Futura Medical plc

Annual Report and Accounts 2022

Welcome to the Futura Medical

Annual Report 2022

WHAT WE DO

Futura Medical is a pharmaceutical company developing innovative products based on our proprietary, transdermal technology DermaSys[®]. Products are optimised for clinical efficacy, safety, mode of administration, patient and consumer convenience and are developed for the prescription and consumer healthcare markets as appropriate.

Current therapeutic areas are sexual health and pain relief. Development and commercialisation strategies are designed to maximise product differentiation and value creation whilst seeking to minimise clinical and regulatory risk.

Futura has a proven track record in delivery and completion of Research and Development ("R&D") projects up to value inflection points at which they are suitable for commercialisation partners.

INVESTMENT CASE

LONG-TERM VALUE CREATION FROM OUR LEAD PRODUCT MED3000

We are prioritising the development and regulatory approval of MED3000, our treatment for erectile dysfunction ("ED"), owing to its significant medium to long-term value creation potential in a large market where there is an unmet need for new treatment options. MED3000's efficacy and safety has been shown in two Phase 3 clinical trials and MED3000 is approved in the EU, as a Class 2 medical device under the MDR EU Quality Management Certificate ("CE mark approval") making it the first clinically proven, pan-European topical treatment for adult men with ED available without a doctor's prescription ("OTC"). MED3000 has also been submitted for marketing authorisation to the US Food and Drug Administration ("FDA").

2 ADVANCED PROPRIETARY TECHNOLOGY DERMASYS®

We are exploiting the potential of our transdermal technology DermaSys® to innovate and develop topical treatments offering a fast onset of action and low systemic side effects. Our long-term strategy is to expand the product pipeline based on DermaSys®. Our products are underpinned by strong IP, usually specific to each product.

Read more about **DermaSys**® on **page 4**

3 CLINICAL DEVELOPMENT OF TREATMENTS IN MARKETS WITH SIGNIFICANT UNMET NEEDS

Our focus is on differentiated products, addressing areas of two large markets, sexual health and pain, seeking to solve unmet needs that will help improve patients and consumers' lives. Our purpose is to enhance quality of life to enable our patients and consumers to enjoy their lives to the full whilst being ethical in all we do.



Read more about our Sustainable Development Goals on page 27

4 DE-RISKED STRATEGY WHICH FOCUSES ON RAPID ROUTES TO MARKET

Our lead product, MED3000, is a product that is or will be available over the counter, without a doctor's prescription and has already received CE mark approval in Europe, which will provide in many non-EU countries a "fast-track" approval. MED3000 was also submitted for US FDA approval as an OTC medical device in October 2022. The USA is the largest potential market for ED over the counter and MED3000 (subject to FDA approval) could be the first OTC product available. This regulatory strategy means that there is a lower development risk and shorter regulatory pathway to monetisation in many countries, especially the USA.



Read more about **our** strategy on page 16

Our purpose is to enhance our patients and consumers' quality of life to enable them to enjoy their lives to the full."

JAMES BARDER

5 DISTRIBUTION NETWORK BASED ON STRATEGIC PARTNERSHIPS

As a semi-virtual company we value our commercial partners and place much emphasis on selecting and establishing a network of licensing and distribution partners with brand building strength, healthcare credibility, regional infrastructure and marketing expertise for long-term distribution of MED3000 across the globe. We look for committed commercial partners who have the regulatory and commercial expertise as well as the tenacity, drive and enthusiasm to make our products a success.



EXPERIENCED

MANAGEMENT TEAM

The management team has significant experience in researching and developing innovative products for the global consumer healthcare and prescription markets and has strengthened the Board's business and commercial expertise as Futura moves into the next phase of MED3000's commercialisation.



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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.

FINANCIAL HIGHLIGHTS

- Net loss of £5.85 million in period of which £4.13 million was related to R&D (2021: net loss of £4.96 million).
- ► Cash resources of £4.03 million.
- ▶ £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.

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.

DermaSys® at a Glance

Futura Medical is an innovative R&D company. We are experts in transdermal delivery and the science of the skin. We have developed an advanced proprietary and patented transdermal technology, DermaSys[®].

APPLYING SKIN SCIENCE TO DELIVER NOVEL TOPICAL TREATMENTS

Our core strength lies in our research and development capabilities in the field of topical formulations and transdermal delivery. Futura's unique technology, expertise and know how, enables targeted and rapid delivery of active pharmaceutical ingredients and GRAS ("Generally Recognized As Safe") ingredients onto and through the skin to the required site of action with a high level of safety. We take off-patent, generic molecules and ingredients and offer improvements over existing products or create novel indications with compelling commercial potential. This means that our products are highly differentiated in their markets whilst avoiding the risks normally associated with the development of new molecules and with a potentially shorter regulatory pathway. We protect this valuable IP and ensure that we maximise both the strength of our patents' protection and their duration.



The combination solvent components and permeation enhancers increases skin penetration and permeation to drive the active through the skin to the site of action. action.

of volatile solvent components creates an evaporative and novel action that stimulates nerve endings and creates a physical



DERMASYS® AND THE PROCESS BEHIND OUR UNIQUE FORMULATIONS

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

DermaSys[®] is a versatile and bespoke technology. Each gel is uniquely formulated using the DermaSys® platform with penetration and permeation enhancer components tailored for each product to suit the specific therapeutic indication, 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.

The gels we develop are versatile, clear and provide effective and local topical application to the required site of action. For our ED treatment, MED3000, this translates into a fast-acting treatment for erectile dysfunction with an excellent safety profile. For CBD100 this translates into a uniquely stable cannabidiol formulation with effective penetration for enhanced therapeutic benefits.

DermaSys® process



profile

Product Pipeline

Futura Medical is developing innovative products for two large markets, sexual health and pain. We have products in late-stage development, with MED3000 being the lead product.

MED300	0 pipeline stage			
	Development	Regulatory	Distribution agreements	Launch
EU	⊘	MED3000 approved as a medical device in the EU ("CE mark approval"). UKCA mark approval received in April 2022.*	Licensing deal signed with Cooper	Initial retail and online launches commenced
Middle East	②	Regulatory submissions made to regulators. Approval received in four countries.	Licensing deal signed with Labatec	Initial launches planned in H2 2023
Brazil/ Mexico	O	Regulatory submissions made to regulator in Mexico.	Licensing deal signed with m8	
USA	Successful completion of Phase 3 FM71 study.	Regulatory dossier submitted in October 2022 with potential approval anticipated in Q2 2023.	Discussions ongoing	
Asia	Discussions being held with regulators to clarify regulatory pathways and scope of additional work.	Regulatory submissions made to regulators.	Licensing deal signed with Menarini for South Korea	

* The UKCA (UK Conformity Assessed) marking is a new UK product marking that is used for goods being placed on the market in Great Britain (England, Wales and Scotland). It covers most goods which previously required the CE marking.

Development stage for other products				
CBD100	Topical cannabidiol formulation	Joint venture collaboration. Early development stage completed. IP application filed. Advisers retained to explore commercial opportunities.		
TPR100	Topical diclofenac pain relief gel	Scientific advisory meeting held with MHRA confirming the need of a Phase 3 study to support the improved skin permeation including potential superior efficacy claims. Exploring the feasibility of a clinical study to satisfy the Phase 3 requirements for both UK and US approval. Development currently on hold.		

Chairman's Statement

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

JOHN CLARKE Non-Executive Chairman 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 ED¹, 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 USA, 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

 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.

Chief Executive's Review

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

JAMES BARDER Chief Executive

COVID-19 UPDATE

Futura Medical monitored closely the constantly evolving situation in relation to the COVID-19 pandemic and all necessary steps were taken to maintain the integrity of the Company's assets and the health and well-being of our employees. We have supported our staff to work from home and implemented a COVID secure workplace with thorough risk assessments updated as and when Government guidance changes.

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. Eroxon[®] is the agreed brand name in certain regions such as the EU whereas MED3000 continues to be the internal code name used by Futura as well as when referring to countries where regulatory approval or commercial distribution agreements have not yet been achieved.

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 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 wellknown 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 nonclinical confirmatory data to which the Company has provided a full response and 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.

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.

Chief Executive's Review

The prevalence of ED disrupts the lives of at least one in five men globally¹ with around 22 million men suffering ED in the USA and 20 million men in the UK, France, Italy, Spain and Germany². 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 2020³.

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 insurance⁴. 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.

- 1. EMA, Withdrawal assessment report for Viagra, 2008
- 2. 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.
- 3. Manufacturers' Selling Prices, IQVIA 2020 market data
- 4. Ipsos research commissioned by Futura, 2022



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 O2 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.

Chief Executive's Review

MED3000 - COMMERCIALISATION AND LAUNCH PLANS

Multiple 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 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.

US 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 advisers. Futura has also received a number of enquiries regarding commercialisation opportunities for MED3000 for the key US market, and the Board, along with its advisers, 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 advisers 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 longlasting 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.

On behalf of the Board

JAMES BARDER Chief Executive Officer

Our Business Model

KEY RESOURCES

HOW WE CREATE VALUE

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People

- Highly experienced and motivated team focused on innovative solutions
- Team of 30 consultants used for their specialist knowledge and leadership in the field
- Strong results driven culture and teamwork

Expertise and innovation

- Highly efficient patented proprietary transdermal technology
- Semi-virtual structure with outsourcing optimised to maximise expertise and minimise overhead cost

Strong leadership

 Experienced management team with expertise in researching and developing innovative products as well as business and commercial acumen in the global consumer healthcare and prescription markets



Outsourcing – R&D expertise combined with a lean operating model

Semi-virtual model using in-house specialist expertise in Clinical Development, Regulatory and Chemistry, Manufacturing and Controls ("CMC"), Quality and Supply Chain to lead strategy and co-ordinate the outsourcing of key activities with highly regarded subcontractors and manufacturers and a range of experienced consultants.

Expertise – Proven innovation

Expertise in optimising formulations of molecules and excipients to ensure a rapid and targeted action and to minimise side effects.

Market dynamics - Understanding our markets

Our lead asset MED3000 in particular is well positioned to address the unmet needs in the erectile dysfunction market. Our products address growing demand in sexual health and pain relief driven by long-term trends such as ageing populations, increase in conditions such as obesity, stress and anxiety, increasing prosperity and expectations from patients and consumers for a high quality and enjoyable life. Not only are people living longer but they want to live an active, enjoyable and fulfilled lifestyle for longer. Products such as MED3000 are well placed to accommodate such demands.

Impact – Understanding patient and consumer needs

In sexual health, current treatments do not meet the needs of many ED sufferers who are looking for a fast-acting and well tolerated treatment that can help restore spontaneity and intimacy back into their relationship. ED can also contribute to low confidence and selfesteem and have a significant impact on male mental health.

MAXIMISING VALUE

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AS WE EXECUTE THE COMMERCIALISATION OF MED3000 OUR AMBITION AND FOCUS IS TO BUILD A GLOBAL DISTRIBUTION NETWORK AND CONTINUE TO ACCELERATE COMPANY GROWTH TOWARDS LONG-TERM, SUSTAINABLE REVENUES.

Commercialising our products

With the approval in the EU, UK and some Middle Eastern countries of MED3000 as a medical device available without a prescription and with potential approval as an OTC medical device in the USA, we have and continue to focus our efforts on finding the best commercial options and partners, with our attention focused on the USA. We are building our infrastructure, expertise and capabilities which, combined with building a strong distribution network around the world and a strong brand identity will underpin the successful commercialisation of MED3000.

Five licensing deals have been signed for key regions including Europe, the Middle East and South America, as part of our plans to build a global network of licensing and distribution partners with brand building strength, healthcare credibility and regional infrastructure and marketing expertise for longterm distribution of MED3000 across the globe. Our strategy is to work with committed commercial partners who have the regulatory and commercial expertise as well as the drive and enthusiasm to make MED3000 a success.

Patients and sufferers

CREATING VALUE FOR OUR KEY

STAKEHOLDERS

Erectile dysfunction and chronic pain can be debilitating and have a detrimental impact on day-to-day life, leading to low self-esteem, relationship issues and limiting day-to-day activities. Our products focus on improving quality of life to enable patients and consumers to enjoy their lives to the full.

Shareholders

Our aim for MED3000 is to achieve long-term sustainable value for our shareholders. By prioritising resources, we aim to deliver additional value to our shareholders, maximising value for Futura from the over the counter opportunity MED3000 represents. This is being achieved by gaining regulatory approval as an effective clinically proven treatment for erectile dysfunction without the need of a doctor's prescription, in particular in the USA, and through building a strong global network of licensing and distribution partners.

Our Strategy

Our strategy is to develop our portfolio of innovative products for two large market categories, sexual health and pain, and then partner at the optimum time to generate most value.

This strategy is aligned with the well-publicised demographic changes of ageing populations, increasing prosperity, the increased demand from patients and consumers who expect to lead a full and active life well into their later years, their natural desire for an improved and enjoyable quality of life and our expectations that overall patient demand and spending will increase as a result. The objective is to develop products such that each on its own has the potential to generate significant annual revenues.



2022 PRIORITIES AND PERFORMANCE

- Successful completion of Phase 3 study FM71 and submission to the US FDA as an OTC medical device in October 2022.
- Signed agreement with Cooper Consumer Health for the rights to Eroxon[®] in the EEA, the UK and Switzerland. Commenced discussions for the licensing and distribution rights for the USA.
- Supported our commercial partners in their own submissions to local regulatory bodies in the Middle East, South America and Asia with regulatory approvals in four countries to-date.
- Expanded our quality, supply chain, manufacturing and commercial capabilities to supply and support our commercial partners in their launches with first production orders.
- Giving ED sufferers access to MED3000 as quickly as possible and increasing awareness of the product amongst ED KOLs.

2023 FOCUS

- - Approval of MED3000 by the US FDA as an OTC medical device in Q2 2023.
- First launches of MED3000 under the brand name Eroxon[®] in Europe with further launches planned in 2023, with first revenues reported.
- Sign further agreements for key markets and countries worldwide – with the USA being the main focus – to build a strong global network of licensing and distribution partners and a strong brand identity for MED3000.
- Continue to support our commercial partners in their own submissions to local regulatory bodies and in their launch preparations.
- Expand our supply chain and manufacturing capabilities to increase supply chain robustness and capacity.

