Trinity Delta

Futura Medical

Update

On the cusp of MED3000 commercialisation

10 November 2022

During 2022 Futura Medical successfully delivered on several key MED3000 related events, including the highly positive FM71 longer-term clinical data, which are needed to enter the US market and importantly reinforced MED3000's differentiated and rapid onset of action. In addition, a number of commercial deals were executed, notably the European and UK deal with Cooper Consumer Health. The next steps are EU launches (due to start during H123), FDA marketing clearance (potentially by end Q123), and securing a US partner. These should be the final elements in converting MED3000 into a revenue generating OTC product for ED, transforming Futura Medical's prospects. Pending visibility on both US and European launches, our updated model conservatively does not include any near-term MED3000 related revenues. Our Futura Medical valuation is now £270m, equivalent to 94p per share.

Year-end: December 31	2020	2021	2022E	2023E
Revenues (£m)	0.0	0.0	0.0	0.0
Adj. PBT (£m)	(2.9)	(5.9)	(6.2)	(3.8)
Net Income (£m)	(2.4)	(5.0)	(5.5)	(3.0)
EPS (p)	(1.0)	(1.8)	(1.9)	(1.1)
Cash (£m)	1.0	10.4	3.2	0.2
EBITDA (£m)	(2.9)	(5.8)	(6.2)	(3.7)

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

- **US focus shifts to marketing authorisation and partnering** MED3000 was recently filed with the FDA, hence in the US the focus has shifted to commercial aspects, namely successfully executing a deal(s). The search for a US partner recently commenced, albeit visibility is limited, hence timings and deal terms are hard to predict. Granting of US marketing authorisation, hoped for by end Q123, would remove regulatory risk and could accelerate partnering discussions, in our view.
- **Preparing for H123 EU launches with partner Cooper** Futura Medical secured a broad EU & UK deal for MED3000/Eroxon with Cooper Consumer, outlined in our May 2022 Lighthouse. The first wave of launches is anticipated during H123, which could potentially include the UK. The next wave will likely include the rest of the key markets of France, Germany, Italy, and Spain, with the third wave being the distributor-led smaller geographies. A contract manufacturer is in place for commercial production and first orders have already been received from Cooper; Futura Medical receives an agreed price for MED3000 manufacture and supply.
- **Success in the US or EU could be transformational** MED3000 could be the first erectile dysfunction (ED) treatment available OTC (over-the-counter) in both the US and Europe. Commercial access via partners to these significant markets could transform Futura Medical. Deals are also in place in other regions, including South Korea with Menarini, Co-High covering China and the Far East, m8 Pharmaceuticals (moksha8) for Brazil and Mexico, and Labatec for the Gulf and Middle East.
- **Updated valuation of £270m (94p/share)** Our updated model reflects key events in the last year, leading to a valuation of £270m, or 94p per share. Pending launch and partner updates, we do not include any near-term revenues in our financial model. The US opportunity alone more than underpins the current share price.

Price	40.17p
Market Cap	£115.6m
Enterprise Value	£108.9m
Shares in issue	287.8m
12 month range	24.0-51.3p
Free float	54%
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), has been approved as an OTC product for ED (erectile dysfunction) in Europe, and is under FDA review in the US.

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Futura Medical: Commercial execution is key

The recent US FDA regulatory filing for MED3000, following highly positive data from the critical FM71 study, paves the way towards US market entry. This will be contingent on Futura Medical successfully securing a US commercial partner. US marketing authorisation is hoped for by end Q123 and, if granted, this could catalyse any ongoing partnering discussions, in our view. Meanwhile in Europe, partner Cooper Consumer Healthcare is preparing for first MED3000/Eroxon launches during H123, with the first commercial orders already received. Futura Medical also has several MED3000 commercial partners in various other territories. With many elements now in place to support successful MED3000 commercialisation, the key remaining task is a deal(s) to address the commercially important US market, and the search is underway. We continue to see the biggest opportunity for MED3000 in the US and in Europe, and successful commercialisation in either of these territories could transform Futura Medical. Cash of £6.7m, together with a £0.9m tax credit expected during H222, should be sufficient to YE23, beyond the anticipated Q123 FDA regulatory decision. We value Futura Medical at £270m, or 94p per share.

