Trinity Delta

Futura Medical

Update

Commercialisation deal for China and SE Asia

4 March 2021

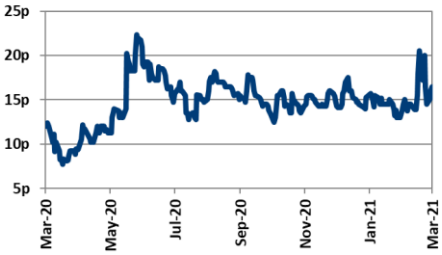
Futura Medical has struck an innovative deal with Atlantis Group to market its MED3000 topical gel for erectile dysfunction throughout China and South East Asia. Atlantis, and its associated companies, will fund any registration studies and commercialisation costs in the region, with the resulting profits being split 50:50. Atlantic will also invest £2.0m in Futura Medical through £1.5m as Convertible Loan Notes and £0.5m in warrants, with a conversion price of 20p and exercise price of 22p respectively. The collaboration addresses market access to the largest target population for MED3000. Updating our model to reflect this deal, our new valuation is £181.5m, equivalent to 73.1p per share (71.3p fully diluted), from £153.8m (60.9p a share), previously.

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)	(3.1)	(3.3)
Net Income (£m)	(5.9)	(8.9)	(2.5)	(2.8)
EPS (p)	(4.5)	(4.4)	(1.0)	(1.1)
Cash (£m)	9.1	2.5	1.0	4.9*
EBITDA (£m)	(7.2)	(11.1)	(3.1)	(3.3)

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

- **Deal addresses China and SE Asia opportunity** The collaboration with Atlantis Group, through its specialist subsidiaries, will see MED3000 developed and marketed as a clinically validated OTC treatment for erectile dysfunction (ED) across China and South East Asia. Atlantis assumes responsibility for any necessary approvals and commercialisation and will split the profit 50:50. Futura Medical will provide reasonable clinical and regulatory support. Atlantis is well connected across the region and will also employ specialist partners to address local market needs.
- **Direct investment of £2.0m extends runway** Atlantis is investing £2.0m in Futura Medical, of which £1.5m is through Convertible Loan Notes (CLNs) with a three-year conversion period and a price of 20p, and £0.5m through warrants with a four-year life and an exercise price of 22p. The CLNs carry a mandatory conversion when MED3000 receives European approval as a Class 2b device for erectile dysfunction or the share price is above 30p for a month. The funds are sufficient to finance the continuing operations through to beyond end-2021.
- **Funding needed for FDA study** The next value inflection points are expected to be European approval of MED3000, further clarity on US filing requirements, and further commercial agreements. Management has been candid that additional financing will be required to perform the supplemental FDA study. Various funding mechanisms are possible, including non-dilutive options such as further local and regional licencing deal(s), debt or an equity raise.
- **Updated valuation is £181.5m (73.1p/share)** Updating our model for the improved visibility on commercialisation strategies lifts our valuation to £181.5m, equivalent to 73.1p a share (71.3p fully diluted), from our previous £153.8m (60.9p per share). Our risk-adjusted DCF model continues to employ conservative assumptions.

Price	16.5p
Market Cap	£40.5m
Enterprise Value	£37.9m
Shares in issue	245.6m
12 month range	7.16-24.49p
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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Futura Medical: attractive profit share deal struck

Futura Medical has struck a 50:50 profit share deal with subsidiaries and associated funds of Atlantis Group for commercialisation of MED3000, its topical gel for erectile dysfunction (ED), in China and South East Asia. The deal sees Atlantis, through another subsidiary, invest £1.5m as CLNs immediately with warrants for a further £0.5m. Atlantis believes a number of Asian countries can be accessed based on a European OTC approval, but will fund the costs of studies and registration for OTC approval in China (expected to be c £4m). The market opportunity is significant, with the highest incidence of ED males worldwide. We had consciously excluded non-US and non-Europe regions from our valuation; for context we model, using conservative assumptions, OTC sales of $225m in Europe and $250m in the US. We reiterate our view that, whilst not without risks, our current valuation of £181.5m, 73.1p per share, fails to reflect the likely prospects.

