Futura Medical plc

Futura confirms it has agreed an early termination fee of US$1.9m* with Haleon plc (LSE: HLN), the Group's exclusive US commercial and marketing partner. This follows discussions that commenced between the two parties back in November 2025 relating to alternative, potentially third party, commercial and distribution strategies/arrangements for the territory. Under the terms of the agreement, Futura has waived its right to the US patent milestone payment for Eroxon® in exchange for the return of the US commercial rights, including those related to use of associated marketing materials generated by Haleon. In tandem, it has also reached agreement with a highly suitable alternative partner, New Jersey-based Market Performance Group ('MPG'), to take control of Eroxon® product distribution across the US. MPG is a well-positioned and highly motivated, leading omnichannel commerce agency that helps brands accelerate profitable growth across retail and eCommerce channels, serving as a trusted partner to many leading health and wellness brands throughout the country. Assuming early receipt from Haleon and subject to certain variables (including anticipated receipt of its annual R&D tax credit, male product sales remaining on current trend etc.), the Group's working capital runway now appears sufficient to sustain operations into October 2026. Noting the material uncertainty statement related to going concern that accompanied Futura's 2025 audited accounts the Board, as previously announced, continues to actively consider a number of dilutive and non-dilutive funding and strategic initiatives to extend the Group's cash runway.

**GBP=1.32US$*

MPG expertise in health, wellness & personal care sectors

MPG is a leading omnichannel commerce agency delivering integrated commercial solutions that accelerate profitable brand growth. Its highly experienced team connects brands with consumers across the 'full funnel' commerce landscape, delivering right-sized strategies, strategic go-to-market plans, advanced analytics and deep retailer relationships. With clear expertise and focus on the health, wellness and personal care sectors, MPG manages US$billions in annual retail sales on behalf of its clients. Through their brand development and innovation arm '(MPG Possibilities'), MPG already builds and launches products that fall under the sexual wellness umbrella, including OTC libido enhancement pills/reproductive health and fertility supplements, premium lubricants and intimate washes, alongside which Eroxon® should sit neatly on retailers' shelves.

Futura's distribution agreement with MPG differs from the US commercial and marketing partnership it had with Haleon. The return of the US rights gives Futura the flexibility to pursue the US Eroxon® opportunity on more beneficial commercial terms and to move forward with MPG, which will provide the focus needed to distribute and support the product effectively in the key US market. Haleon's significant past investment (estimated in excess of US$40m*) in Eroxon® plus transfer of marketing assets/domain names, etc. will provide it with a 'running start' into this obvious market opportunity.

Male product demand may be bolstered early in 2027

Futura's Distribution Agreement with MPG will commence from 1 September

Stock Data

Share Price:	0.58p
Market Cap.:	£3.37m
Shares in issue:	581.33m
52 week high/low:	15.00p/0.50p

Company Profile

Sector:	Health Care
Ticker:	FUM
Exchange:	AIM

Activities

Futura Medical plc ('FUM', 'Futura', 'the Group') is the developer of innovative sexual health products, including lead product Eroxon® along with development products Eroxon® Intense and WSD4000.

www.futuramedical.com/

1-year share price performance

5-year share price performance

Source: *LSE*

Past performance is not an indication of future performance.

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when the Transitional Services Agreement ('TSA') period agreed with Haleon ends. There is not expected to be any disruption to existing US retailer listings or availability of stock prior to the passing of control. The marketing and promotional drive MPG can then be expected to kick-off early in Q4 2026 across the largest global market for erectile dysfunction ('ED') is, however, expected to coincide with the FDA's US launch clearance of Futura's Eroxon® derivative, Eroxon® Intense, for which it also assumes responsibility. In their selected demographic, both Eroxon® and Eroxon® Intense were judged to have high efficacy rates. Results from a Home User Test ('HUT') released on 29 March 2026 , however, confirmed that Intense's prototype formulation compared positively with the original product. Detailing an overall improvement on the original Phase 3 study for Eroxon®, the HUT also provided confidence that the new Intense formula delivers a statistically significant greater sensorial effect over the original formulation, particularly in the first two minutes after application. It was also able to confirm that a more targeted marketing approach to consumers under 60 years of age with mild to moderate ED will likely lead to improved efficacy and satisfaction rates, thus offering potential for higher in-market repeat purchases.

With Eroxon® Intense expected to be placed on retailers' shelves during Q1 2027, a phase of stock building amongst drugstores, pharmacies, large chains and wholesale clubs (including CVS Pharmacy, Walgreens and big box retailers like Walmart) that is likely to gather pace toward the year end, possibly even generating Christmas and New Year interest from US users. With EU launch approval expected to precede the FDA by a month or two, a similar lift demand throughout the region may be encountered toward the year end. Based on retailer-supplier payment terms (typically net 60 or 90 days post invoice across both territories), Futura may register an improved cash position during the opening months of 2027, although of course sustaining this into following quarters remains dependent on sustained repeat purchases.

