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Futura Medical PLC
05 April 2023

5 April 2023

Futura Medical plc
("Futura" or the "Company")

Full Year Results for the year ended 31 December 2022

Futura Medical plc (AIM: FUM), a pharmaceutical company developing a portfolio of innovative products based on its proprietary, transdermal DermaSys® drug delivery technology and currently focused on sexual health and pain, is pleased to announce its audited results for the year ended 31 December 2022.

Operational Highlights

MED3000 - Regulatory

- **Europe:** MED3000, brand name Eroxon® is the first pan-European topical treatment for erectile dysfunction ("ED") available without the need of a doctor's prescription and available over the counter ("OTC").
  - In April 2022, Futura received approval for a UKCA mark for Eroxon®, supplementing the CE Mark approval received in April 2021.
- **USA:** In August 2022, Futura received highly positive results from the confirmatory Phase 3 clinical study, ("FM71") for MED3000 for the treatment of ED meeting all primary and secondary endpoints.
  - Results demonstrated that MED3000 presents an effective clinically proven treatment for ED with a rapid speed of onset and a favourable benefit versus risk profile ideally suited for OTC classification.
  - In October 2022, Futura filed a regulatory dossier with the US Food and Drug Administration ("FDA"), for marketing authorisation for MED3000 as De Novo Medical Device - with the potential to be the first major ED treatment available OTC in the USA.
- **Middle East**: In December 2022, Futura announced that MED3000 had received marketing authorisation in three Middle Eastern countries including the United Arab Emirates ("UAE").

MED3000 - Commercialisation and Manufacturing

- Futura signed multiple commercial agreements across key markets.
  - In March 2022, Futura entered into a licensing agreement with Menarini Korea, a wholly owned subsidiary of Menarini Group, for the exclusive rights to commercialise MED3000 in South Korea.
  - In May 2022, Futura entered into an exclusive licensing agreement with Cooper Consumer Health ("Cooper") for the rights to commercialise Eroxon® throughout the European Economic Area, the United Kingdom and Switzerland.
  - In December 2022 Futura formally commenced the search for a US partner ahead of planned FDA approval and continues to be engaged in several ongoing discussions.
  - Futura's contract manufacturing supply chain is now ready for commercial production, with capacity for initial launch supplies of Eroxon® and beyond.
  - In September 2022, the first production order of Eroxon® was received to fulfil initial launches through Futura's European and UK distribution partner.
  - First production orders for initial launches of Eroxon® in the Middle East, which are planned for 2023, were also received from its Middle Eastern distribution partner.
- In Q2 2022, as part of its overall IP protection strategy, Futura filed national patent applications considered necessary to protect the commercial interests of MED3000 in line with normal PCT filing procedures in all key ED markets. If successful, this will provide patent protection until 2040.

MED3000 - Environmental awareness and education

- In October 2022, Futura attended the joint meeting of the Sexual Medicine Society of North America and the International Society of Sexual Medicine in Miami.
  - An Advisory Panel meeting comprised of eight world renowned experts discussed MED3000's clinical data, its unique mode of action and how it could be used as a treatment alternative for ED. This panel acknowledged MED3000 as a potential, safe, fast-acting and effective treatment for addressing the medical unmet need of many men with ED without the requirement for a doctor's prescription.

Post period Highlights

- Formal production batches of Eroxon® successfully completed and initial retail and online launches of Eroxon® in Europe have now commenced with further manufacturing orders received.
- MED3000 has been granted initial marketing authorisation in the Middle East, which now covers four Middle Eastern countries including the UAE. Further approvals are expected in 2023 alongside initial launches, where regulatory approval has been received, under the Eroxon® brand.
- In February 2023, Futura presented MED3000 data in a Poster presentation at the European Society for Sexual Medicine Congress in Rotterdam.
  - The Poster presented the positive FM71 Phase 3 study results, announced in August 2022.

