CORPORATE NEWS

FINANCIAL RESULTS 2019

PAION AG REPORTS ON SUCCESSFUL FISCAL YEAR 2019

- Market approval granted for remimazolam in Japan in January 2020
- NDA for general anesthesia filed in South Korea in December 2019
- MAA submitted in the EU for procedural sedation in November 2019
- NDA accepted for review by the U.S. FDA – review extension with new PDUFA date 05 July 2020
- Dr. James (Jim) Phillips started as CEO in October 2019
- Cash and cash equivalents of EUR 18.8 million as of 31 December 2019, loan greement with European Investment Bank strengthens financial position
- Conference call today at 2:00 p.m. CET (1:00 p.m. GMT/9:00 a.m. EDT)

Aachen (Germany), 26 March 2020 – 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 2019.

Dr. Jim Phillips, CEO of PAION AG, commented: "*2019 was a highly productive year for PAION. We were pleased to see the substantial progress made by our licensees, including several regulatory filings, and were gratified to see the first market approval of remimazolam to kick off 2020. We succeeded in gaining important financial partners such as the EIB and in increasing our milestone revenues. We look forward to another fruitful year ahead. In the U.S., we expect our partner will receive a decision from the FDA on the application for procedural sedation in July 2020, to be followed shortly thereafter by market launch.*

Our focus in Europe is to complete recruitment for the Phase III study in general anesthesia, which will be delayed as hospitals focus on Coronavirus and have suspended clinical trials in some countries, as well as to set up the supply chain and to produce remimazolam at commercial scale. We also look forward to additional regulatory filings by our licensees, as well as market approvals and product launches in various territories, as soon as the Coronavirus pandemic abates.

In the current extraordinary circumstances of the Coronavirus pandemic, PAION is well funded and has a strong balance sheet & usable facilities (like the EIB loan facility) to allow us to steer the company through the current uncertainties, as we move to be revenue-generating."

Update and outlook on remimazolam development and commercialization activities

U.S.

The New Drug Application (NDA) in procedural sedation was prepared together with licensee Cosmo Pharmaceuticals (Cosmo) and submitted to the FDA (U.S. Food and Drug Administration) by Cosmo in April 2019. The filing was accepted by the FDA in June 2019. After announcement of an extension of the review period of up to three months for the evaluation of additional data in March 2020, the FDA set 05 July 2020 (previously 05 April 2020) as target date for completion of the review under the Prescription Drug User Fee Act (PDUFA date). On this basis, a decision and subsequent potential launch in the U.S. are expected in 2020.

In January 2020, Cosmo announced that it had sublicensed remimazolam (ByFavo™) U.S. rights to Acacia Pharma (Acacia). Going forward, Acacia will be responsible for the commercialization of remimazolam in the U.S. In 2016, PAION entered into a U.S. license agreement for remimazolam with Cosmo which remains unchanged. The sublicensee Acacia expects to launch remimazolam in the U.S. in the second half of 2020.

EU

In Europe, PAION is seeking approval for remimazolam in general anesthesia and in procedural sedation.

Procedural sedation: PAION submitted a Marketing Authorization Application (MAA) for procedural sedation to the European Medicines Agency (EMA) in November 2019 after it had been discussed in the course of a pre-submission meeting with the EMA held in February 2019 that the existing data package from the U.S. Phase III clinical development program is sufficient for submitting an MAA in procedural sedation. A decision on market approval is currently expected in the beginning of 2021 at the earliest.

General anesthesia: PAION is currently conducting a Phase III study in general anesthesia evaluating ASA III/IV (American Society of Anesthesiologists classification III to IV) patients. As of 25 March 2020, 424 of the planned 500 patients had been enrolled in the trial. Due to the Coronavirus pandemic, completion of patient recruitment previously planned in the first half of 2020 will be delayed until hospitals which are currently increasingly working to capacity with the treatment of patients infected with the Coronavirus will have capacities for the recruitment of patients for planned interventions available again.

Assuming approval in procedural sedation and positive results in the Phase III trial in general anesthesia, PAION plans to submit an extension of the marketing authorization for remimazolam for general anesthesia. The review process for an extension is generally faster than for an MAA. The complete data from the ongoing EU Phase III study in general anesthesia, which are required for the submission of an extension of marketing authorization, are expected to be available at the time of the regulatory decision on the MAA in procedural sedation. PAION could submit an MAA in general anesthesia after EMA's decision on the MAA in procedural sedation at the earliest.

Commercialization plans: PAION continues to conduct pre-commercialization activities. The build-up of an own distribution structure in Europe is dependent on the possibility of extending the portfolio by additional products. Therefore,

PAION is also considering outlicensing remimazolam for commercialization in Europe.