Key Performance Indicators

The Directors consider the successful achievement of development, licensing and commercialisation milestones and the number of products under development (beyond the evaluation stage) to be the major drivers of value creation for the Group.

There are other financial and non-financial key performance indicators ("KPIs") which the Directors use as a measure of the Group's performance.



commercial deals were also incurred in the year.

Product Review – MED3000

MED3000 (brand name Eroxon® throughout the EU) is a treatment applied directly to the glans (head) of the penis for 15 seconds. It is fast-acting, helping men get an erection within 10 minutes and easy to use helping to restore spontaneity and intimacy in the relationship. As a topically applied gel, men with erectile dysfunction ("ED") or their partners can apply it as part of foreplay.

MED3000 generates a rapid cooling and recovery warming action, promoting a sensory stimulation of the nerves on the glans penis leading to fast smooth muscle relaxation, tumescence and erection. MED3000 works rapidly to help achieve and maintain an erection whilst offering an excellent safety profile.

Our product review on MED3000 should be read in conjunction with the Chief Executive's Review on pages 8 to 13 which gives a detailed overview of the current status of MED3000. This section focuses on the findings from the Ipsos US market research, the results of the FM71 clinical study for FDA dossier submission and our focus on building a global distribution network. Eroxon® is the agreed brand name in certain regions such as the EU, whereas MED3000 continues to be the internal code name used by Futura as well as when referring to countries where regulatory approval or commercial distribution agreements have not yet been achieved.

KEY INSIGHTS FROM THE IPSOS US MARKET RESEARCH

In 2022 Futura commissioned independent market research from Ipsos in the USA¹. With oral PDE5i's going generic in the USA in recent years, the Company wanted to understand what impact this had on the erectile dysfunction market and on attitudes towards MED3000 (branded Eroxon® in the research) as well as ensure the Company had the most up to date market insights before engaging with potential US licensing and distribution partners. Ipsos conducted extensive research talking to both doctors and ED sufferers before conducting an online survey with 400 ED sufferers and 100 female partners.

KEY LEARNINGS FROM THE IPSOS US MARKET RESEARCH

- Research was very aligned with previous research conducted by Ipsos on behalf of Futura with strong interest and purchase intent.
- Strong positive reactions to the Eroxon[®] concept from men, women and doctors with speed of onset the key benefit for consumers.
- Overall cost of treatment (drug costs and healthcare charges) remains high between US\$600 and US\$3,500 per annum for most men on ED treatment.
- Availability of low-cost generics has not eroded the opportunity for Eroxon[®] with peak sales achieved at US\$5 retail.
- Partners want to play a key role in treatment with high levels of interest from female partners in using Eroxon[®] and buying Eroxon[®] themselves.

Even with increasing volumes and low-cost availability of oral PDE5i's, the requirement for a doctor's prescription remains both an economic and emotional barrier to treatment for ED sufferers.

1. Data on file

SOME OF THE OTHER RESEARCH FINDINGS

- ► **Top 3 concerns** amongst ED sufferers using oral PDE5i's were: "it does not work as well as I would like", "it takes too long to work/requires planning", "the side effects concern me/are unacceptable".
- 1 in 4 times an 'on demand' oral PDE5i's is taken men do not then attempt intercourse.
- ▶ 81% of female partners would probably/definitely buy Eroxon[®].
- ▶ 90% of ED sufferers would probably/ definitely buy Eroxon[®] if their partner brought it home.



FM71 – SUCCESSFUL PHASE 3 CLINICAL TRIAL SUPPORTED OUR US REGULATORY DOSSIER SUBMISSION

FM71 CLINICAL TRIAL STUDY DESIGN

Phase 3, 24-week multicentre, comparative, randomised, open-label, home use, parallel group study in 96 subjects with mild, moderate or severe ED from Eastern Europe and the USA.





* Comparator product was a well-known US prescription oral medication.

FM71 STUDY DEMONSTRATED CLINICAL EFFICACY AND SAFETY

CLINICALLY PROVEN EFFICACY OVER A 24 WEEKS PERIOD

- Primary efficacy endpoints agreed with FDA both met
- Secondary endpoint related to fast onset of action met
- At 24 weeks 61% of MED3000 subjects exceeded the MCID¹
- MCID is the Minimal Clinically Important Difference which is an outcome measure that would be noticeable to a patient and be of clinical relevance. An overall MCID of a four-unit change over baseline is used by KOLs as a threshold for success in ED clinical studies and was used by FDA as a primary endpoint.

Mean IIEF-EF change from baseline at 4, 8, 12, 16, 20 and 24 weeks for MED3000



 MCID is the minimal clinically important difference (4 IIEF-EF units), Rosen et al 2011.

EXCELLENT SAFETY PROFILE

- Very favourable side-effect profile versus comparator product (a well-known US prescription oral medication)
- No serious adverse events recorded in any patients on MED3000
- No known drug interactions
- Potential use in ED sufferers using nitrate, alpha-blocker and antihypertensive medications
- No local side-effects in female partners

Adverse Events - Men	MED3000 Subjects	MED3000 Total AEs	Comparator Product Subjects	Comparator Product Total AEs
Headache				
	0 (0%)			
	0 (0%)			
			0 (0%)	
Local side effects	1 (2%)		0 (0%)	

2. All occurred in African-American subjects on the comparator product.

Product Review – MED3000

Results from the FM71 study were in line with data generated in the previous Phase 3 clinical study used to support the EU CE Mark approval 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 overall a highly favourable side effect profile. All primary and secondary endpoints were achieved at 24 weeks and the secondary endpoint showing a 10-minute onset of action was met.

Data from this confirmatory clinical study, FM71, alongside additional data from FM57 was used to support the US regulatory submission to the FDA for MED3000 as a medical device for ED treatment.



Read more about the **submission to the FDA** in the Chief Executive's Review on **page 11.**

SIGNIFICANT PROGRESS IN BUILDING A GLOBAL DISTRIBUTION NETWORK WITH A STRONG BRAND IDENTITY



distribution partners in the Chief Executive's Review on pages 8 to 13.

*Excludes Indian subcontinent

Data sources: Data on doses from IQVIA, standard units, 2020; Data on ED sufferers from 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 (n=1626); source Kleinman et al. J Clin Epidemiol 2000.



* Pack from our licensing and distribution partner in Europe

In March 2023 Eroxon® was launched online across Europe marking a milestone for the brand and the Company. This was followed in April 2023 with the first launch in Belgium in retail pharmacies supported with marketing and promotional advertising, with other countries expected in the coming months.

Futura is committed to delivering long-term and sustainable value to the Company allowing a longlasting growth franchise to be built around MED3000 either under the Eroxon® brand or potentially an alternative brand depending on regulatory and commercial circumstances in different markets. Whereas Futura's priority remains the approval and subsequent successful launch of Eroxon[®] in major markets throughout the world, Futura aims to build a significant 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 that will support the long-term success of MED3000/ Eroxon[®].



Read more about our **commercial progress and initial launch in Europe** in the Chief Executive's Review on **pages 8 to 13.**



Product Review – Other Products

CBD100 - DERMASYS® FOR THE DELIVERY OF CANNABIDIOL

MARKET AND OVERVIEW

In recent years there has been significant interest in cannabidiol as more data is emerging on its potential benefits in a wide range of conditions. An independent report commissioned in 2021 by Futura to provide market insights into the cannabidiol market estimates the European market to be worth €1.4 billion in 2020 of which between oneguarter and one-fifth of the total European market are made up of the topicals market. DermaSys® may be able to provide a rapid and targeted local delivery of cannabidiol through the skin to the required site of action with a high level of safety and more effectively than other cannabidiol products. Studies demonstrate highly efficient penetration of cannabidiol into and through the skin, superior to an established, marketed, comparator product.

STATUS

Futura has signed an agreement with CBDerma Technology which includes Futura developing and optimising a DermaSys® cannabidiol formulation and conducting early proof of concept studies highlighting the known permeation and stability qualities of our DermaSys[®] technology when used in conjunction with cannabidiol. We are aiming for CBD100 to be highly differentiated from existing, largely unregulated, low-tech products in the fast growing cannabidiol market on the basis of quality, stability and efficient delivery to the skin for a number of applications and indications expected to range from cosmeceutical through to pharmaceutical dermal and pain relief treatments. All Intellectual Property will be owned jointly by the Company and CBDerma Technology Limited.

Whilst Futura's resources are focused on key asset MED3000, the Company continues to explore commercial opportunities for CBD100 with discussions and potential further validation work to validate the power of the DermaSys® technology.



MARKET AND OVERVIEW

The rapid skin permeation rate offered by our transdermal delivery system, DermaSys®, is ideally suited for targeted topical pain relief. Rapid, targeted and effective skin permeation offers potential benefits in pain management including: improved onset of action, duration and degree of pain relief. TPR100 is a nonsteroidal anti-inflammatory diclofenac gel that brings relief from the pain and inflammation associated with sprains, strains, bruises and soft tissue rheumatism offering long-lasting pain relief. It is applied to the local site of pain or inflammation.

STATUS

At a scientific advisory meeting with the Medicines and Healthcare products Regulatory Agency ("MHRA") by Futura in conjunction with its commercial partner, the regulator recognised the improved skin permeation characteristics of TPR100 compared to market-leading diclofenac formulations. In vitro studies demonstrated that a 20% TPR100 dose relative to certain market-leading diclofenac formulations delivered the same permeation of active pharmaceutical ingredient through the skin. Due to this increased potency, a key differentiating characteristic for TPR100, MHRA now require data from a patient efficacy study with TPR100 in support of a marketing authorisation and are willing to consider superiority claims if the study is successful.

The UK market opportunity for TPR100 does not justify the potential costs of a patient efficacy study without the ability for Futura to be able to use the same data to support US approval. However, this will require a US distribution partner prior to the commencement of any Phase 3 programme and currently Futura's priority and resources are clearly focused on the successful US approval for MED3000 and worldwide rollout.





Financial Review

Focused management of operating costs as Futura prepares for MED3000 commercialisation and first revenues."

ANGELA HILDRETH Finance Director and Chief Operating Office

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 (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 9 to the consolidated financial statements.

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 Consolidated Financial Statements, 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 Consolidated Financial Statements.

ANGELA HILDRETH Finance Director and Chief Operating Officer

Key Risks and Mitigation

The Audit Committee and the Risk and Oversight Committee are responsible to the Board for risk management and internal controls and for ensuring that procedures are in place, and are being effectively implemented to identify, evaluate and manage the significant risks faced by the Group.

The internal controls are designed to manage rather than eliminate risk and provide assurance against material misstatement or loss. Given the current size and transparency of the operations of the Group, the Board has concluded that an internal audit function is not required and this will be continually reviewed as the Company grows.



The development of pharmaceutical drugs and medical devices requires the necessary safety, quality and efficacy to be demonstrated in clinical and technical programmes in order to meet the requirements of the appropriate regulatory bodies. Clinical programmes may not achieve their endpoints. The Board considers that the key risks of the Group are:

Risk	Potential Impact	Mitigation
R&D risk	There can be no guarantee that any of the Group's products will be able to obtain or maintain the necessary regulatory approvals in any or all of the countries in respect of which applications for such approvals are made. There can also be no guarantee that the approval timelines estimated are accurate. The estimates are based on information from the regulators but the time taken to review the dossiers is not within our control. Where regulatory approvals are obtained, there can be no guarantee that the conditions attached to such approvals will not be considered too onerous by the Group or its distribution partners in order to be able to market its products effectively.	The Group has reduced this risk by developing products using safe, well- characterised active compounds and ingredients, has sought and will continue to seek, where appropriate, advice from regulatory advisers, consultations with regulatory approval bodies and by working with experienced commercial partners. During 2022, following highly positive results from the FM71 clinical study, the Group submitted the regulatory dossier to the US FDA and is targeting granting of the marketing authorisation in 2023.
Commercial risk	The lead product has not yet launched in key markets and there can be no guarantee that the Group will succeed in establishing and maintaining the necessary contractual relationships with licensing partners for the Group's products under development. Even if the Group's products are successfully developed and approved by the appropriate regulatory bodies, they may not be launched by the Group's licensing partners, be successfully promoted or enjoy commercial acceptance. The Group is reliant on commercial partners to carry out their contractual obligations and the degree to which these can be enforced by the Group is limited. The Group cannot rely upon any historical sales data to accurately predict revenues generated from commercial sales of the products and revenues may fall short of expectations.	The Group seeks to reduce this risk by carefully selecting experienced commercial and distribution partners, maintaining and developing these relationships and seeking to develop new products of commercial interest to these and other partners. In 2022, the Company entered into licensing and distribution agreements for the European Economic Area, United Kingdom and Switzerland and South Korea. The agreements ensure that the commercial partners are contractually and financially committed to advertise and promote the product. The Company has worked closely with partners to understand their commercial forecasts and will continue to monitor sales against forecast expectations.
Financial risk	 Whilst the Group is focused on delivering revenue, it is expected to continue to be loss-making in the short term. The Group cannot rely upon any historical sales data to accurately predict revenues generated from commercial sales of the products and revenues may fall short of expectations. The successful development of the Group's assets requires financial investment. There can be no guarantee that Futura will have sufficient funds to execute its business plans. 	Whilst the Group is at an early stage of its commercial execution, a number of commercial agreements have been entered into with initial launches of MED3000 expected to result in revenues in 2023. The Group will work closely with commercial partners to understand their commercial forecasts and monitor sales against forecast expectations. The Group places considerable emphasis on communication with existing shareholders and potential investors, to maximise the chances of successful future fundraising.

