Trinity Delta

Futura Medical

Update

MED3000 on course for OTC approval in Europe and US

16 September 2020

Futura Medical's H120 results confirm progress is maintained as expected. The key developments with MED3000, its novel treatment for erectile dysfunction (ED), suggest that European OTC approval is likely during 2021 and in the US, pending a small six-month trial to show longer term efficacy, is expected in 2022. The format of this supplementary trial will be discussed at the next FDA meeting, expected before end-October. Current funds of £2.62m (at end-June 2020) provide a cash runway to Q221, although this does not include the costs of the US study. We value Futura Medical at £153.8m, equivalent to 60.9p a share.

Year-end: December 31	2018	2019	2020E	2021E
Sales (£m)	0.0	0.0	0.0	0.0
Adj. PBT (£m)	(7.2)	(11.1)	(3.1)	(3.3)
Net Income (£m)	(5.9)	(8.9)	(2.5)	(2.8)
EPS (p)	(4.5)	(4.4)	(1.0)	(1.1)
Cash (£m)	9.1	2.5	1.0	3.4*
EBITDA (£m)	(7.2)	(11.1)	(3.1)	(3.3)

Source: Trinity Delta Note: Adjusted PBT excludes exceptionals, Cash includes short-term investments. *FY21e cash includes assumed additional funding of £5m

- **MED3000 to be OTC in US and Europe** Constructive discussions with the FDA confirmed MED3000 will be approvable immediately as an OTC (over-the-counter) medical device, without the need for a prescription-only phase. The quality of the data submitted has been accepted and the next meeting will discuss the scope and format of a six-month clinical study to confirm longer-term efficacy. This study should be relatively modest in size and cost, with the details likely to be known by end-October. OTC label and patient leaflet development should be straightforward and not a time-limiting process. Management is targeting a 2022 US approval.
- **European filing completed and review underway** MED3000's clinical dossier has been successfully filed with the European Notified Body: the Clinical Study Report (CSR) is under review, and the Quality Management System (QMS) has received a positive audit. The data is deemed robust and complete which, assuming a smooth review process, could result in first approval during 2021. To date COVID-19 has not impacted on the timeline, but we are conscious that it remains a consideration.
- **Funding needed for FDA study** Cash resources of £2.62m are sufficient to fund the continuing operations through to Q221; however management is candid that additional financing will be required to perform the supplemental FDA study. Various funding mechanisms are possible, including non-dilutive options such as debt or local/regional licencing deal(s), or an equity raise.
- **£153.8m (60.9p/share) valuation maintained** We value Futura Medical at £153.8m (equivalent to 60.9p per share) using a risk-adjusted DCF model with conservative assumptions. Confirmation that MED3000 can be approved as a medical device for the OTC market in both the US and Europe has improved the company's risk profile. The upcoming FDA meeting should clarify US timelines. We intend to revisit our assumptions as visibility of the commercialisation strategies improves.

Price	17.25p
Market Cap	£42.4m
Enterprise Value	£39.8m
Shares in issue	245.6m
12 month range	7.16-36.00p
Free float	62%
Primary exchange	AIM
Other exchanges	N/A
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), is approaching regulatory approval as a medical device for ED (erectile dysfunction) in Europe and the US.

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Futura Medical: getting closer to the key point

The regulatory filings for MED3000, Futura Medical's topical gel for erectile dysfunction (ED), are progressing well in both Europe and the US. Positive discussions with the European Notified Body and FDA suggest approval as an OTC product is expected in both geographies. Such ready availability, coupled with a proven clinical efficacy, rapid onset of action, and a clean side-effect profile, suggests that it is well placed to capture a sizeable share of a large, and growing, market. Management have engaged a specialist corporate advisor to initiate licensing discussions with suitable commercial partners. We have modelled, using conservative assumptions, OTC sales of $225m in Europe and $250m in the US. We reiterate our view that, whilst not without risks, the current valuation fails to reflect the likely prospects.

H120 results have confirmed that progress is as expected. The regulatory filings for MED3000 are the key near-term determinants of Futura Medical's prospects.

