CORPORATE NEWS

EARNINGS

PAION AG PUBLISHES GROUP QUARTERLY STATEMENT FOR THE FIRST NINE MONTHS OF 2017

- Financial results in line with plan
- Cash position of EUR 29.6 million as of 30 September 2017
- Positive remimazolam data in procedural sedation in U.S. Phase III study during bronchoscopy and in U.S. safety trial in high-risk colonoscopy patients
- EU Phase I trial successfully conducted
- Remimazolam partners make good progress:
  - Pre-NDS meeting held with Health Canada
  - Phase III trial in general anesthesia initiated in Russia
- Patent portfolio strengthened
- Successful capital measures: Capital increase with subscription rights and private placement with U.S. investors
- Conference call (in English) today at 2:00 p.m. CET (1:00 p.m. GMT/8:00 a.m. ET)

Aachen (Germany), 08 November 2017 – 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 2017.

"*We have had a very productive and successful year to date, highlighted by positive Phase III data, solid progress by our partners, a strengthened patent portfolio, as well as two successful financings. Our Phase III bronchoscopy trial data in procedural sedation attracted a lot of both pulmonologists' and anesthesiologists' interest in the U.S. and beyond. Correspondingly intense were the discussions at our booth beforehand Prof. Silvestri's presentation at the CHEST meeting in the U.S.",* Dr. Wolfgang Söhngen, CEO of PAION AG, commented.

Remimazolam development activities: Update and outlook

In the first nine months of 2017, PAION focused on the completion of its Phase III U.S. development program for **remimazolam** in procedural sedation. PAION's major goals for the remainder of 2017 are the completion of the ongoing clinical trials in the U.S. and the handover to Cosmo Pharmaceuticals (Cosmo) to move forward with NDA (New Drug Application) filing.

U.S.

In June 2017, PAION announced positive headline data from the second pivotal U.S. Phase III clinical trial with remimazolam in procedural sedation during bronchoscopy. The Phase III trial enrolled 446 patients at 15 U.S. sites and 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.

Additionally, 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 Food and Drug Administration (FDA), PAION has started additional Phase I studies to further assess the abuse potential of remimazolam. Two aspects are being studied: if remimazolam could inappropriately be used as a knock-out cocktail in combination with alcohol and if it could be abused intranasally.

Recruitment of a trial evaluating the oral administration of remimazolam with alcohol has been completed in the third quarter of 2017. Recruitment of the first of two planned trials evaluating the intranasal administration of remimazolam has been completed in the second quarter of 2017. PAION plans to discuss further details of the human abuse liability program with the FDA in the fourth quarter of 2017, prior to initiating the second intranasal study.

Conditional on successful study results and dependent on discussions with the FDA, PAION currently expects to complete the human abuse liability program in the first half of 2018.

The FDA publishes drug classification schedules under the Controlled Substance Act (CSA). The drug classification schedule classifies drugs into groups based on risk of abuse. Midazolam, for example, is included in Schedule IV. Substances in this schedule have a lower potential for abuse relative to substances in Schedule III. PAION expects that remimazolam will receive the same classification as midazolam.

PAION is allocating significant resources to achieve the completion of the U.S. clinical development program. The company has regular interactions with the FDA to ensure that all relevant data for the NDA submission have been collected. This will be followed by an integrated "overall" analysis of all clinical studies with remimazolam. Subject to the successful completion of the clinical development program, including the completion of all analyses and reports, filing for approval in the U.S. could take place subsequently after finalization of a market approval dossier. Before filing, usually a pre-NDA meeting with the U.S. regulatory authority FDA is 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 filing for approval in the second half of 2018.

EU

In consultation with key opinion leaders in general anesthesia, PAION has successfully conducted a Phase I trial to serve as a means to define key elements and sample size calculation for the planned Phase III trial. Based on the results of this study and subsequent simulations, PAION currently assumes that approximately 500 patients will be required for the EU Phase III study in general anesthesia.

