Trinity Delta

Futura Medical

Update

A year of delivery, with key milestones achieved

30 September 2021

Futura Medical's H121 results provide a timely reminder of the progress achieved this year. MED3000 was approved in Europe, with the CE Mark granted in April 2021. Collaboration agreements are in place for China and the Far East, Brazil and Mexico, and the Gulf/Middle East. The US regulatory pathway has been established, with the confirmatory FM71 study now underway. The £12m equity raise in May removes a major uncertainty, providing a cash runway through to expected US OTC approval (as early as Q123). The next major event should be announcement of the first European partner(s), followed by first MED3000 launch expected during H222. Updating our model to reflect this progress generates a Futura Medical valuation of £264m, equivalent to 92p per share.

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)	(6.2)	(4.9)
Net Income (£m)	(8.9)	(2.4)	(5.2)	(4.3)
EPS (p)	(4.4)	(1.0)	(1.8)	(1.5)
Cash (£m)	2.5	1.0	8.6	4.8
EBITDA (£m)	(11.1)	(2.9)	(6.2)	(4.9)

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

- **Material progress during 2021** Operational progress this year has been significant. The CE Mark grant in April means MED3000 is the first clinically validated OTC therapy for ED (erectile dysfunction) approved across Europe. The FDA has clarified the OTC approval pathway, with only a 100 patient confirmatory trial (FM71) and Human Factors Study required. With FM71 now underway, all elements needed for FDA filing should be in place by Q322, with US approval possible from Q123.
- **Three commercialisation deals now in place** The first agreement, with Atlantis covering China and the Far East, was secured in March. This was followed by partnerships with m8 Pharmaceuticals (moksha8) for Brazil and Mexico in August, and with Labatec for the Gulf and Middle East in September. These should preface more material deals covering European regions, with the emphasis still on prioritising longer-term value creation and brand building rather than near-term payments. These deals could form a template for the commercially important US market. Even limited success in these larger markets could transform the company.
- **June 2021 £12m equity raise removes uncertainty** The over-subscribed £12.0m equity raise (£10m institutional, £2m retail) has effectively removed a major investor uncertainty. The current solid cash balance, £12.8m at H121, provides the resources to fund the FM71 study and all supporting work required for FDA submission. Additionally, it will support all central expenditure (such as patenting, out-licensing, manufacturing scale-up) through to expected US OTC approval.
- **Updated valuation is £264m (92p/share)** We value Futura Medical using a risk-adjusted DCF model with conservative assumptions. We reinstate our valuation following the equity raise, reflecting progress and signing of new collaborations; our new valuation is £264m, equivalent to 92p per share.

Price	39.4p
Market Cap	£113.1m
Enterprise Value	£100.3m
Shares in issue	287.1m
12 month range	12.2-84.0p
Free float	60%
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, with final trials underway in the US.

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Futura Medical: commercialisation is key

Futura Medical's H121 results highlight the progress achieved through the period, with MED3000's regulatory approval in Europe in April as the most significant event. Three commercialisation deals have been struck, with Atlantis covering China & South-East Asia ahead of EU approval, and two subsequently: m8 addressing Brazil & Mexico, and most recently Labatec for the Gulf & Middle East region. Other notable events include initiation of the US confirmatory study, FM71, which is on track for a Q222 completion; and the £12m equity raise which provides funding beyond expected FDA approval. Collectively, these achievements have materially de-risked the investment case, with the focus shifting to successful execution. Looking ahead, we expect further deals, especially for several major European markets, and the first product launch(es). Sales performance will be scrutinised closely, especially the rate of repeat purchase, and will influence the commercial interest for the important US market. Our view remains that, whilst not without risks, Futura Medical's share price does not reflect likely prospects.

Investment risk in Europe shifts from regulatory to execution

The MED3000 CE Mark grant in April has shifted the major sensitivities in the European markets from regulatory to execution risk. Certification as a Class 2b approved medical device means MED3000 will be the first erectile dysfunction (ED) treatment available OTC (over the counter, ie without a doctor's prescription) across Europe. Several other geographies, including countries in the Middle East, Africa, the Far East, and Latin America use the CE Mark as the basis for "fast track" reviews. Manufacturing scale up appears to have progressed well and capacity to meet projected demand is expected to be in place to support first product launches during 2022. During the period Futura Medical has secured three regional commercialisation deals:

- **China and South-East Asia (Atlantis Group):** The first agreement, struck in March, covers commercialisation in China and the South-East Asia region through specialist subsidiaries of Atlantis Group. This innovative deal contains three distinct elements (March 2021 Update), with Atlantis effectively assuming responsibility for any necessary approvals and commercialisation and then splitting the profit 50:50 with Futura Medical, who in turn will provide reasonable clinical and regulatory support. Discussions with the National Medical Products Administration (NMPA) have confirmed an approval in China, the largest commercial opportunity, will require a local pivotal study to establish safety and efficacy in Chinese men. Atlantis has already budgeted c £4m for approval. In countries that recognise the CE Mark, first approvals are expected during 2022.
- **Brazil and Mexico (m8 Pharmaceuticals):** The second deal, secured in August, is an exclusive development and commercialisation collaboration with m8 Pharmaceuticals (also known as moksha8), a specialist company owned by Montreux Equity Partners. This 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

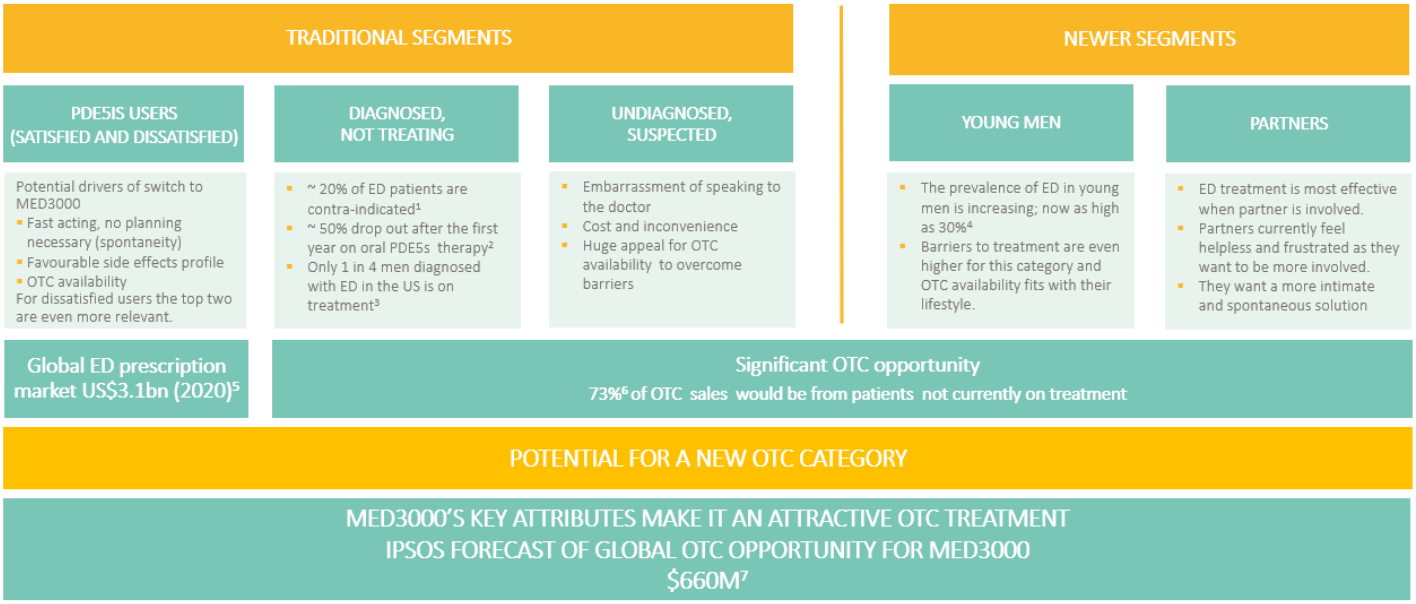
Futura Medical will receive undisclosed sales-related payments, plus four milestones totalling up to $8.5m that are based on agreed cumulative sales volume targets.

- **Gulf and Middle East (Labatec Pharma)**: The most recent licencing deal, signed in September, with Labatec Pharma, a Swiss based specialty pharma business, 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.

Partnerships for key markets are awaited with anticipation

With commercialisation in these geographies addressed through partnerships, investor attention will turn to the nature and timing of licensing deals for the key European markets. As we have previously stated, the geographic differences in consumer profile, marketing, and even local legislation, suggest that a single partnership would not result in optimal sales penetration over the longer term. Although logistically more complex, the variations in attitudes and social norms, even between some adjacent countries, are such that these markets are probably best addressed with a number of regional players that know their marketplace intimately. The deal structures will likely see a focus on longer term returns, with appropriate financial incentives that reward a partner prepared to invest in creating a strong and resilient brand. It is here, and the US, that we may see more flexible profit-sharing deal structures.