  - There was an Eroxon® stand at the congress where good interest was received from congress attendees who welcomed the new innovation in ED.
- In March 2023, Futura announced that MED3000 was under active review with the FDA, including a recent meeting, regarding US marketing authorisation. As a regular part of its review process, the FDA asked some additional questions and requested some non-clinical confirmatory data, to which the Company has provided a full response and the requested confirmatory data to enable the FDA to complete its review. Based on the FDA's published target review period guidelines to include time to review the newly provided information, grant of the De Novo request is now expected to be achieved in Q2 2023.

Financial Highlights

- Net loss of £5.85 million in period of which £4.13 million was related to R&D (2021: Net loss £4.96 million)
- Cash resources of £4.03 million including
- £1.02 million tax credit refund due mid 2023
- Current cash runway extends beyond initial Eroxon® launches expected over the next year and expected US regulatory approval in 2023.

James Barder, Chief Executive Officer, Futura Medical said: "2022 has been a year of significant progress as we have moved steadily towards the initial launch of Eroxon® which I am now delighted to say commenced in March 2023. This is a milestone achievement for the Company and a testimony to the dedication, tenacity and hard work of a small, loyal and highly professional team at Futura. We are proud and excited for Eroxon® to have now commenced launch for what we believe will become the world's first fast-acting clinically proven topical gel treatment for ED available without the need of a doctor's prescription.

We continue to focus on achieving US regulatory approval in the near term and progressing commercial discussions. We look forward to updating shareholders during 2023 as well as reporting first meaningful revenues at our interims in September 2023."

Webcast
The Executive Team will host a webcast of the presentation which will be available within the Investor Centre section of the Futura company website at www.futuramedical.com from 10.00am BST on 5 April 2023.

For further information please contact:

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About Futura Medical plc

Futura Medical plc (AIM: FUM), is a pharmaceutical company developing a portfolio of innovative products based on its proprietary, transdermal DermaSys® technology. Each DermaSys® formulation is separately patented and specifically tailored for the selected indication and application, as well as being optimised for clinical efficacy, safety, administration and patient convenience. The products are developed for the prescription and consumer healthcare markets as appropriate. Current therapeutic areas are sexual health, including erectile dysfunction, and pain relief. Development and commercialisation strategies are designed to maximise product differentiation and value creation whilst minimising risk.

MED3000 is Futura's topical gel formulation that is a novel treatment for erectile dysfunction ("ED") through a unique evaporative mode of action. Futura has previously conducted an initial Phase 3 study using MED3000 in ED, referred to as "FM57" which enabled Futura to be granted a CE Mark in 2021. A second confirmatory Phase 3 clinical study, "FM71" was also conducted to support Futura's regulatory submission to the FDA with 96 ED patients and endpoints at 24 weeks, demonstrating that MED3000 presents an effective clinically proven treatment for ED with a rapid speed of onset and a favourable benefit versus risk profile ideally suited for OTC classification.

Eroxon® is CE marked in Europe and UKCA marked in the UK as a clinically proven topical treatment for adult men with erectile dysfunction under the brand Eroxon® with a key claim of "Helps you get an erection within 10 minutes".

Eroxon® is the agreed brand name in certain regions such as the EU whereas MED3000 continues to be the internal code name used by the Company and also in reference to countries where regulatory approval or commercial distribution agreements have not yet been achieved. www.eroxon.com

Futura is based in Guildford, Surrey, and its shares trade on the AIM market of the London Stock Exchange. www.futuramedical.com

Chairman's Statement

With initial commercialisation now underway, our focus remains on execution in an exciting market segment.

Futura continues to transform into a potentially high growth Company now in commercialisation phase and poised for first reported revenues in 2023.

In 2021 we expanded the Board's international commercial consumer expertise with the appointment of Jeff Needham and Andrew Unitt as Board Directors. They have, in conjunction with the entire Futura team, brought their considerable OTC market expertise and exceptional skills in strategic development and business management to bear in a multitude of ways. This covers the full breadth of activities that go hand in hand with the launch of an exciting and innovative product such as: working with and supporting partners' marketing, patient and physician awareness and education efforts, ensuring seamless manufacturing and supply with an eye on future demand for Eroxon®/MED3000 and a focus on commercial partnering, particularly in terms of first gaining FDA approval and then leveraging this de-risking event to optimise a US partnering deal.

