

# Futura Medical Update

# Earlier US Eroxon launch brings forward profitability

We have upgraded our revenue forecasts and valuation following interim results and the earlier and imminent US launch by partner Haleon, which we previously anticipated in 2025. The US launch, expected in October, will trigger a milestone and recurring royalties on net Eroxon sales. Commercial success in the US will be transformational, ensuring Futura's sustainable and growing profitability. Meanwhile, existing partners outside of the US continue to execute on launches, with Eroxon now available in over ten countries and further launches planned in H224 and into 2025. Real-world evidence remains consistent in terms of Eroxon's efficacy, and learnings from initial launches are being effectively utilised to refine marketing strategies in order to optimally target key audiences. This will likely be key for Eroxon's success, with encouraging signs from initial, albeit limited, repurchase rate data from first launches. Our Futura Medical valuation is increased to £392m, or 130p per share.

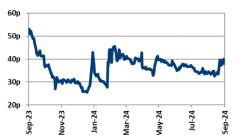
Year-end: December 31	2022	2023	2024E	2025E
Revenues (£m)	0.0	3.1	13.3	18.5
Adj. EBITDA (£m)	(6.2)	(4.1)	2.7	8.6
Adj. PBT (£m)	(6.2)	(4.2)	2.6	8.3
Net Income (£m)	(5.8)	(6.5)	0.5	7.1
EPS (p)	(2.0)	(2.2)	0.2	2.4
Cash (£m)	4.0	7.7	4.6	6.2

Source: Trinity Delta Note: Adjusted numbers exclude share-based payments and exceptionals

- US launch in October triggers revenue upgrades With Haleon confirming that Eroxon will be available in October in stores and online (online pre-orders are currently being taken for delivery next month), we have upgraded our revenue forecasts +45% to £13.3m in FY24e (from £9.2m), and +22% to £18.5m in FY25e (from £15.1m), in-line with management commentary. These are driven by the earlier than anticipated US launch, notably with increased milestones in both years. We caveat that forecasting revenues remains challenging given unpredictable launch dynamics (channel fill and stocking effects) and limited disclosure from partners (including variable milestone elements and undisclosed deal terms).
- More launches on the horizon Eroxon is now available in over ten countries, with further launches planned for Europe and RoW. Post-period, M8 Pharmaceuticals confirmed the first Latin America launch in Mexico. Futura continues to evaluate partnering opportunities in China and South-East Asia, with regulatory experience and consumer marketing credentials both important given regional complexities.
- Insights from first launches will be key for targeting optimal audiences Real-world evidence from four "home-user" studies has confirmed Eroxon's benefit is consistent with clinical trial data. This, together with market research insights, are helping to refine product positioning in order to optimally target an audience that is most likely to benefit from Eroxon, which should drive future reorder rates.
- Valuation updated to £392m or 130p/share Our NPV-based valuation has been updated following H124 results, and the imminent confirmed US launch. These lead to an increased valuation of £392m (from £371m) or 130p/share. The US remains the main component of our valuation, worth more than EU and RoW combined.

# 11 September 2024

Price	38.00p
Market Cap	£108.1m
Enterprise Value	£104.1m
Shares in issue	301.9m
12 month range	23.3-53.0p
Free float	61.4%
Primary exchange	AIM
Other exchanges	N/A
Sector	Healthcare
Company Code	FUM
Corporate client	Yes



### **Company description**

Futura Medical is the developer of innovative sexual health products; its core strength lies in its research, development, and commercialisation of topically delivered gel formulations. Lead product Eroxon (MED3000) is approved as an OTC product for ED (erectile dysfunction) in Europe and the US.

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# **Futura Medical: Commercial transition complete**

Futura Medical has delivered all the critical elements to position Eroxon, a topical gel treatment for erectile dysfunction (ED), for successful launches and uptake in the key EU and US markets. There are already encouraging reordering signs from first EU launches, and these experiences have helped fine-tune the positioning for roll-outs across other major markets. Launches by partners across other geographies will similarly tailor promotional activities to local market needs. Exciting as these are, the biggest commercial opportunity lies in the US, where launch is imminent by partner Haleon, the renowned consumer health specialist. Commercial success in the US or EU could be transformational, with the upcoming US launch ensuring Futura's sustainable profitability. Our valuation is £392m (130p/share).