Deal execution in the US will be key, with MED3000 now submitted for FDA review

Following highly positive data from the FDA required FM71 trial, Futura Medical recently submitted MED3000 for regulatory review in the US, with a decision expected by end Q123. The US regulatory dossier includes data from both FM71, the longer-term 24-week study, and from FM57, the 12-week trial. Together these showed consistent effects, sustained over the longer-term, with excellent safety and tolerability (FM71 details are outlined below), which should pave the way towards formal marketing clearance in the US. Assuming this is granted as expected, the key remaining step for US commercialisation is securing a marketing partner. The search has already commenced, and a number of inquiries have been received. This is encouraging, albeit we have limited visibility on the potential timing and terms, given various structures and options could be considered. Importantly, current cash resources should be sufficient to reach beyond the anticipated US regulatory decision by end Q123, and to secure a US deal, assuming a positive regulatory outcome catalyses discussions.

Partner Cooper to initiate first EU launches during H123

In Europe and the UK, commercial partner Cooper Consumer Healthcare is preparing to launch MED3000/Eroxon as the first erectile dysfunction (ED) treatment available OTC (over-the-counter, ie without a doctor's prescription). The first launch wave is expected during H123, which could potentially include the UK. The next wave will likely include the rest of the key markets of France, Germany, Italy, and Spain, with the third wave being the distributor-led smaller geographies. An external third-party contract manufacturer is in place for commercial production and first orders have been received from Cooper.

First straight to OTC ED product with a promising clinical profile

Futura Medical now has several deals in place for MED3000 commercialisation across a number of territories, including with Cooper, which are summarised later in this report. 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 to the market leading class of PDE5 inhibitors.

Positive FM71 data could support differentiated US label

FM71 met primary and secondary endpoints and could support a rapid onset claim

Data from the critical FM71 study conducted over 24 weeks to support the US FDA application for MED3000 were highly positive, meeting FDA agreed primary and secondary endpoints. The results of FM71 were consistent with those seen in the previous 12-week FM57 Phase III study, with the improvements in erectile function sustained throughout the longer 24-week period explicitly requested by the FDA. In addition, MED3000 was shown to have a rapid onset of action, which could be a key differentiator. There were two co-primary endpoints:

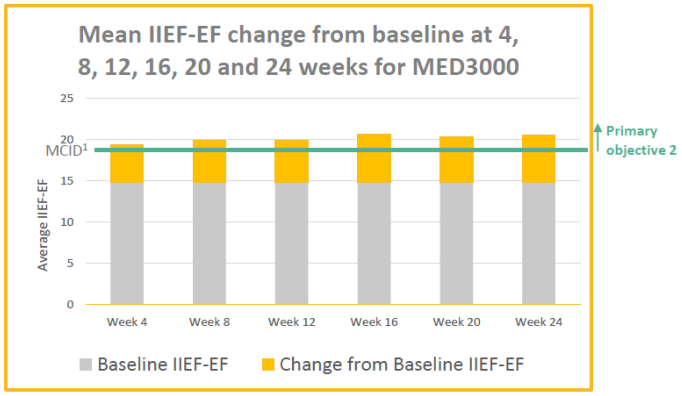
- The first showed a highly statistically significant improvement in erectile function (p<0.001) against baseline at 24 weeks (measured by the gold standard, internationally recognised IIEF-EF score) across 'pooled' severities of ED (mild, moderate and severe);
- The second showed a 5.73 unit change in IIEF-EF score versus baseline at 24 weeks. This comfortably exceeded the 4 unit difference agreed with the FDA and defined as the Minimal Clinical Important Difference (MCID).

