CORPORATE NEWS

EARNINGS

PAION AG PUBLISHES GROUP QUARTERLY STATEMENT FOR THE FIRST NINE MONTHS OF 2018

- EU Phase III trial successfully started, trial on track
- Successful pre-NDA meeting held with FDA; remimazolam market approval dossiers in preparation for the U.S. and Japan
- Phase III trial in Russia successfully completed
- Phase III trial patient recruitment in South Korea completed
- EUR 5.2 million raised in private placement with new institutional investor
- Cash and cash equivalents of EUR 19.8 million as of 30 September 2018; cash reach until beginning of 2020
- Conference call (in English) today at 2:00 p.m. CET (1:00 p.m. GMT/8:00 a.m. ET)

Aachen (Germany), 07 November 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 nine months of 2018.

"*We have had a very productive and successful year to date, highlighted in solid progress by our partners, positive interaction with the regulatory authorities as well as a successful financing. The EU Phase III clinical trial is making good progress and we are receiving positive feedback from the study centers, so we expect to complete patient recruitment of the trial according to plan in the course of next year", Dr. Wolfgang Söhngen, CEO of PAION AG, commented*.

Update on remimazolam development 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 as planned in the fourth quarter 2018/first quarter 2019.

In July 2018, under the leadership of license partner Cosmo, together with participants from PAION, a pre-NDA meeting with the FDA took place, in which the appropriateness of the content of their submission package as well as the approval pathway and the preferred label were discussed. During the meeting, the main questions raised for discussion following the preliminary assessment of remimazolam by the FDA were clarified.

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. The trial is on track and 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 to file for market approval for general anesthesia.

Partner activities in other territories

PAION's license partners are extending the database 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 towards year-end 2018.

Russia: In November 2018, PAION’s license partner **R-Pharm** announced the successful completion of a Phase III trial in general anesthesia. R-Pharm plans to file for market approval in the first quarter of 2019.

South Korea: PAION’s license partner **Hana Pharm** has successfully completed patient recruitment of a Phase III trial in general anesthesia in October 2018. Before filing for market approval, the production process needs to be established in South Korea. Accordingly, Hana Pharm plans to file for market approval in 2020.

Other regions: License partners 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 nine months of 2018 amounted to KEUR 758 compared to KEUR 5,097 in the prior-year period and mainly resulted from partial revenue recognition in the reporting period of the upfront payment of KEUR 1,000 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 KEUR 9,118 in the first nine months of 2018 and mainly related to expenses for 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 KEUR 4,410 compared to the prior-year period is mainly due to lower costs for Phase III and Phase I studies which had been incurred to a significant extent in the first nine months of 2017, particularly in connection with the U.S. development program.

General administrative and selling expenses decreased by KEUR 227 to KEUR 2,568 in the first nine months of 2018 compared to the prior-year period. General administrative expenses increased by KEUR 73 to KEUR 2,325 and selling expenses decreased by KEUR 300 to KEUR 243.

Tax income amounted to KEUR 2,066 in the first nine months of 2018 (prior-year period: KEUR 2,786) and 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 2018 amounted to KEUR 8,764 compared to a net loss of KEUR 8,508 in the prior-year period. This means an increase of the net loss in the amount of KEUR 256 compared to the prior-year period which is mainly attributable to lower revenues and lower research and development expenses than in the prior-year period.

Cash and cash equivalents amounted to KEUR 19,820 as of 30 September 2018, a decrease of KEUR 5,019 compared to 31 December 2017.

The decrease of cash and cash equivalents primarily stems from **cash flows from operating activities** of KEUR -10,219 and **cash flows from financing activities** of KEUR 5,214. Cash flows from operating activities mainly result from the net loss of KEUR 8,764, changes in the working capital and the tax credit payment from British tax authorities in the amount of KEUR 3,729 received in September 2018, adjusted for the current tax credit claim towards the British tax authorities (KEUR 2,066) which has not had a cash effect yet. Cash flows from financing activities result from the net proceeds of the capital increase conducted in June 2018 (KEUR 5,040) as well as the exercise of stock options.

Risks and Opportunities

Material risks and opportunities relating to future development are presented in detail in the group management report for fiscal year 2017 and have not changed significantly in the first nine months of 2018.

Outlook 2018

PAION's focus remains on completing the regulatory activities for the U.S. and Japan and continuing the EU Phase III general anesthesia trial. In addition, PAION expects to complete the work on the validation of commercial scale production of remimazolam.

Financial outlook 2018

PAION expects revenues of about EUR 3 million in 2018, of which EUR 2 million are 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 the course of the remimazolam license agreement for Japan. In case of a 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 12 million and approx. EUR 14 million, (changed from: 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 2.5 million (changed from: 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 10.0 million and approx. EUR 12.5 million (changed from: between approx. EUR 12.5 million and approx. EUR 15.0 million) in 2018. Should filing for market approval in Japan be delayed to 2019, revenues amounting to EUR 2 million would shift into 2019. In this case net result in 2018 would be EUR 2 million lower.

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, 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 a cash reach until beginning of 2020. PAION expects to require additional funds of approximately EUR 10 million until filing for the 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 (not audited)

(all figures in EUR thousand unless noted otherwise)	Q3 2018	Q3 2017	Q1-Q3 2018	Q1-Q3 2017
Revenues	241	1,014	758	5,097
Research and development expenses	-2,574	-3,598	-9,118	-13,528
General administrative and selling expenses	-807	-812	-2,568	-2,795
Income taxes	577	743	2,066	2,786
Net result for the period	-2,521	-2,737	-8,764	-8,508
Earnings per share in EUR for the period (basic)	-0.04	-0.05	-0.14	-0.15
Earnings per share in EUR for the period (diluted)	-0.04	-0.05	-0.14	-0.15

	Q1-Q3 2018	Q1-Q3 2017
Cash flows from operating activities	-10,219	-13,002
Cash flows from investing activities	-13	-24
Cash flows from financing activities	5,214	12,494
Change in cash and cash equivalents (incl. exchange rate differences)	-5,019	-552
Average number of employees in the Group	39	32

	30-09-2018	31-12-2017
Intangible assets	2,283	2,415
Cash and cash equivalents	19,820	24,839
Equity	21,908	25,229
Current liabilities	3,905	6,656
Total assets	25,813	31,885

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 07 November 2018 at 2 p.m. CET (1 p.m. GMT, 8 a.m. ET) to present the financial results of the first nine months of 2018, 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=m31d535d09f589b8d4e67229628efe21c.

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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