Licensee activities in other territories

In Japan, licensee **Mundipharma** received market approval for remimazolam (Anerem®) for general anesthesia in January 2020. Mundipharma currently plans to launch remimazolam in mid-2020.

In China, licensee **Yichang Humanwell** submitted a market approval dossier for remimazolam for procedural sedation to the Chinese National Medical Products Administration (NMPA) in November 2018. Market approval is expected in 2020.

In South Korea, licensee **Hana Pharm** submitted a market approval dossier in general anesthesia in December 2019. Market approval is currently expected in the second half of 2020. In January 2020, PAION and Hana Pharma extended their license agreement for remimazolam to include Southeast Asia (Indonesia, Malaysia, Philippines, Singapore, Thailand, Vietnam), and Hana Pharm is responsible for the development and marketing approval process in these territories.

In Russia, licensee **R-Pharm** announced the successful completion of a Phase III trial in general anesthesia in November 2018. R-Pharm is currently preparing first market approval dossiers for the licensed territories.

In Canada, PAION expects its licensee **Pharmascience** to use the U.S. market approval dossier as the basis for filing for market approval.

Supply chain activities

PAION is building up the supply chain in order to be able to provide remimazolam product to the licensees timely for commercial use as well as having it available early enough for PAION's potential own commercialization. Activities include establishing structures and processes and obtaining all necessary pharmaceutical permits.

Funding activities

In June 2019, PAION and the European Investment Bank (EIB) signed a loan agreement for up to EUR 20 million. The loan is available until June 2021 and can be drawn down in a total of three tranches based on certain conditions, such as e.g. the achievement of operational milestones. The first tranche is already available, and the two additional tranches could become available in 2020. PAION has not utilized the loan yet.

In August 2019, PAION and Yorkville Advisors (Yorkville) signed an agreement for the issue of convertible notes with a nominal amount of up to EUR 15 million. The first tranche with a nominal amount of EUR 5 million was issued in September 2019 of which to date EUR 2.9 million have been converted into equity. A further utilization of the financing agreement with Yorkville in addition to the first tranche already issued is not planned.

Changes to the Management Board

On 16 October 2019, Dr. James (Jim) Phillips joined PAION AG as the new Chief Executive Officer (CEO). Dr. Wolfgang Söhngen, co-founder and long-

standing CEO, left the Management Board in November 2019, as he reached the retirement age according to the Company's bylaws.

Results of operations, net assets and financial position in the reporting period

Revenues recognized in the reporting period amounted to EUR 8.0 million and include a milestone payment of EUR 7.5 million from Cosmo related to the filing of the NDA in the U.S. and a milestone payment of EUR 0.5 million related to the transfer of the Japanese filing dossier to R-Pharm. Revenues in the previous year of EUR 2.8 million mainly resulted from the remimazolam license agreements with Mundipharma, Hana Pharm and Yichang Humanwell.

Research and development (R&D) expenses amounted to EUR 13.1 million in 2019 (2018: EUR 12.2 million) and mainly relate to the ongoing EU Phase III trial in general anesthesia and the validation of commercial-scale production. The increase of EUR 0.9 million compared to the previous year is mainly due to higher expenses for the EU Phase III study.

General administrative and selling expenses amounted to EUR 5.0 million and increased by EUR 1.6 million compared to the previous year (2018: EUR 3.4 million). Administrative expenses increased by EUR 0.4 million to EUR 3.4 million, and selling expenses increased by EUR 1.2 million to EUR 1.6 million. The increase in general administrative expenses is mainly related to the loan agreement with the EIB and the issuance of convertible notes during the reporting period. The increase in selling expenses mainly results from pre-commercialization activities and the start of the build-up of a supply chain for remimazolam.

Income taxes for the fiscal year relate to tax claims for reimbursement of parts of R&D expenses from the British tax authorities and amounted to EUR 2.4 million (2018: EUR 2.5 million). The slight decrease in comparison to the prior year despite increased R&D expenses is mainly due to a cap of the claim based on the net result of the subsidiary PAION UK Ltd.

PAION closes fiscal year 2019 with a **net loss** of EUR 7.0 million compared to a net loss of EUR 9.9 million in the previous year.

Cash and cash equivalents amounted to EUR 18.8 million as of 31 December 2019, an increase of EUR 1.6 million compared to EUR 17.2 million as of 31 December 2018.

Cash flow from operating activities was EUR -2.8 million and primarily results from the net loss in the amount of EUR 7.0 million and changes of the working capital, particularly an increase in trade payables of EUR 2.6 million and a decrease in trade receivables of EUR 1 million.