The USA is the biggest potential OTC market for ED treatments, and we are committed to achieving success there, particularly with an innovative product that has demonstrated the ideal characteristics for an OTC treatment and a rapid speed of onset which could vastly improve access to treatment for the 22 million men suffering from ED[1], particularly with mild to moderate ED. Whilst some hurdles still exist with regards to the US FDA granting marketing authorisation and Eroxon® launching commercially in the US, we are confident that we will be able to successfully execute on the strategic objectives and make Eroxon® available to consumers.

2022 was a busy year for execution. I would like to thank Futura's shareholders for their continued support and Futura's employees for their unstinting efforts in driving forward the progress of the Company.

John Clarke
Non-executive Chairman

Chief Executive Officer's Review

A year of regulatory progress and commercial activities for MED3000, as we prepared for initial launches of Eroxon® which commenced in March 2023.

2022 has been another strong year, building on the transformational progress and momentum achieved during 2021. The two major highlights were our partnering deal for the commercialisation of Eroxon® in the EEA, the UK and Switzerland with Cooper Consumer Health, ("Cooper"), a leading European independent self-care organisation, and delivering highly positive data from the confirmatory "FM71" Phase 3 study of MED3000 in ED.

In May 2022 we were excited to announce the exclusive licensing agreement with Cooper, for the rights to commercialise Eroxon® throughout the European Economic Area ("EEA"), the United Kingdom ("UK") and Switzerland. As part of our close strategic partnership and in line with our expectations we are pleased to confirm that from 1 April 2023 Eroxon® became available in our first market in "bricks and mortar" stores and retail pharmacies, supported by marketing and advertising with a second launch to follow shortly. Eroxon® is also available online throughout Europe.

As the retail roll-out around Europe continues and gains momentum, we will provide high level updates but would like to remind our shareholders that for commercial reasons our distribution partners may ask us not to disclose launch timings and some learnings from individual markets. However, we look forward to reporting revenues for the first time with our interim results in September 2023.

Futura now has a strong and expanding distribution platform in place for regions outside the key US market. Having signed two commercial agreements in 2022, adding to those from 2021, Futura now has licensing agreements in place in key markets throughout the EEA, the UK, Switzerland, the Gulf Co-operation Council (GCC) region, Latin America and South Korea.

As announced in September 2022, Co-High Investment Management Limited, has been unable to deliver on the key development and regulatory milestones previously set out in the agreement which both companies entered into in March 2021 and matters have not progressed. As the awareness of MED3000 spreads within the pharmaceutical industry we continue to receive growing interest from a number of other potential parties for the commercialisation of MED3000 in South East Asia, including China as well as other countries where MED3000 is not yet out-licensed. Our priority remains the US OTC market, as the biggest potential OTC ED market in the world, nevertheless discussions are also ongoing elsewhere and we look forward to providing shareholders with updates in due course.

Marketing authorisation has now been received in four Middle Eastern countries and initial launches are now planned in the Middle East in the second half of 2023. Our partners are taking a measured and controlled approach, which we fully endorse, in launching this new product, and there will undoubtedly be some learnings given the sensitivities around the need for, and purchasing of, an ED treatment. We must be mindful of these to ensure we position Eroxon® in the most appropriate way in different countries and diverse cultures, as this will enable us to maximise the success of future launches of such a truly innovative and accessible product.

With regards to manufacturing, the first production runs of Eroxon® have been completed and have been successfully delivered, enabling initial launches as planned. In addition, a number of other orders are in the process of being manufactured. It is essential that Futura has a robust supply chain, and we are currently evaluating additional manufacturers in both Europe and the USA to provide greater supply certainty and inter-manufacturer competition, as well as additional capacity based on both Futura and commercial partners' sales projections moving forwards.

As the initial launches and strategic scale-up of commercialisation of Eroxon® continue in 2023, we hope to be able to transform the lives of ED sufferers around the world with our novel fast-acting OTC treatment.