Eroxon's unique features should lead to strong uptake in the significant ED market

Eroxon is a topical gel for ED (erectile dysfunction). It has demonstrated clinically relevant and consistent benefits across a broad spectrum of ED sufferers. In contrast to mainstay prescription ED treatments, Eroxon has a rapid onset of action, few side effects, no drug interactions, and most notably is available over-the-counter (OTC), ie without a prescription. Given these unique features, Eroxon should be an attractive treatment option for a wide range of ED patients. Commercialisation has been entrusted to consumer health specialists, with the notable partners being Cooper Consumer Health for Europe and Haleon (formerly part of GSK) for the US.

Forecasting revenues and tracking the launch remain particularly challenging

As we have previously highlighted, tracking Eroxon's launch and forecasting near-term revenues is, and remains, particularly challenging. This is owing to limited disclosure from partners, coupled with differing and unknown precise deal terms in various regions. An overview of the structure of the typical partnering deals that Futura has in place is shown in Exhibit 1; the US deal with Haleon is an IP licence model, whereas the deal with Cooper is a direct sales model. Whilst royalty income should correlate fairly directly with in-market sales, other components of Futura's revenues, such as non-recurring and unpredictable milestone income or manufacturing fees, will not.

**Exhibit 1: Futura typical partnering and operating models** 

	IP LICENCE MODEL	DIRECT SALES MODEL	
Manufacture	Licensee	Futura	
Regulatory and Quality	Licensee	Futura and Licensee	
Sales and Marketing	Licensee	Licensee	
We generate revenue through:	<ul><li>Royalty payments</li><li>Milestone payments</li></ul>	<ul><li>Direct sales</li><li>Milestone payments</li></ul>	

Source: Futura Medical



#### Hard to track reorder rates...

As Eroxon is available OTC and therefore without the ability to track prescription data, there is limited quantitative data in order to track repeat use. As an OTC product, consumers are able to purchase Eroxon from a variety of sources and are effectively anonymous. The only real data that could identify repeat purchases would be via loyalty card schemes; however, not all consumers (and particularly men) will be part of these schemes and there is also no guarantee that a repeat user will purchase Eroxon via the same source each time. Nevertheless, despite these limitations, initial (albeit limited) reorder data from the UK suggest a repurchase rate of 15-20%. This is hard to contextualise, although management commented that the repurchase rate for a consumer healthcare product would typically be within the 20-40% range and the repurchase rate for Viagra and Cialis is around 30%. We also note two observations:

- Initial pent-up demand may have included ED sufferers for whom existing PDE5is do not work, and thus are potentially less likely to benefit from Eroxon, and may therefore be unlikely to repurchase; and
- The UK market is unique (in terms of regions where Eroxon has been launched) as some PDE5is are already available OTC, and thus this increases competition (compared to markets where these are only available with a prescription), which may also impact the reorder rate.

Hence, we believe the initial UK repurchase rate is encouraging at this stage, and should improve as marketing is refined to target users that are more likely to benefit. Market research and learnings that are being implemented in order to target Eroxon more effectively are summarised in Exhibit 2.

...but initial signs are encouraging in the context of the UK market and launch

## **Exhibit 2: Market research observations**

- Clinical studies show improved satisfaction of around 30% when used as part of foreplay yet only 1 in 2 men are using Eroxon this way
- Satisfaction levels are higher in men less than 60 years old and especially in the 30 to 45 age group
- Satisfaction levels are also higher between couples rather than in single men using Eroxon on a date or solo use
- 1 in 5 men are unnecessarily using Eroxon to pre-empt activity, rather than using the treatment spontaneously or indulging in foreplay
- Not using the entire contents of the single dose Eroxon tube
- Side effect profile remains extremely low with a reported incidence rate of less than one in 14,000 packs and all side effects non-serious

Source: Adapted from Futura Medical

Haleon appears to be incorporating these learnings in their materials

With Haleon preparing for imminent US launch, an <u>Eroxon</u> product website is now available and contains imagery depicting younger males and couples. This seems to suggest that these learnings are being incorporated into Haleon's marketing and product positioning.

