Futura Medical

MED3000 continues to progress towards first sales

13 December 2022

- Futura Medical's business update signals continued progress of MED3000 towards commercialisation and potential first sales in 2023. In the key region of the US, the regulatory process continues to advance and MED3000 is now under formal FDA review following filing as a *De Novo* medical device in October 2022. The FDA has indicated that the regulatory dossier has passed the initial technical screening. The dossier includes the highly positive data from FM71, the longer-term 24-week study, and from FM57, the 12-week trial. Based on progress and published FDA timelines, granting of marketing authorisation in the US continues to be expected by the end of Q123.
- The search for a US commercial partner is underway, which was initiated following FDA filing. The business update highlights that a number of discussions are now ongoing. Meanwhile in Europe, initial launches remain on track for H123 with partner Cooper Consumer Health. The deal with Cooper was agreed in H122 and first orders from Cooper have already been received. Futura Medical has an external third-party contract manufacturer in place for commercial production, with capacity that should be sufficient to meet initial demand and beyond.
- First marketing authorisations have now also been granted for Eroxon (MED3000) in three countries in the Middle East, including the United Arab Emirates. Further approvals and initial launches are expected in the Middle East in 2023. Futura Medical executed a deal in this region with Labatec Pharma in September 2021 which covers the Gulf countries (Saudi Arabia, United Arab Emirates, Kuwait, Qatar, Oman, and Bahrain) as well as Jordan, Lebanon and Iraq. The deal includes milestones on regulatory approvals. Futura Medical will provide finished product, from its contract manufacturer, for an agreed price and will also receive royalties on net sales; first production orders have been agreed with partner Labatec Pharma.

Trinity Delta view: 2023 is set to be a pivotal year for Futura Medical, with first potential launches of MED3000/Eroxon. These include in the key regions of Europe during H123, and in the US, once marketing authorisation has been granted; this continues to be expected by end-Q123. US commercialisation will be dependent on securing a partner, and it is encouraging that discussions are ongoing. First approvals in the Middle East is a positive step towards broadening Eroxon's reach, although we continue to see the biggest potential for MED3000 in the US and in Europe, as outlined in our November 2022 Update. Successful commercialisation in either of these territories could transform Futura Medical, in our view. 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. Our Futura Medical valuation is £270m, equivalent to 94p per share, with the US opportunity alone more than underpinning the current share price.

Price	47.97p
Market Cap	£138.2m
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.

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