Key Risks and Mitigation

Risk	Potential Impact	Mitigation		
Disruption to supply products	The Group relies upon third party manufacturers to supply its products to commercial partners. Failure to provide products at prices and quantities that are commercially acceptable could potentially result in a financial and reputational loss to	The Group has clearly defined agreements with its suppliers and maintains close oversight of their processes. In addition, the Group has ensured that the third-party manufacturers have stockpiled key raw materials and packaging.		
	the Group.	The Group is also considering options for other sources of supplies to add capacity, protect prices and reduce risk of reliance on individual sources of supply.		
Intellectual property risk	The commercial success of the Group and its ability to compete effectively with other companies depend, amongst other things, on its ability to obtain and maintain patents sufficiently broad in scope to provide protection for the Group's intellectual property rights against third-parties and to exploit its medical products. The absence of any such patents may have a material adverse effect on the Group's ability to develop its business.	The Group seeks to reduce this risk by only developing products where legal advice indicates patent protection would be available, seeking patent protection for the Group's products, maintaining confidentiality agreements regarding Group know-how and technology and monitoring technological developments and the registration of patents by other parties.		
Key people	The expertise and experience of its key people can have an enormous impact on business results. Poor recognition and incentivisation could undermine the Group's success.	The Group appreciates the high level of expertise and contributions made by its key people. It offers a merit-based, stimulating work environment with a culture focused on teamwork and freedom to operate. In addition there is a competitive performance- based reward structure, including annual performance bonus and share options that vest over a number of years.		

The following risk has also been identified by the Group and will be kept under review as the situations develop and any potential impact becomes clearer.

Risk	Potential Impact	Mitigation
Economic and political conditions	The Group is not immune from the risk of downturn in economic conditions resulting from events outside of its control. Whilst the impact of Brexit and COVID-19 are both now relatively low, the impact of the Russia- Ukraine conflict (as an example) continues to impact on the prices of raw materials and energy.	The impact of economic and political events continue to be monitored as they arise. To date, there has been limited impact from events such as Brexit, COVID-19 and the Ukraine-Russia conflict.
	The availability of capital could also be impacted in any economic downturn.	

Sustainability Review

Our approach to sustainability is an important part of living our purpose.

We are committed to maintaining a culture whereby we behave in a responsible and ethical manner and make a positive impact on all our stakeholders. We believe that operating responsibly and ethically is vital to our long-term success. Our approach is underpinned by our Corporate Governance principles of responsibility, transparency and integrity for the benefit of our shareholders, employees, commercial partners and other stakeholders. We strive to be fair, accountable and responsible in all our dealings. We monitor and report on our activities in a way that is accurate, balanced, reliable and clear and enables our shareholders and stakeholders to compare our progress year on year. The focus of our sustainability reporting is the UN Sustainable Development Goals ("SDGs"). The UN SDGs are a universal call to action to end poverty, protect the planet and ensure that all people enjoy peace and prosperity. Each SDG has global sustainable development priorities and aspirations for 2030, which give a common set of goals and targets to mobilise global efforts around.

Our focus is on the four SDGs where we believe we can have the greatest impact and therefore the greatest opportunity to make a real and lasting difference. These are:



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GOOD HEALTH AND WELL-BEING

- We are developing medical products that are optimised for clinical efficacy, safety, mode of administration and patient and consumer convenience, and will lead to improved health and well-being.
- ► We continue to place the health and safety of our staff and consultants at the heart of our business and have adopted a policy to allow our staff to optionally work approximately 50% of the time from home giving them the flexibility to balance their work and family commitments.



GENDER EQUALITY

 We believe in a diverse and gender balanced workforce. We are committed to supporting employment policies and practices that make provision for equal opportunities and nondiscrimination in our workforce. We aim to have a balanced workforce across the Group.







DECENT WORK AND ECONOMIC GROWTH

- ► Our employees are our most important asset. We are reliant on a skilled workforce for the success of the Group. We treat our employees fairly and support their ongoing development. We seek to empower them and ensure that they are fully engaged in all aspects of Futura's objectives and high quality standards. Each of our employees contributes and shares in Futura's success.
- We are focused on commercialising our technology and growing the value of the Group, which will lead to developmental benefits for the shareholders and employees of the Group.



INDUSTRY, INNOVATION AND INFRASTRUCTURE

- ▶ We invest heavily in R&D to develop a portfolio of innovative products based on our proprietary technology, DermaSys® to generate future revenue and value for our shareholders. We invest in clinical research to test our products and optimise their safety and efficacy and we share and publish the results of this research with the medical community to enhance scientific research.
- Our semi-virtual structure supports economic and infrastructure development through the
 outsourcing of numerous activities. If we are successful with our products this creates more
 opportunities for our partners.

Our Stakeholders

The Board sought to understand the views of the stakeholders through its interactions with them during the year and had regards for their interests in Board discussion and decision-making. The Board was delighted to resume face to face engagement in 2022.

S172 COMPANIES ACT 2006

The Board is aware of its duties under s172 of the Companies Act and has worked throughout the year to promote the success of the Company for the benefit of its members as a whole. In doing so, it has regard to those stakeholders identified under s172, as well as the additional stakeholders set out here.

HOW WE ENGAGE WITH OUR STAKEHOLDERS

SHAREHOLDERS

The Board naturally considers its shareholders to be key stakeholders of the Company and is focused upon delivering long-term value for their benefit. The Company engages with its shareholders and potential shareholders on a regular basis with investor meetings throughout the year as well as focused roadshows at the time of our published results. The Company produces regular webcasts and interviews which are posted to the Investor section of the website. The results of this investor engagement are reported to the Board to help inform our strategy and communications.



COMMERCIAL PARTNERS

The Board places great emphasis on selecting the most suitable commercial partners who have the regulatory and commercial expertise as well as the drive and enthusiasm to make our products a success. When looking to license the rights to one of our products, the Company appoints specialist advisers to identify and target the right potential partners and facilitate discussions and negotiations. The Company has signed a number of deals around the world to build a network of licensing and distribution partners for MED3000. The Company is working closely with its new commercial partners building mutually beneficial long-term relationships to ensure the success of MED3000. The Company is supporting commercial partners with regulatory, IP, supply chain management and commercial input.



PATIENTS AND SUFFERERS

The people our therapies are designed to treat are at the heart of why we do it. Our purpose is clear, "to enhance our patients and consumers' quality of life to enable them to enjoy their lives to the full". We consult with key opinion leaders regularly, hold Advisory Boards at key stages and conduct market research to help us with patient and consumer insights. We are focused on bringing innovative products to market where there are unmet patient needs with existing treatments. We are excited to bring MED3000 our treatment for erectile dysfunction to sufferers across the world.

DEVELOPMENT PARTNERS, MANUFACTURERS AND SUPPLIERS

Our development partners, manufacturers and suppliers want to work in a collaborative way that allows them to plan work and become part of the team. As a semi-virtual company, Futura relies upon its relationships with external service providers, manufacturers, consultants and subcontractors to provide resources on an "as needed" basis. These resources provide the Company with specialist skills and insights as well as additional capacity. We work closely with our partners, define clear responsibilities, work in an ethical and collaborative manner to achieve mutually beneficial outcomes to build sustainable and longterm relationships. As the Company prepares to supply MED3000 to commercial partners around the globe our contract manufacturing partners are central to the long-term success of the product and we are working closely with them to deliver continuity of supply, with a product of high quality at the lowest cost possible.



EMPLOYEES

The Board considers its employees to be a primary stakeholder of the Company and is conscious of the regard it has to them under s172. Employees want to be valued and rewarded for their contribution to the Company's development and success. The executive team favours an open-door policy where employee feedback is encouraged. There are regular formal and informal meetings and gatherings to keep employees informed of key developments in the Company as well as Company events to promote team spirit and thank employees. The Board, and especially the Remuneration Committee, has had particular regards to employees as it reviewed and revised the long-term incentive arrangements as part of its strategy to attract, retain and motivate employees in order to deliver value for shareholders.



REGULATORS

Regulators are agencies that regulate medicines and/or medical devices in their territories. They play a leading role in protecting and improving public health and supporting innovation. Futura works proactively and collaboratively with regulators through the presubmission and submission process with an open and constructive dialogue which enables Futura to optimise its clinical development programme. Constructive discussions with regulators enables Futura to optimise its clinical development costs and timeline and shorten the time from development of the product to access by consumers and patients.



Board of Directors

The Board is responsible to shareholders for the proper management of the Group and meets at least six times per year to set the overall direction and strategy of the Group, to review scientific, operational and financial performance and to advise on other strategic matters as they arise. All key operational and investment decisions are subject to Board approval.



JOHN CLARKE Non-Executive Chairman

Current roles

John Clarke is the Chairman of Futura Medical plc. He chairs the Nominations Committee, and is a member of the Audit Committee and the Remuneration Committee. He is also the Non–Executive Chairman of Science in Sport plc and is a senior adviser to Helios Investment Partners LLP.

Past roles

Retired from GSK as President of GSK Consumer Healthcare. Non–Executive Chairman of Quantum Pharma plc, which was subsequently acquired by Clinigen plc, and Kind Consumer Holdings Limited.

Brings to the Board

Extensive experience of the healthcare sector, having worked at a senior level at GSK for more than 35 years.



JAMES BARDER

Chief Executive

Current roles

James Barder is the Group's Chief Executive. He assists the Remuneration Committee and the Nominations Committee (but is not a member of and does not vote on either). He has overall responsibility for all activities of the Group, is a principal contact for shareholder and investor relations and leads commercial negotiations. He is also a Non-Executive Director of Caisson IO Group Limited and a Director of the Mary How Trust for Cancer Prevention.

Past roles

Managing Director of Aon Capital Markets Limited and Non-Executive Director of Lorega Limited. James predominantly worked in the field of reinsurance and finance including firms he founded.

Brings to the Board

Over 30 years of experience in setting up, managing and running companies.



ANGELA HILDRETH

Finance Director, Chief Operating Officer and Company Secretary

Current roles

Angela joined the Group in 2018. She leads the Group's finance, HR and IT functions, inputs into commercial and financial strategy, ensures its compliance procedures and is a principal contact for shareholder and investor relations matters. She is also an Independent Non-Executive Director and Chair of the Audit Committee at AIM-listed Aptamer plc.

Past roles

Senior financial roles in a diverse range of industries, including seven years as UK Finance Director at Shield Therapeutics plc (quoted on AIM).

Brings to the Board

Over 15 years' strategic and operational financial experience of developing and commercialising pharmaceutical products.



KEN JAMES

Executive Director and Head of R&D

Current roles

Ken James is the Head of R&D. He oversees the development, regulatory and manufacturing strategies for the Group's existing pipeline and the evaluation of early stage pipeline opportunities. He is also an Executive Director.

Past roles

Senior Vice President of Research and Development for GlaxoSmithKline Worldwide Consumer Healthcare, having worked in the UK and the USA.

Brings to the Board

Over 40 years' experience in the research, development and commercialisation of consumer healthcare products.



JEFF NEEDHAM

Independent Non-Executive Director

Current roles

Jeff Needham is an Independent Non-Executive Director and Chair of the Remuneration Committee. He is also a member of the Nominations Committee. Jeff is currently on the Board of McKee Foods Corp.

Past roles

President of Perrigo Consumer Self-Care Americas (including USA) and Executive Vice President at Perrigo Company plc, the US-based manufacturer and marketer of consumer healthcare products, and a board director of the US Consumer Healthcare Products Association for 11 years.

Brings to the Board

Over 35 years of experience in manufacturing and marketing of consumer healthcare products with strategic and corporate management expertise, with particular expertise in the US market.



ANDREW UNITT

(joined 1 January 2022) Senior Independent Non-Executive Director

Current roles

Andrew Unitt is an Independent Non-Executive Director and Chair of the Audit Committee. He is also a member of the Remuneration Committee and the Nominations Committee. Andrew is currently Independent Non-Executive Director of AIM-listed company Oncimmune Holdings plc.

Past roles

Chief Financial Officer at the University of Nottingham until 2016. Andrew spent 11 years at Boots plc, where he was Managing Director and Finance Director for four years of Boots Healthcare International, its over the counter medicines business.

Brings to the Board

Over 20 years of experience as a Finance Director in a wide range of industries with strong financial experience and OTC market expertise.

Remuneration Committee Report

REMUNERATION COMMITTEE: COMPOSITION AND TERMS OF REFERENCE

During the period under review the Remuneration Committee comprised the independent Non-Executive Directors and was chaired by Jeff Needham. The Company has adopted the Quoted Companies Alliance's Corporate Governance Code (the "QCA Code") and the report has been prepared in accordance with the principles of the QCA Code. The contents of this report are unaudited unless otherwise stated.

The purpose of the Remuneration Committee is to ensure that the Executive Directors and other employees are fairly rewarded for their individual contribution to the overall performance of the Group. The Committee considers and recommends to the Board the remuneration of the Executive Directors and is kept informed of the remuneration packages of senior staff and invited to comment on these. There were three Remuneration Committee meetings during 2022.

The Board retains responsibility for overall remuneration policy. The terms of reference of the Remuneration Committee are set out in the Investor Centre/Corporate Governance section on the Group's website at *www.futuramedical.com*.

POLICY ON EXECUTIVE DIRECTORS' REMUNERATION

Executive remuneration packages are designed to attract and retain executives of the necessary skill and calibre to run the Group. Direct benchmarking of remuneration is difficult given the specialised nature and size of the Group. The Remuneration Committee recommends to the Board remuneration packages by reference to individual performance and uses the knowledge and experience of the Committee members, published surveys relating to AIM companies, the pharmaceutical industry and market changes generally. The Remuneration Committee has responsibility for recommending any long-term incentive plans.

The Board determines whether or not Executive Directors are permitted to serve in roles with other companies. Such permission is only granted where a role is on a strictly limited basis, where there are no conflicts of interest or competing activities and providing there is not an adverse impact on the commitments required to the Group. Earnings from such roles are not disclosed to the Group.

The table below sets out the elements of the Executive Director's compensation and how each element operates as well as the maximum level of each element and any applicable performance measures.

Element and Purpose Operation		Maximum Level		
Fixed Remuneration				
Basic Salary				
To provide a competitive base salary for the market and size of the Company in order to attract and retain Executive Directors	Usually reviewed annually by the Remuneration Committee and recommended to the Board, taking account of: Salary increases awarded to the	Salary increases will generally be in line with salary increases to other employees, but may be adjusted to take account of: ► Promotion		
of a suitable calibre.	wider workforce	 Change in scope of role 		
	 Group performance 	 Realignment with market; and 		
	► Role and experience	 Development and performance in the role 		
	 Individual performance; and 			
	 Competitive environment 			
Benefits				
To provide a competitive range of benefits as part	Executive Directors usually receive: Private medical insurance	No overall maximum has been set, but the level of benefits provided is determined		
of total remuneration.	 Salary-related death-in-service life insurance 	taking into account the overall cost to the Company.		
Retirement Benefits				
To provide an appropriate level of retirement benefit (or cash allowance equivalent).	Executive Directors are eligible to participate in the Group defined contribution pension scheme. In appropriate circumstances, Directors may be permitted to take benefits as a salary cash supplement (which will usually be reduced to take into account employer National Insurance contributions).	Contributions for 2021 and 2022 were set at 10% of base salary.		