PAION plans to continue the EU clinical development program for remimazolam with a study design 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. Prior to initiating the Phase III program, which is planned for 2018, PAION will obtain Scientific Advice from the European Medicines Agency (EMA), the relevant European regulatory authority.

Japan

Based on the positive pre-NDA meeting with the Japanese Pharmaceuticals and Medical Devices Agency (PMDA), PAION is continuing to prepare a market approval dossier for remimazolam in Japan. The dossier is being prepared by an experienced contract research organization (CRO) in close consultation with PAION.

This is an important prerequisite to continue partnering discussions with potential licensees. PAION plans to partner remimazolam for the Japanese market during or following the preparation of the market approval dossier. Such a dossier could serve as a reference dossier for market approval in certain other markets. This would significantly reduce the necessary additional investment by partners in the respective markets, depending on the regulatory environment. Subject to further coordination with the regulatory authority, filing for market approval in Japan is expected mid-2018.

Partner activities in other regions

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

In May 2017, PAION's remimazolam licensing partner for Canada, Pendopharm, a division of Pharmascience Inc., together with PAION delegates, had a pre-NDS (New Drug Submission) meeting with Health Canada for remimazolam 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 clinical data package available at the time, including the human abuse liability data, were regarded as adequate for filing in Canada.

In August 2017, R-Pharm, PAION's Russian licensing partner, announced the start of a Phase III study in Russia with remimazolam in general anesthesia.

Results of operations, financial position and net assets

Revenues in the first nine months of 2017 amounted to KEUR 5,097 compared to KEUR 2,230 in the prior-year period and mainly resulted from the upfront payment received from Cosmo under the remimazolam license agreement entered into in 2016.

Research and development expenses amounted to KEUR 13,528 in the first nine months of 2017 and mainly relate to the clinical development program for remimazolam in the U.S. The decrease of KEUR 2,903 compared to the prior-year period is mainly due to lower costs for Phase III studies on the one hand and higher costs for Phase I studies on the other hand.

General administrative and selling expenses decreased by KEUR 1,395 to KEUR 2,795 in the first nine months of 2017 compared to the prior-year period. General administrative expenses decreased by KEUR 919 to KEUR 2,252 and selling expenses decreased by KEUR 476 to KEUR 543. Higher general administrative expenses incurred in the prior-year period mainly resulted from the preparation of 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 not been incurred in the first nine months of 2017.

Tax income amounted to KEUR 2,786 in the first nine months of 2017 (prior-year period: KEUR 3,430) and mainly relates 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 nine months of 2017 amounted to KEUR 8,508. In the prior-year period, a net loss of KEUR 16,061 was reported. This means a decrease of the net loss in the amount of KEUR 7,553 compared to the prior-year period. The change is mainly attributable to higher revenues and lower research and development expenses than in the prior-year period.

Cash and cash equivalents amounted to KEUR 29,559 as of 30 September 2017, a decrease of KEUR 552 compared to 31 December 2016.

The decrease of cash and cash equivalents primarily stems from **cash flows from operating activities** of KEUR -13,002 and **cash flows from financing activities** of KEUR 12,494. Cash flows from operating activities mainly result from the net loss of KEUR 8,508 and the tax credit payment from British tax authorities in the amount of KEUR 4,597 received in June 2017, adjusted for the current tax credit claim towards the British tax authorities (KEUR 2,805) which has not had a cash effect yet, as well as revenues recognized from the upfront payment from Cosmo (KEUR 5,073) that already had a cash effect in 2016. Cash flows from financing activities primarily result from the capital increase with subscription rights conducted in February 2017 and the capital increase under exclusion of subscription rights of existing shareholders conducted in July 2017.

Risks and Opportunities

Material risks and opportunities relating to future development are presented in detail in the group management report for fiscal year 2016 and have not changed significantly in the first nine months of 2017.