Launches continue ex-US, with more to come

Outside of the US, Eroxon has been launched in ten countries, including France, Italy and Spain with Cooper Consumer Health. In the Middle East, Labatec has launched in two markets. In Central and Latin America, a digital launch was started in Mexico in mid-August with a store roll-out to follow.



Partnering interest is high in China and Asia, but complicated by regulatory requirements In China and South-East Asia, interest levels from potential partners remain high. The key criteria for securing any deals include finding a partner with appropriate consumer marketing credentials and market reach, plus an understanding of what is likely to be complex and nuanced regulatory processes as these regions may require additional trials to be completed. This is now the case in South Korea where regulators have outlined that Eroxon will be classified as a drug, requiring further clinical studies. Because of this regulatory requirement, this market is not currently being progressed and the deal with Menarini for South Korea has consequently been terminated.

Update on initial proof-ofconcept work for Eroxon range extensions expected by YE24 Beyond these Eroxon launches, part of Futura's strategy is to broaden the product range and Futura is also exploring potential range extensions (which is of interest to existing commercial partners). In the near-term, this includes completing initial proof-of-concept studies whilst remaining mindful of costs. We expect an update on these before the end of this year.



# **Valuation and Financials**

Updated NPV valuation of £392m, or 130p per share

We value Futura Medical using a sum-of-the-parts NPV (net present value), including various assumptions for Eroxon in the main geographies (US, Europe, and Other Regions). These are summed and netted against core costs and cash. Our NPV has been updated to reflect the earlier than anticipated US launch, plus we have incorporated the last reported cash position and rolled forwards in time. These lead to a Futura Medical valuation of £392m, equivalent to 130p per share (Exhibit 3). For more on our valuation methodology see our April 2024 Outlook.

**Exhibit 3: Futura Medical NPV valuation** 

	Year of Launch	Partner	Peak Sales (\$m)	NPV (\$m)	NPV (£m)	NPV/ share (p)
Eroxon (US)	2024	Haleon	356	270.7	225.6	74.7
Eroxon (Europe)	Launched	Cooper	132	153.9	128.2	42.5
Eroxon (Other Regions)	Launched	Various	102	66.8	55.7	18.4
Non-R&D OpEx				(25.3)	(21.1)	(7.0)
Net cash				4.7	3.9	1.3
Total				470.8	392.3	130.0

Source: Trinity Delta Note: Assumptions include a 10% discount rate; a 1.2 \$/£ FX rate, and 10% tax rate from 2027 with the benefit of the UK patent box

# Revenues upgraded on earlier US launch

Following H124 interim results (discussed in our <u>September 2024 Lighthouse</u>) we have increased our FY24e revenue forecast to £13.3m (from £9.2m), which reflects inclusion of a \$5m/£4m milestone from Haleon on US launch (which we previously included in FY25), initial first recurring royalties on US sales of £0.5m, whilst slightly lowering our EU/RoW revenue forecasts to £5.5m (from £6m), given unpredictable launch dynamics and stocking. Our updated FY25e revenue forecast is £18.5m (from £15.1m) which comprises slightly lower product sales and royalties of £10.5m (from £11.1m), albeit the mix has shifted with higher US royalties, whilst electing to conservatively keep EU/RoW product revenues broadly flat vs FY24e. Our FY25e forecast also now includes two milestones of c \$5m/£4m. A breakdown of our revenue forecasts are shown in Exhibit 4.

**Exhibit 4: Revenue forecast breakdown** 

£m	2023	2024e	2025e
Product sales & royalties	3.1	6.0	10.5
Milestones	0.0	7.2	8.0
Total revenues	3.1	13.3	18.5

Source: Trinity Delta

With only minor adjustments to core operating expenses (R&D and G&A), the higher revenues drive a swing to a net profit in FY24e to £0.5m, with FY25e increased to £7.1m (Exhibit 5). Our updated forecasts are in Exhibit 6.