MED3000 was clinically effective at all timepoints

MED3000 was clinically effective at all timepoints, as shown in Exhibit 1. Whilst tadalafil showed greater improvement (at 24 weeks 61% of MED3000 users exceeded the MCID compared to 87% on tadalafil), the OTC approval is not contingent on equivalence being shown.

Exhibit 1: FM71 primary endpoints achieved

Week	Mean IIEF change from baseline [1]
Week 4	4.59
Week 8	5.20
Week 12	5.12
Week 16	5.83
Week 20	5.57
Week 24 – Primary objective 1	5.73 (P<0.001)



Source: Futura Medical

Rapid onset of action could support a differentiated label claim in the US

A key secondary endpoint examined speed and onset of action. The data, using FDA agreed criteria where patients experienced an erection, showed a highly statistically significant improvement (p<0.001) at 10 minutes. This endpoint was included to demonstrate a rapid onset, which the oral tadalafil 5mg tablet comparator failed to show. Typically, oral PDE5 treatments take 30-60 minutes to work. This could be important in supporting a differentiating label claim in the US.

Results were consistent across endpoints and subgroups

Additional results from FM71 include: MED3000 exceeded the 4.0 MCID IIEF-EF score at all timepoints throughout the study; over the 24 weeks the MCID was also exceeded for each of the mild, moderate and severe ED subgroups; and, using the SEAR (Self Esteem and Relationship) questionnaire, at week 24 85.4% of MED3000 users felt sex could be spontaneous.

MED3000 was well tolerated

No serious adverse events were recorded in any patients on MED3000; 19.1% of subjects on tadalafil experienced headache vs 4.3% on MED3000; there were no

instances of back pain or 'non-cardiac' chest pain on MED3000 vs 4.3% for each on tadalafil, whereas 4.3% on MED3000 noted nausea.

FM71 trial was requested by FDA to provide longer-term MED3000 efficacy data

FM71 was a clinical study which was specifically requested by the US FDA to support marketing clearance as an OTC treatment for ED. The trial was conducted over 24 weeks in order to satisfy FDA concerns that the efficacy of MED3000 may diminish over a longer period compared to the 12 weeks examined in the FM57 trial. Endpoints were agreed with the FDA and were the same as prior studies, albeit over 24 weeks, and also included speed of onset. The trial enrolled 100 patients, which included a mix of mild, moderate, and severe ED patients (including African Americans). A representative half used MED3000 topically and half the lowest dose (5mg) of tadalafil (Cialis) orally in a randomised, open-label, at home study.

Home use study provides consistent real-world evidence

MED3000 performed consistently in a real-world setting

As part of its due diligence, Cooper undertook a consumer marketing home use test (HUT) in the UK, France, and the Netherlands. The size of the HUT has not been disclosed but would typically involve c 200 consumers. In this case men with self-diagnosed ED were supplied with a four-pack sample of MED3000 and the appropriate packaging leaflet. The results were in-line with those seen in the FM57 clinical trial, where over two-thirds of patients saw a clinically meaningful benefit. In the HUT the majority of men with ED, other than men suffering from severe ED with significant co-morbidities, saw an improvement in erectile performance. The importance of the HUT lies in the confirmation that MED3000 works as expected in a real-world setting.

Data package supports attractive market positioning

Data package provides consistent evidence

The data from FM71 and from the HUT provide additional, consistent evidence, together with data from the FM57 12-week study, that MED3000's market positioning, summarised in Exhibit 2, could be very attractive.

Exhibit 2: 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

Five commercial deals already secured

EU deal secured in May 2022 with Cooper Consumer Healthcare

In May 2022, Futura Medical secured a deal with Cooper Consumer Health to commercialise MED3000 across Europe, including the UK. Cooper is a Paris-based specialist in self-care, with brands spanning from cough syrup to burn treatment. It has sales of over €500m, with a direct presence in the seven largest European markets and via distributors in remaining geographies.

Initial EU launches expected during H123

Initial launches are anticipated during H123, which could potentially include the UK. The next wave will likely address the rest of the key markets of France, Germany, Italy, and Spain, with the third wave being the distributor-led smaller geographies.