Results from the "FM71" study were in line with data generated in the previous 1,000 patient, "FM57" Phase 3 clinical study and broadly comparable with data from a "real world" home use study conducted by one of Futura's distribution partners. Safety and tolerability data were highly positive, with no serious adverse events recorded in any subjects on MED3000 and overall, a highly favourable side effects profile. All primary and secondary endpoints were achieved at 24 weeks, notably showing a clinically important improvement in erectile function across mild, moderate and severe ED sufferers, as well as statistically significant improvement in erectile function compared to baseline. Furthermore, a secondary endpoint showing a 10-minute onset of action was met, demonstrably faster than the well-known US prescription oral medication used in a comparator treatment arm of the study.

Accumulated MED3000 clinical data demonstrates that the product presents an effective treatment option with a rapid onset of action and a favourable risk versus benefit profile ideally suited to men with mild to moderate ED. MED3000 is expected to provide an alternative to existing ED treatments, that require a doctor's prescription, for those men seeking fewer systemic side-effects, and a spontaneous intercourse experience.

Data from this confirmatory clinical study, FM71, alongside additional data from FM57, supports the US regulatory submission for MED3000 as a medical device for ED treatment. In March 2023, Futura announced that MED3000 was under active review with the FDA, including a recent meeting, regarding US marketing authorisation. As a regular part of its review process, the FDA asked some additional questions and requested some non-clinical confirmatory data to which the Company has provided a full response and the requested confirmatory data to enable the FDA to complete its review. Based on the FDA's published target review period guidelines to include time to review the newly provided information, grant of the De Novo request is now expected to be achieved in Q2 2023.

Achieving FDA approval remains a critical focus as it will significantly de-risk MED3000 and optimise the negotiating position as discussions regarding US commercialisation rights progress.

In early 2023, Futura personnel, alongside representatives from our commercial partners, attended the European Society for Sexual Medicine Congress in Rotterdam where we presented clinical data on MED3000. We co-hosted an Eroxon® stand and were pleased with the positive interest from congress attendees who welcomed the new innovation in ED. It is an exciting prospect that we are bringing a truly unique and differentiated treatment option to the market.

The Company is currently fully focused on achieving MED3000 FDA approval and US launch, however post approval, our attention will move towards the next stage of innovation as we look to extend the Eroxon® pipeline and grow the business further.

2023 is going to be an exciting and pivotal year for the Company, with several further significant milestones expected, including first reported revenues and we look forward to providing further updates to shareholders as Eroxon® is launched in a growing number of countries and we continue to sign further commercial agreements and expand our business globally.

James Barder

Chief Executive Officer
On behalf of the Board

Operational Review

DermaSys® - Futura Medical's innovative, proprietary patented transdermal technology platform

Futura's unique patented technology DermaSys® is designed to deliver clinically proven effective medical treatments via the skin.

DermaSys® is a versatile and bespoke technology. Each product is uniquely formulated using the DermaSys® platform with volatile solvent component formulations tailored for each product to suit the specific therapeutic indication and desired speed of onset and duration of action. Such targeted delivery offers an optimised profile in terms of dose, onset time and duration of effect, as well as an improved safety profile reducing the risk of side effects. Each product is formulated to maximise its benefits for patients and consumers. Each new unique formulation offers the opportunity for additional patent applications and potential patent protection.

MED3000 - Futura's novel, fast acting topical gel formulation for the treatment of Erectile Dysfunction ("ED")

MED3000 is CE marked in Europe and UKCA marked in the UK, as a clinically proven topical treatment for adult men with ED that helps men get an erection within 10 minutes. Studies have shown MED3000 to be an effective treatment for ED with an excellent safety profile. MED3000 has a unique physical evaporative mode of action which the Company believes stimulates nerve endings in the glans penis to cause an erection.

Faster than on-demand oral tablet phosphodiesterase-5 inhibitors ("PDE5i's" - oral treatments for the treatment of ED such as Viagra®, Levitra ® and Cialis ® and their generic equivalents), MED3000 has significant benefits allowing spontaneous rather than pre-planned sexual intercourse.