Innovative deal for China and SE Asia nets 50:50 profit split

Futura Medical has struck a commercialisation deal where it will retain half of the profits from commercialising MED3000, its proprietary topical gel for erectile dysfunction (ED), in China and regions within South East Asia. The deal consists of several elements, including direct investments, funding and the commercialisation collaboration, with subsidiaries of the Atlantis Group.

Immediate £1.5m CLN plus £0.5m warrants investment

The first element sees HT Riverwood Multi-Growth Fund, a fund managed by Atlantis Investment Management, invest up to £2m in cash, £1.5m of which will be received immediately, into Futura Medical. The £1.5m be in the form of convertible loan notes (CLN), with a three-year conversion period and a price of 20p (a 25% premium to the 30-day closing share price). The CLNs carry no interest for six months then have a 2% coupon through to conversion. Futura Medical can request a mandatory conversion when it receives European regulatory approval for MED3000 as a Class 2B Medical device or the share price trades at or above 30p for one month. The £0.5m is linked to warrants issued to HT Riverwood that have a four-year life and an exercise price of 22p. The conversion terms of the £1.5m CLNs are such that they are essentially equity.

Collaboration with regional specialist structured for long-term returns

The second element is a commercialisation collaboration with Pride Century Ventures, a vehicle owned by Co-High Investment Management, that will have the rights to exclusively develop and commercialise MED3000 across China and South East Asia. Futura Medical and Co-High will split the resulting profits of the Joint Collaboration equally. Co-High is a 60% owned subsidiary of the Atlantis Group. Co-High is well-connected in the region and has identified a number of local partners for specific geographies. These partner profits will form part of the Joint Collaboration and will be included in the profit split. The market opportunities in the regions covered by the deal are significant and it is interesting to note that Futura Medical has struck a profit share arrangement rather than a royalty licensing deal with an upfront payment.

Removes regulatory and commercialisation worries

The third element covers the financing of the commercial operations, in particular the costs of registration studies for China. Co-High will be responsible for all costs relating to the development, registration, and marketing of MED3000. Co-High management, and its local partners, believe that market access as an OTC product for a number of countries can be achieved based on the OTC registration in

Europe. Approval in China, the largest commercial opportunity, will require a pivotal study and is expected to cost c £4m. Chinese approval would open up the remaining countries in the region. The study will likely only need to demonstrate that MED3000's safety and efficacy is replicated in Chinese males, suggesting approval could be achieved within 18 months. Futura Medical would provide reasonable technical support for OTC product development and eventual commercialisation.

Redressing the negotiation imbalance inherent in the region

The Atlantis deal, through their majority-owned subsidiary Co-High, is innovative and addresses the key difficulty of how a small Western company can realise the optimal value for its assets when it lacks the know-how, connections (both business and political), and local infrastructure. These are the skills that Co-High and its affiliates provide. The market dynamics in China and South East Asia region are complex, especially so when dealing with a sexual health medical product available through multiple OTC channels. It will be interesting to see if other regions will be addressed through similar profit-sharing structures.

Unlikely to be replicated in other regions, though US will likely need creative solutions

Looking at Latin America and the Middle East regions, it could be argued that the complexities and differing social and market access challenges, even between neighbouring countries, are similar to those in South East Asia. Nonetheless, we would expect these regions to be addressed through more traditional upfront payment and royalty deals. Europe is interesting but, as we have said before, the variations in attitudes and social norms are such that it is probably best addressed with three or four regional players that know their marketplace intimately. 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 mean a similar overarching deal could work well.

European regulatory approval will unlock further deals

However, in our view, any such distribution or licensing agreement is unlikely to happen before the regulatory status is clear. We believe the regulatory filings for MED3000 are the key near-term determinants of Futura Medical's prospects.