Exhibit 1: 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

A sizeable opportunity, both in existing and newer segments

Exhibit 1 details the commercial opportunities for a safe and effective OTC topical gel. The MED3000 product launches, initial sales and, importantly in our view, subsequent repeat purchases in all markets will be scrutinised closely by potential partners. We expect this to be especially pertinent for the important US market, where the regulatory timings should allow potential partners an opportunity to gauge consumer reactions in the initial launch markets. Interestingly, the rapid evolution of multi-channel marketing for OTC healthcare products in the US means that, despite being a single country, the varied channel characteristics may also result in a series of specialist partners being selected there.

FM71 study for FDA approval is underway

FDA has clarified the approval pathway for OTC status

In the US, the FDA has confirmed MED3000 will be reviewed as a De Novo classification and a small confirmatory clinical trial (FM71), coupled with a Human Factors Study (HFS), are the only 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 HFS is a straightforward non-clinical study, typically involving 15 patients, that assesses how easily someone understands the label and directions for use; this is an important factor with an OTC product to ensure that the label is understood and the product is used correctly. FM71 enrolled its first patient in September and both FM71 and HFS are expected to complete in Q222, with OTC marketing authorisation on track for approval in Q123.

Exhibit 2: US regulatory milestones – de novo medical device

1st Pre-Submission meeting	De Novo classification, existing FM57 clinical data discussed	Feb 2020
2nd Pre-Submission meeting	FDA – New clinical study required; Route to OTC discussed	Jul 2020
3rd Pre-Submission meeting	Study designs required for OTC discussed	Oct 2020
4th Pre-Submission meeting	Supplementary clinical study design agreed – FM71	Feb 2021
5th Pre-Submission meeting	Human Factors Study Protocol to test OTC label finalised	Jul 2021
Data Generation	Completion of FM71 & Human Factors study	Q2 2022
Application Submission	Submission of MED3000's dossier	Q3 2022
USA Regulatory Approval	Potential USA OTC marketing authorisation	Q1 2023

Source: Futura Medical

FM71 study aims to confirm results seen in larger FM57 trial

The FM71 trial involves c 100 patients; 20 of whom are to be African American (from a US medical centre), and the remainder recruited from similar study centres as FM57. A representative half will use MED3000 topically and half the lowest dose (5mg) of tadalafil (Cialis) orally. A mix of mild, moderate, and severe ED patients will be examined over a 24-week 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 efficacy improved during the three-month period, being noticeably greater in the third month than the first. The primary endpoints are the same as FM57, but speed of onset is also being examined to support a rapid onset claim (FM57 showed 60% had an erection within 10 minutes). Whilst a comparison with the tadalafil arm will be made regarding safety, speed of onset and efficacy, the OTC approval is not contingent on equivalence being shown.

MED3000 market positioning could be very attractive

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.

Exhibit 3: 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

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 other regions (updated to include those covered by the three commercial partnerships). Clearly much depends on the marketing prowess of the relevant commercial partners but, assuming the clinical benefits seen in the trials are replicated consistently in a real-world setting, we raise our five-year sales assumptions for MED3000 to $238m (vs $225m previously) in Europe and $289m (vs $250m) in the US.

Other regions, which now covers China and South-East Asia, Brazil and Mexico, and the Gulf and Middle East, represent the largest potential user group in terms of volume, but the monetary value is likely to be tempered by lower pricing. For simplicity, and reflecting likely regional splits, we have modelled on five-year sales of $245m 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, commercially astute partners, could result in materially faster adoption curves and higher peak sales.

Assumed an income stream equivalent to a 20% royalty rate and 12.5% for Other regions

We assume 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, tiered royalties on sales, and finished product supply agreements. In Other regions, as mentioned, 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.

Exhibit 4: Futura Medical risk-adjusted DCF model

	Total NPV ($m)	Total NPV (£m)	Risk adjustments	rNPV ($m)	rNPV (£m)	rNPV/ share (p)	Notes
MED3000 (Europe)	191.1	147.0	80%	152.8	117.6	40.95	Peak sales: $238m Launch year: 2022
MED3000 (US)	199.9	153.8	57%	113.9	87.6	30.52	Peak sales: $289m Launch year: 2023
MED3000 (Other regions)	93.0	71.5	70%	65.1	50.1	17.44	Peak sales: $245m Launch year: 2024
Non-R&D opex	(5.3)	(4.1)		(5.3)	(4.1)	(1.4)	
Net cash	16.6	12.8		16.6	12.8	4.45	As at end-H121
Total	**495.2**	**380.9**		**343.1**	**263.9**	**91.9**	

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 £264m, or 92p per share (fully diluted)

The effect of updating our model for the June institutional placing and retail offer, the clinical and regulatory progress for US approval, and recent partnering agreements (Exhibit 3) lifts our prior Futura Medical valuation of £181.5m, or 73.1p per share (71.3p fully diluted), to £264m, or 92p per share.