MED3000 filing submitted in Europe, approval expected 2021

In Europe MED3000 has been submitted for approval as a Class 2B medical device. Continuing positive interactions with the designated EU Notified Body has seen the Technical Documentation (essentially the efficacy, safety and quality data from the clinical trials and supporting pre-clinical evidence) and the Quality Management System (QMS) documentation being submitted, with the latter having received a positive audit opinion. The Technical Dossier has been accepted and is currently under formal review, which, in our view, would support a regulatory approval in 2021.

Exhibit 1: Key milestones on EU Class II Medical Device regulatory pathway

QMS Evaluation	▪ Map out EU requirements for company QMS	Dec 2019	✓
EU Notified [2] Body Selection	▪ Selection and commission of EU Notified Body[2]	Q1 2020	✓
QMS[3] Update	▪ Updating of Futura's QMS[3] for MED3000	July 2020	✓
Application Submission	▪ Submission of MED3000 Technical Dossier	July 2020	✓
QMS approval	▪ Positive opinion issued on QMS[3] for MED3000	Aug 2020	✓
EU Regulatory approval	▪ Expected EU marketing authorisation	2021	

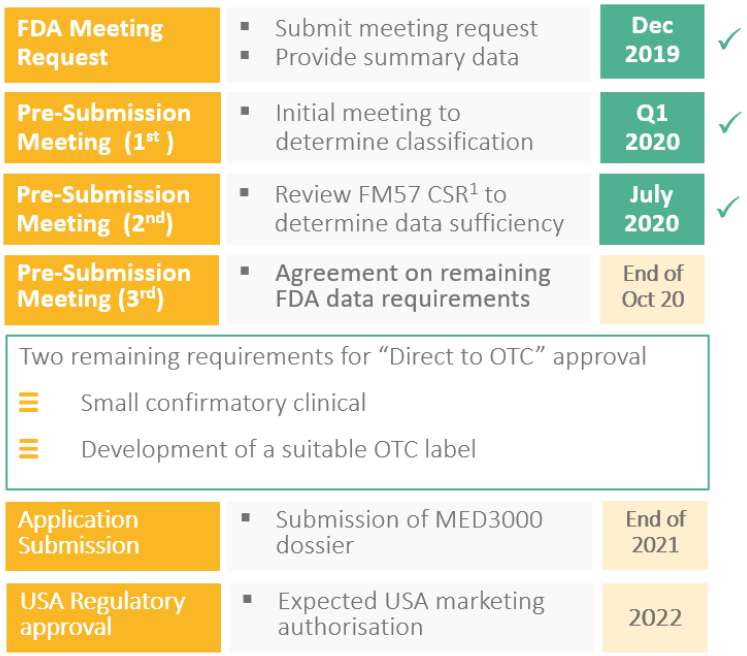
Source: Futura Medical. Note: 2 = Notified Bodies are the regulatory authorities that oversee the approval of medical devices within the EU including the UK; 3 = Quality Management System

US filing needs a six-month study, so 2022 approval likely

In the US MED3000 is being filed as a medical device with a De Novo Classification, as there is no similar predicate device to allow a 510(k) submission. Two pre-submission meetings with the FDA (February and July 2020) clarified the OTC route to market and the need for an additional six-month clinical trial to demonstrate longer term efficacy. The details and scope of this small study will be subject of a third meeting (provisionally expected by end-October), as will the

development of the OTC label and patient leaflet. The clinical study report (CSR), and additional clinical, safety, stability, and manufacturing information are similar to the European requirement and the package has already been collated.

Exhibit 2: Key milestones on FDA De Novo Medical Device pathway



Source: Futura Medical. Note: 1 = Clinical Study Report

OTC label requirements are complex but not expensive

The form of the supplementary study will be known after the next FDA meeting, but the indications are that the patient numbers required will modest, with active cooperation to determine the 'least burdensome design'. Developing the OTC label and associated patient information leaflet is a crucial process that seeks to minimise all risks; for example, consumer panels are employed to establish wording that is clear and unambiguous. Although multifaceted, the procedure is not expected to be a time limiting step. Management appears confident that a US OTC approval will be granted during 2022.

