Futura Medical

MED3000 soft launch in Europe, FDA approval now Q2

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- Futura Medical's erectile dysfunction (ED) treatment MED3000, branded as Eroxon, is now available through online channels in Europe. An advertising and promotional campaign is planned for April to coincide with a launch through retail pharmacies in Belgium. Cooper Consumer Health, the partner for the EU countries, UK, and Switzerland, remains on track for Eroxon's roll-out across other European countries during H123. Cooper has a direct presence in the seven largest European markets, operating via distributors in the remaining countries. We believe the launches will cover these major geographies, including the UK, during 2023. As a reminder, Eroxon is the first ED treatment available OTC (ie without a prescription) in most of Europe.
- In the US, MED3000 regulatory clearance is now expected in Q223. Dialogue with the FDA remains constructive, with the additional information and non-clinical data requested expected to be provided by the end of March. The regulatory package as a *De Novo* medical device was submitted October 2022, and is supported by the clinical data from the 24-week FM71 and 12-week FM57 trials, as well as the home use test (HUT) study. Approval would result in Eroxon becoming the first OTC clinically proven treatment for ED in the large and commercially important US market. Management has yet to announce its US commercial partner, but a number of active discussions are believed to be underway.
- We highlight that Futura Medical has retained production rights, receiving an agreed price for MED3000's manufacture and supply. The contract manufacturer is known to have sufficient capacity in place for the expected commercial demand. The first orders for launch stocks were completed successfully, suggesting the supply process is now validated and in place. The focus is now firmly on commercial execution in Europe and regulatory approval in the US.

Price	44.96p
Market Cap	£132.30m
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, and is under FDA review in the US.

Trinity Delta view: The first launch of Eroxon marks the start of what should be a pivotal year for Futura Medical. Cooper is known to have high expectations for Eroxon's commercial potential and its roll-out across Europe is keenly anticipated. The slippage of the expected FDA approval into Q223 is not unexpected, such novel products are often subject to requests for clarification. The more important aspect is that management reports these discussions as active and constructive. As we have noted previously, the market opportunity as the first clinically proven erectile dysfunction (ED) treatment available OTC (over-the-counter) and with a differentiated and rapid onset of action (ahead of typical oral PDE5 treatments) could be significant. Even modest success would be transformational for Futura Medical. Our valuation is £264m, equivalent to 94p per share.

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