Trinity Delta

Futura Medical

Update

FY21 is set to be a year of execution

14 April 2021

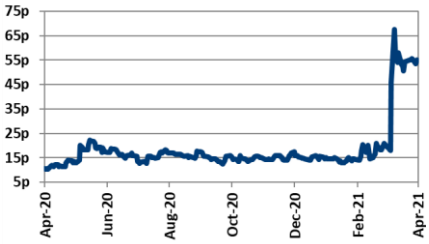
Futura Medical reported FY20 results in line with expectations, with net loss reduced from £8.9m to £2.4m. Net cash of £1.0m, coupled with £2.0m received in connection with the China and Far East MED3000 collaboration agreement and a £0.5m R&D tax credit, provides a cash runway that extends to Q122. The major events centre on MED3000's progress along the respective regulatory paths in Europe and the US, with CE Marking expected by end-May. The FDA's requirement is confirmed as a small study, FM71, involving 100 patients over six months. FY21 should see several commercialisation agreements established, notably in Latin America, Middle East, and Europe. Updating our model generates a valuation of £190.3m, equivalent to 76.6p (74.4p fully diluted) vs £181.5m and 73.1p (71.3p fully diluted) previously.

Year-end: December 31	2019	2020	2021E	2022E
Revenues (£m)	0.0	0.0	0.0	0.0
Adj. PBT (£m)	(11.1)	(2.9)	(3.3)	(3.1)
Net Income (£m)	(8.9)	(2.4)	(2.8)	(2.7)
EPS (p)	(4.4)	(1.0)	(1.1)	(1.1)
Cash (£m)	2.5	1.0	5.4*	3.0
EBITDA (£m)	(11.1)	(2.9)	(3.3)	(3.1)

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

- **FY20 was a year of material progress** Management has focused on gaining approval for MED3000 as a clinically validated OTC treatment for ED (erectile dysfunction) in Europe and the US. Post period, in March 2021, the designated EU Notified Body recommended its certification as a Class 2b approved medical device; the CE Mark is expected to be confirmed by end-May. On grant MED3000 will become the first pan-European OTC product approved for ED. FDA has clarified it requires a small confirmatory study, FM71, in 100 patients over six months.
- **Commercialisation deals expected** An innovative agreement with Atlantis covering China and the Far East was secured in March 2021. Atlantis is responsible for any necessary approvals and commercialisation and will split profits 50:50. The months following CE Marking should see further commercialisation agreements addressing Latin America, Middle East, and European markets. The aim is to structure deals that prioritise long-term value rather than near-term payments.
- **Further funds needed for FDA study** The £2.0m received from Atlantis, coupled with end-FY20 cash of £1.0m and a £0.5m tax credit expected to be received mid-2021, provides a cash runway to Q122 (excluding the FDA confirmatory study). The size and format of the FM71 study suggests a cost of $3.5m to $4.5m (£2.5m to £3.2m). As we have stated previously, various funding mechanisms are possible, including non-dilutive options such as further regional licencing deal(s), debt or an equity raise (ideally netting around £5m).
- **Updated valuation is £190.3m (74.4p/share)** Updating our model for these results sees our valuation rise slightly to £190.3m, equivalent to 76.6p (74.4p fully diluted) from our previous £181.5m, equivalent to 73.1p a share (71.3p fully diluted).

Price	55.0p
Market Cap	£136.6m
Enterprise Value	£134.6m
Shares in issue	248.3m
12 month range	9.03-84.00p
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: focus shifts to execution

Futura Medical reported FY20 results that highlight achievement of several key milestones, the most notable being MED3000's regulatory approval in Europe, with CE Marking expected by end-May. This single outcome materially de-risks the investment case, removing a major uncertainty and paving the way for commercialisation discussions for a number of geographies to proceed at pace. In the key US market, the FDA has clarified that it requires a single 100-patient study, FM71, examining efficacy and safety over six months. We assume FM71 costs to be between £2.5m and £3.0m, suggesting additional funding is needed. Assuming a H221 start, smooth progress and successful results could see US approval for MED3000 by mid-2023. The market opportunity for a clinically proven OTC ED treatment is significant, although we consciously employ conservative assumptions in our model, with sales of $225m in Europe and $250m in the US. Our view is that, whilst not without risks, Futura Medical's share price does not reflect the likely prospects.