The prevalence of ED disrupts the lives of at least 1 in 5 men globally[2] with around 22 million men suffering ED in the US and 20 million men in the UK, France, Italy, Spain and Germany[1]. There has been little innovation in ED treatments for nearly two decades and many patients continue to suffer dissatisfaction with existing treatments. The US market, in particular, continues to evolve following the expiry of the PDE5i's patent protection and the advent of subscription services such as For Hims and Go Roman which offer a branded concierge service for ED prescription medicines online. This increased affordability of generic PDE5i's is driving volumes, especially in the USA which has increased by 85% between 2018 and 2020[3].

US market research conducted in 2022 by IPSOS and commissioned by Futura has confirmed that even with increasing volumes, the requirement of a doctor's prescription remains both an economic and emotional barrier to use: US patients spend between US$600 and US$3,500 per annum on ED treatments, when taking into account both prescription costs and doctors' visits not covered by insurance[4]. This reconfirms the significant opportunity that MED3000 represents with OTC availability.

Futura's objective of OTC status as a clinically proven treatment for ED for MED3000, particularly in the USA, continues to be a top priority given the limited availability of OTC PDE5i's around the world.

In January 2022 BfArM's (the Federal Institute for Drugs and Medical Devices in Germany) Expert Committee for Prescription rejected the prescription to OTC reclassification of sildenafil (50mg) for oral use to treat ED. Sildenafil currently has OTC status only in Ireland, New Zealand, Norway, Poland, and the UK.

In March 2022, the Office for Registration of Medicinal Products, Medical Devices and Biocidal Products approved the prescription to OTC reclassification of Adamed Pharma's Tadalafil Maxon (10 mg) in Poland. Similarly, a proposal for OTC availability of Tadalafil 10 mg is believed to be under consideration by the Medicines and Healthcare products Regulatory Agency ("MHRA"), in the UK.

Continuing regulatory and commercial progress for MED3000

CE marked as Class 2 medical device from the EU Notified Body and UKCA marked (following Brexit), Futura's novel, fast-acting topical gel formulation MED3000, is the first clinically proven topical treatment for adult men with ED available without a doctor's prescription that helps men get an erection within 10 minutes.

The CE mark approval of MED3000 from the EU Notified Body paves the way for approval in many countries around the world, including in Latin America, the Middle East, Africa and the Far East regions, with many countries considering "fast-track" review based on recognition of the EU CE mark.

USA - the largest potential OTC ED market globally

In October 2022, Futura filed an application for Marketing Authorization as a De Novo Medical Device, presenting the case that MED3000 is an effective clinically proven treatment for ED with a 10-minute onset of action and a favourable benefit versus risk profile ideally suited for OTC classification. This followed positive results achieved in the FDA required, confirmatory, Phase 3 clinical trial, FM71, designed to provide supplementary efficacy data to the previously reported Phase 3 clinical study FM57.

The submission of the marketing application has opened the pathway for commercialisation of MED3000 in the USA, the biggest potential OTC ED market worldwide, with our key differentiator of a clinically proven treatment for ED with a rapid speed of onset.

FM71 - Highly positive results with all primary and secondary endpoints achieved

In August 2022, Futura announced positive results from FM71, in line with data generated in FM57 and broadly comparable with a recent "real world", home use study conducted by one of Futura's distribution partners.

FM71 was a multi-centre, randomised, open-label, home use, parallel group, clinical investigation of MED3000 compared to a well-known US prescription oral medication. The trial design and clinical endpoints were agreed with the FDA and the trial used gold standard, internationally accepted clinical trial endpoints in ED.

FM71 investigated the efficacy and safety of MED3000 in 96 male subjects clinically diagnosed with a mix of mild, moderate and severe ED against baseline (pre-treatment).

FM71 results demonstrated that MED3000 presents an effective clinically proven treatment for ED with a 10-minute onset of action and a favourable benefit versus risk profile ideally suited for OTC classification.

MED3000 has the opportunity to provide an alternative option to existing ED treatments, that require a doctor's prescription, for those patients seeking fewer systemic side-effects, and a spontaneous intercourse experience. It also provides an important treatment option for those patients who are currently precluded from using current prescription treatments such as those men taking nitrate medication.

