

Futura Medical

Update

Are these unprecedented results a major opportunity?

10 December 2019

Futura Medical has reported the results of the pivotal Phase III study (FM57) for its lead compound, MED2005. Whilst all doses achieved all primary endpoints against baseline ($p < 0.001$) at 12 weeks, there was no differentiation between any active arms and placebo. The placebo arm consisted of the DermaSys formulation and these results suggest that this proprietary gel has an effect comparable to the active arms at all three glyceryl trinitrate doses (0.2%, 0.4%, and 0.6%). This data is clinically relevant and suggests that DermaSys alone may be effective in treating Erectile Dysfunction (ED). Clearly the data needs to be digested before licensing discussions with possible partners continue. Equally, the commercial opportunity, especially the OTC potential, will need to be assessed. Until we have greater visibility, we suspend our valuation and forecasts; for context our model valued Futura Medical at £127m (62p a share).

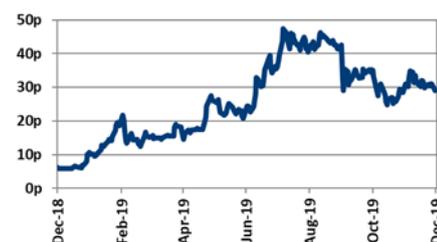
Year-end: December 31	2017	2018	2019E	2020E
Sales (£m)	0.4	0.0	0.0	-
Adj. PBT (£m)	(4.8)	(7.2)	(10.4)	-
Net Income (£m)	(3.9)	(5.9)	(8.6)	-
EPS (p)	(3.2)	(4.5)	(4.2)	-
Cash (£m)	8.4	9.2	1.5	-
EBITDA (£m)	(4.8)	(7.2)	(10.4)	-

Source: Trinity Delta Note: Adjusted PBT excludes exceptionals, Cash includes short-term investments.

- What has happened?** MED2005 is a fast-acting glyceryl trinitrate (GTN) gel that was evaluated in a pivotal FM57 Phase III study. The trial had three active dose arms (0.2%, 0.4%, and 0.6%) and a DermaSys gel formulation alone arm to act as a placebo. The headline results have shown that all three active arms and the placebo arm showed highly statistically significant improvements ($p < 0.0001$) across all three primary endpoints (IIEF-EF, SEP2 and SEP3). However, there was no differentiation between any active arm and placebo. The effect was consistent across the three patient groups of Mild-, Moderate-, and Severe-ED. Similar outcomes were seen for the secondary endpoints such as efficacy, speed of onset, and duration of action.
- What does this mean?** The data appears to show that the action of the proprietary DermaSys formulation alone has an effect comparable to all the GTN active doses studied. The results are clinically significant (FM57 was a 1,000 patient study) and Futura Medical has now filed patents to protect this use. Interestingly, this opens the path to apply for market authorisation, in both the US and Europe, using the simpler medical device routes. Some small studies may be required but these will be simpler than the previously proposed confirmatory Phase III study (FM59).
- What are the next steps?** These remarkable results have created understandable uncertainty and until we have greater visibility, we are obliged to suspend our valuation and forecasts (beyond FY19). There are clear opportunities, not least in terms of patent life and market opportunities, but equally there are potential unknowns that may unexpectedly crop up to dampen our enthusiasm. For context, our last published current valuation was £127m (equivalent to 62p/share).

Price	29.0p
Market Cap	£59.3m
Enterprise Value	£52.7m
Shares in issue	205m
12 month range	5.65-49.2p
Free float	70.4%
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, MED2005, is a topically applied gel that is in Phase III trials for erectile dysfunction (ED). A pain relief gel, TPR100, is awaiting UK approval.

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Exhibit 1: Summary of historic financials and our previous estimates

Year-end: December 31	£'000s	2017	2018	2019E	2020E	2021E
INCOME STATEMENT						
Revenues		363	0	0	0	0
Cost of goods sold		0	0	0	0	0
Gross Profit		363	0	0	0	0
R&D expenses		(4,100)	(6,039)	(9,346)	(8,556)	(4,962)
General and administrative expenses		(1,118)	(1,228)	(1,084)	(1,583)	(1,706)
Underlying operating profit		(4,856)	(7,266)	(10,430)	(10,139)	(6,669)
Other revenue/expenses		0	0	0	0	0
EBITDA		(4,843)	(7,247)	(10,411)	(10,115)	(6,643)
Operating Profit		(4,856)	(7,266)	(10,430)	(10,139)	(6,669)
Interest expense		19	28	19	(1)	17
Profit Before Taxes		(4,837)	(7,239)	(10,411)	(10,140)	(6,652)
Adj. PBT		(4,837)	(7,239)	(10,411)	(10,140)	(6,652)
Current tax income		936	1,358	1,836	1,925	1,117
Cumulative preferred stock dividend		0	0	0	0	0
Net Income		(3,900)	(5,881)	(8,574)	(8,215)	(5,535)
EPS (p)		(3.2)	(4.5)	(4.2)	(4.0)	(2.7)
Adj. EPS (p)		(3.2)	(4.5)	(4.2)	(4.0)	(2.7)
DPS (p)		0.0	0.0	0.0	0.0	0.0
Average no. of shares (m)		120.6	131.9	204.7	204.7	204.7
<i>Gross margin</i>		100%	N/A	N/A	N/A	N/A
BALANCE SHEET						
Current assets		9,541	10,830	3,856	10,711	5,247
Cash and cash equivalents		8,363	9,158	1,473	8,390	3,129
Accounts receivable		181	306	98	98	98
Inventories		70	8	8	8	8
Other current assets		927	1,358	2,276	2,214	2,012
Non-current assets		64	47	64	86	111
Property, plant & equipment		64	47	64	86	111
Other non-current assets		0	0	0	0	0
Current liabilities		(499)	(2,026)	(3,535)	(18,535)	(18,535)
Short-term debt		0	0	0	(15,000)	(15,000)
Accounts payable		(499)	(2,026)	(3,535)	(3,535)	(3,535)
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	385	(7,739)	(13,178)
Share capital		44,913	50,393	50,412	50,412	50,412
Other		(35,807)	(41,541)	(50,028)	(58,151)	(63,590)
CASH FLOW STATEMENTS						
Operating cash flow		(4,155)	(4,680)	(7,669)	(8,037)	(5,211)
Profit before tax		(4,837)	(7,239)	(10,411)	(10,140)	(6,652)
Non-cash adjustments		195	140	87	117	105
Change in working capital		(385)	1,464	1,718	0	0
Interest paid		19	28	19	(1)	17
Taxes paid		851	927	918	1,987	1,319
Investing cash flow		(56)	(5)	(35)	(46)	(51)
CAPEX on tangible assets		(56)	(5)	(35)	(46)	(51)
Other investing cash flows		0	0	0	0	0
Financing cash flow		221	5,480	19	15,000	0
Proceeds from equity		221	5,480	19	0	0
Increase in loans		0	0	0	15,000	0
Other financing cash flow		0	0	0	0	0
Net increase in cash		(3,990)	795	(7,685)	6,917	(5,262)
Cash at start of year		12,353	8,363	9,158	1,473	8,390
Cash at end of year		8,363	9,158	1,473	8,390	3,129
Net cash at end of year		8,363	9,158	1,473	(6,610)	(11,871)

Source: Company, Trinity Delta Note: Adjusted numbers exclude exceptionals. The funding requirement is shown as short-term debt in FY20e, until transaction type, source and size are confirmed.

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