Financial Outlook

PAION confirms its outlook for the current fiscal year announced on 09 August 2017 with the publication of the half-year results for 2017. In 2017, PAION expects revenues of approximately EUR 5.8 million, mainly related to the upfront payment of EUR 10 million received from Cosmo in connection with

the U.S. license agreement for remimazolam in July 2016, of which EUR 4.3 million were already recognized as revenues in 2016. Depending on the progress of certain development components, the remaining EUR 5.7 million of the upfront payment are expected to be recognized as revenues in 2017. Additional license agreements and milestone payments from existing license agreements are not included in the financial outlook for 2017.

Due to the ongoing investment in the development of remimazolam, PAION expects research and development expenses between approximately EUR 18 million and approximately EUR 20 million in the financial year 2017, depending on the progress of development. Income from tax credits on portions of the research and development expenses from British tax authorities is expected to amount to approximately EUR 4 million. General administrative and selling expenses are expected to amount to approximately EUR 4 million. Net loss is expected to be between approximately EUR 12 million and approximately EUR 14 million, a decrease compared to the prior year (2016: EUR 20.1 million).

This outlook assumes that development activities for remimazolam in the U.S. will progress as expected. Otherwise, certain costs would shift into 2018. Expense forecasts are also based on the current status of discussions with the FDA. Costs could be higher than planned and lead to a delay in approval, should the FDA impose additional requirements for filing for market approval.

Based on current plans, PAION believes that cash and cash equivalents of EUR 29.6 million as of 30 September 2017 will be sufficient to complete all remaining development activities in the indication procedural sedation in the U.S. Thereafter, PAION expects to receive further payments from Cosmo, subject to the achievement of certain regulatory milestones in the U.S., and, once remimazolam is approved, royalties on net sales. To conduct a Phase III clinical program for the EU, funding of approximately EUR 25 million is required until filing for approval, subject to further coordination with regulatory authorities. As a first step, funds in the amount of EUR 8 million were raised through a capital increase in July 2017.

Cash and cash equivalents, including expected R&D tax credits from the British tax authorities, secure a cash reach into the second half of 2019. This does not take into account potential milestone payments or potential costs for the targeted continuation of the Phase III development program in the EU.

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Key consolidated financial figures, IFRS (not audited)

(all figures in EUR thousand unless noted otherwise)	Q3 2017	Q3 2016	Q1-Q3 2017	Q1-Q3 2016
Revenues	1,014	2,032	5,097	2,230
Research and development expenses	-3,598	-4,276	-13,528	-16,431
General administrative and selling expenses	-812	-940	-2,795	-4,190
Income taxes	743	907	2,786	3,430
Net result for the period	-2,737	-2,858	-8,508	-16,061
Earnings per share in EUR for the period (basic)	-0.05	-0.05	-0.15	-0.31
Earnings per share in EUR for the period (diluted)	-0.05	-0.05	-0.15	-0.31

	Q1-Q3 2017	Q1-Q3 2016
Cash flows from operating activities	-13,002	-5,799
Cash flows from investing activities	-24	-149
Cash flows from financing activities	12,494	9,199
Change in cash and cash equivalents (incl. exchange rate differences)	-552	3,226
Average number of employees in the Group	32	38

	30-09-2017	31-12-2016
Intangible assets	2,482	2,688
Cash and cash equivalents	29,559	30,111
Equity	28,802	24,943
Current liabilities	6,509	13,040
Total assets	35,311	37,983

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 08 November 2017 at 2 p.m. CET (1 p.m. GMT, 8 a.m. ET) to present the financial results of the first nine months of 2017, highlight key events and provide a pipeline and strategy update and financial outlook.

To access the call starting at 2 p.m., participants may 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, you will be asked to give the password “PAION”. The conference call will be supplemented by a webcast presentation, which can be accessed during the call under the following link: https://paion-events.webex.com/paion-events/j.php?MTID=mf163340d7a656519ed8d3fcb481d7484.

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 ongoing clinical development program in procedural sedation. 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 and PAION is preparing filing in Japan. In the EU, PAION is currently planning to continue the clinical development program. 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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