Investment risk in Europe shifts from regulatory to execution

The imminent CE Mark for MED3000, expected by end-May, means that Futura Medical's major sensitivities in the European markets, now shift from regulatory to execution risk. The designated EU Notified Body certification as a Class 2b approved medical device means that MED3000 will be the first clinically proven ED treatment that is available OTC (over the counter, ie without a prescription) across the European Union. There are number of other geographies, including countries in the Middle East, Africa, the Far East, and Latin America that allow "fast track" reviews.

Further commercialisation deals are expected to be struck

We expect several commercialisation agreements addressing these regions to be struck in the coming six months. We believe management aims to focus on maximising longer term returns rather than seeking sizeable upfront payments that could address its funding requirements to undertake the FM71 study required for FDA approval. The recent Atlantis commercialisation deal covering China and most countries within South East Asia (March 2021 Update) has foregone sizeable upfront and milestone payments in return for 50:50 profit split. Whilst we would anticipate most of the Middle East and Latin America markets to be addressed through traditional upfront payment and royalty deals, we expect Europe to be covered through three or four regional players that know their marketplace intimately. It is here, and the US, that we may see more flexible profit-sharing deal structures.

FDA clarifying requirements for MED3000 submission…

In the US, the fourth meeting with the FDA has confirmed MED3000 will be reviewed as a De Novo classification with a small confirmatory clinical trial and a Human Factors Study as its remaining requirements. 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. The Human Factors Study is a straightforward non-clinical study that assesses how easily a patient understands the label and directions for use; this is an important factor with an OTC product to ensure that it is not inadvertently misused by patients. A fifth pre-submission meeting with the FDA is planned for H221 to define and confirm the details of the OTC application.

...assuming H221 start for FM71 and a positive outcome could see approval by mid-2023

FM71, the confirmatory clinical trial, will involve c 100 patients, 20 of whom are to be African American (from a US medical centre) and the remainder recruited from the same study centres as FM57. It will examine a mix of mild, moderate, and severe ED patients over a six-month period, compared to a three-month duration for FM57, to reassure the FDA that efficacy does not diminish over a longer period. Management is confident this will be successful as FM57 showed that efficacy improved during the three-month period. The primary endpoints are the same as FM57, but speed of onset is also being examined to support a rapid onset claim. The size and format of the FM71 study suggests a cost of $3.5m to $4.5m (£2.5m to £3.2m). If funding is in place a H221 start is likely, which assuming smooth progress with completion by Q222, and successful results, could see US OTC approval for MED3000 by mid-2023.

New patent protection for MED3000 could extend to 2040

Initial new patents covering MED3000 were filed in the UK in December 2019 with additional filings made in August and October 2020. An initial examination by the Patent Office supports the patentability of MED3000 and forms the basis of a Patent Cooperation Treaty (PCT) application filed in October 2020. The PCT currently has 153 contracting countries, which means that management (and its commercial partners) have until Q222 to decide in which countries it will seek patents. These national applications, if successful, will grant MED3000 protection through to 2040.

First straight to OTC ED product with a promising clinical profile

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. Market research analyses conducted by management suggest sales of $500m three years post-launch, rising to $584m by year five and $661m by year ten.

Exhibit 1: 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 sales estimates are based on conservative assumptions

Our assumptions and expectations for MED3000 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. China and South East Asia represent the largest potential user group in terms of volume, but the monetary value is likely to be tempered by lower pricing. We have, again using conservative assumptions, modelled on five-year sales of $143m for the region, with half of profits (equivalent to a 12.5% royalty based on a 25% net margin assumption) accruing to Futura Medical. Clearly, using more aggressive assumptions, notably on having motivated and commercially astute partners, could result in materially faster adoption curves and higher peak sales (Exhibit 2).