Third-party CMO in place and ready for commercial production

Futura Medical does not manufacture MED3000 itself, but has an external third-party contract manufacturer in place, ready for commercial production. Scale up has been completed and capacity should be sufficient to meet initial demand and beyond. First orders have already been received from Cooper on which Futura Medical receives an agreed manufacture and supply price.

Futura Medical to receive upfronts, milestones and agreed manufacture and supply price

As previously outlined in our May 2022 Lighthouse, the agreement has four main elements: (1) Futura Medical to receive an upfront payment, assumed to be modest; (2) potential receipt(s) of cumulative undisclosed sales-based milestones; (3) an agreed price paid by Cooper for MED3000 manufacture and supply (by third-party contractors), and (4) Cooper commitment to sizeable, but undisclosed, commercialisation spend to support launch roll outs and continuing marketing and promotional costs.

Four deals and counting outside EU and US

In addition to the deal with Cooper, Futura Medical has also already successfully secured four deals outside of the Europe and US:

- **South Korea (Menarini):** The next most recent deal, executed in March 2022, is with Menarini Korea, a wholly owned subsidiary of Menarini Group. The deal has three main elements: (1) Futura Medical receives an initial upfront payment, which we assume to be modest; (2) Menarini Korea pays an agreed price for the manufacture and supply of MED3000, likely to be the key value driver for Futura Medical; and (3) Menarini Korea is responsible for local development, including any clinical bridging studies, regulatory work, and commercialisation costs, which effectively caps Futura Medical's responsibility to providing reasonable technical support. The South Korea ED market ranks ninth by value (US is largest) and sixth by volume (Brazil is the largest, with the US second).
- **Brazil and Mexico (m8 Pharmaceuticals):** The deal with m8 Pharmaceuticals (also known as moksha8) was secured in August 2021 and is an exclusive development and commercialisation collaboration. m8 Pharmaceuticals is a specialist company owned by Montreux Equity Partners. The agreement covers Brazil and Mexico and is for an initial 15 years. m8 has responsibility for all local development, regulatory and approval costs, as well as marketing, promotion, and regulatory compliance. For context, Brazil and Mexico account for 63% of the Latin America pharmaceutical market. In return Futura Medical will receive undisclosed sales-related payments, plus four milestones totalling up to $8.5m that are based on agreed cumulative sales volume targets.
- **Gulf and Middle East (Labatec Pharma**): The deal with Labatec Pharma, a Swiss based specialty pharma business, was signed in September 2021 and covers the Gulf countries (Saudi Arabia, United Arab Emirates, Kuwait, Qatar, Oman, and Bahrain) as well as Jordan, Lebanon and Iraq. The term is for eight years initially, extendable in two-year terms, with an undisclosed upfront payment and milestones on regulatory approvals. Labatec will be responsible for all development and approval costs, which

are expected to be minor, and for all marketing, distribution, and compliance costs. Futura Medical will provide finished product, from its contract manufacturer, for an agreed price and will also receive royalties on net sales.

- **China and South-East Asia (Atlantis Group):** Futura Medical struck its first agreement in March 2021 for commercialisation in China and the South-East Asia region through specialist subsidiaries of Atlantis Group, with details in our March 2021 Update. However, given continued COVID-19 restrictions in China, several development and regulatory milestones agreed as part of the deal have not been delivered, delaying potential launches. Futura Medical is now exploring options in China and South-East Asia, within the terms of the existing agreement, given this remains a significant commercial opportunity.

Valuation and Financials

Risk-adjusted DCF model yields valuation of £270m, or 94p per share

We continue to value Futura Medical using a DCF model, with MED3000 the key value driver. The effect of updating our model for events over the last year leads to a Futura Medical valuation of £270m, or 94p per share. We view the US market opportunity as the most significant, forecasting conservative peak sales of around $250-300m for MED3000, which we assume are reached around five years post launch. Europe could also have significant potential, albeit given the more fragmented nature of the market, which encompasses distinct commercial models in different countries, we conservatively forecast peak sales of $100-150m in Europe, with similar in Other Regions. These are summed and netted against the costs of running the operation and net cash.