Exhibit 1: Key milestones on EU Class II Medical Device regulatory pathway

QMS Evaluation	▪ Map out EU requirements for company QMS	Dec 2019	✓
EU Notified [2] Body Selection	▪ Selection and commission of EU Notified Body[2]	Q1 2020	✓
QMS[3] Update	▪ Updating of Futura's QMS[3] for MED3000	July 2020	✓
Application Submission	▪ Submission of MED3000 Technical Dossier	July 2020	✓
QMS approval	▪ Positive opinion issued on QMS[3] for MED3000	Aug 2020	✓
EU Regulatory approval	▪ Expected EU marketing authorisation	2021	

Source: Futura Medical. Note: 2 = Notified Bodies are the regulatory authorities that oversee the approval of medical devices within the EU including the UK; 3 = Quality Management System

MED3000 filing submitted in Europe, approval expected mid-2021

In Europe MED3000 has been submitted for approval as a Class 2B medical device. The positive interactions with the designated EU Notified Body has seen

the Technical Documentation (essentially the efficacy, safety and quality data from the clinical trials and supporting pre-clinical evidence) and the Quality Management System (QMS) documentation submitted, with the latter having received a positive audit opinion. The Technical Dossier has been accepted and is currently under formal review, which, in our view, would support a regulatory approval around mid-2021. Anecdotal evidence suggests that COVID-19 impacts have been minimal and the agency has been working very effectively with little, if any, backlog.

US filing needs a six-month study, so 2022 possible but 2023 approval more likely

In the US MED3000 will be filed as a medical device with a De Novo Classification, as there is no similar predicate device to allow a 510(k) submission. Three pre-submission meetings with the FDA (February, July, and October 2020) clarified the OTC route to market and the need for an additional six-month clinical trial to demonstrate longer term efficacy. The details and scope of this small study, together with the development of the OTC label and patient leaflet, were discussed at a meeting in February 2021, with management awaiting the formal meeting minutes. 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.

OTC label requirements are complex but not expensive

The indications are that the patient numbers required for this supplementary study will modest, with active cooperation to determine the 'least burdensome design'. Developing the OTC label and associated patient information leaflet is a crucial process that seeks to minimise all risks; for example, consumer panels are employed to establish wording that is clear and unambiguous. Although multifaceted, the procedure is not expected to be a time limiting step. Management appears confident that a US OTC approval will be granted relatively smoothly.

First straight to OTC ED product with a promising clinical profile

Assuming a smooth regulatory pathway, MED3000 would be the first clinically proven ED product that is approved OTC in Europe and the US. 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. Management has conducted market research analyses that suggest sales of $500m three years' post-launch, rising to $584m by year five and $661m by year ten.

