Futura Medical

Management update details degree of 2021 progress

20 December 2021

- Futura Medical continues to progress its regulatory and commercial activities for MED3000, a topical gel formulation for the treatment of erectile dysfunction (ED). MED3000 received its CE Mark, in April 2021, for OTC use (without a doctor's prescription) in Europe and is undergoing final clinical trials for FDA approval in the US. Successful approval would mean MED3000 is the first clinically validated OTC therapy for ED approved globally.
- The FDA had clarified that MED3000's OTC approval pathway, as a *de novo* medical device, requires only a 100-patient confirmatory trial (FM71) and a Human Factors Study (HFS). FM71 is designed to provide six-month efficacy data in a defined mix of patients (including African Americans) with mild, moderate, and severe ED. The first patient was enrolled in September and just over 100 are now being treated. Enrolment should complete shortly, a further ten participants would provide sufficient headroom for the inevitable drop out seen in such studies. Timelines suggest expectations of regulatory submission around end-Q322 and potential approval in Q123 are realistic.
- The Human Factors Study has been completed successfully. 32 patients showed they were able to correctly self-diagnose ED, made the correct self-selection decisions (considering their own health history), understood the instructions for use, and took appropriate heed of the warnings on the label. The high degree of comprehension is an important element in satisfying the FDA's criteria for use in the OTC setting, and in supporting an OTC filing.
- During 2021 commercialisation discussions were initiated. The first agreement, with Atlantis covering China and Far East, was secured in March. This was followed by partnerships with m8 Pharmaceuticals (moksha8) for Brazil and Mexico in August, and with Labatec for the Gulf and Middle East in September. More deals covering European and other regions are said to be in advanced discussions, with the emphasis still on prioritising longer-term value creation and brand building rather than near-term payments. Scale-up of manufacturing and production capacity to meet projected demand is progressing well. Further updates on both fronts are expected during 2022.

Trinity Delta view: MED3000's CE Mark effectively removed regulatory risk for the European markets (plus other geographies that recognise the CE Mark). In these regions the emphasis switches to commercial execution. Several agreements, notably addressing the important European markets, are expected to be struck in the coming six months. Manufacturing and capacity to meet projected demand should be in place to support first product launches during 2022. The US regulatory risks remain, albeit reduced as FM71 is nearing completion of patient enrolment (many study enrolments have been delayed by Covid related factors) and the successful completion of the HFS study. 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.

Price	33.75p
Market Cap	£96.9m
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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