Two key WSD4000 studies for female sexual dysfunction ('FSD') expected imminently

Results from Futura's two key WSD4000 studies for FSD (an in-clinic placebo-controlled sensory study and a 200-subject HUT) are expected to be released imminently. These have been designed to inform the design of a single pivotal Phase 3 clinical study and follow highly positive initial data from the Early Feasibility Study ('EFS') released in January 2026 demonstrating statistically significant improvements in overall sexual function. Based on the male Eroxon® precedent to secure OTC clearance, required cohorts could range up to 500 subjects. This implies trial costs in the range of US$4m to US$6m*, to which additional scientific studies to support the FDA submission might possibly increase manufacturing and monitoring overheads by a further c.US$0.7m*. Subject to the Group securing such funding and receiving detailed FDA trial design guidelines, primary clinical evidence for safety and efficacy generated is expected to enable it to submit a De Novo request. Since no predicate device exists for an OTC female sexual health topical gel, this pathway allows the FDA to establish a brand-new medical device product code. Futura plans to run a parallel regulatory track for European CE Mark approval, mirroring Eroxon®'s dual-region commercialisation rollout strategy with targeted commercial launch in Q1 2028.

Assuming a positive outcome from the two WSD4000 studies, the product offers potential to become an effective breakthrough treatment, with significant commercial opportunity in a market where no other regulated OTC treatments are available. The two FDA-approved (prescriptive) drugs for presently available for treating FSD have to date registered disappointing sales. Flibanserin (Addyi) and Bremelanotide (Vyleesi) both target hypoactive sexual desire disorder (albeit for different demographics). Flibanserin is a daily pill taken at bedtime that works on brain neurotransmitters to increase desire; it introduces side-effects including low blood pressure, dizziness, drowsiness, fatigue and upset stomach while requiring the avoidance of alcohol and the medication fluconazole (Diflucan); Bremelanotide is an injectable that is administered before sexual activity that works by stimulating melanocortin receptors, but can only be administered up to 8 times/month and can cause nausea, vomiting, flushing, headache plus a skin reaction at the injection site. The fact that many women are not routinely prepared to discuss/seek treatment with/from their doctor for such a highly personal issue, along with concern regarding side effects, seems to be the reason for their market performances to have been considerably lower than initial predictions. Launched in 2015, Addyi sales are believed to have been just 10% or less of their originally projected market of up to US$300m/year*; Vyleesi has reported similarly, producing a gross product sales figure of just US$12.5 million* for the year ended June 2023.

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This suggests there remains a significant unmet need in this area. In the US alone, it is estimated that 34m women are presently incurring symptoms of sexual dysfunction. Of these, between 40% and 60% highlighted specific symptoms and were sufficiently motivated to seek a solution, even if 2 in 3 then went on to express dissatisfaction with the outcome. Diseases such as dyspareunia and related arousal conditions are most evident among menopausal women globally, owing to a decrease in circulating oestrogen concentrations following the change of life. Such hormonal changes plus varying physiological attributes, including age and depression, increase prevalence, which is compounded further by the rising number of chronic disorders (i.e., cancer, diabetes or cardiovascular disorders) amongst females. The fact that sector researchers and forecasting institutes produce a wide range in terms of current and projected market size for the global FSD treatment market, points to a lack of both familiarity and reliable background statistics. Eliminating the outliers, a consensus of available published reports indicates a 2025 global market size (albeit overwhelmingly dominated by the USA) of a US$550m*, although it is projected to deliver a quite dramatic CAGR (of c.13.6%) out as far as 2034. Contributing factors behind these data include increased awareness of sexual health, availability of related research and a growing demand for both therapeutic solutions, which suggests they are still underestimating the true scale of the global sales opportunity.

A new patent for WSD4000 was filed in February 2024, with the potential for further filings based on the outcomes of ongoing studies. The innovation behind WSD4000 falls outside of existing commercial partner agreements for Eroxon®.

Strategic review and funding options

The conclusion of the Board's Strategic Review was detailed with the Group's Full Year results to 31 Dec 2025. It concluded that Futura will move from a 'launch and step back' model focused on R&D and full out-licensing, to an 'actively manage and optimise' model focused on a hybrid R&D and commercial approach which will provide greater flexibility, insight development/sharing and improved economic participation across markets.

In order to keep to its target schedule for, amongst other things, WSD4000 to enter Phase 3 trials in Q1 2027, with completion expected in Q3 2027 followed by regulatory approval around year end, TPI estimates Futura will likely need to plug an overall funding gap of as much £7.5m during Q4 2026. This should be sufficient to support clinical development and ongoing commercialisation of both its male and female product offerings. Having stated that the Group continues to actively consider a number of dilutive and non-dilutive funding and strategic initiatives to extend its operating runway, the cash sale of a milestone and royalty-based licence for WSD4000 or otherwise the securing of a regional partnership agreement(s) for the product with an interested party(ies) to cover such outgoings appears presently to be the most obvious solution.

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