Our forecasts are based on conservative assumptions, with significant upside potential

Our forecasts assume a MED3000 price of c $5/dose in the US and similar in EU, and whilst our market penetration rates continue to assume the clinical benefits seen in the trials are replicated consistently in a real-world setting, uptake will largely depend on the marketing experience and expertise of the relevant commercial partners. Motivated and commercially astute partners could result in materially faster adoption curves and higher peak sales. We assume modest penetration rates, hence there could be significant upside if uptake exceeds our expectations.

Exhibit 3: Futura Medical risk-adjusted DCF model

	Total NPV ($m)	Total NPV (£m)	Risk adjustment	rNPV ($m)	rNPV (£m)	rNPV/share (p)
MED3000 (Europe)	107.9	90.0	100%	107.9	90.0	31.3
MED3000 (US)	210.9	175.8	90%	189.8	158.2	55.0
MED3000 (Other Regions)	44.9	37.4	60%	26.9	22.4	7.8
Non-R&D OpEx	(8.5)	(7.1)		(8.5)	(7.1)	(2.5)
Last reported net cash	8.0	6.7		8.0	6.7	2.3
Total	**363.2**	**302.7**		**324.2**	**270.2**	**93.9**

Source: Trinity Delta Note: Assumptions include a 12.5% discount rate; a 1.2 $/£ FX rate, and 10% tax rate from 2026 with the benefit of the UK patent box

Assume US and EU deals could generate payments equivalent to a 20% royalty

For the purposes of modelling, we assume any deal(s) in the US will largely replicate the deal in Europe, which encompasses a combination of modest upfront payments, sales milestones, and finished product supply agreements. However, pending visibility on the US terms, and given limited disclosure of precise terms in Europe (which includes multiple revenue layers based on various accounting practices) for simplicity we assume Futura Medical receives payments from partners that are equivalent to a royalty rate of 20% on in-market sales. In the US we assign a 90% risk adjustment pending regulatory authorisation.

Other regions could yield an income stream equivalent to a 12.5% royalty

Other regions, which includes South Korea, China & South-East Asia, Brazil and Mexico, and the Gulf and Middle East, represent the largest potential user group in terms of volume. However, lower pricing vs the US and Europe reduces the monetary value. For simplicity we continue to model half of profits accruing to Futura Medical (equivalent to a 12.5% royalty based on a 25% net margin assumption).

Financial forecasts do not include any MED3000 revenues and are largely illustrative

Our financial model has been updated to reflect recent interim H122 results. As previously outlined, given limited visibility on precise launch timings and details on likely revenue and cost recognition in Europe, in addition to as yet unknown and unpredictable US deal terms, we do not currently include any potential MED3000 revenues in our Profit and Loss forecasts. Our forecasts instead focus on the key Operating Expenses, R&D and SG&A, with FY22 forecasts based on the H122 run rate. For R&D we assume a decrease in spend in FY23 given MED3000 clinical trials are complete. For SG&A we assume a small increase in FY23. MED3000 related revenues could allow Futura Medical to expand current R&D efforts beyond MED3000 and hence our forecasts are largely illustrative. Our financial forecasts are shown in Exhibit 4.

Cash should be sufficient beyond expected US approval by end-Q123

Cash at end-June 2022 of £6.7m (FY21: £10.4m; H121: £12.8m), together with a £0.9m tax credit expected during H222, should provide a runway beyond the anticipated US regulatory decision, which is hoped for by end Q123, assuming a fairly standard six-month review, and to secure a US commercial partner, depending on discussions and timing.