First straight to OTC ED product with a promising clinical profile

Assuming a smooth regulatory pathway, MED3000 would be the first clinically proven ED product that is approved OTC in Europe and the US. 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. Management has conducted market research analyses that suggest sales of $500m three years post-launch, rising to $584m by year five and $661m by year ten.

Exhibit 3: User benefits of MED3000

Benefit	Key enabling feature
Well tolerated	No systemic side-effect potential, especially compared to PDE5 inhibitors
Works rapidly	Potential to have one of the fastest speeds of onset (5-10 minutes) for any ED treatment
Enables spontaneity	Removes the need for planning of sex associated with some oral PDE5 inhibitor medications
Restores intimacy	Direct mode of application (by the male or his sexual partner) can form part of foreplay, which combined with speed of onset can help restore intimacy

Source: Trinity Delta, Futura Medical

Our $475m peak sales estimate is based on conservative assumptions

Our assumptions and expectations were detailed in our June 2020 Outlook report and, despite our conservative approach, we arrive at five-year sales for MED3000 of $225m in Europe and $250m in the US. Using more aggressive assumptions, notably on having motivated and commercially astute partners, could result in materially faster adoption curves and higher peak sales (Exhibit 4). Futura Medical has recently engaged a specialist corporate advisor to initiate discussions with potential licensing and marketing partners.

Exhibit 4: OTC availability opens a large untapped ED market

Source: Futura Medical. Note: 1 - Cello Healthcare Consulting research amongst physicians in the US, France and Germany, commissioned by Futura; 2 - Corona G., Andrology, 2016, 4, 1002–1009; 3 - Frederick L., J Sex Med, 2014, Oct, (10):2546-53; 4 - Nguyen Sex Med Rev. 2017 Oct, vol 5, 508-520; 5 - MSP 2018: Data for 75 countries, IQVIA IMS Health; 6 - Ipsos research commissioned by Futura 7 - Directors' belief based on market research conducted on Company's behalf by Ipsos

TRP100 pain relief gel awaiting next MHRA meeting

The update on the other development programmes also showed progress. The additional laboratory data the UK regulator, MHRA, had requested to support submission of the TRP100 diclofenac pain relief gel was completed during Q320. This will be submitted at the next scientific advisory meeting, which is expected to take place before end-2020. Thornton & Ross, part of STADA, has UK rights to TRP100. We expect existing commercial discussions with potential partners for other geographies will depend on the outcomes of the next MHRA meeting.

CBD100 feasibility studies show clear permeation benefits

The topical cannabidiol programme, CBD100, in development with CBDerma showed promising pre-clinical study results. The permeation of CBD100 into the skin was markedly superior to the comparator cannabidiol product, with the through the skin permeation clearly demonstrating why DermaSys is such an attractive dermal formulation technology. Next steps are under evaluation with CBDerma.

Cash runway to Q121 but funding needed for FDA study

Futura Medical's H120 results showed careful cost control, with cash resources of £2.62m at end-June 2020. Low overheads mean the cash runway for the ongoing operations extends to Q221. Management remains candid that additional funding will be required to perform the supplementary clinical trial required for FDA approval. Although the amount needed will not be known until the scope of the study in known (end-October), the amount is expected to be modest, and could be funded by a licensing deal, debt, other non-dilutive funding, or an equity raise.

