018. Development of remimazolam in the indication intensive care unit (ICU) sedation is also part of the longer term life-cycle plan for remimazolam.

PAION is headquartered in Aachen (Germany) with a further site in Cambridge (United Kingdom).

PAION's vision is to become an acknowledged “PAIONeer” in sedation and anesthesia.

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