Element and Purpose Operation		Maximum Level		
Variable Remuneration				
Annual Bonus				
Rewards performance over the financial year, including in relation to performance which supports the Company's longer-term objectives.	Awards for Executive Directors are based on performance, measured over the financial year to which they relate, and split between strategic and corporate, and individual objectives split 75% and 25% respectively.	The maximum annual bonus level in 2021 and 2022 was 50% of base salary. In 2021/22, an additional bonus was in place relating to the achievement of a separate performance milestone. Any bonus is granted on a discretionary basis.		
Annual Share Options Awa	ards			
To create alignment between Executive Directors' and shareholders' interests through annual share options issued through the approved and unapproved share options schemes.	Awards are made annually in the form of market value share options. Vesting is subject to performance criteria being met and the Directors remaining in office.	The schemes are overseen by the Remuneration Committee, which recommends to the Board all grants of share options based on the Remuneration Committee's assessment of personal performance and specifying the terms under which eligible individuals may be invited to participate. The share options granted in 2022 will vest three years from the date of grant providing the Executive Director remains in office, or is not under notice, at the date of vesting.		
Long-term Incentive Plan	("LTIP")			
To create alignment between Executive Directors' and shareholders' interests through the delivery of performance- based awards.	Awards are based in the form of nominal cost share options with the quantum of options dependent on a target share price achieved.	In 2022, performance milestones were achieved and the target share price reached. The options granted will vest 25% immediately with a further 25% vesting annually following the date of grant, subject to the Executive Directors remaining in office at the date of vesting. Other performance milestones are expected to be met in 2023 which could trigger further awards under this plan.		

SERVICE CONTRACTS

The Executive Directors are employed under service contracts requiring six months' notice by either party. Non-Executive Directors and the Chairman receive payments under appointment letters which are terminable by three months' notice by either party. The service contracts of the Non-Executive Directors are made available for inspection on request.

POLICY ON NON-EXECUTIVE DIRECTORS' REMUNERATION

The Non-Executive Directors and the Chairman each receive a fee for their services as a director, which is approved by the Board, mindful of the time commitment and responsibilities of their roles and of current market rates for comparable organisations and appointments. Non-Executive Directors and the Chairman are reimbursed for travelling and other incidental expenses incurred on Group business in line with the Group Expenses Policy. The Chairman is also included under the long-term incentive plan.

The Board encourages the ownership of Futura shares by Executive and Non-Executive Directors alike and in normal circumstances does not expect Directors to undertake dealings of a short-term nature.

The Non-Executive Directors receive a proportion of their remuneration in the form of shares. The quantum of shares is determined at the start of each calendar year based on the average closing mid-price of the last ten trading days prior to the year-end. The award for 2022 was settled in January 2023 by the issue of 87,430 shares at 36.36 pence per share. The 2023 award has been determined at 51.50 pence per share and the Non-Executive Directors will accrue these shares over 2023 and receive them, or such lower number as have accrued if they leave the Group earlier, in January 2024.

The Board considers ownership of Futura shares by Non-Executive Directors as a positive alignment of their interest with shareholders. The Board periodically reviews the shareholdings of the Non-Executive Directors and will seek guidance from its advisers if, at any time, it is concerned that a shareholding may, or could appear to, conflict with their duties as an independent Non-Executive Director of the Group.



Remuneration Committee Report

DIRECTORS' EMOLUMENTS

The emoluments of the Directors, who represent the key management personnel were as follows, in 2022:

	Year ended 31 December 2022				-		
	Salary & Directors' Fees £	Bonus £	Share Awards £	Benefits in Kind £	Pension £	Total £	Year ended 31 December 2021 £
James Barder	251,478	139,420	37,975	6,186	-	435,059	356,858
Ken James	186,465	98,129	-	-	-	284,594	267,266
Angela Hildreth	187,200	103,194	-	1,685	18,720	310,799	289,259
Non-Executive Directors							
John Clarke	68,988	-	28,079	-	-	97,067	93,333
Jeff Needham	37,500	-	15,625	-	-	53,125	9,375
Andrew Unitt	37,500	-	12,500	-	-	50,000	-
Totals	769,131	340,743	94,179	7,871	18,720	1,230,644	1,016,091

The above fees and emoluments exclude reimbursed expenditure incurred in the conduct of Group business.

DIRECTORS' INTERESTS IN SHARES

	31 December 2022		31 December 2021	
	Beneficial Interests	Non- beneficial Interests	Beneficial Interests	Non- beneficial Interests
John Clarke	795,100	_	642,542	_
James Barder	1,323,472	117,500	1,093,472	117,500
Ken James	299,581	-	299,581	_
Angela Hildreth	142,857	-	142,857	_
Jeff Needham	20,612	-	_	_
Andrew Unitt	26,526	-		
Totals	2,608,148	117,500	2,178,452	117,500

DIRECTORS' INTERESTS IN SHARE OPTIONS

The Board uses share options to align Directors and employees' interests with those of shareholders in order to provide incentives and reward them based on improvements in Group performance. Options granted to the Directors included options granted under the LTIP scheme and were as follows:

	31 December 2022		31 December 2021	
	Options Held	Share-based Payment Expense	Options Held	Share-based Payment Expense
James Barder	2,085,716	100,119	1,880,000	37,501
Ken James	1,945,227	87,113	1,304,000	30,001
Angela Hildreth	1,508,340	83,789	904,000	30,001
John Clarke	463,343	42,846	_	_
Totals	6,002,626	313,867	4,088,000	97,503

All share options were granted with an exercise price at or above market value on the date of grant. The main vesting condition of the share options is that the Director remains employed with the Group as at the date of exercise or continues to provide consultancy services as at the date of exercise. The share options of the Directors under the Futura Medical plc Enterprise Management Incentive Scheme are set out on the opposite page.
		Number	Exercise Price/	Earliest	
	Grant Date	Awarded	Share	Exercise Date	Expiry Date
James Barder	13 January 2017	124,348	57.50 pence	1 October 2018	30 September 2023
James Barder	17 September 2019	250,000	31.00 pence	1 October 2021	30 September 2026
James Barder	21 September 2020	300,000	15.50 pence	1 October 2022	30 September 2027
James Barder	5 October 2021	94,322	37.90 pence	1 October 2023	30 September 2028
Ken James	13 January 2017	200,000	57.50 pence	1 October 2018	30 September 2023
Ken James	12 September 2017	200,000	30.50 pence	1 October 2019	30 September 2024
Ken James	19 November 2018	200,000	7.50 pence	1 October 2020	30 September 2025
Ken James	17 September 2019	200,000	31.00 pence	1 October 2021	30 September 2026
Angela Hildreth	19 November 2018	200,000	7.50 pence	1 October 2020	30 September 2025
Angela Hildreth	17 September 2019	200,000	31.00 pence	1 October 2021	30 September 2026
Angela Hildreth	21 September 2020	240,000	15.50 pence	1 October 2022	30 September 2027
Angela Hildreth	5 October 2021	264,000	37.90 pence	1 October 2023	30 September 2028
Angela Hildreth	14 September 2022	79,425	45.00 pence	1 October 2025	30 September 2030
Totals		2,552,095			

The share options of the Directors under the Futura Medical plc Unapproved Option Scheme are set out below:

	Grant Date	Number Awarded	Exercise Price/ Share	Earliest Exercise Date	Expiry Date
James Barder	13 January 2017	125,652	57.50 pence	1 October 2018	30 September 2023
James Barder	12 September 2017	250,000	30.50 pence	1 October 2019	30 September 2024
James Barder	5 October 2021	235,678	37.90 pence	1 October 2023	30 September 2028
James Barder	14 September 2022	165,000	45.00 pence	1 October 2025	30 September 2030
Ken James	21 September 2020	240,000	15.50 pence	1 October 2022	30 September 2027
Ken James	5 October 2021	264,000	37.90 pence	1 October 2023	30 September 2028
Ken James	14 September 2022	132,000	45.00 pence	1 October 2025	30 September 2030
Angela Hildreth	14 September 2022	52,575	45.00 pence	1 October 2025	30 September 2030
Totals		1,464,905			

DIRECTORS' INTERESTS IN LONG-TERM INCENTIVE PLAN

Some performance milestones, which are non-market related milestones, were met in 2022. The options granted will vest 25% immediately with a further 25% vesting annually following the date of grant. In 2022, a performance milestone was met at the target share price and the following number of share options were granted:

	Grant Date	Number Awarded	Exercise Price/ Share	Earliest Exercise Date	Expiry Date
James Barder	7 December 2022	540,716	0.02 pence	10 January 2023	30 September 2030
Ken James	7 December 2022	509,227	0.02 pence	10 January 2023	30 September 2030
Angela Hildreth	7 December 2022	472,340	0.02 pence	10 January 2023	30 September 2030
John Clarke	7 December 2022	463,343	0.02 pence	10 January 2023	30 September 2030
Totals		1,985,626			

A share-based remuneration charge has been included in the Consolidated Statement of Comprehensive Income in respect of the Approved Share Option Scheme, Unapproved Share Option Scheme and the LTIP scheme.

JEFF NEEDHAM Chairman of the Remuneration Committee

Corporate Governance Statement

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The Board is committed to the highest standards of corporate governance and to maintaining a sound framework for the control and management of the Group's business."

JOHN CLARKE Non-Executive Chairman

DEAR SHAREHOLDER,

As Chairman of Futura Medical, and on behalf of the Board, I am pleased to present our Corporate Governance Statement for the year ended 31 December 2022.

I have overall responsibility for corporate governance and in promoting high standards throughout the Group. As well as leading and chairing the Board my responsibilities are to ensure:

- Committees are properly structured and operate with appropriate terms of reference;
- The performance of individual Directors, the Board and its committees are reviewed on a regular basis;
- The Company has a coherent strategy and sets objectives against this;
- There is effective communication between the Company and its shareholders.

Futura Medical has adopted the QCA Corporate Governance Code (the "QCA Code") as it considers that this is the most suitable framework for smaller listed companies. The Board is committed to the highest standards of corporate governance and to maintaining a sound framework for control and management of Futura Medical plc. The Board is responsible for leading and controlling the activities of the Group, with overall authority for the management and conduct of the business, together with its strategy and development. The Board believes that good corporate governance improves long-term success and the support from our shareholders is vital to our success. We remain responsive to our shareholders' and stakeholders' views to deliver on our objectives.

The principal methods of communicating our application of the QCA Code are this Annual Report and the Investor section of our website at *www.futuramedical.com*. The QCA Code sets out ten principles and in the Corporate Governance Report on pages 36 to 40 we have set out the Group's application of the QCA Code, including, where appropriate, cross references to other sections of this Annual Report and to our website.

JOHN CLARKE Non-Executive Chairman

4 April 2023

Corporate Governance Report

PRINCIPLE 1 - BUSINESS MODEL AND STRATEGY

The strategy and business operations of the Group are set out in the Strategic Report section of the Annual Report. The full Board meets formally at least six times per year and informally as required. It is responsible for formulating and monitoring Group strategy, as well as complying with legal, regulatory and corporate governance matters. The strategy and business model and amendments thereto, are developed by the Chief Executive Officer and his senior management team and approved by the Board. The management team, led by the Chief Executive Officer, is responsible for implementing the strategy and managing the business at an operational level.

The Group's overall strategic objective is to develop innovative products with compelling commercial potential in the pharmaceutical and consumer healthcare markets, leveraging our core skills in transdermal technology. This strategy is aligned with the well-publicised demographic changes of ageing populations, increasing prosperity, government initiatives to increase self-medication, pressures on payers and healthcare systems, the rapid growth of prescription and over the counter ("OTC") opportunities in developing countries, the natural desire for an improved quality of life and our expectations that consumer healthcare spending will increase as a result. The objective is to develop products such that each on its own has the potential to generate significant annual revenues.

OVERNAND

Now that MED3000 has had regulatory approval in the EU, the Group has chosen to realise monetary value via out-licensing deals with distribution partners. If resources permit, the Group may choose to advance other products through clinical development and approval in order to retain the full value of the product within the Group.

The Group operates in a high risk and heavily regulated sector and this is reflected in the principal risks and uncertainties set out on pages 24 to 26 of our Strategic Report. The key challenge to the successful development of this strategy is ensuring that there are sufficient financial resources that can be deployed in the short-term in advance of the products being able to generate financial rewards for the Group in the longer term.

PRINCIPLE 2 – UNDERSTANDING SHAREHOLDER NEEDS AND EXPECTATIONS

The Group seeks to maintain a regular dialogue with both existing and potential new shareholders in order to communicate the Group's strategy and progress and understand the needs and expectations of shareholders. Institutional shareholders and analysts have the opportunity to discuss general issues and provide feedback at meetings with the Company. In addition, all shareholders are encouraged to attend the Company's Annual General Meeting now that face to face meetings can be held again without restrictions.

PRINCIPLE 3 – STAKEHOLDER RESPONSIBILITIES

The Group is aware of its corporate and social responsibilities and the need to maintain effective working relationships across a range of stakeholder groups. In addition to shareholders, these include the Group's employees, regulators, commercial partners, suppliers, patients involved in the Group's clinical development activities as well as people affected by the conditions we seek to treat. The Group's operations and working practices need to balance the needs of all of these stakeholder groups while maintaining focus on the Board's primary responsibility to promote the success of the Group for the benefit of its members as a whole.

The Group endeavours to take feedback received from stakeholders by meeting regularly and responding accordingly. This feedback ensures that the Group can respond to new issues and opportunities that arise to further the Group in the delivery of its long-term strategy. Further information can be found on pages 28 and 29.