Exhibit 5: Summary of financials

Year-end: December 31 £'000s	2017	2018	2019	2020E	2021E
INCOME STATEMENT					
Revenues	**363**	**0**	**32**	**0**	**0**
Cost of goods sold	0	0	0	0	0
Gross Profit	**363**	**0**	**32**	**0**	**0**
R&D expenses	(4,100)	(6,039)	(10,051)	(1,989)	(2,135)
General and administrative expenses	(1,118)	(1,228)	(1,144)	(1,117)	(1,176)
Underlying operating profit	**(4,856)**	**(7,266)**	**(11,164)**	**(3,106)**	**(3,311)**
Other revenue/expenses	0	0	0	0	0
EBITDA	**(4,843)**	**(7,247)**	**(11,143)**	**(3,086)**	**(3,298)**
Operating Profit	**(4,856)**	**(7,266)**	**(11,164)**	**(3,106)**	**(3,311)**
Interest expense	19	28	22	4	1
Profit Before Taxes	**(4,837)**	**(7,239)**	**(11,141)**	**(3,102)**	**(3,310)**
Adj. PBT	**(4,837)**	**(7,239)**	**(11,141)**	**(3,102)**	**(3,310)**
Current tax income	936	1,358	2,222	569	491
Cumulative preferred stock dividend	0	0	0	0	0
Net Income	**(3,900)**	**(5,881)**	**(8,919)**	**(2,533)**	**(2,819)**
EPS (p)	**(3.2)**	**(4.5)**	**(4.4)**	**(1.0)**	**(1.1)**
Adj. EPS (p)	**(3.2)**	**(4.5)**	**(4.4)**	**(1.0)**	**(1.1)**
DPS (p)	**0.0**	**0.0**	**0.0**	**0.0**	**0.0**
Average no. of shares (m)	120.6	131.9	204.7	244.0	245.6
Gross margin	*100%*	*N/A*	*100%*	*N/A*	*N/A*
BALANCE SHEET					
Current assets	**9,541**	**10,830**	**4,842**	**1,616**	**3,942**
Cash and cash equivalents	8,363	9,158	2,511	974	3,378
Accounts receivable	181	306	101	65	65
Inventories	70	8	8	8	8
Other current assets	927	1,358	2,222	569	491
Non-current assets	**64**	**47**	**60**	**44**	**36**
Property, plant & equipment	64	47	60	44	36
Other non-current assets	0	0	0	0	0
Current liabilities	**(499)**	**(2,026)**	**(4,848)**	**(950)**	**(5,950)**
Short-term debt	0	0	0	0	(5,000)
Accounts payable	(499)	(2,026)	(4,848)	(950)	(950)
Other current liabilities	0	0	0	0	0
Non-current liabilities	**0**	**0**	**0**	**0**	**0**
Long-term debt	0	0	0	0	0
Other non-current liabilities	0	0	0	0	0
Equity	**9,106**	**8,852**	**54**	**710**	**(1,972)**
Share capital	44,913	50,393	50,412	53,305	53,305
Other	(35,807)	(41,541)	(50,359)	(52,596)	(55,277)
CASH FLOW STATEMENTS					
Operating cash flow	**(4,155)**	**(4,680)**	**(6,634)**	**(4,590)**	**(2,591)**
Profit before tax	(4,837)	(7,239)	(11,141)	(3,102)	(3,310)
Non-cash adjustments	195	140	100	147	149
Change in working capital	(385)	1,464	3,027	(3,861)	0
Interest paid	19	28	22	4	1
Taxes paid	851	927	1,358	2,222	569
Investing cash flow	**(56)**	**(5)**	**(33)**	**(5)**	**(5)**
CAPEX on tangible assets	(56)	(5)	(33)	(5)	(5)
Other investing cash flows	0	0	0	0	0
Financing cash flow	**221**	**5,480**	**19**	**3,059**	**5,000**
Proceeds from equity	221	5,480	19	3,059	0
Increase in loans	0	0	0	0	5,000
Other financing cash flow	0	0	0	0	0
Net increase in cash	**(3,990)**	**795**	**(6,647)**	**(1,536)**	**2,404**
Cash at start of year	12,353	8,363	9,158	2,510	974
Cash at end of year	**8,363**	**9,158**	**2,510**	**974**	**3,378**
Net cash at end of year	**8,363**	**9,158**	**2,511**	**974**	**(1,622)**

Source: Company, Trinity Delta Note: Adjusted numbers exclude exceptionals. The funding requirement is shown as short-term debt in FY21e, until transaction type, source and size are confirmed.

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Disclaimer

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