Exhibit 4: Summary of financials

Year-end: December 31 £'000s	2019	2020	2021	2022E	2023E
INCOME STATEMENT					
Revenues	**32**	**0**	**0**	**0**	**0**
Cost of goods sold	0	0	0	0	0
Gross Profit	**32**	**0**	**0**	**0**	**0**
R&D expenses	(10,051)	(1,928)	(3,774)	(3,717)	(1,227)
General and administrative expenses	(1,144)	(1,001)	(2,092)	(2,465)	(2,585)
Underlying operating profit	**(11,164)**	**(2,928)**	**(5,866)**	**(6,182)**	**(3,811)**
Other revenue/expenses	0	0	0	0	0
EBITDA	**(11,143)**	**(2,903)**	**(5,847)**	**(6,152)**	**(3,717)**
Operating Profit	**(11,164)**	**(2,928)**	**(5,866)**	**(6,182)**	**(3,811)**
Interest expense	22	1	0	0	6
Profit Before Taxes	**(11,141)**	**(2,927)**	**(5,866)**	**(6,182)**	**(3,805)**
Adj. PBT	**(11,141)**	**(2,927)**	**(5,866)**	**(6,182)**	**(3,805)**
Current tax income	2,222	519	909	711	761
Cumulative preferred stock dividend	0	0	0	0	0
Net Income	**(8,919)**	**(2,408)**	**(4,958)**	**(5,471)**	**(3,044)**
EPS (p)	**(4.4)**	**(1.0)**	**(1.8)**	**(1.9)**	**(1.1)**
Adj. EPS (p)	**(4.4)**	**(1.0)**	**(1.8)**	**(1.9)**	**(1.1)**
DPS (p)	**0.0**	**0.0**	**0.0**	**0.0**	**0.0**
Average no. of shares (m)	204.7	243.7	271.0	287.5	287.8
Gross margin	*100%*	*N/A*	*N/A*	*N/A*	*N/A*
BALANCE SHEET					
Current assets	**4,842**	**1,577**	**11,360**	**4,949**	**1,974**
Cash and cash equivalents	2,511	1,019	10,373	3,230	205
Short-term investments	0	0	0	0	0
Accounts receivable	101	40	79	100	100
Inventories	8	0	0	0	0
Other current assets	2,222	519	908	1,620	1,669
Non-current assets	**60**	**43**	**443**	**944**	**1,115**
Property, plant & equipment	60	43	443	944	1,115
Other non-current assets	0	0	0	0	0
Current liabilities	**(4,848)**	**(767)**	**(2,078)**	**(1,389)**	**(1,389)**
Short-term debt	0	0	0	0	0
Accounts payable	(4,848)	(767)	(2,078)	(1,389)	(1,389)
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	**54**	**854**	**9,725**	**4,504**	**1,700**
Share capital	50,412	53,305	66,952	66,974	66,974
Other	(50,359)	(52,452)	(57,228)	(62,470)	(65,274)
CASH FLOW STATEMENTS					
Operating cash flow	**(6,634)**	**(4,542)**	**(3,873)**	**(6,633)**	**(2,759)**
Profit before tax	(11,141)	(2,927)	(5,866)	(6,182)	(3,805)
Non-cash adjustments	100	173	202	259	328
Change in working capital	3,027	(4,012)	1,272	(710)	0
Interest paid	22	1	0	0	6
Taxes paid	1,358	2,222	519	0	711
Investing cash flow	**(33)**	**(8)**	**(420)**	**(532)**	**(266)**
CAPEX on tangible assets	(33)	(8)	(420)	(532)	(266)
Other investing cash flows	0	0	0	0	0
Financing cash flow	**19**	**3,059**	**13,647**	**22**	**0**
Proceeds from equity	19	3,059	13,647	22	0
Increase in loans	0	0	0	0	0
Other financing cash flow	0	0	0	0	0
Net increase in cash	**(6,647)**	**(1,492)**	**9,354**	**(7,143)**	**(3,025)**
Cash at start of year	9,158	2,510	1,019	10,373	3,230
Cash at end of year	**2,510**	**1,019**	**10,373**	**3,230**	**205**
Net cash at end of year	**2,511**	**1,019**	**10,373**	**3,230**	**205**

Source: Company, Trinity Delta Note: Adjusted numbers exclude exceptionals.

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