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

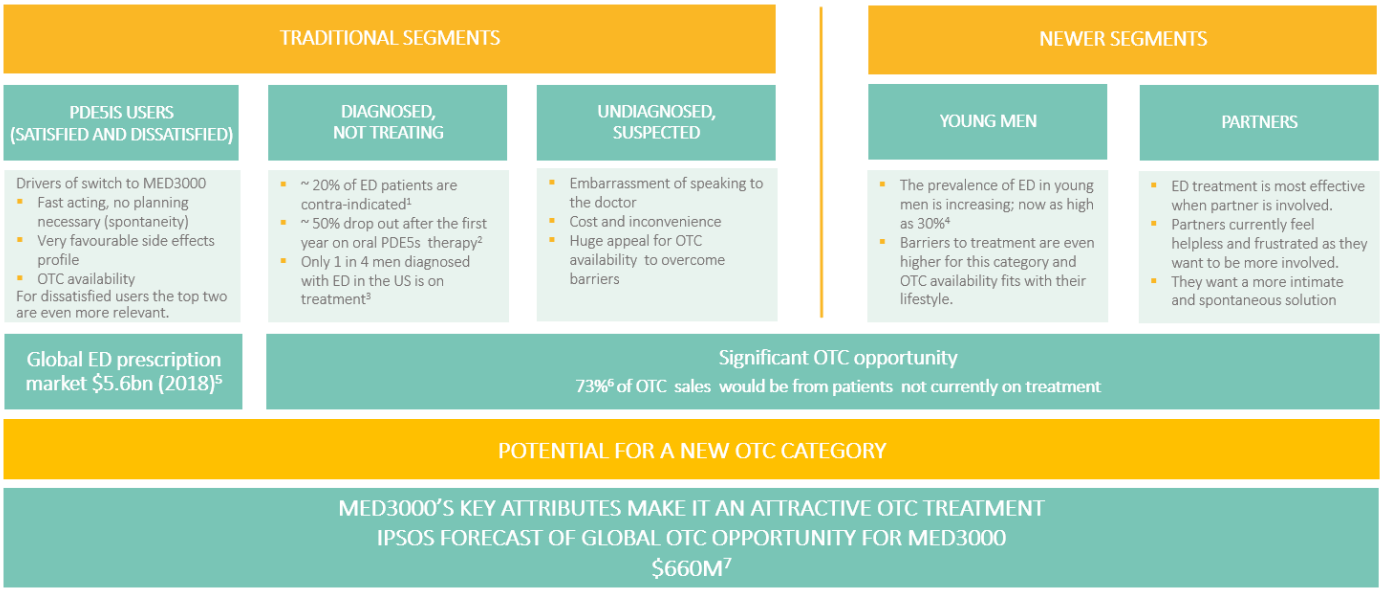
Source: Trinity Delta, Futura Medical

Our revised $618m peak sales estimate is still based on conservative assumptions

Our assumptions and expectations were detailed in our June 2020 Outlook report and, despite our conservative approach, we arrive at five-year sales for MED3000 of $225m in Europe and $250m in the US. As mentioned earlier, we have consciously ignored non-Europe and non-US markets until there was greater visibility on how they would be accessed. China and South East Asia represent the

largest potential user group in terms of volume, but the monetary value is likely to be tempered by lower pricing. We have, again using conservative assumptions, modelled on five-year sales of $143m for the region, with half of profits (equivalent to a 12.5% royalty based on a 25% net margin assumption) accruing to Futura Medical. We remind that using more aggressive assumptions, notably on having motivated and commercially astute partners, could result in materially faster adoption curves and higher peak sales (Exhibit 3).

Exhibit 3: 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

Valuation

Risk-adjusted DCF model is the best valuation tool

We use a DCF model to value Futura Medical. The key value driver is MED3000 and we examine its sales potential and launch timings in the US, European and now China & SE Asian markets. We assume that MED3000 has a high likelihood of being approved as an OTC medical device in Europe in the near-term, whereas in the commercially important US market we have been more cautious with our success probabilities and timings.

Assumed an income stream equivalent to a 20% royalty rate and 12.5% for China/SE Asia

We have assumed that 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 small upfront payments, sales milestones, and tiered royalties on sales. In China and SE Asia we have assumed 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)	165.2	127.1	63%	104.1	80.0	31.7	Peak sales: $225m Launch year: 2022
MED3000 (US)	163.2	125.5	54%	88.1	67.8	27.6	Peak sales: $250m Launch year: 2023
MED3000 (China / SE Asia)	51.2	39.4	59%	46.1	35.4	14.4	Peak sales: $143m Launch year: 2024
TPR100	2.3	1.7	40%	0.9	0.7	0.3	Peak sales: $6.2m Launch year: 2022
Non-R&D opex	(4.4)	(3.4)		(4.4)	(3.4)	(1.3)	
Net cash	1.3	1.0		1.3	1.0	0.4	At FY20e
Total	**378.8**	**291.3**		**236.1**	**181.5**	**73.1**	
Total (fully diluted)					**182.0**	**71.3**	Riverwood CLN and warrants

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 £181.5m, or 71.3p per share (fully diluted)

The effect of updating our model (Exhibit 4) sees our previous valuation for Futura Medical of £153.8m, or 60.9p per share, rise to £181.5m, or 73.1p per share (71.3p on a fully diluted basis).

The specifics of our Europe and US assumptions, and other details of our model, are covered in our last Outlook note (available on our website).

