

## Futura Medical

### Interims highlight positive first signs in key markets

13 September 2022

- Futura Medical's interim H122 results were largely as expected, with the focus on execution on MED3000's potential. Cash at end-June 2022 was £6.7m (FY21: £10.4m; H121: £12.8m), excluding a £0.9m tax credit expected during H222, which together should provide a runway to reach key value inflection points, notably potential MED3000 US approval in Q123.
- The highly positive FM71 data was the key post period highlight. These pave the way for MED3000 to be submitted for FDA review, as a *De Novo* medical device, for the OTC treatment of erectile dysfunction. The dossier, including data from FM57, is still expected to be submitted by end-September, with US marketing authorisation potentially by end-Q123. The trial met both co-primary and secondary endpoints, as outlined in our [August 2022 Lighthouse](#), with the improvements in erectile function sustained throughout the longer 24-week period explicitly requested by the FDA. Importantly, the data showed a highly statistically significant improvement ( $p < 0.001$ ) at 10 minutes, which could help support this as a label claim in the US. Following the successful study, the search for a US commercial partner has commenced and encouragingly a number of inquiries have been received.
- During H122 Futura Medical also secured a major deal in Europe with Cooper Consumer Health to commercialise MED3000 across Europe, including the UK. The agreement, outlined in our [May 2022 Lighthouse](#), has four main elements: (1) an upfront payment, assumed to be modest; (2) potential receipt(s) of cumulative undisclosed sales-based milestones; (3) an agreed price paid by Cooper for MED3000 manufacture and supply (by third-party contractors); and (4) Cooper commitment to sizeable, but undisclosed, commercialisation spend to support launch roll outs and continuing marketing and promotional costs. A contract manufacturer is in place for commercial production and first orders have been received from Cooper.
- In Europe initial launches are anticipated during H123, which could potentially include the UK. The next wave will likely include the key markets of France, Belgium, Germany, Italy, and Spain, with the third wave being the distributor-led smaller geographies. In the US, positive FM71 should now catalyse commercial discussions. Even limited success in any of these larger markets could transform Futura Medical, in our view

Price	46.85p
Market Cap	£134.6m
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 now complete in the US.

**Trinity Delta view:** The positive outcome of the critical US FM71 longer-term study for MED3000 removes clinical uncertainty, shifting the focus to regulatory and commercial execution. The MED3000 regulatory package for the OTC treatment of erectile dysfunction, including data from FM57, is expected to be submitted to the FDA by end-September and following five pre-submission meetings, a rapid review for a decision by end Q123 is hoped for. In parallel, the search for a US commercial partner has commenced, whilst in Europe a widespread deal with Cooper Consumer Healthcare is already in place. Our last published Futura Medical valuation was £264m, equivalent to 92p per share.

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