Trinity Delta

Futura Medical

Update

FDA green lights MED3000 for OTC approval

14 July 2020

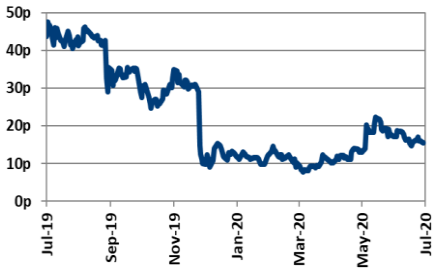
Futura Medical's update on MED3000, its novel treatment for erectile dysfunction (ED), confirms progress is in line with our expectations. The regulatory filings with both the US FDA and European Notified Body are progressing well. Importantly, the FDA has indicated there is a pathway for MED3000 to be launched as an OTC product in the US. This will require an additional, albeit modest, supplementary clinical trial to demonstrate longer term efficacy. More details should be known by the time of H120 results, likely in early-September. Our DCF-based model, using conservative assumptions, values 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)	(4.8)	(3.9)
Net Income (£m)	(5.9)	(8.9)	(4.0)	(3.9)
EPS (p)	(4.5)	(4.4)	(1.6)	(1.3)
Cash (£m)	9.1	2.5	1.0	3.1*
EBITDA (£m)	(7.2)	(11.1)	(4.8)	(3.9)

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

- **MED3000 set to be an OTC product** Productive discussions with the FDA have confirmed MED3000 will likely be approvable immediately as an OTC (over-the-counter) medical device, without the need for a prescription-only phase. Importantly, the FDA is comfortable with the quality of the data generated to date and will require only a small six-month clinical study to confirm the efficacy seen in FM57. The patient numbers required have yet to be established; however, we expect these, and hence the cost of the trial, to be modest, with the company and the FDA cooperating on establishing the 'least burdensome design' for the study.
- **European regulatory pathway also clear** The MED3000 clinical dossier, including the Clinical Study Report (CSR) for FM57 and the Quality Management System (QMS) documentation, has been filed with the European Notified Body for review. Early indications suggest the data is sound and complete, confirming that our expectations of a first approval by Q421 are realistic. To date COVID-19 has not impacted on the timeline, but we are conscious that it remains a consideration.
- **Partnering discussions will now be simpler** The direct to OTC pathway for the commercially important US market removes a degree of complexity from partnering discussions. The intricacies of requiring a prescription-only phase would have probably needed separate companies to address each of the prescription-only and subsequent OTC stages. In Europe, MED3000 is expected to be available immediately as an OTC product in those countries, such as the UK, that have established precedents. Some other countries are expected to take longer.
- **Undervalued and relatively low risk** We value Futura Medical at £153.8m (60.9p/share) using a risk-adjusted DCF model with conservative assumptions. We shall revisit our assumptions as further regulatory progress is achieved and as the visibility of the commercialisation and partnering strategies improves.

Price	15.5p
Market Cap	£38.1m
Enterprise Value	£26.5m
Shares in issue	245.6m
12 month range	7.16-47.9p
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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Exhibit 1: 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)	(3,554)	(2,575)
General and administrative expenses	(1,118)	(1,228)	(1,144)	(1,238)	(1,312)
Underlying operating profit	**(4,856)**	**(7,266)**	**(11,164)**	**(4,792)**	**(3,887)**
Other revenue/expenses	0	0	0	0	0
EBITDA	**(4,843)**	**(7,247)**	**(11,143)**	**(4,774)**	**(3,873)**
Operating Profit	**(4,856)**	**(7,266)**	**(11,164)**	**(4,792)**	**(3,887)**
Interest expense	19	28	22	4	5
Profit Before Taxes	**(4,837)**	**(7,239)**	**(11,141)**	**(4,788)**	**(3,882)**
Adj. PBT	**(4,837)**	**(7,239)**	**(11,141)**	**(4,788)**	**(3,882)**
Current tax income	936	1,358	2,222	809	592
Cumulative preferred stock dividend	0	0	0	0	0
Net Income	**(3,900)**	**(5,881)**	**(8,919)**	**(3,979)**	**(3,290)**
EPS (p)	**(3.2)**	**(4.5)**	**(4.4)**	**(1.6)**	**(1.3)**
Adj. EPS (p)	**(3.2)**	**(4.5)**	**(4.4)**	**(1.6)**	**(1.3)**
DPS (p)	**0.0**	**0.0**	**0.0**	**0.0**	**0.0**
Average no. of shares (m)	120.6	131.9	204.7	242.2	245.6
Gross margin	*100%*	*N/A*	*100%*	*N/A*	*N/A*
BALANCE SHEET					
Current assets	**9,541**	**10,830**	**4,842**	**1,965**	**3,794**
Cash and cash equivalents	8,363	9,158	2,511	1,048	3,093
Accounts receivable	181	306	101	101	101
Inventories	70	8	8	8	8
Other current assets	927	1,358	2,222	809	592
Non-current assets	**64**	**47**	**60**	**49**	**42**
Property, plant & equipment	64	47	60	49	42
Other non-current assets	0	0	0	0	0
Current liabilities	**(499)**	**(2,026)**	**(4,848)**	**(2,909)**	**(7,909)**
Short-term debt	0	0	0	0	(5,000)
Accounts payable	(499)	(2,026)	(4,848)	(2,909)	(2,909)
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**	**(894)**	**(4,072)**
Share capital	44,913	50,393	50,412	53,337	53,337
Other	(35,807)	(41,541)	(50,359)	(54,231)	(57,409)
CASH FLOW STATEMENTS					
Operating cash flow	**(4,155)**	**(4,680)**	**(6,634)**	**(4,381)**	**(2,947)**
Profit before tax	(4,837)	(7,239)	(11,141)	(4,788)	(3,882)
Non-cash adjustments	195	140	100	120	121
Change in working capital	(385)	1,464	3,027	(1,939)	0
Interest paid	19	28	22	4	5
Taxes paid	851	927	1,358	2,222	809
Investing cash flow	**(56)**	**(5)**	**(33)**	**(7)**	**(8)**
CAPEX on tangible assets	(56)	(5)	(33)	(7)	(8)
Other investing cash flows	0	0	0	0	0
Financing cash flow	**221**	**5,480**	**19**	**2,925**	**5,000**
Proceeds from equity	221	5,480	19	2,925	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)**	**(1,463)**	**2,045**
Cash at start of year	12,353	8,363	9,158	2,510	1,048
Cash at end of year	**8,363**	**9,158**	**2,510**	**1,048**	**3,093**
Net cash at end of year	**8,363**	**9,158**	**2,511**	**1,048**	**(1,907)**

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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