Cash position provides runway through to US approval

Cash position of £12.8m funds runway though to US approval

The successful £12m (gross) equity raise, structured as an institutional placing of £10m and a £2m retail offer, in June effectively removes financial uncertainty. The raise was to provide funding for the FM71 confirmatory study, allow the scale-up and preparation for volume manufacture ahead of commercialisation, and fund central costs and working capital beyond US approval. The strong cash position of £12.8m at end-June 2021 reflects both the raise and commendably tight cost control. R&D expenses were £1.2m (H120: £0.9m), general and administrative costs were £0.7m (H120: £0.5m) and included one-off costs of £150k associated with the funding transactions. Operating loss was £1.9m (H120: £1.4m), with net loss of £1.6m (H120: £1.1m).

Our financial forecasts for FY21 and FY22 are shown in Exhibit 5.

Exhibit 5: 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)	(4,495)	(2,652)
General and administrative expenses	(1,228)	(1,144)	(1,001)	(1,672)	(2,265)
Underlying operating profit	**(7,266)**	**(11,164)**	**(2,928)**	**(6,167)**	**(4,918)**
Other revenue/expenses	0	0	0	0	0
EBITDA	**(7,247)**	**(11,143)**	**(2,903)**	**(6,151)**	**(4,909)**
Operating Profit	**(7,266)**	**(11,164)**	**(2,928)**	**(6,167)**	**(4,918)**
Interest expense	28	22	1	13	17
Profit Before Taxes	**(7,239)**	**(11,141)**	**(2,927)**	**(6,155)**	**(4,901)**
Adj. PBT	**(7,239)**	**(11,141)**	**(2,927)**	**(6,155)**	**(4,901)**
Current tax income	1,358	2,222	519	943	597
Cumulative preferred stock dividend	0	0	0	0	0
Net Income	**(5,881)**	**(8,919)**	**(2,408)**	**(5,212)**	**(4,304)**
EPS (p)	**(4.5)**	**(4.4)**	**(1.0)**	**(1.9)**	**(1.5)**
Adj. EPS (p)	**(4.5)**	**(4.4)**	**(1.0)**	**(1.9)**	**(1.5)**
DPS (p)	**0.0**	**0.0**	**0.0**	**0.0**	**0.0**
Average no. of shares (m)	131.9	204.7	243.7	273.3	287.1
Gross margin	*N/A*	*100%*	*N/A*	*N/A*	*N/A*
BALANCE SHEET					
Current assets	**10,830**	**4,842**	**1,577**	**10,144**	**6,029**
Cash and cash equivalents	9,158	2,511	1,019	8,599	4,830
Accounts receivable	306	101	40	84	84
Inventories	8	8	0	0	0
Other current assets	1,358	2,222	519	1,461	1,116
Non-current assets	**47**	**60**	**43**	**29**	**23**
Property, plant & equipment	47	60	43	29	23
Other non-current assets	0	0	0	0	0
Current liabilities	**(2,026)**	**(4,848)**	**(767)**	**(735)**	**(735)**
Short-term debt	0	0	0	0	0
Accounts payable	(2,026)	(4,848)	(767)	(735)	(735)
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**	**9,438**	**5,317**
Share capital	50,393	50,412	53,305	66,928	66,928
Other	(41,541)	(50,359)	(52,452)	(57,490)	(61,611)
CASH FLOW STATEMENTS					
Operating cash flow	**(4,680)**	**(6,634)**	**(4,542)**	**(6,039)**	**(3,767)**
Profit before tax	(7,239)	(11,141)	(2,927)	(6,155)	(4,901)
Non-cash adjustments	140	100	173	178	174
Change in working capital	1,464	3,027	(4,012)	(75)	0
Interest paid	28	22	1	13	17
Taxes paid	927	1,358	2,222	0	943
Investing cash flow	**(5)**	**(33)**	**(8)**	**(2)**	**(3)**
CAPEX on tangible assets	(5)	(33)	(8)	(2)	(3)
Other investing cash flows	0	0	0	0	0
Financing cash flow	**5,480**	**19**	**3,059**	**13,622**	**0**
Proceeds from equity	5,480	19	3,059	13,622	0
Increase in loans	0	0	0	0	0
Other financing cash flow	0	0	0	0	0
Net increase in cash	**795**	**(6,647)**	**(1,492)**	**7,580**	**(3,769)**
Cash at start of year	8,363	9,158	2,510	1,019	8,599
Cash at end of year	**9,158**	**2,510**	**1,019**	**8,599**	**4,830**
Net cash at end of year	**9,158**	**2,511**	**1,019**	**8,599**	**4,830**

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

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Disclaimer

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