FM71 also included pre-agreed FDA criteria for proving a rapid onset of action. Data demonstrated a highly statistically significant improvement, P<0.001, at 10 minutes where subjects noticed an erection. The comparator product, a well-known US prescription oral medication, did not meet the criteria at the same time point. Oral "on demand" tablets typically take 30-60 minutes to work and therefore a claim regarding MED3000's rapid onset of action represents a significant advancement in therapy over existing oral on demand treatments.

USA Regulatory status
Following the successful FM71 study results, Futura filed an application for Marketing Authorization of MED3000 as a De Novo Medical Device, presenting the case that MED3000 is an effective clinically proven treatment for ED with a rapid onset of action and a favourable benefit versus risk profile ideally suited for OTC classification, without the need for a doctor's prescription.

The FDA has now confirmed that the dossier is under formal review having passed the initial technical screen, and the application is now undergoing further review. In March 2023, Futura announced that MED3000 was under active review with the FDA, including a recent meeting, regarding US marketing authorisation. As a regular part of its review process, the FDA asked some additional questions and requested some non-clinical confirmatory data to which the Company has provided a full response and the requested confirmatory data to enable the FDA to complete their review. Based on the FDA's published target review period guidelines to include time to review the newly provided information, grant of the De Novo request is now expected to be achieved in Q2 2023.

In anticipation of FDA approval, Futura is actively seeking a US commercial partner and is engaged in several ongoing active discussions. Further updates will be provided in due course.

MED3000 - Commercialisation and launch plans

M*ultiple commercial agreements in key markets*

Futura is establishing a network of licensing and distribution partners with strength in brand building, pharmaceutical credibility, regional infrastructure and marketing expertise for long-term distribution of MED3000 across the globe.

With multiple commercial agreements in key markets, Futura is continuing to expand its strong network of licensing and distribution partners and initial launches have commenced under the brand name Eroxon® in March 2023 with further launches planned through the remainder of 2023 and beyond.

European Economic Area, United Kingdom and Switzerland - Cooper Consumer Health ("Cooper")
In May 2022, Futura announced an exclusive licensing agreement with Cooper, a leading European independent self-care organisation, for the rights to commercialise MED3000 throughout the EEA, the UK and Switzerland. Under the terms of the agreement, Futura received an initial upfront payment, and will receive undisclosed cumulative sales milestone payments. The agreement is for an initial term of five years complying with EU competition law.

Futura will remain legal manufacturer and will be responsible for the supply of MED3000, through its third-party contract manufacturers.

South Korea - Menarini Korea Limited ("Menarini Korea")
In March 2022, Futura announced that it had entered into a licensing agreement with Menarini Korea, a wholly owned subsidiary of Menarini Group, for the exclusive rights to commercialise MED3000 in South Korea. Under the terms of the agreement, Menarini will be responsible for all costs related to the regulatory approval and marketing of the product in the region, including a clinical bridging study if necessary. Futura will provide reasonable technical support for product development and commercialisation and received an upfront payment and will supply MED3000 from Futura's third party contract manufacturers. Menarini is now in discussions with the Korean regulator relating to the marketing authorisation of Eroxon®.

Gulf Co-operation Council ("GCC") region and Middle East - Labatec Pharma ("Labatec")
Swiss-based specialty pharma company Labatec has the rights to exclusively commercialise MED3000 in the GCC region as well as Jordan, Lebanon and Iraq. The initial licence agreement term is for eight years with the ability to extend for successive two-year terms by mutual consent.

Brazil and Mexico - m8 Pharmaceuticals Inc ("m8")
Specialty biopharmaceutical company m8 has the rights to exclusively develop and commercialise MED3000, in Brazil and Mexico, the two biggest countries and healthcare markets in Latin America. The agreement is for an initial term of 15 years. m8 will be responsible for all costs related to the regulatory approval and marketing of the product. Futura will provide reasonable ongoing technical support for OTC product development and commercialisation.

