

## EP Vantage Interview - Paion looks at solo strategy after share price surge



[Amy Brown](#)

Thanks to a share price that has almost tripled in the past three months, the German drug developer Paion is considering pushing on alone with a pivotal trial of its novel anaesthetic remimazolam.

Three regional licensing deals and encouraging phase III data released by its Japanese partner Ono Pharmaceutical have contributed to the surge in Paion's market cap, which last week touched a three-year high and stands at €54m (\$73m). This valuation makes it viable to raise enough money to run a European phase III trial, chief executive Wolfgang Söhngen says, although talks with potential partners in Europe and the US are ongoing and a variety of options are being explored.

### Differentiation

Paion expects Ono to file for Japanese approval of remimazolam on the back of data generated from a phase II/III study it conducted in 375 patients undergoing general anaesthesia. The project proved non-inferior to the widely used propofol in terms of effectiveness, with no adverse events of concern and confirming what Paion sees as the unique selling point of remimazolam – a significantly lower cardio-depressive effect than propofol, with patients experiencing much smaller dips in blood pressure.

The anaesthetic market being essentially generic, remimazolam will need to differentiate itself to make any inroads and demand a higher price. Mr Söhngen, who estimates that the drug could generate peak sales of \$500m worldwide in each of its three indications, believes its limited cardiac suppression is key. As well as general anaesthesia, the drug is being investigated in procedural and ICU sedation.

"Cardiac stability is a very important issue, particularly in elderly patients who are the growing segment in the industrialised world. Lowering blood pressure in a patient undergoing anaesthesia with an already vulnerable heart can be very damaging. So this is how we want to position the drug and this is why we are running a study in cardiac surgery patients in Europe," he says.

That study, currently seeking 90 patients, will report in the first half of next year. Together with data from the Ono trial, it should then only take one more phase III trial to get to registration in Europe, Paion estimates. Given that remimazolam has been used in more than 900 patients and has already undergone IND studies in the US, the FDA should consider it phase III-ready, Mr Söhngen says.

### Wider possibilities

Talks with potential partners to help run those studies and eventually sell the drug are ongoing, but the share price rise has opened up wider possibilities, he says.

"We now have other options to finance this. We have interest from investors, and we are discussing Europe and US with a variety of partners. But we are not under pressure here; we will take the time to make the right decision."

That decision will have to be made by next year, however, when pivotal trials in Europe need to get going. Paion ended September with €13m in cash, enough to last until the first quarter of 2015 and finish the phase II cardiac study.

Since then it has licensed remimazolam to R-Pharm in Russia and Hana Pharm in South Korea, both for €1m up front and royalties of 10%. Last year, Yichange bought China rights in a deal worth €3m up front. Extrapolated to other markets these deals provide a good benchmark to the sort of transactions that might be achievable in the larger markets of the US and Europe, Mr Söhngen says.

It seems likely that a deal of some sort will emerge from Paion next year, perhaps with a larger stake in the project retained. The phase III trial required in Europe would probably cost around €10-15m; despite the share price run-up this would still represent a big commitment from investors.

But, at least now, Paion can enter discussions from a stronger position.

To contact the writer of this story email Amy Brown in London at [AmyB@epvantage.com](mailto:AmyB@epvantage.com) or follow [@AmyEPVantage](https://twitter.com/AmyEPVantage) on Twitter.