Cash flow from financing activities was EUR 4.4 million, mainly resulting from gross proceeds from the convertible notes issued in the reporting period with a discount of 5% of EUR 4.8 million (nominal amount: EUR 5 million) less transaction costs (EUR 0.3 million) as well as the principal portion of lease payments (EUR 0.1 million).

Financial outlook 2020

PAION expects revenues of about EUR 20 million in 2020, thereof EUR 15 million from Cosmo for the market approval of remimazolam in the U.S. Additional revenues relate to the market approval of remimazolam in Japan, the license extension signed with Hana Pharm in January 2020 to include six additional countries in Southeast Asia, as well as milestone payments in connection with possible market approvals in other regions. Royalties from the commercialization of remimazolam in the U.S. and Japan are expected to total less than EUR 1 million in 2020.

R&D expenses are expected to be between approx. EUR 10 million and approx. EUR 12 million, depending on the progress of development. General administrative and selling expenses are expected to amount to between approx. EUR 7 million and approx. EUR 9 million, depending on the progress of the build-up of the supply chain and the level of pre-commercialization activities. Net result is expected to amount to between approx. EUR -1 million and approx. EUR 3 million.

Income from tax credits on parts of R&D expenses from British tax authorities is not expected or only expected in a small amount of up to EUR 0.5 million and therefore not included in the outlook due to a change in calculation and capping rules and the amount of expected revenues.

This outlook assumes that PAION and licensee activities progress as expected. In the case of delays, essential cost blocks and/or revenues would shift into 2021 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 revenues based thereon. Also, potential effects of the Coronavirus pandemic on our business and the business of our partners could lead to delays and a shift of revenues and/or costs.

Based on current planning, cash and cash equivalents at hand and expected payments from milestones and royalties secure a liquidity runway into the second half of 2021.

Additional funds could be required for a potential own commercialization of remimazolam in selected European markets, the execution of the multi-year pediatric development plan as well as for potential portfolio extensions. The total magnitude of potentially required funds will be dependent on PAION's decision on building up an own distribution and what an actual setup would look like, as well as on the magnitude and timing of incoming milestone and royalty payments from licensees. A final decision on building up an own distribution has not been made yet. The financing agreement with the EIB of up to EUR 20 million and milestone and royalty payments expected in the next years could partially or completely cover a potential financing requirement depending on the decision on an own commercialization. The magnitude of royalties from licensees will depend on the success of commercialization in the U.S., Japan and other territories, remimazolam's pricing and the pace of market penetration. However, this can only be evaluated with sufficient certainty after the launch phase.

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Key consolidated financial figures, IFRS

(all figures in KEUR unless otherwise noted)	**2019**	**2018**
Revenues	8,000	2,766
Research and development expenses	-13,099	-12,167
General administrative and selling expenses	-5,023	-3,408
Income taxes	2,432	2,510
Net result	-7,016	-9,939
Earnings per share in EUR (basic)	-0.11	-0.16
Earnings per share in EUR (diluted)	-0.11	-0.16
Cash flows from operating activities	-2,847	-12,813
Cash flows from investing activities	-14	-13
Cash flows from financing activities	4,414	5,214
Intangible assets	2,137	2,212
Cash and cash equivalents	18,787	17,227
Equity	14,732	20,822
Current liabilities	10,154	3,501
Balance sheet total	24,912	24,323
Average number of group employees	44	39

The full annual financial report will be available on 26 March 2020 on PAION's corporate website: https://www.paion.com/medien-und-investoren/investorcenter/finanzberichte/.

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 26 March 2020 at 2 p.m. CET (1 p.m. GMT, 9 a.m. EDT) to present the 2019 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: http://view-w.tv/819-1574-23620/en

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. Remimazolam is partnered in multiple territories outside of Europe. In Japan, remimazolam was approved for general anesthesia in January 2020. In the U.S., a New Drug Application (NDA) for procedural sedation is under review, with a PDUFA date of 5 July 2020. In China, licensee Yichang Humanwell filed for market approval

for remimazolam in procedural sedation in November 2018 and in South Korea, licensee Hana Pharm filed for market approval for remimazolam in general anesthesia in December 2019.

In Europe, PAION is seeking approval of remimazolam for general anesthesia and for procedural sedation. PAION submitted a Marketing Authorization Application (MAA) for procedural sedation in November 2019. A Phase III trial in general anesthesia is ongoing.

PAION's mission is to be a leading specialty pharmaceutical company in the fields of anesthesia & critical care by bringing novel products to market to benefit patients, doctors & stakeholders in healthcare.

PAION is headquartered in Aachen (Germany) with an additional site in Cambridge (United Kingdom).

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