

Futura Medical

FY21 results reassure on cash runway and hint at EU deal

26 April 2022

- Futura Medical's FY21 results were largely as expected, but cash of £10.4m at end-December 2021 (FY20: £1.0m) was better than forecast. This should provide a runway to reach key value inflection points, notably potential MED3000 US approval in Q123. This filing will be supported by data from the ongoing FM71 US confirmatory trial. FM71 completed patient recruitment at end-2021 and, being a 24-week study, is on track for US filing by end-Q322, for Q123 approval (assuming FDA is able to normalise its review timings post-COVID as planned this year).
- The key event was the CE Mark grant in April 2021, which means MED3000 is ready to launch across Europe as the first erectile dysfunction (ED) treatment available OTC (over the counter), namely without a doctor's prescription. Suitable manufacturing capacity has now been established ahead of potential launch(es), with commercialisation contingent on securing agreements with experienced marketing partners.
- Four commercialisation deals are already in place, with the most [recent](#) a deal with Menarini for commercialisation of MED3000 in South Korea. The first agreement, with Atlantis covering China and the Far East, was secured in March 2021. This was followed by partnerships with m8 Pharmaceuticals (moksha8) for Brazil and Mexico in August 2021, and with Labatec for the Gulf and Middle East in September 2021. Further deals in regions ex-US and ex-EU are also being pursued. We believe these existing deals are a useful blueprint for future EU and US agreements, prioritising longer-term value creation and brand building rather than near-term payments.
- Deals in the key US and EU markets remain the main focus, with Futura Medical currently in a period of exclusivity with an unnamed party for European and UK marketing rights. Although there is no guarantee of a deal, this is nevertheless encouraging given commercial access via quality partners for the significant EU and US markets could transform Futura Medical.

Price	30.58p
Market Cap	£87.8m
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.

Trinity Delta view: Last April's CE Mark grant materially de-risked the ex-US investment case, with the focus shifting from regulatory aspects to execution. FY21 results reassure that Futura Medical has sufficient cash to reach key value inflection points including, pending successful FM71 clinical data, beyond potential MED3000 US approval in Q123. A European deal is anticipated eagerly and so it is highly encouraging that exclusive discussions are underway. We believe a US deal is likely once FDA approval visibility improves. Although the timings, and financial terms, of potential Europe and US deals remain uncertain at this point, and not without risks, we continue to believe that Futura Medical's share price does not reflect the commercial potential of MED3000. We maintain our Futura Medical valuation of £264m (92p per share).

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