PRINCIPLE 4 – RISK MANAGEMENT

The Audit Committee and the Risk and Oversight Committee are responsible to the Board for risk management and internal controls and for ensuring that procedures are in place, and are being effectively implemented to identify, evaluate and manage the significant risks faced by the Group. The internal controls are designed to manage rather than eliminate risk and provide assurance against material misstatement or loss.

The Audit Committee is responsible for reviewing the effectiveness of these internal controls on an annual basis and the Risk and Oversight Committee ("ROC") provides additional oversight of its operational compliance in respect of its assets. During 2022 the ROC provided oversight of the Company's Medical Device Quality Management System ("QMS") as defined in the Medical Device Quality Manual. The ROC meets at least once a year or more frequently if required and agenda items are driven by a management review which assesses compliance against the QMS and any issues arising out of the clinical trials that the Company is planning and undertaking .

Given the current size and transparency of the operations of the Group, the Board has concluded that an internal audit function is not required and this will be continually reviewed as the Company grows. A summary of principal risks and uncertainties facing the Group, as well as mitigating actions, are set out on pages 24 to 26 of our Strategic Report.

PRINCIPLE 5 - A WELL-FUNCTIONING BOARD OF DIRECTORS

Futura's Board comprises three Non-Executive Directors and three Executive Directors. All of the Directors are subject to election by shareholders at the first Annual General Meeting after their appointment and will continue to seek re-election by rotation at least once every three years.

BOARD OF DIRECTORS

During the year under review, the Board comprised three Executive Directors, a Non-Executive Chairman and two Non-Executive Directors. Details of the Directors who served in the year can be found on page 41.

ATTENDANCE AT BOARD AND COMMITTEE MEETINGS

The Board is responsible to shareholders for the proper management of the Group and meets at least six times per year to set the overall direction and strategy of the Group, to review scientific, operational and financial performance and to advise on other strategic matters as they arise. All key operational and investment decisions are subject to Board approval. The Board met formally six times during 2022 and, in addition, authority was delegated on an ad hoc basis to subcommittees to deal with statutory matters, such as the approval of the full year results and interim statements.

Corporate Governance Report

Director	Board	Audit Committee	Remuneration Committee	Nominations Committee
John Clarke	6/6	3/3	3/3	N/A
Andrew Unitt	6/6	3/3	3/3	N/A
Jeff Needham	6/6		3/3	
James Barder	6/6			
Angela Hildreth	6/6			
Ken James	6/6			

Attendance is expressed by the number of meetings attended/number eligible to attend. Directors' attendance by invitation at meetings of committees of which they are not a member is not reflected in the table above.

Non-Executive Directors' letters of appointment stipulate that they are expected to devote such time as is necessary for the proper performance of their duties, being not less than 25 days per year. Non-Executive Directors are required to notify the Chairman before taking on any additional commitments that may impact the time available to devote to the Non-Executive Director role. The Board is satisfied that all Directors have continued to be effective and demonstrate commitment to their respective roles.

INDEPENDENCE OF BOARD DIRECTORS

The Board considers itself independent. The QCA code suggests that a Board should have at least two independent Non-Executive Directors who currently sit on the Board of the Company and are regarded as independent under the QCA's guidance for determining such independence.

The Non-Executive Directors receive their fees in the form of a basic cash fee and an equity-based fee which takes the form of nominal price share options under the Company's Non-Executive Share Option Scheme. To avoid any incentive that may influence the Non-Executive Directors' independence, the options grants are not deemed significant, either for any individual Non-Executive Director or in aggregate. The current remuneration structure for the Board's Non-Executive Directors is deemed to be proportionate and in line with market rates. The Directors commit the time required to fulfil their duties.

PRINCIPLE 6 - APPROPRIATE SKILLS AND EXPERIENCE OF THE DIRECTORS

The Board considers that all of the Non-Executive Directors are of sufficient competence and calibre to add strength and objectivity to its activities and bring significant experience in commercial, operational and financial development of the Group's products.

The Board regularly reviews the composition of the Board to ensure that it has the necessary depth and breadth of skills to support the ongoing delivery of the Group's long-term strategy and the Board is committed to ensuring diversity of skill, experience and gender.

Andrew Unitt joined the Board on 1 January 2022 and brings strong financial experience having spent eleven years at Boots plc, where he was Finance Director for four years of Boots Healthcare International, its over the counter medicines business.

Board members maintain their skillsets through practice in day-to-day roles, enhanced with attending specific training where required. This is a combination of in-house Company-arranged briefings and external courses.

The Board uses external advisers where necessary to enhance knowledge or to gain access to particular skills or capabilities. Accountants and lawyers are used for diligence work on specific projects. Both the Nominations Committee and the Remuneration Committee use recruitment and employment consultants and specialist advisers have been used by the Board to ensure compliance in specific areas.

The Chairman, in conjunction with the Company Secretary, ensures that the Directors' knowledge is kept up to date on key issues and developments pertaining to the Group, its operational activities and the Directors' responsibilities as members of the Board. During the course of the year, the Directors received updates from the Company Secretary on a number of corporate governance matters.

The Company Secretary provides information and advice on corporate governance and to individual Directors on any aspect of their role, particularly supporting the Chairman and those who chair Board Committees. The Company Secretary is also responsible for ensuring that Board procedures are followed, that the Company complies with company law and AIM Rules and that the Board receives the information it needs to fulfil its duties effectively.

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Director	Pharma/ OTC sector	Financial	General management	Other public company (Board level)
John Clarke	$\checkmark$		$\checkmark$	$\checkmark$
Jeff Needham	$\checkmark$		$\checkmark$	$\checkmark$
Andrew Unitt	$\checkmark$	$\checkmark$	$\checkmark$	$\checkmark$
James Barder	$\checkmark$	$\checkmark$	$\checkmark$	$\checkmark$
Angela Hildreth	$\checkmark$	$\checkmark$	$\checkmark$	$\checkmark$
Ken James	$\checkmark$			

## PRINCIPLE 7 - EVALUATION OF BOARD PERFORMANCE

Internal evaluation of the Board, the Committees and individual Directors is undertaken on an annual basis and was recently completed in February 2023 in the form of peer appraisal, guestionnaires and discussions led by the Chairman to determine their effectiveness and performance as well as the Non-Executive Directors' continued independence. The Board may utilise the results of the evaluation process when considering the adequacy of the composition of the Board, to identify any training and development needs and for succession planning.

The Board as a collective is evaluated on diversity, balance, governance and strategy and individual members are evaluated on a range of criteria such as leadership, strategy, governance, interpersonal skills and integrity. The performance of the Chairman was also evaluated in the same way and this was led by Senior Non-Executive Director Andrew Unitt.

The Chairman is responsible for the annual performance assessment of the Chief Executive Officer and the Chief Executive Officer reviews the performance of the other Executive Directors, the Finance Director/Chief Operating Officer and Head of R&D where performance against corporate objectives set at the start of the year is measured.

The review in February 2023 concluded that the Directors were satisfied with Board operations and processes with no major issues raised.

The Nominations Committee continues to monitor the requirement for succession planning.

## PRINCIPLE 8 - CORPORATE CULTURE

The Board recognises that its decisions regarding strategy and risk will impact on the culture of the Group as a whole and that this will impact the performance of the Group. The Board seeks to maintain the highest standards of integrity in the conduct of the Group's operations. An open culture is encouraged within the Group with regular communications with staff regarding progress and staff feedback regularly sought. The Board assessment of the culture within the Group at the present time is one where there is respect for all individuals, there is open dialogue within the Group and there is a commitment to provide the best service possible to all the Group's customers which include commercial partners and patients and clinicians who are participating in our clinical development programmes.

## PRINCIPLE 9 - MAINTENANCE OF GOVERNANCE STRUCTURES AND PROCESSES

The Board has overall responsibility for promoting the success of the Group. The Executive Directors have dayto-day responsibility for the operational management of the Group's activities. The Non-Executive Directors are responsible for the overall operational management of the Group's activities and for bringing independent and objective judgement to Board decisions.

There is a clear separation of the roles of Chief Executive Officer and Non-Executive Chairman. The Chairman is responsible for overseeing the running of the Board, ensuring that no individual or group dominates the Board's decision-making and ensuring the Non-Executive Directors are properly briefed on matters. The Chairman has overall responsibility for corporate governance matters in the Group and chairs the Nominations Committee. The Chief Executive Officer has responsibility for implementing the strategy of the Board and managing the day-to-day business activities of the Group. The Company Secretary is responsible for ensuring that Board procedures are followed and applicable rules and regulations are complied with.

## THE AUDIT COMMITTEE

The Audit Committee normally meets two to three times per year and has responsibility for, amongst other things, reviewing the annual report and accounts and interim statements involving, where appropriate, the External Auditor. The Committee also approves the External Auditor's fees and ensures the Auditor's independence as well as focusing on compliance with legal requirements and accounting standards. It is also responsible for ensuring that an effective system of internal control is maintained. The ultimate responsibility for approving the annual financial statements and interim statements remains with the Board.

## **Corporate Governance Report**

The Finance Director and Chief Operating Officer, and the External Auditor attend meetings by invitation only. The Audit Committee meets privately (without any other Board member present) with the External Auditor at least once per year.

The Group's Auditor is Grant Thornton UK LLP based at 20 Valpy Street, Reading, Berkshire, RGI 1AR and was appointed in 2019 as part of a tender process. The senior statutory auditor is Jonathan Oakey.

### THE REMUNERATION COMMITTEE

The Remuneration Committee, which meets as required, but at least once per year, has responsibility for making recommendations to the Board on the compensation of senior executives and determining, within agreed terms of reference, the specific remuneration packages for each of the Executive Directors. It also supervises the Group's share incentive schemes and sets performance conditions for share options granted under the schemes. The Independent Non-Executive Directors and the Non-Executive Chairman sit on the Committee, and the Chief Executive Officer attends by invitation only.

The Directors' remuneration can be found in the Remuneration Committee Report on pages 32 to 35.

The Directors believe that the disclosures in that report constitute sufficient disclosure to meet the requirements of the QCA Code for a Remuneration Committee Report. Consequently, a separate Directors' Remuneration Report is not presented in the Group's Annual Report. However, the Committee will continue to review guidance in relation to the contents of remuneration reports and ensure the reporting evolves as the Committee considers appropriate.

### THE NOMINATIONS COMMITTEE

The Nominations Committee, which meets as required, has responsibility for reviewing the size and composition of the Board, the appointment or replacement of Directors, the monitoring of compliance with applicable laws, regulations and corporate governance guidance and making appropriate recommendations to the Board.

The Independent Non-Executive Directors and the Non-Executive Chairman sit on the Committee, and the Chief Executive Officer attends by invitation only.

The terms of reference for the above committees can be found in the Investors section of our website at *www.futuramedical.com*.

The Board also oversees the Group's share dealing code and its whistle-blowing policies and procedures.

## **PRINCIPLE 10 - SHAREHOLDER COMMUNICATION**

The Group places a high priority on regular communication with its shareholders and aims to ensure that all communications concerning the Group's activities are clear, fair and accurate. The website is regularly updated and users can register to be alerted when announcements or details of presentations and events are posted onto the website.

The Group's financial reports can be found in the Investor section of our website at www.futuramedical.com.

Notice of General Meetings of the Company and results of voting on all resolutions in future general meetings can be found in the RNS section of our website at *www.futuramedical.com*.

The results of voting on all resolutions in future general meetings will be posted to the Group's website after the relevant meeting.

#### JOHN CLARKE Non-Executive Chairman 4 April 2023

# **Directors' Report**

## DIRECTORS

The Directors during the year were:

John Clarke	Non-Executive Chairman
Andrew Unitt	Non-Executive Director ¹
Jeff Needham	Non-Executive Director
James Barder	Chief Executive Officer
Angela Hildreth	Finance Director/Chief Operating Officer
Ken James	Head of R&D/Executive Director

1. Appointment commenced 1 January 2022

## **GENERAL INFORMATION**

Futura Medical plc is a public limited company incorporated in the United Kingdom, registered number 04206001, which is listed on the Alternative Investment Market ("AIM") of the London Stock Exchange.

## **REVIEW OF BUSINESS**

The Group continues to invest in the development of its transdermal technology DermaSys® with the focus being on sexual health and pain relief management. The Strategic Report on pages I to 29 provides a review of the business, including the Group's trading for the year ended 31 December 2022, an indication of likely future developments, key performance indicators and risks.

## DIVIDENDS

The Group has reported its consolidated financial statements in accordance with International Financial Reporting Standards ("IFRSs") as adopted by the UK. The results for the year and financial position of the Company and the Group are set out in the financial statements and reviewed in the Financial Review within the Strategic Report. The Directors do not recommend the payment of a dividend (2021: £nil).

## DIRECTORS' INTERESTS

The Directors' interests in the Company's shares and options over ordinary shares are shown in the Remuneration Committee Report on pages 32 to 35. No Director has any beneficial interest in the share capital of any subsidiary or associate undertaking.

## DIRECTORS' REMUNERATION

Details of the Directors' remuneration appear in the Remuneration Committee Report on pages 32 to 35.

## DIRECTORS' AND OFFICERS' LIABILITY INSURANCE

The Company has, as permitted by the Companies Act 2006, maintained insurance cover on behalf of the Directors, indemnifying them against certain liabilities which may be incurred by them in relation to the Company.

## POLITICAL DONATIONS

The Group made no political donations during the current or prior year.

## FINANCIAL INSTRUMENTS – RISK MANAGEMENT

The Group's financial risk management policy is set out in Note 4 to the financial statements.

## RESEARCH AND DEVELOPMENT ("R&D")

During the year ended 31 December 2022 the Group's expenditure on R&D was £4,131,224 (2021: £3,774,269).

## ADEQUACY OF INFORMATION SUPPLIED TO EXTERNAL AUDITOR

Each Director who held office at the date of approval of this Report confirms that, so far as the Director is aware, there is no relevant audit information of which the Company's External Auditor is unaware and the Director has taken all the steps that he or she ought to have taken as a Director to make himself or herself aware of any relevant audit information and to establish that the Company's External Auditor is aware of that information. This confirmation is given and should be interpreted in accordance with the provisions of section 418 of the Companies Act 2006.

