

Futura Medical

Encouraging FY19 results and MED3000 update

1 April 2020

- Futura Medical reported FY19 results in line with expectations and provided an update on positive developments with progressing MED3000 as a medical device for the treatment of erectile dysfunction (ED). As most operational activity centres on collating FM57 data and preparing regulatory submissions for MED3000, the impact of COVID-19 on corporate activities is limited.
- FY19 loss was £8.92m, up from £5.88m, due to increased R&D spend (FY19: £10.05m vs FY18: £6.03m) reflecting the cost of the FM57 Phase III study, that was completed on time and on budget. Administrative costs of £1.14m were down from £1.23m in FY18, due to effective cost control.
- Futura Medical had cash of £2.51m at end December 2019 (£9.16m at end-FY18), which was subsequently bolstered by a £3.25m fund raise in January 2020. The costs associated with FM57 increased FY19 cash burn to £8.01m (up from £5.63m in FY18). FY20 burn is expected to be materially lower and the cash runway is expected to last through to Q221, assuming no major clinical work is required to support MED3000 filings.
- Analysis of FM57 data confirms the remarkable initial findings (reported in Dec 2019), with MED3000 (the specific DermaSys placebo formulation) achieving clear and statistically meaningful improvements over baseline across primary and secondary endpoints in the three classes of ED examined.
- MED3000 appears to work through a targeted evaporative effect that specifically stimulates the nerve endings in the glans penis, causing an erection. A patent filing has been made that, if granted, could protect MED3000 through to 2040. Additional IP protection is also being prepared.
- The positive interactions with the FDA and European regulators support the view that MED3000 would be submitted as a *de novo* medical device for the treatment of ED. Whether additional clinical evidence would be required should be clarified after the next FDA discussions in April. If not, then European submission is possible by end-July, with US submission targeted by end-Q320.

Price	8.9p
Market Cap	£21.86m
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). A pain relief gel, TPR100, is awaiting UK approval.

Trinity Delta view: A detailed analysis of the initial FM57 pivotal study results confirms that the erectogenic effect of the MED3000 DermaSys formulation was remarkably consistent across all treatment groups. Positive and collaborative discussions with US and European regulators have improved clarity on the approval pathways. The commercial opportunities are potentially greater than previously thought; with not only the extended patent life but a wider market, eg potential use with existing ED medications such as PDE5 inhibitors, and a possibly quicker route to OTC use. Clearly significant unknowns remain, but the outlook is increasingly positive. We suspended our forecasts and valuation at the time of the FM57 results and intend to reinstate them as soon as practicable.

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