Paion

Pharma & biotech

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Commercialisation of remimazolam underway

Paion has gained approvals in the US, China and Japan for its fast-onset, short-recovery anaesthesia product remimazolam. In the US, partner Acacia is expected to launch it in Q420 for procedural sedation (PS). In Japan, Mundipharma launched it in Q320 for general anaesthesia (GA). In China, Yichang Humanwell launched it for PS in August with GA trials ongoing. Initial European PS approval is expected by H121. European marketing will be either direct or by using regional partners. Paion indicates that it has cash until H221. Our valuation is €283m.

Three approvals so far

The FDA approved remimazolam for PS in Q320. In the US, it is branded as ByFavo and licensed to Acacia. Acacia states that the US procedural colonoscopy market is 25m procedures with marketing targeted to hospitals where ByFavo use can be supervised. However. most colonoscopies are carried out in private clinics. Launch is expected in Q420 as Drug Enforcement Agency classification has completed. We expect a price of about $25 per 20mg vial with royalties of 20–25% from H221. In Japan it is approved for GA; Mundipharma instigated launch in July (branded as Anerem) with Paion receiving royalties of 16–18%. In China, branded as Ruima, it is approved for PS and was launched in August by Yichang Humanwell; a GA trial is ongoing.

Europe – a staged approval and market uncertainty

Remimazolam is undergoing a European Medicines Agency review for PS with the outcome likely by H121. The European GA Phase III closed with 424 patients enrolled (of 500 planned), potentially allowing a follow-on, faster, abbreviated EMA GA application. Currently, the European sales strategy is unclear. Paion might sell direct, but the market is too small to support a salesforce unless additional marketed products can be sourced. The major European market is seen as GA. A more likely strategy will be using one or more regional marketing partners to generate royalties; this remains our current valuation assumption.

Valuation: Potential profitability within five years

Paion aims to become profitable within five years. Our indicative value remains at €283m. Paion expects strong 2020 revenues from approval milestones but royalties will be under €1m. COVID-19 might limit the number of procedures carried out in 2021. Paion had €12.4m in cash on 30 June, gained a H220 US approval milestone of €15m and has an EIB loan facility of €20m.

Edison estimates

Year end	Revenue (€m)	PBT (€m)	EPS (c)	DPS (c)	P/E (x)	Yield (%)
12/18	2.77	(12.45)	(15.9)	0.0	N/A	N/A
12/19	8.00	(9.35)	(10.8)	0.0	N/A	N/A
12/20e	20.30	2.42	5.9	0.0	40.2	N/A
12/21e	4.21	(20.88)	(31.2)	0.0	N/A	N/A

Source: Paion reports, Edison forecasts

Price	€2.37
Market cap	€157m

Share price graph

Share details

Code	PA8
Shares in issue	66.2m
Net cash at end June 2020	€12.4m

Business description

Paion owns the fast-onset and short-recovery anaesthesia product remimazolam. This is approved in Japan for GA and in the US and China for PS. ByFavo is licensed in the US to Acacia. It is filed in the EU and South Korea. A European GA filing is expected in H121. The European marketing strategy needs to be confirmed.

Bull

- An approved product in the US, Japan and China with marketing partners.
- EMA PS submission due to complete by H21 with European GA Phase III in final stages
- Cash until H221 including EIB €20m loan facilities.

Bear

- No clear European marketing strategy against entrenched, cheaper generic alternatives.
- Acacia is building a salesforce, its own product, and has no marketing track record.
- US label requires supervision, unlike the main generic competitor in PS, midazolam.

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Edison profile page

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