

Futura Medical

Menarini to commercialise MED3000 in South Korea

- Futura Medical has entered into a licensing agreement with Menarini Korea, a wholly owned subsidiary of Menarini Group, to commercialise MED3000 in South Korea. The deal has three main elements: Futura Medical receives an initial upfront payment (which we assume to be modest as management has previously stated its desire to maximise long-term value); Menarini Korea pays an agreed price for the manufacture and supply of MED3000 (which is were we expect the key value to be for Futura Medical); and Menarini Korea is responsible for local development, including any clinical bridging studies, regulatory work, and commercialisation costs (effectively capping Futura Medical's responsibility to providing reasonable technical support).
- Menarini Korea has provided some key local erectile dysfunction (ED) market data to give an indication of the market opportunity. Whilst the US is the largest market by value South Korea ranks ninth; and Brazil is the largest by volume (US is second) with South Korea ranking sixth. For context, the UK is also ranked ninth by value and 14th by volume. Some 2.3m men suffer from a degree of ED in South Korea.
- The Menarini deal is the fourth MED3000 commercialisation deal so far. The first agreement, with Atlantis covering China and Far East, was secured in March 2021. This was followed by partnerships with m8 Pharmaceuticals (moksha8) for Brazil and Mexico in August 2021, and with Labatec for the Gulf and Middle East in September 2021.
- More deals covering the remaining top 15 markets are being pursued, with the emphasis on prioritising longer-term value creation and brand building rather than near-term payments. Updates on progress are expected during 2022. These deals could form a template for the commercially valuable US and European markets. Even limited success in these larger markets could transform the company.

Trinity Delta view: Futura Medical's various commercialisation deals will allow for broad geographic availability of MED3000 once launched. Europe partnership(s) are anticipated in the near-term; however, in the key US market, deal timing is likely to be after FDA approval. The FDA will review MED3000 as a De Novo classification with a small confirmatory clinical trial being the only outstanding requirement. This c 100 patient study, known as FM71, began patient enrolment in September 2021 and is expected to complete in Q222. FM71 has a similar mix of mild, moderate, and severe ED patients to the earlier FM57 study but is performed over a 24-week period, compared to a three-month duration for FM57. The aim is to reassure the FDA that efficacy does not diminish over a longer period. A positive trial outcome and subsequent approval would open the door to commercial discussions for the important US market. Our view remains that, whilst not without risks, Futura Medical's share price does not reflect likely prospects. Our valuation is £264m, equivalent to 92p per share.

23 March 2022

Price	24.75p
Market Cap	£82.7m
Primary exchange	AIM
Sector	Healthcare
Company Code	FUM
Corporate client	Yes

Company description:

Futura Medical is an R&D driven small pharma company, with a novel DermaSys transdermal delivery platform. The lead programme, a topically applied gel (MED3000), has been approved as an OTC product for ED (erectile dysfunction) in Europe, with final trials underway in the US.

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