China and South East Asia
As previously referenced, our prospective Chinese commercial partner, Co-high is unable to deliver on key development and regulatory milestones previously set out in the agreement which was announced in March 2021. Futura is continuing to explore alternative options and has received interest from several potential parties for the commercialisation of MED3000 in South East Asia including China. South East Asia and China remain a significant commercial opportunity, although further clinical trials will be required, as previously disclosed.

USA commercialisation strategy
In line with the Board's US commercialisation strategy, following the successful completion of FM71 and the FDA dossier submission completed in October 2022, Futura commenced the search for a US commercial partner through its specialist corporate advisors. Futura has also received a number of enquiries regarding commercialisation opportunities for MED3000 for the key US market, and the Board, along with its advisors, is focused on securing the best options in order to maximise long-term value and sustainable revenues, whilst minimising risk for Futura's shareholders.

Manufacturing

Manufacturing scale up was completed in H2 2022 with sufficient production capacity on-stream to meet projected initial demand and beyond. First commercial manufacturing orders have been received. Options for additional manufacturing sites to increase supply chain robustness continue to progress. MED3000 supply is ISO 13485 accredited with a competitive cost of goods and has an approved 42-month shelf-life in Europe, giving significant distribution flexibility, mindful of transport times between the country of manufacture and final country of sale.

Intellectual Property: Patents, Trademarks and exclusively supplied, Critical Ingredients

Futura's corporate strategy is to develop layers of protection around its products, in particular MED3000. The Company continues to work with specialist patent and trademark advisors to further refine and optimise this strategy. In line with normal PCT filing procedures, MED3000 patents are now filed in all major ED markets considered necessary to protect the commercial interests of MED3000. A request to the European Patent Office was made in August 2021 for examination of the MED3000 patent application and in Q2 2022 it confirmed the novel and inventive nature of the application, which is required before a patent can be granted, although further review continues.

Education and outreach on erectile dysfunction and MED3000

In October 2022, Futura held an Advisory Panel meeting at the Sexual Medicine Society of North America ("SMSNA") in Miami, USA. The Panel was comprised of eight world renowned experts in Sexual Medicine from the USA, Europe, UK and Brazil who convened to discuss MED3000's clinical data, its unique mode of action and how it could be used as a treatment alternative for ED. MED3000 was acknowledged by the Advisory Panel as a potentially safe, fast-acting and effective treatment for addressing the unmet medical need of ED via OTC. Two members of the Panel, Professor Hellstrom and Dr Glina recorded their specific thoughts on how MED3000 might be of benefit to patients. The video can be accessed via the Futura Medical website www.futuramedical.com.

In February 2023, Futura presented clinical data on MED3000 as part of a Poster presentation at the European Society for Sexual Medicine ("ESSM") Congress in Rotterdam, highlighting the recent, confirmatory FM71 Phase 3 study results. The Company co-hosted an Eroxon® booth with its distribution partners and received strong interest from a number of congress attendees who welcomed the new innovation in the ED sector.

Futura is delighted with the feedback from attendees, which very much echoed the sentiment seen at the 2022 advisory meeting.

Research and Development

Futura is committed to delivering long-term and sustainable value to the Company allowing a long-lasting growth franchise to be built around MED3000 and DermaSys® formulated products.

Whereas Futura's priority remains the approval and subsequent successful launch of MED3000 in major markets throughout the world, Futura aims to build a significant MED3000 franchise across sexual health by leveraging and expanding its unique knowledge and expertise in underserved and new categories in sexual health, building upon market research already undertaken to identify product extensions and potentially new market segments for OTC products.

Outlook

Futura is pleased and excited by the progress made in accomplishing its strategic objective of creating a global network of distribution partners with strength in brand building, pharmaceutical credibility, infrastructure and marketing expertise, for long-term profitable distribution of MED3000 across the world.

We are delighted that the initial launch of MED3000 under the brand name Eroxon® has recently commenced and look forward to further launches through our distribution partners as soon as practicable after regulatory approval allows.

We are also firmly focused on gaining marketing authorisation in the key market of the USA in the near term to enable the marketing of MED3000 as a clinically proven topical treatment for ED with a rapid speed of onset and without the need for a doctor's prescription.

