

Futura Medical

Update

AGM statement confirms MED3000 filings on track

29 June 2020

Futura Medical confirms the timelines for the regulatory filings for MED3000, its novel erectile dysfunction (ED) treatment, are on track. Dialogues with both the US FDA and European Notified Body have been constructive. The EU Notified Body has begun its review of the supporting documentation and the FDA filing is still expected by end-Q320. There have been no COVID-19 related delays but, in our view, these remain a consideration. We assume the review processes will take a minimum of 12 months in both cases, so have approvals pencilled in for Q421. Commercialisation discussions are expected to start in earnest once the status of the regulatory approvals is known. Our DCF-based model, using conservative assumptions, values Futura Medical at £153.8m, equivalent to 60.9p a share.

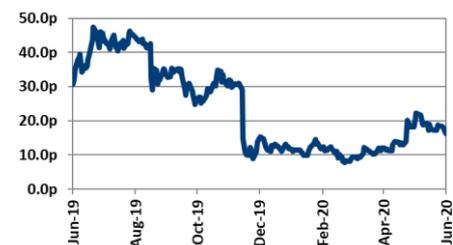
Year-end: December 31	2018	2019	2020E	2021E
Sales (£m)	0.0	0.0	0.0	0.0
Adj. PBT (£m)	(7.2)	(11.1)	(4.8)	(3.9)
Net Income (£m)	(5.9)	(8.9)	(4.0)	(3.9)
EPS (p)	(4.5)	(4.4)	(1.6)	(1.3)
Cash (£m)	9.1	2.5	1.0	3.1*
EBITDA (£m)	(7.2)	(11.1)	(4.8)	(3.9)

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

- Regulatory filings for MED3000 on track** Productive discussions with the FDA and the European Notified Body suggest that our expectations of first MED3000 approvals in Q421 are realistic. A date for the second FDA pre-submission meeting to discuss the final clinical requirements has been agreed and, if successful, could result in a filing by end-Q320. The EU Notified Body has started to review the QMS (Quality Management System) documentation, with management confident the TD (Technical Dossier) will be complete when the Notified Body requests it. COVID-19 has not, to date, impacted Futura Medical's operations or its dealings with the regulatory agencies; however, this remains a sensitivity to be considered.
- MED3000 has an attractive clinical profile** MED3000's proven clinical efficacy, coupled with a rapid onset of action and a clean side-effect profile, suggests that it is well placed to capture a meaningful share of a large, and growing, ED market. The complexities of the ED demographic segments, coupled with differing geographic marketing requirements, means we do not expect partnering discussions to be straightforward. Importantly, in our view, serious dialogues will likely advance once the regulatory status in each region is clearer.
- Undervalued and relatively low risk** We continue to value Futura Medical at £153.8m (60.9p/share) using a risk-adjusted DCF model with conservative assumptions. We expect to revisit our assumptions as further regulatory progress is achieved and as the visibility of the commercialisation and partnering strategies improves.

Price	16.25p
Market Cap	£39.9m
Enterprise Value	£28.3m
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
<i>Gross margin</i>		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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