

## Futura Medical

### MED3000 FDA clearance marks a major step in the US

12 June 2023

- The FDA has granted marketing authorisation for MED3000, Futura Medical's erectile dysfunction (ED) treatment, to be marketed as an OTC (over-the-counter) product ie without a prescription. MED3000 is approved as an effective and clinically proven treatment for ED, with the important claim that it has a 10-minute onset of action. This is a major differentiator to the oral PDE5i's (such as Cialis and Viagra), which typically take around 30 minutes. Uniquely, this is the first ED treatment in the US that can be sold OTC, without any intervention by a clinician.
- The US has c 22m men suffering with ED and represents MED3000's largest commercial opportunity and investor attention will now focus on how to best address this significant market. Management has previously disclosed that discussions are ongoing with a number of potential partners, describing the conversations as active and constructive. We conservatively expect the selected partner(s) to be announced before end-2023.
- As a reminder, Cooper Consumer Health, the partner for the EU countries, UK, and Switzerland, has initiated MED3000's OTC roll-out, branded as [Eroxon](#). It is now available selectively in the UK and Belgium, backed by an effective advertising and promotional campaign. We expect launches in additional countries during the coming 12 months. An Investor Seminar for analysts and institutional investors is planned for 22 June, with contributions from clinical specialists and representatives of Cooper. This meeting could provide valuable insights into Eroxon's commercial traction in these test markets. An additional meeting for retail investors is scheduled for 26 June.
- As expected, the FDA clearance has triggered Lombard Odier AM to exercise their existing warrants, representing 10.9m shares at 40p a share. This provides c £4.4m additional cash, extending the runway. Recall that at FY22 results, end-December 2022 cash was already sufficient well beyond key upcoming catalysts, including securing a US commercial deal, with initial MED3000 sales also extending the runway. Hence cash from the warrants provides a position of strength during the key US partner negotiations.

Price	42.90p
Market Cap	£125.52m
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 the US.

**Trinity Delta view:** 2023 is proving to be a pivotal year for Futura Medical and the FDA's clearance of MED3000 as an over-the-counter treatment for ED is another significant milestone. The clearance is the best hoped for, with MED3000 available without a prescription, and includes the rapid 10-minute onset of action claim, faster than typical oral PDE5 treatments (which take around 30 minutes). Both of these should position MED3000 favourably in the sizeable US market, with the US opportunity alone broadly underpinning the current share price. A commercial partner in the US is the key next step and we anticipate a deal(s) this year. Meanwhile, we expect an update on initial EU launches at the upcoming investor event on 22 June. Even modest success in any of the regions targeted for launch would be transformational for Futura Medical. Our valuation is £270m, equivalent to 94p per share.

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