The Directors confirm that:

- so far as each Director is aware, there is no relevant audit information of which the Company's Auditor is unaware; and
- the Directors have taken all the steps that they ought to have taken as Directors in order to make themselves aware of any relevant audit information and to establish that the Company's Auditor is aware of that information.

## CHANGE OF CONTROL PROVISIONS

There are some agreements that may take effect, alter or terminate on a change of control of the Company, such as commercial contracts, property leases and share option schemes. None of these are considered to be significant in their likely impact on the business as a whole.

# **Directors' Report**

## STATEMENT OF ENGAGEMENT WITH SUPPLIERS, CUSTOMERS AND OTHERS IN A BUSINESS RELATIONSHIP WITH THE COMPANY

The Directors are mindful of their statutory duty to act in the way they each consider, in good faith, would be most likely to promote the success of the Company for the benefit of its members as a whole, as set out in our s.172(1) statement on page 28. A consideration of the Company's relationship with wider stakeholders, including suppliers and commercial partners, is disclosed in the Stakeholders section on pages 28 and 29.

## SIGNIFICANT INTERESTS

On 31 March 2023 the Company was notified of the following shareholders with 3% or more of the issued share capital of the Company in accordance with the Disclosure Guidance and Transparency rules:

Lombard Odier Asset Management (Europe) Limited	26.99%
TAdams	6.89%
WT Lamb Investments Limited	4.51%
RA Lamb	3.28%
Chelverton Asset Management	3.01%

Most recently notified details of significant shareholdings may be found in the Investor section of our website, at *www.futuramedical.com*.

## STATEMENT OF DIRECTORS' RESPONSIBILITIES IN RESPECT OF THE ANNUAL REPORT AND THE FINANCIAL STATEMENTS

The Directors are responsible for preparing the Annual Report and the Group and Parent Company financial statements in accordance with applicable law and regulations. Company law requires the Directors to prepare Group and Parent Company financial statements for each financial year. Under the AIM Rules of the London Stock Exchange they are required to prepare the Group financial statements in accordance with UK-adopted International Standards (IFRSs as adopted by the UK) and applicable law and they have elected to prepare the Parent Company financial statements in accordance with UK accounting standards and applicable law (UK Generally Accepted Accounting Practice), including FRS 101 'Reduced Disclosure Framework'.

Under company law the Directors must not approve the financial statements unless they are satisfied that they give a true and fair view of the state of affairs of the Group and Parent Company and of their profit or loss for that period. In preparing each of the Group and Parent Company financial statements, the Directors are required to:

- select suitable accounting policies and then apply them consistently;
- make judgements and estimates that are reasonable, relevant, reliable and prudent;
- state whether they have been prepared in accordance with IFRSs as adopted by the UK;
- for the Parent Company financial statements, state whether applicable UK accounting standards have been followed, subject to any material departures disclosed and explained in the financial statements;
- assess the Group and Parent Company's ability to continue as a going concern, disclosing, as applicable, matters related to going concern; and
- use the going concern basis of accounting unless they either intend to liquidate the Group or the Parent Company or to cease operations, or have no realistic alternative but to do so.

The Directors are responsible for keeping adequate accounting records that are sufficient to show and explain the Parent Company's transactions and disclose with reasonable accuracy at any time the financial position of the Parent Company and enable them to ensure that its financial statements comply with the Companies Act 2006. They are responsible for such internal control as they determine is necessary to enable the preparation of financial statements that are free from material misstatement, whether due to fraud or error, and have general responsibility for taking such steps as are reasonably open to them to safeguard the assets of the Group and to prevent and detect fraud and other irregularities.

The Directors have decided to prepare voluntarily a Remuneration Committee Report in accordance with Schedule 8 to The Large and Medium-sized Companies and Groups (Accounts and Reports) Regulations 2008 made under the Companies Act 2006, as if those requirements applied to the Company. The Directors have also decided to prepare voluntarily a Corporate Governance Statement as if the Company were required to comply with the Listing Rules and the Disclosure Guidance and Transparency Rules of the Financial Conduct Authority in relation to those matters. Under applicable law and regulations, the Directors are also responsible for preparing a Strategic Report and a Directors' Report that comply with that law and those regulations.

We consider the Annual Report and Accounts, taken as a whole, are fair, balanced and understandable and provide the information necessary for shareholders to assess the Group's position and performance, business model and strategy.

## **GOING CONCERN**

The Directors believe that it remains appropriate to prepare the financial statements on a going concern basis. However, they also acknowledge 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 financial statements do not include any adjustments that would result from the basis of preparation being inappropriate. Further details can be found in Note 2.2.

## WEBSITE PUBLICATION

The Directors are responsible for the maintenance and integrity of the corporate and financial information included on the Company's website. Legislation in the United Kingdom governing the preparation and dissemination of financial statements may differ from legislation in other jurisdictions.

By order of the Board

#### ANGELA HILDRETH Company Secretary 4 April 2023



# Audit Committee Report

## THE AUDIT COMMITTEE

During the year the Audit Committee considered the adequacy of financial standards and how existing and new accounting standards apply to the business. In addition, the Audit Committee considered how applying these standards may flow through into internal processes and controls, the Group's accounting policies and the Group's financial reporting to shareholders.

Whilst the Board has overall responsibility for the review and approval of the annual and interim accounts, certain aspects are delegated to the Audit Committee including:

- Monitoring the integrity of the financial statements of the Group and any formal announcements relating to the Group's financial performance.
- Reviewing accounting standards, policies and judgements.
- Reviewing internal controls and risk management procedures which arise during the external audit process, or if concerns are raised by a member of the Board or by an employee under the Company's whistle-blowing process.
- Oversight of the Group's compliance with legal requirements ensuring that an effective internal control system is maintained.

Full terms of reference for the Audit Committee can be found in the Investor section of the Company website at *www.futuramedical.com*.

There were three meetings held in the year and matters discussed were as follows:

### JANUARY 2022

Presentation of 2021 Audit Plan

### APRIL 2022

Presentation of 2021 Audit Report (see 2021 Annual Report for 2021 Audit Report)

Review of 2021 audit performance

### DECEMBER 2022

Review of audit planning including audit risk areas for the year ended 2022

Key areas of risks discussed were as follows:

- The valuation of the investment in the Parent Company books of the carrying value of its subsidiaries – the Committee concluded that the carrying value was justified by the commercial prospects for MED3000 which were supported by market research, the licensing agreements to commercialise MED3000 in Latin America, the Middle East, the UK and EU where approval is already granted and the potential US approval of MED3000 as a treatment for ED without the need for a doctor's prescription.
- Capitalisation of R&D costs Whilst commercial agreements are in place in some regions the product may not yet have launched as further regulatory approval is required within those regions and where regulatory approval is granted, commercial agreements are not yet in place.

The Committee continued to be of the view that as the product had not yet launched in one major market, R&D costs would continue to be recognised in the Consolidated Statement of Comprehensive Income as incurred.

Going concern – the Group's latest cash flow ► forecast demonstrated sufficient cash resources to last at least 18 months. In addition, the Committee noted that the Company had good prospects of achieving further licensing deals for MED3000 with upfront payments and relatively conservative product sales were included within the cashflow forecasts and if higher than forecasted, could further extend the cash runway. On this basis the Committee concluded that it was appropriate to prepare the 2022 financial statements on the going concern basis. However, it was noted that a material uncertainty exists that may cast a 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.

## **EXTERNAL AUDITOR**

The Audit Committee has responsibility for the relationship between the Group and its External Auditor. Representatives from the External Auditor are invited to attend Audit Committee meetings and whilst the Finance Director and other Executives are invited to attend the Committee meetings, time at the end of a meeting is allowed without any other Executive Directors or other executives present, to give the External Auditor an opportunity to raise any issues of concern.

The Audit Committee is responsible for reviewing the scope of work and fee proposals presented by the External Auditor to ensure that its independence is not compromised. The independence of the Auditor is kept under review and is reported once per year, as part of the Audit Committee Report presented to the Audit Committee by the External Auditor.

The Group's External Auditor, Grant Thornton UK LLP, is engaged to provide its independent opinion on the Group's financial statements. A full scope of its work for the year ended 31 December 2022 is included within the Independent Auditor's Report on pages 45 to 53. Grant Thornton was appointed in 2019 following a tender process. The senior statutory auditor is Jonathan Oakey.

## **INTERNAL AUDIT**

The Audit Committee reviews the requirement for an internal audit function on an annual basis, taking into account the scale and complexity of the Group's activities and any issues identified in the assessment of controls. The Committee remains of the opinion that an internal audit function is currently not appropriate for the Group and the Committee will continue to review the appropriateness of these arrangements.

### ANDREW UNITT Chairman of the Audit Committee

# Independent Auditor's Report

to the Members of Futura Medical plc for the year ended 31 December 2022

## OPINION

## OUR OPINION ON THE GROUP FINANCIAL STATEMENTS IS UNMODIFIED

We have audited the group financial statements of Futura Medical plc (the 'Parent Company') and its subsidiaries (the 'Group') for the year ended 31 December 2022, which comprise the Consolidated statement of comprehensive income, the Consolidated statement of changes in equity, the Consolidated statement of financial position, the Consolidated statement of cash flows, the Parent company balance sheet, the Parent Company statement of changes in equity and notes to the financial statements, including a summary of significant accounting policies.

The financial reporting framework that has been applied in their preparation is applicable law and UKadopted international accounting standards. The financial reporting framework that has been applied in the preparation of the parent company financial statements is applicable law and United Kingdom Accounting Standards, including Financial Reporting Standard 101 'Reduced Disclosure Framework' (United Kingdom Generally Accepted Accounting Practice).

In our opinion:

- the financial statements give a true and fair view of the state of the Group's and of the Parent Company's affairs as at 31 December 2022 and of the Group's loss for the year then ended;
- the Group financial statements have been properly prepared in accordance with UK-adopted international accounting standards;
- the Parent Company financial statements have been properly prepared in accordance with United Kingdom Generally Accepted Accounting Practice; and
- ▶ the financial statements have been prepared in accordance with the requirements of the Companies Act 2006.

## **BASIS FOR OPINION**

We conducted our audit in accordance with International Standards on Auditing (UK) (ISAs (UK)) and applicable law. Our responsibilities under those standards are further described in the 'Auditor's responsibilities for the audit of the group financial statements' section of our report. We are independent of the Group and the Parent Company in accordance with the ethical requirements that are relevant to our audit of the financial statements in the UK, including the FRC's Ethical Standard as applied to listed entities, and we have fulfilled our other ethical responsibilities in accordance with these requirements. We believe that the audit evidence we have obtained is sufficient and appropriate to provide a basis for our opinion.

### MATERIAL UNCERTAINTY RELATED TO GOING CONCERN

We draw attention to the going concern note included in Note 2.2 in the notes to the consolidated financial statements. This indicates the risks of the Group's and the Parent Company's ability to continue as a going concern due to the uncertainty around its ability to generate sufficient revenues or to 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. As stated in the Going concern note included in Note 2.2 in the notes to the consolidated financial statements, these events or conditions, along with the other matters as set forth in the Going concern note included paragraph in Note 2.2, indicate that a material uncertainty exists that may cast significant doubt on the Group's and the Parent

Company's ability to continue as a going concern. Our opinion is not modified in respect of this matter.

In auditing the financial statements, we have concluded that the directors' use of the going concern basis of accounting in the preparation of the financial statements is appropriate.

### OUR EVALUATION OF MANAGEMENT'S ASSESSMENT OF THE ENTITY'S ABILITY TO CONTINUE AS A GOING CONCERN

Our evaluation of the directors' assessment of the group's ability to continue to adopt the going concern basis of accounting included obtaining management's going concern assessments covering the period to 30 June 2024 and performing the following procedures:

- obtaining an understanding of relevant controls over management's going concern models, including those over the inputs and assumptions used in the models;
- corroborating key assumptions, such as assessing the timing and quantity of future sales, increases of costs in line with inflation, delays in R&D tax credit receipts, availability of future funding and challenging management where necessary;
- assessing the impact of not achieving expected revenue and evaluating the impact of a reduced revenue scenario. We considered whether the assumptions are consistent with our understanding of the business and other audit work undertaken;

# Independent Auditor's Report

to the Members of Futura Medical plc for the year ended 31 December 2022

- assessing the impact of the mitigating factors available to management in respect of the ability to reduce expenditure through cost saving exercises, such as reducing bonus payments, and raise finance through a share issue or alternative options;
- assessing the accuracy of management's past forecasting by comparing management's future forecasts modelled in the two prior financial years to the actual results for that relevant year and considering the impact on the going concern models;
- evaluating events that occurred post balance sheet date and challenging management as to whether these have been correctly reflected in the forecasts prepared;
- assessing management's sensitivity analysis on the going concern models and considering if they
  appropriately consider reasonably possible adverse movements, as well as performing our own further
  sensitivity analysis; and
- ▶ assessing the adequacy of related disclosures within the annual report and accounts.

### **OUR RESPONSIBILITIES**

We are responsible for concluding on the appropriateness of the directors' use of the going concern basis of accounting and, based on the audit evidence obtained, whether a material uncertainty exists related to events or conditions that may cast significant doubt on the Group's and the Parent Company's ability to continue as a going concern. If we conclude that a material uncertainty exists, we are required to draw attention in our report to the related disclosures in the financial statements or, if such disclosures are inadequate, to modify the auditor's opinion. Our conclusions are based on the audit evidence obtained up to the date of our report. However, future events or conditions may cause the Group or the Parent Company to cease to continue as a going concern.

The responsibilities of the directors with respect to going concern are described in the 'Responsibilities of directors for the financial statements' section of this report.

## OUR APPROACH TO THE AUDIT



## **KEY AUDIT MATTERS**

Key audit matters are those matters that, in our professional judgement, were of most significance in our audit of the financial statements of the current period and include the most significant assessed risks of material misstatement (whether or not due to fraud) that we identified. These matters included those that had the greatest effect on: the overall audit strategy; the allocation of resources in the audit; and directing the efforts of the engagement team. These matters were addressed in the context of our audit of the group financial statements as a whole, and in forming our opinion thereon, and we do not provide a separate opinion on these matters.

