

Futura Medical

MED3000 receives CE Mark as a Class II(b) device

30 April 2021

- Futura Medical has received the approval certificate for MED3000 from the designated [EU Notified Body](#). The CE Mark as a Class II(b) medical device means MED3000, a proprietary topical gel for erectile dysfunction (ED), the first clinically proven OTC treatment is approved across Europe.
- The CE Mark is recognised by a number of territories globally, including many countries in Latin America, Middle East and South East Asia, and paves the way for faster market introductions.
- We have viewed European approval as a prerequisite for the conclusion of commercial partnerships. Management has confirmed that it has received proposals from various potential partners and discussions are believed to be progressing well. We expect the first agreement should be in place within a matter of several months.
- Manufacturing scale-up is also said to be progressing well, suggesting that the production process will not be a rate-determining step in the launch preparations.
- The market opportunity for the first clinically proven ED product approved for OTC use could be significant. Its rapid onset of effect, undoubted safety, and ease of use suggest MED3000 would offer an attractive, clearly differentiated (not 'me too'), and competitive clinical profile compared not only to the market leading class of PDE5 inhibitors, but other classes of competing ED therapies.

Price	45.0p
Market Cap	£115.2m
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, MED3000, is a topically applied gel being developed for erectile dysfunction (ED).

Trinity Delta view: Although MED3000's imminent approval in Europe was flagged in March, the receipt of the official documentation paves the way for commercialisation discussions for a number of geographies to proceed at pace. The timings remain uncertain, but we would expect to see a number of deals in place within the next six months. For these geographies, the key sensitivity shifts from regulatory risk to execution risk, particularly the nature and scope of the commercialisation agreements. Our valuation model employs conservative assumptions and values Futura Medical at £190.3m which, following the full conversion of the loan notes held by HT Riverwood Multi-Growth Fund (Atlantis Group) earlier this month, is equivalent to 74.3p per share.

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