Thank you for your continued support of Futura Medical.

1. *2021 JSB Partners estimate based on US Census International Programs Population by age groups and "Prevalence of erectile dysfunction: Massachusetts Male Aging Study", 1987 ± 1989; source Kleinman et al. J Clin Epidemiol 2000.*
2. *EMA, Withdrawal assessment report for Viagra, 2008*
3. *Manufacturers' Selling Prices, IQVIA 2020 market data*
4. *Ipsos research commissioned by Futura, 2022*

Financial Review

As outlined in the Chairman's Statement and Chief Executive's Review, Futura continued to focus its financial resources on MED3000, its fast-acting gel treatment for erectile dysfunction ("ED") concentrating on the US path to regulatory submission, and enabling commercialisation through securing licensing and distribution deals with commercial partners to build and grow a worldwide distribution and marketing network.

In 2022, the Company entered into licensing agreements with Menarini Korea for exclusive rights to commercialise MED3000 in South Korea and with Cooper Consumer Health for rights throughout the European Economic Area, the United Kingdom and Switzerland. First orders were received from Cooper Consumer Health to fulfil initial launches.

Following highly positive results from the FM71 Phase 3 clinical study, the Company filed a regulatory dossier with the US FDA in October 2022 and also formally commenced the search for a US partner ahead of the planned approval in 2023.

Revenue
Initial orders for Eroxon® were received during the year with delivery anticipated early 2023. No revenue was recognised in the period (please see Note 2.4 for more information).

Research and Development costs
Research and Development (R&D) costs for the period ended 31 December 2022 were £4.13 million, compared to £3.77 million for the period ended 31 December 2021. The increase of £0.36 million reflects the completion of the FM71 study and continuing manufacturing scale-up activities ahead of anticipated Eroxon® launches.

There was no capitalisation of R&D costs in 2022. (2021: nil)

Administrative costs
Administrative costs were £2.74 million for the period ended 31 December 2022 compared to £2.09 million for the period ended 31 December 2021. This is an increase on the prior year and partly driven by higher costs associated with supporting commercial partners and supply chain activities in readiness for launching Eroxon® over the next year. In addition, there were some one-off costs incurred relating to fees associated with negotiating and concluding commercial arrangements for MED3000.

Tax
It is expected that an R&D tax credit of £1.02 million will be claimed in respect of 2022 and the cash refund is expected to be received mid-2023 from HMRC.

Loss per share
The basic loss per share for 2022 was 2.03p (2021: 1.83p). Details of the loss per share calculations are provided in Note 10 to the Preliminary Results.

Cash balance
The cash balance at the end of 2022 was £4.03 million (2021: £10.37 million). Cash burn during the year was £6.34 million (2021: £4.39 million) primarily in relation to the completion of the FM71 clinical study, manufacturing capital

equipment and scale-up activities associated with MED3000. Other one-off costs associated with the conclusion of commercial agreements with MED3000 licensing and distribution partners were also incurred.

Current cash runway extends beyond initial Eroxon® launches expected over the next year and expected US regulatory approval in 2023, assuming conservative revenues are received from existing launches.

Going Concern
The Board has considered the applicability of the going concern basis in the preparation of the financial statements. Notwithstanding a loss for the year ended 31 December 2022 of £5,846,495, the Board considers that, based on the reasons set out in Note 2.2 of the Preliminary Results, the preparation of the financial statements on a going concern basis remains appropriate. However, it also acknowledges that a material uncertainty exists that may cast significant doubt on the Group's ability to generate sufficient net revenues and raise sufficient finance to meet its expected costs and to continue as a going concern and to realise its assets and discharge its liabilities in the normal course of business.

The auditor's report includes reference to the material uncertainty relating to going concern. Further information in relation to going concern can be found in Note 2.2 of the Preliminary Results.

Angela Hildreth
Finance Director and Chief Operating Officer

Preliminary Results - http://www.rns-pdf.londonstockexchange.com/rns/3928V_1-2023-4-4.pdf to view Futura Medical's Preliminary Results

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