Exhibit 5: 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)	(1,989)	(2,135)
General and administrative expenses	(1,118)	(1,228)	(1,144)	(1,117)	(1,176)
Underlying operating profit	**(4,856)**	**(7,266)**	**(11,164)**	**(3,106)**	**(3,311)**
Other revenue/expenses	0	0	0	0	0
EBITDA	**(4,843)**	**(7,247)**	**(11,143)**	**(3,086)**	**(3,298)**
Operating Profit	**(4,856)**	**(7,266)**	**(11,164)**	**(3,106)**	**(3,311)**
Interest expense	19	28	22	4	3
Profit Before Taxes	**(4,837)**	**(7,239)**	**(11,141)**	**(3,102)**	**(3,308)**
Adj. PBT	**(4,837)**	**(7,239)**	**(11,141)**	**(3,102)**	**(3,308)**
Current tax income	936	1,358	2,222	569	491
Cumulative preferred stock dividend	0	0	0	0	0
Net Income	**(3,900)**	**(5,881)**	**(8,919)**	**(2,533)**	**(2,817)**
EPS (p)	**(3.2)**	**(4.5)**	**(4.4)**	**(1.0)**	**(1.1)**
Adj. EPS (p)	**(3.2)**	**(4.5)**	**(4.4)**	**(1.0)**	**(1.1)**
DPS (p)	**0.0**	**0.0**	**0.0**	**0.0**	**0.0**
Average no. of shares (m)	120.6	131.9	204.7	244.0	245.6
Gross margin	*100%*	*N/A*	*100%*	*N/A*	*N/A*
BALANCE SHEET					
Current assets	**9,541**	**10,830**	**4,842**	**1,616**	**5,443**
Cash and cash equivalents	8,363	9,158	2,511	974	4,880
Accounts receivable	181	306	101	65	65
Inventories	70	8	8	8	8
Other current assets	927	1,358	2,222	569	491
Non-current assets	**64**	**47**	**60**	**44**	**36**
Property, plant & equipment	64	47	60	44	36
Other non-current assets	0	0	0	0	0
Current liabilities	**(499)**	**(2,026)**	**(4,848)**	**(950)**	**(7,450)**
Short-term debt	0	0	0	0	(6,500)
Accounts payable	(499)	(2,026)	(4,848)	(950)	(950)
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**	**710**	**(1,971)**
Share capital	44,913	50,393	50,412	53,305	53,305
Other	(35,807)	(41,541)	(50,359)	(52,596)	(55,276)
CASH FLOW STATEMENTS					
Operating cash flow	**(4,155)**	**(4,680)**	**(6,634)**	**(4,590)**	**(2,589)**
Profit before tax	(4,837)	(7,239)	(11,141)	(3,102)	(3,308)
Non-cash adjustments	195	140	100	147	147
Change in working capital	(385)	1,464	3,027	(3,861)	0
Interest paid	19	28	22	4	3
Taxes paid	851	927	1,358	2,222	569
Investing cash flow	**(56)**	**(5)**	**(33)**	**(5)**	**(5)**
CAPEX on tangible assets	(56)	(5)	(33)	(5)	(5)
Other investing cash flows	0	0	0	0	0
Financing cash flow	**221**	**5,480**	**19**	**3,059**	**6,500**
Proceeds from equity	221	5,480	19	3,059	0
Increase in loans	0	0	0	0	6,500
Other financing cash flow	0	0	0	0	0
Net increase in cash	**(3,990)**	**795**	**(6,647)**	**(1,536)**	**3,905**
Cash at start of year	12,353	8,363	9,158	2,510	974
Cash at end of year	**8,363**	**9,158**	**2,510**	**974**	**4,880**
Net cash at end of year	**8,363**	**9,158**	**2,511**	**974**	**(1,620)**

Source: Company, Trinity Delta Note: Adjusted numbers exclude exceptionals. A £5m funding requirement is shown as short-term debt in FY21e, until transaction type, source and size are confirmed.

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