Exhibit 2: 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

Valuation and Financials

Risk-adjusted DCF model is the best valuation tool

We value Futura Medical using a DCF model. MED3000 is the key value driver, and we examine its sales potential and launch timings in the US, European, and China & SE Asian markets. We assume that MED3000 has a high likelihood of being approved as an OTC medical device in Europe in the near-term, whereas in the commercially important US market we have been more cautious with our success probabilities and timings. The specifics of our Europe and US assumptions, and other details of our model, are covered in our last Outlook note (available on our website).

Assumed an income stream equivalent to a 20% royalty rate and 12.5% for China/SE Asia

We assume that Futura Medical receives payments from partners that are equivalent to a royalty rate of 20%, although in reality they will likely be a combination of modest upfront payments, sales milestones, and tiered royalties on sales. In China and SE Asia we assume a 50% profit contribution, equivalent to a 12.5% royalty. The risk adjustments used reflect the remaining regulatory risks and inherent commercial and execution sensitivities for each market. These are summed and netted against the costs of running the operation and net cash.

Underlying business needs funded through Q122

Futura Medical's end-December cash balance of £1.02m was subsequently boosted in March 2021 with a £2m investment (£1.5m in convertible loan notes, CLNs, and £0.5m in warrants which were exercised by HT Riverwood Fund in April 2021) in connection with the MED3000 China and SE Asia collaboration. The CLNs have a three-year conversion period, a price of 20p, and carry a mandatory conversion when MED3000 receives European approval as a Class 2b device for ED or the share price is above 30p for a month.

Exhibit 3: Futura Medical risk-adjusted DCF model

	Total NPV ($m)	Total NPV (£m)	Risk adjustments	rNPV ($m)	rNPV (£m)	rNPV/ share (p)	Notes
MED3000 (Europe)	175.2	134.8	63%	110.4	84.9	34.2	Peak sales: $225m Launch year: 2022
MED3000 (US)	168.1	129.3	54%	90.7	69.8	28.1	Peak sales: $250m Launch year: 2023
MED3000 (China / SE Asia)	52.7	40.5	59%	47.4	36.5	14.7	Peak sales: $143m Launch year: 2024
TPR100	2.4	1.8	40%	1.0	0.7	0.3	Peak sales: $6.2m Launch year: 2022
Non-R&D opex	(4.1)	(3.2)		(4.1)	(3.2)	(1.3)	
Net cash	2.0	1.5		2.0	1.5	0.6	Pro forma FY20 + April warrant exercise
Total	**396.3**	**304.9**		**247.4**	**190.3**	**76.6**	
Total (fully diluted)					**190.3**	**74.4**	Riverwood CLN

Source: Trinity Delta Note: Assumptions include a 12.5% discount rate; a 1.3 $/£ FX rate, and 10% tax rate from 2026 with the benefit of the UK patent box

Valuation of £190.3m, or 74.4p per share (fully diluted)

The effect of updating our model (Exhibit 3) sees our prior Futura Medical valuation of £181.5m, or 73.1p per share (71.3p fully diluted), rise to £190.3m, or 76.6p per share (74.4p on a fully diluted basis). Our financial forecasts are presented in Exhibit 4.