In the graph below, we have presented the key audit matters, significant risks and other risks relevant to the audit.



#### KEY AUDIT MATTER -PARENT COMPANY

#### IMPAIRMENT OF THE INVESTMENT IN THE SUBSIDIARY

We identified impairment of the investment in Futura Medical Developments Limited as one of the most significant assessed risks of material misstatement due to error.

The carrying value of the investment as at 31 December 2022 was £65.2m. The assessment of impairment of the investment is required when there is an indication of impairment. An indicator of impairment arises due to the uncertainty in the market potential of the MED3000 medical device post EU approval.

### HOW OUR SCOPE ADDRESSED THE MATTER - PARENT COMPANY

Description

Disclosures

Audit response

Our results

In responding to the key audit matter, we performed the following audit procedures:

- obtaining management's impairment review and comparing the recoverable amounts to the value of the investment;
- assessing the accounting policy applied for compliance with IAS 36 'Impairment of Assets';
- inspecting in detail the key underlying assumptions within management's impairment review, assessing each of the key assumptions against market data, where relevant and available, and performing sensitivity analysis on each of these assumptions. The key assumptions included:
  - the discount rate used in the calculation;
  - the market potential for the underlying products and the group's ability to obtain a share of this market.

# Independent Auditor's Report

to the Members of Futura Medical plc for the year ended 31 December 2022

KEY AUDIT MATTER - PARENT COMPANY	HOW OUR SCOPE ADDRESSED THE MATTER - PARENT COMPANY
The assessment of any potential impairment requires management to make significant assumptions and judgements about the recoverability of the investment in particular around the future cash flows of the subsidiary.	<ul> <li>corroborating the key inputs used in support of the key underlying assumptions to relevant supporting documentation;</li> </ul>
	<ul> <li>assessing the competence and objectivity of managements expert used to assist in the impairment assessment;</li> </ul>
	<ul> <li>calculating fair value less costs of disposal by considering the group's market capitalisation and compared this to the carrying value of the investment in subsidiary; and</li> </ul>
	<ul> <li>assessing the disclosures of estimates and judgements made in the financial statements for compliance with the requirements of International Accounting Standard (IAS) 1 'Presentation of Financial Statements' and IAS 36 'Impairment of Assets'.</li> </ul>
RELEVANT DISCLOSURES	<b>OUR RESULTS</b> Based on our work we concluded that management's judgement tha

## **AND ACCOUNTS 2022**

Based on our work we concluded that management's judgement that no impairment was required as at 31 December 2022 was reasonable.

- ► Notes to the Parent Company financial statements: Note 2
- ► Audit committee report.

## **OUR APPLICATION OF MATERIALITY**

We apply the concept of materiality both in planning and performing the audit, and in evaluating the effect of identified misstatements on the audit and of uncorrected misstatements, if any, on the financial statements and in forming the opinion in the auditor's report.

Materiality was determined as follows:

MATERIALITY MEASURE	GROUP	PARENT
MATERIALITY FOR FINANCIAL STATEMENTS AS A WHOLE	We define materiality as the magnitude statements that, individually or in the age influence the economic decisions of the use materiality in determining the nature	gregate, could reasonably be expected to users of these financial statements. We
Materiality threshold	£295,000, which is 4.293% of the group's loss before tax for the year.	£206,500, which is 0.307% of the company's total assets.
Significant judgements made by auditor in	In determining materiality, we made the following significant judgements:	In determining materiality, we made the following significant judgements:
determining materiality	<ul> <li>The group's loss before tax is considered the most appropriate benchmark because it is a prominent key performance measure for the users of the financial statements.</li> </ul>	<ul> <li>The company's total assets are considered the most appropriate benchmark because its principal activity is that of a holding company, with the largest financial statement line items being investments.</li> </ul>

MATERIALITY MEASURE	GROUP	PARENT
Significant judgements made by auditor in determining materiality	<ul> <li>4.293% was deemed to be an appropriate measurement percentage to take into account the</li> </ul>	<ul> <li>This has been restricted to be lower than group materiality as it is a component of the group.</li> </ul>
	additional risk of being listed and the associated shareholder expectations. The percentage is in line with the prior year.	Materiality for the current year is higher than the level that we determined for the year ended 31 December 2021 to reflect the increase in group materiality.
	Materiality for the current year is higher than the level that we determined for the year ended 31 December 2021 to reflect the increase in the group's loss before tax during the year.	
PERFORMANCE MATERIALITY USED TO DRIVE THE EXTENT OF OUR TESTING	statements as a whole to reduce to an ap	nount less than materiality for the financial opropriately low level the probability that sected misstatements exceeds materiality
Performance materiality threshold	£206,500, which is 70% of financial statement materiality.	£144,550, which is 70% of financial statement materiality.
Significant judgements made by auditor in determining	In determining performance materiality, we made the following significant judgements:	In determining performance materiality, we made the following significant judgements:
performance materiality	<ul> <li>Our experience with auditing the financial statements in previous years, including the number of misstatements identified; and</li> </ul>	<ul> <li>Our experience with auditing the financial statements in previous years, including the number of misstatements identified; and</li> </ul>
	<ul> <li>Our risk assessment and consideration of the Group's control environment.</li> </ul>	<ul> <li>Our risk assessment and consideration of the Parent Company's control environment.</li> </ul>
SPECIFIC MATERIALITY		
Specific materiality	We determined a lower level of specific r	nateriality for the following areas:
	<ul> <li>directors' remuneration; and</li> </ul>	
	<ul> <li>related party transactions outside the</li> </ul>	normal course of business.
COMMUNICATION OF MISSTATEMENTS TO THE AUDIT COMMITTEE	We determine a threshold for reporting committee.	unadjusted differences to the audit
Threshold for communication	£14,750 and misstatements below that threshold that, in our view, warrant reporting on qualitative grounds.	£10,300 and misstatements below that threshold that, in our view, warrant reporting on qualitative grounds.

# Independent Auditor's Report

to the Members of Futura Medical plc for the year ended 31 December 2022

The graph below illustrates how performance materiality interacts with our overall materiality and the tolerance for potential uncorrected misstatements.

### **OVERALL MATERIALITY - GROUP**



**OVERALL MATERIALITY - PARENT** 



FSM: Financial statements materiality PM: Performance materiality

## TFPUM: Tolerance for potential uncorrected misstatements

## AN OVERVIEW OF THE SCOPE OF OUR AUDIT

We performed a risk-based audit that requires an understanding of the Group's business and in particular matters related to:

### UNDERSTANDING THE GROUP, ITS COMPONENTS, AND THEIR ENVIRONMENTS, INCLUDING GROUP-WIDE CONTROLS

- We evaluated the group's internal control environment and documented our understanding of controls relevant to the audit.
- We evaluated IT systems and controls. ISA (UK) 315 (Revised July 2020) requires us to consider the risks arising from the use of IT and the entity's ITGCs related to each internal control relevant to the audit.
- ► We performed process walkthroughs and documented and assessed, the relevant controls covering the Key Audit Matters and certain other risks in the financial reporting system identified as part of our risk assessment.
- The processes and systems are centralised and as such our understanding of the Group's controls are the same for all components.

### **IDENTIFYING SIGNIFICANT COMPONENTS**

We identified the significant components of the group based on the relative contribution of revenue, loss before tax and net assets of each component to the group.

#### TYPE OF WORK TO BE PERFORMED ON FINANCIAL INFORMATION OF PARENT AND OTHER COMPONENTS (INCLUDING HOW IT ADDRESSED THE KEY AUDIT MATTERS)

- We performed a full scope audit on the financial statements of Futura Medical plc and Futura Medical Developments Limited.
- We tested the consolidation process and carried out analytical procedures on the financial statements of Futura Medical Healthcare Limited to confirm our conclusion that there were no significant risks of material misstatement of the aggregated financial information of the remaining component.

### PERFORMANCE OF OUR AUDIT

- The year-end audit was conducted through a mixture of remote and onsite working. This was supported through the use of software collaboration platforms for the secure and timely delivery of requested audit evidence.
- ► 100% of the Group's revenue, Group's total assets and of the Group's loss before tax were included in the scope of our full scope audit procedures.

### **CHANGES IN APPROACH FROM PREVIOUS PERIOD**

 There are no changes in the scope of the current year audit from the scope of that of the prior year.

## OTHER INFORMATION

The directors are responsible for the other information. The other information comprises the information included in the annual report and accounts, other than the financial statements and our auditor's report thereon. Our opinion on the financial statements does not cover the other information and, except to the extent otherwise explicitly stated in our report, we do not express any form of assurance conclusion thereon.

In connection with our audit of the Group financial statements, our responsibility is to read the other information and, in doing so, consider whether the other information is materially inconsistent with the Group financial statements or our knowledge obtained in the audit or otherwise appears to be materially misstated. If we identify such material inconsistencies or apparent material misstatements, we are required to determine whether there is a material misstatement of the group financial statements or a material misstatement of the other information. If, based on the work we have performed, we conclude that there is a material misstatement of this other information, we are required to report that fact.

We have nothing to report in this regard.

## OUR OPINION ON OTHER MATTERS PRESCRIBED BY THE COMPANIES ACT 2006 IS UNMODIFIED

In our opinion, based on the work undertaken in the course of the audit:

- the information given in the strategic report and the directors' report for the financial year for which the financial statements are prepared is consistent with the financial statements; and
- the strategic report and the directors' report have been prepared in accordance with applicable legal requirements.

## MATTER ON WHICH WE ARE REQUIRED TO REPORT UNDER THE COMPANIES ACT 2006

In the light of the knowledge and understanding of the group and the parent company and their environment obtained in the course of the audit, we have not identified material misstatements in the strategic report or the directors' report.

## MATTERS ON WHICH WE ARE REQUIRED TO REPORT BY EXCEPTION

We have nothing to report in respect of the following matters in relation to which the Companies Act 2006 requires us to report to you if, in our opinion:

- adequate accounting records have not been kept by the parent company, or returns adequate for our audit have not been received from branches not visited by us; or
- the Parent Company financial statements are not in agreement with the accounting records and returns; or
- certain disclosures of directors' remuneration specified by law are not made; or
- we have not received all the information and explanations we require for our audit.

## RESPONSIBILITIES OF DIRECTORS FOR THE FINANCIAL STATEMENTS

As explained more fully in the Statement of directors' responsibilities on page 42, the directors are responsible for the preparation of the financial statements and for being satisfied that they give a true and fair view, and for such internal control as the directors determine is necessary to enable the preparation of financial statements that are free from material misstatement, whether due to fraud or error.

In preparing the financial statements, the directors are responsible for assessing the group's and parent company's ability to continue as a going concern, disclosing, as applicable, matters related to going concern and using the going concern basis of accounting unless the directors either intend to liquidate the group or the parent company or to cease operations, or have no realistic alternative but to do so.

# Independent Auditor's Report

to the Members of Futura Medical plc for the year ended 31 December 2022

## AUDITOR'S RESPONSIBILITIES FOR THE AUDIT OF THE GROUP FINANCIAL STATEMENTS

Our objectives are to obtain reasonable assurance about whether the financial statements as a whole are free from material misstatement, whether due to fraud or error, and to issue an auditor's report that includes our opinion. Reasonable assurance is a high level of assurance, but is not a guarantee that an audit conducted in accordance with ISAs (UK) will always detect a material misstatement when it exists.

Misstatements can arise from fraud or error and are considered material if, individually or in the aggregate, they could reasonably be expected to influence the economic decisions of users taken on the basis of these financial statements.

A further description of our responsibilities for the audit of the financial statements is located on the Financial Reporting Council's website at: www.frc.org.uk/auditorsresponsibilities. This description forms part of our auditor's report.

#### EXPLANATION AS TO WHAT EXTENT THE AUDIT WAS CONSIDERED CAPABLE OF DETECTING IRREGULARITIES, INCLUDING FRAUD

Irregularities, including fraud, are instances of non-compliance with laws and regulations. We design procedures in line with our responsibilities, outlined above, to detect material misstatements in respect of irregularities, including fraud. Owing to the inherent limitations of an audit, there is an unavoidable risk that material misstatements in the financial statements may not be detected, even though the audit is properly planned and performed in accordance with ISAs (UK).

The extent to which our procedures are capable of detecting irregularities, including fraud, is detailed below:

► We obtained an understanding of the legal and regulatory frameworks that are applicable to the Group and Parent Company and determined that the most significant which are directly relevant to the financial statements are those related to the reporting framework, being the Companies Act 2006, Financial Reporting Standard 101 (for the Parent Company) and UK-adopted international accounting standards, together with the QCA Corporate Governance Code and the AIM Rules for Companies.

- We obtained an understanding of how the Group is complying with those legal and regulatory frameworks by making enquiries of management. We corroborated our enquiries through our review of board minutes and correspondence received from regulatory bodies.
- We assessed the susceptibility of the financial statements to material misstatement, including how fraud might occur, by making enquiries of management and those charged with governance. We utilised internal and external information to corroborate these enquiries and to perform a fraud risk assessment. We considered the risk of fraud to be highest through the potential for management override of controls. Our audit procedures involved:
  - evaluation of the design and implementation of controls that management has in place to prevent and detect fraud;
  - journal entry testing, with a focus on material manual journals, including those posted directly to cash and those impacting areas of estimation uncertainty; and
  - challenging assumptions and judgements made by management in its significant accounting estimates.
- In addition, we completed audit procedures to conclude on the compliance of disclosures in the annual report and accounts with applicable financial reporting requirements.
- These audit procedures were designed to provide reasonable assurance that the financial statements were free from fraud or error. The risk of not detecting a material misstatement due to fraud is higher than the risk of not detecting one resulting from error and detecting irregularities that result from fraud is inherently more difficult than detecting those that result from error, as fraud may involve collusion, deliberate concealment, forgery, or intentional misrepresentations. Also, the further removed non-compliance with laws and regulations is from events and transactions reflected in the financial statements, the less likely we would become aware of it.