**Exhibit 5: Summary of main changes to forecasts** 

£m	2023A		2024E	2025E			
		Old	New	% Change	Old	New	% Change
Revenues	3.1	9.2	13.3	+45%	15.1	18.5	+22%
Adj. EBITDA	(4.1)	(1.1)	2.7	N/A	4.0	8.6	+115%
Net Income	(6.5)	(3.1)	0.5	N/A	2.5	7.1	+186%

Source: Trinity Delta



**Exhibit 6: Summary of financials** 

Year-end: December 31	£'000s	2021	2022	2023	2024E	2025E
INICOME CTATEMENT						
INCOME STATEMENT				0.404	40.050	40.450
Revenues		0	0	3,101	13,259	18,452
Cost of goods sold  Gross Profit		0	0	(1,327)	. , ,	
		(2.774)	(4.121)	1,774		
R&D expenses		(3,774)	(4,131)	(2,046)		
General and administrative	expenses	(2,092)	(2,740)			
o/w stock options		(182)	(672)	(2,720)		
Other revenue/expenses		(5.044)	0	0	(40)	0
Operating Profit		(5,866)	(6,871)		(48)	6,621
EBITDA		(5,847)	(6,847)			7,080
Adj. EBITDA		(5,665)	(6,175)			8,631
Interest expense		(5.044)	0	72	154	93
Profit Before Taxes		(5,866)	(6,871)		106	6,714
Adj. PBT		(5,684)	(6,200)			8,265
Current tax income		909	1,025	379	409	417
Net Income		(4,958)	(5,846)	(6,513)	515	7,131
EPS (p)		(1.83)	(2.03)	(2.21)	0.17	2.36
Adj. EPS (p)		(1.76)	(1.80)	(1.29)	1.00	2.88
DPS (p)		0.00	0.00	0.00	0.00	0.00
Average no. of shares (m)		271.0	287.5	294.9	301.6	301.9
Gross margin		N/A	N/A	57%	73%	82%
BALANCE SHEET						
Current assets		11,360	5,315	9,332	6,879	15,097
Cash and cash equivalents		10,373	4,026	7,714	4,626	6,212
Accounts receivable		79	266	1,240	1,653	8,291
Inventories		0	0	0	193	179
Other current assets		908	1,023	377	407	415
Non-current assets		443	1,158	2,485	4,169	4,493
Property, plant & equipment	t	443	1,158	2,485	4,169	4,493
Other non-current assets		0	0	0	0	´ 0
Current liabilities		(2,078)	(1,753)	(6,340)	(2,554)	(2,413)
Short-term debt		, o	0	v o	v o	· o
Accounts payable		(2,078)	(1,753)	(6,340)	(2,554)	(2,413)
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		9,725	4,720	5,477	8,495	17,177
Share capital		66,952			71,672	
Other .		(57,228)	(62,402)	(66,195)	(63,177)	(54,494)
	_					
CASH FLOW STATEMENT	S	(0.070)	/F 775\	F70	(4.400)	0.070
Operating cash flow		(3,873)	(5,775)	570	(1,130)	2,369
Profit before tax		(5,866)	(6,871)	(6,892)	106	6,714
Non-cash adjustments		202	697 (512)	2,828	2,622	1,918
Change in working capital		1,272	(512)	3,612	(4,391)	(6,764)
Interest paid		0 510	0	1 000	154	93
Taxes paid		519 (420)	910 (741)	1,023	379	409
Investing cash flow		(420)	<b>(741)</b>	(1,434)		(783)
CAPEX on tangible assets		(420)	(741)	(1,506)	(1,958)	(783)
Other investing cash flows		0 12447	0 170	72 4 550	0	0
Financing cash flow		13,647	170 170	4,550	0	0
Proceeds from equity		13,647	170	4,550	0	0
Increase in loans		0	0	0	0	0
Other financing cash flow		0 254	0	0	(2.000)	0 1 507
Net increase in cash		9,354	(6,346)	3,686	(3,088)	1,586
Exchange rate effects		1.010	10.272	4.024	7 71 4	0
Cash at start of year		1,019	10,373	4,026	7,714	4,626
Cash at end of year		10,373	4,026	7,714	4,626	6,212
Net cash at end of year		10,373	4,026	7,714	4,626	6,212

Source: Company, Trinity Delta Note: Adjusted numbers exclude share-based payments and exceptionals



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