Exhibit 4: Summary of financials

Year-end: December 31 £'000s	2018	2019	2020	2021E	2022E
INCOME STATEMENT					
Revenues	**0**	**32**	**0**	**0**	**0**
Cost of goods sold	0	0	0	0	0
Gross Profit	**0**	**32**	**0**	**0**	**0**
R&D expenses	(6,039)	(10,051)	(1,928)	(2,146)	(1,932)
General and administrative expenses	(1,228)	(1,144)	(1,001)	(1,128)	(1,211)
Underlying operating profit	**(7,266)**	**(11,164)**	**(2,928)**	**(3,274)**	**(3,142)**
Other revenue/expenses	0	0	0	0	0
EBITDA	**(7,247)**	**(11,143)**	**(2,903)**	**(3,262)**	**(3,132)**
Operating Profit	**(7,266)**	**(11,164)**	**(2,928)**	**(3,274)**	**(3,142)**
Interest expense	28	22	1	3	11
Profit Before Taxes	**(7,239)**	**(11,141)**	**(2,927)**	**(3,271)**	**(3,132)**
Adj. PBT	**(7,239)**	**(11,141)**	**(2,927)**	**(3,271)**	**(3,132)**
Current tax income	1,358	2,222	519	494	435
Cumulative preferred stock dividend	0	0	0	0	0
Net Income	**(5,881)**	**(8,919)**	**(2,408)**	**(2,777)**	**(2,697)**
EPS (p)	**(4.5)**	**(4.4)**	**(1.0)**	**(1.1)**	**(1.1)**
Adj. EPS (p)	**(4.5)**	**(4.4)**	**(1.0)**	**(1.1)**	**(1.1)**
DPS (p)	**0.0**	**0.0**	**0.0**	**0.0**	**0.0**
Average no. of shares (m)	131.9	204.7	243.7	245.6	245.6
Gross margin	*N/A*	*100%*	*N/A*	*N/A*	*N/A*
BALANCE SHEET					
Current assets	**10,830**	**4,842**	**1,577**	**5,964**	**3,436**
Cash and cash equivalents	9,158	2,511	1,019	5,430	2,962
Accounts receivable	306	101	40	40	40
Inventories	8	8	0	0	0
Other current assets	1,358	2,222	519	493	434
Non-current assets	**47**	**60**	**43**	**36**	**31**
Property, plant & equipment	47	60	43	36	31
Other non-current assets	0	0	0	0	0
Current liabilities	**(2,026)**	**(4,848)**	**(767)**	**(7,267)**	**(7,267)**
Short-term debt	0	0	0	(6,500)	(6,500)
Accounts payable	(2,026)	(4,848)	(767)	(767)	(767)
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	**8,852**	**54**	**854**	**(1,267)**	**(3,799)**
Share capital	50,393	50,412	53,305	53,805	53,805
Other	(41,541)	(50,359)	(52,452)	(55,072)	(57,605)
CASH FLOW STATEMENTS					
Operating cash flow	**(4,680)**	**(6,634)**	**(4,542)**	**(2,583)**	**(2,462)**
Profit before tax	(7,239)	(11,141)	(2,927)	(3,271)	(3,132)
Non-cash adjustments	140	100	173	166	165
Change in working capital	1,464	3,027	(4,012)	0	0
Interest paid	28	22	1	3	11
Taxes paid	927	1,358	2,222	519	494
Investing cash flow	**(5)**	**(33)**	**(8)**	**(5)**	**(6)**
CAPEX on tangible assets	(5)	(33)	(8)	(5)	(6)
Other investing cash flows	0	0	0	0	0
Financing cash flow	**5,480**	**19**	**3,059**	**7,000**	**0**
Proceeds from equity	5,480	19	3,059	500	0
Increase in loans	0	0	0	6,500	0
Other financing cash flow	0	0	0	0	0
Net increase in cash	**795**	**(6,647)**	**(1,492)**	**4,412**	**(2,468)**
Cash at start of year	8,363	9,158	2,510	1,019	5,430
Cash at end of year	**9,158**	**2,510**	**1,019**	**5,430**	**2,962**
Net cash at end of year	**9,158**	**2,511**	**1,019**	**(1,070)**	**(3,538)**

Source: Company, Trinity Delta Note: Adjusted numbers exclude exceptionals. A £5m funding requirement is shown as short-term debt in FY21e, until transaction type, source and size are confirmed.

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