- The engagement partners assessed the appropriateness of the collective competence and capabilities of the engagement team, including consideration of the engagement team's:
  - understanding of, and practical experience with, audit engagements of a similar nature and complexity, through appropriate training and participation;
  - knowledge of the industry in which the group operate; and
  - understanding of the legal and regulatory requirements specific to the Group and Parent Company. These include following EU Directive 2001/83/EC, being regulated, and licensed by the medicines and healthcare products regulatory agency (MHRA) and being ISO 13485 accredited.
- ► Team communications in respect of potential non-compliance with laws and regulations and fraud included the potential for fraud in revenue recognition through manipulation of the identified performance obligations in contracts. In assessing the potential risks of material misstatement we obtained an understanding of the Group's operations, including the nature of its revenue sources, products and services to understand the classes of transactions, account balances, expected financial statement disclosures and business risks that may result in risks of material misstatement.

## USE OF OUR REPORT

This report is made solely to the company's members, as a body, in accordance with Chapter 3 of Part 16 of the Companies Act 2006. Our audit work has been undertaken so that we might state to the company's members those matters we are required to state to them in an auditor's report and for no other purpose. To the fullest extent permitted by law, we do not accept or assume responsibility to anyone other than the company and the company's members as a body, for our audit work, for this report, or for the opinions we have formed.

### JONATHAN OAKEY FCA Senior Statutory Auditor

for and on behalf of Grant Thornton UK LLP Statutory Auditor, Chartered Accountants Crawley

4 April 2023

# Consolidated Statement of Comprehensive Income

for the year ended 31 December 2022

		Year ended 31 December 2022	Year ended 31 December 2021
	Notes	£	£
Revenue	2.4	-	-
Research and development costs		(4,131,224)	(3,774,269)
Administrative costs		(2,740,265)	(2,092,042)
Operating loss	6	(6,871,489)	(5,866,311)
Finance income		-	-
Loss before tax		(6,871,489)	(5,866,311)
Taxation recoverable	8	1,024,994	908,600
Loss for the year being total comprehensive loss attributable to			
owners of the Parent Company		(5,846,495)	(4,957,711)
Basic and diluted loss per share (pence)	9	(2.03)	(1.83)

All amounts relate to continuing activities.

The Notes on pages 58 to 76 form part of these consolidated financial statements.

# Consolidated Statement of Changes In Equity

for the year ended 31 December 2022

	Notes	Share Capital £	Share Premium £	Merger Reserve £	Other Reserves £	Retained Losses £	Total Equity £
At 1 January 2021		491,254	52,814,090	1,152,165	165,868	(53,769,837)	853,540
Total comprehensive loss for the year		-	_	_	_	(4,957,711)	(4,957,711)
Share-based payment	16	-	_	-	-	181,822	181,822
Shares issued during the year	15	63,503	11,661,978	_	_	_	11,725,481
Convertible loan notes and warrants	17	_	_	_	118,864	196,909	315,773
Convertible loan notes conversion and warrant exercise	17	19,545	1,901,935	_	(118,864)	(196,909)	1,605,707
Transactions with owners	5	83,048	13,563,913			181,822	13,828,783
At 31 December 2021		574,302	66,378,003	1,152,165	165,868	(58,545,726)	9,724,612
Total comprehensive loss for the year		_	_	_	_	(5,846,495)	(5,846,495)
Share-based payment	16	_	_	_	-	671,852	671,852
Shares issued during the year	15	1,791	167,793	-	_	_	169,584
Transactions with owners	5	1,791	167,793	_	_	671,852	841,436
At 31 December 2022		576,093	66,545,796	1,152,165	165,868	(63,720,369)	4,719,553

Merger reserve represents the reserve arising on the acquisition of Futura Medical Developments Limited in 2001 via a share for share exchange accounted for as a group reconstruction previously using merger accounting under UK GAAP.

Retained losses represent all other net gains and losses not recognised elsewhere.

Share premium represents amounts subscribed for share capital in excess of nominal value, less the related costs of share issues.

Warrants issued are held as a separate 'warrant reserve' within equity. The warrant reserve will be transferred to retained earnings on exercise or lapse, as it is treated as distributable profit from the point of issue.

The Notes on pages 58 to 76 form part of these consolidated financial statements.

## Consolidated Statement of Financial Position

as at 31 December 2022

		As at 31 December 2022	2021
Assets	Notes	£	£
Non-current assets			
Plant and equipment	10	1,158,035	442,657
Total non-current assets	10	1,158,035	442,657
		1,130,035	
Current assets			
Trade and other receivables	12	265,684	79,256
Current tax asset	8	1,022,831	908,312
Cash and cash equivalents	13	4,026,112	10,372,571
Total current assets		5,314,627	11,360,139
Liabilities Current liabilities			
Trade and other payables	14	(1,753,109)	(2,078,184)
Total liabilities		(1,753,109)	(2,078,184)
Total net assets		4,719,553	9,724,612
Capital and reserves attributable to owners of the Parent Company			
Share capital	15	576,093	574,302
Share premium		66,545,796	66,378,003
Merger reserve		1,152,165	1,152,165
Warrant reserve		165,868	165,868
Retained losses		(63,720,369)	(58,545,726)
Total equity		4,719,553	9,724,612

The consolidated financial statements were approved and authorised for issue by the Board on 4 April 2023.

The Notes on pages 58 to 76 form part of these consolidated financial statements. By order of the Board

JAMES BARDER Chief Executive Registered number: 04206001

## Consolidated Statement of Cash Flows

for the year ended 31 December 2022

		Year ended 31 December 2022	2021
Cash flows from operating activities	Notes	£	£
Loss before tax		(6,871,489)	(5,866,311)
Adjustments for:		(0,071,-09)	(3,000,011)
Depreciation	10	24,734	19,808
Loss on disposal of fixed assets		585	125
Finance income		_	_
Share-based payment charge	16	671,852	181,822
Cash flows used in operating activities before changes in working capital		(6,174,318)	(5,664,556)
(Increase)in trade and other receivables	12	(186,429)	(39,466)
(Decrease)/increase in trade and other payables	14	(325,075)	1,311,659
Cash used in operations		(6,685,822)	(4,392,363)
Income tax received		910,476	519,093
Net cash used in operating activities		(5,775,346)	(3,873,270)
Cash flows from investing activities			
Purchase of plant and equipment	10	(740,697)	(419,722)
Cash used in investing activities		(740,697)	(419,722)
Cash flows from financing activities			
Issue of ordinary shares	15	169,584	14,319,281
Expenses paid in connection with share issue		-	(672,319)
Cash generated by financing activities		169,584	13,646,962
(Decrease)/increase in cash and cash equivalents		(6,346,459)	9,353,970
Cash and cash equivalents at beginning of year		10,372,571	1,018,601
Cash and cash equivalents at end of year	13	4,026,112	10,372,571

The Notes on pages 58 to 76 form part of these consolidated financial statements.

for the year ended 31 December 2022

## **1. CORPORATE INFORMATION**

Futura Medical plc (the "Company") is a public limited company incorporated and domiciled in the United Kingdom and whose shares are publicly traded on the AIM Market of the London Stock Exchange. The registered office is located at Surrey Technology Centre, 40 Occam Road, Guildford, Surrey, GU2 7YG.

These Group financial statements consolidate those of the Company and its subsidiaries (together referred to as "the Group" and individually as "Group entities") for the year ended 31 December 2022.

The consolidated financial statements of the Company and the Group for the year ended 31 December 2022 were authorised for issue by the Board of Directors on 4 April 2023.

The Group is principally engaged in the development of pharmaceutical and healthcare products.

## 2. ACCOUNTING POLICIES

### **2.1 BASIS OF PREPARATION**

The consolidated financial statements have been prepared on a going concern basis and under the historical cost convention and have been prepared and approved by the Directors in accordance with UK-adopted International accounting standards in conformity with the requirements of the Companies Act 2006. The principal accounting policies applied in the preparation of the consolidated financial information are set out below. These policies have been consistently applied to all years presented, unless otherwise stated.

The consolidated financial statements are presented in sterling.

### **2.2 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 below, the preparation of the financial statements on a going concern basis remains appropriate.

In assessing the appropriateness of adopting the going concern assumption, the Group has prepared a detailed budget ("the budget") for the period ending December 2023 and a further forecast ("the forecast") for the period ending 30 June 2024. The budget and forecast include estimated revenues arising from the launch of MED3000 in the UK, EU, Middle East and Latin America, based on orders of MED3000 to December 2022 together with Management's estimate, based on extensive market research and commercial partners' forecasts, of ongoing demand. Operating costs reflect the current cost base, with some increased spend to support the commercialisation of MED3000, and expenditure to support the manufacture of MED3000 to meet demand from commercial partners.

The Board considers that the budget and forecast represent a reasonable best estimate of the Group's performance over the period to 30 June 2024 and is satisfied that the Group would be able to continue as a going concern.

However, in preparing the budget and forecast, the Board also noted the existence of a number of factors that increase the difficulty inherent in predicting the Group's performance, in particular its revenue generation. These include a lack of any historical information from which to reliably predict sales volume and growth, long-term prices and timing of receipts from customers in respect of MED3000 as the product has not yet launched in any key market with any of the commercial partners. Forecasts provided by commercial partners have been highly encouraging but are not guaranteed. In addition to the budget and forecast, the Board therefore considered a possible scenario in which MED3000 revenues were reduced compared to the budget and forecast (the "downside scenario"). The Board further considered remedial action within Management's control to delay some discretionary spending. In this downside scenario, after taking the remedial actions, the Board believes that the Group's resources could still extend beyond June 2024.

The Board is confident that the US FDA will grant marketing authorisation for MED3000 before the end of June 2023, and considers that with the marketing authorisation granted, a number of options to access both dilutive and non-dilutive funding would be available in the event that revenues from MED3000 or operating cost savings were lower than expected.

The Group also remains actively engaged in a number of business development interactions with several potential commercial partners in respect of rights for MED3000 in the USA and where commercial partners currently are not in place.

## 2. ACCOUNTING POLICIES (CONTINUED)

### 2.2 GOING CONCERN (CONTINUED)

The Board does not believe that the Group's position at this point in the execution of its strategy is unusual. However, despite the mitigations available to the Group, it 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.

### 2.3 STANDARDS, AMENDMENTS AND INTERPRETATION TO EXISTING STANDARDS

At the date of authorisation of these consolidated financial statements, several new, but not yet effective, Standards and amendments to existing Standards, and Interpretations have been published by the International Accounting Standards Board ("IASB"). None of these Standards or amendments to existing Standards have been adopted early by the Group.

Management anticipates that all relevant pronouncements will be adopted for the first period beginning on or after the effective date of the pronouncement. New Standards, amendments and Interpretations not adopted in the current year have not been disclosed as they are not expected to have a material impact on the Group's financial statements.

### 2.4 REVENUE

To determine whether to recognise revenue, the Group follows a five-step process:

- 1. Identifying the contract with a customer
- 2. Identifying the performance obligations
- 3. Determining the transaction price
- 4. Allocating the transaction price to the performance obligations
- 5. Recognising revenue when/as performance obligation(s) are satisfied.

In accordance with IFRS 15, revenue is calculated based on the consideration to which the Group expects to be entitled and is recognised over the length of services provided under the contract and once performance obligations have been met. The transaction fee is allocated over the length of the service being provided in accordance with the project plan. It is recognised as a contract liability at the time of the initial transaction and is released over the expected period of service on the basis of work completed and performance obligations delivered. The progress is re-evaluated by Management at each reporting date and the revenue recognised is re-measured accordingly.

During the year, the Company entered into contracts for supply of goods to external customers against orders received. The majority of contracts that the Company enters into relate to sales orders containing single performance obligation for the delivery of pharmaceutical products. Revenue is recognised when control of the goods is passed to the customer. The point at which control passes is determined by each customer arrangement, but generally occurs when title passes to the customer, either on shipment or on receipt of goods by the customer, depending on local trading terms.

Product revenue represents net invoice less estimated volume discounts, which are considered to be variable consideration and include significant estimates. Other variable considerations such as milestone payments and royalties are not recognised in full until it is highly probable that a significant reversal in the amount of cumulative revenue recognised will not occur. In Management's opinion, that will be when the Group's customer confirms that the milestone has been met or that a royalty is due. Estimates associated with variable consideration are revisited at each reporting date or when they are resolved and revenue is adjusted accordingly. At 31 December 2022, our customers were preparing to launch or still in the process of seeking regulatory approval for the sale of the product in the relevant jurisdictions. As a result, no sales have been made and no revenue has been recognised during the year.

The Group applies the practical expedient in paragraph 121 of IFRS 15 and does not disclose information about remaining performance obligations that have original expected durations of one year or less.

for the year ended 31 December 2022

## 2. ACCOUNTING POLICIES (CONTINUED)

### 2.5 LEASED ASSETS

For any new contracts entered into on or after 1 January 2019, the Group considers whether a contract is, or contains a lease. A lease is defined as a contract, or part of a contract, that conveys the right to use an asset (the underlying asset) for a period of time in exchange for consideration. To apply this definition, the Group assesses whether the contract meets three key evaluations which are whether:

- The contract contains an identified asset, which is either explicitly in the contract or implicitly specified by being identified at the time the asset is made available to the Group.
- The Group has the right to obtain substantially all of the economic benefits from the use of the identified asset throughout the period of use, considering its rights within the defined scope of the contract.
- ► The Group has the right to direct the use of the identified asset throughout the period of use. The Group assesses whether it has the right to direct "how and for what purpose" the asset is used throughout the period of use.

The Group makes the use of leasing arrangements principally for the provision of the main office space and IT equipment. The rental contracts for offices are typically negotiated on a short-term rolling basis with one month's notice. Lease terms for IT equipment have lease terms of three years without any extension terms. The Group does not enter into sale and leaseback arrangements. All the leases are negotiated on an individual basis and contain a wide variety of different terms and conditions such as purchase options and escalation clauses.

The Group assesses whether a contract is or contains a lease at inception of the contract. A lease conveys the right to direct the use and obtain substantially all of the economic benefits of an identified asset for a period of time in exchange for consideration.

The Group has elected to account for short-term leases and leases of low-value assets using the practical expedients. These leases relate to items of certain low value IT equipment and short term office leases. Instead of recognising a right-of-use asset and lease liability, the payments in relation to these are recognised as an expense in profit or loss on a straight-line basis over the lease term.

### **2.6 INTANGIBLE ASSETS**

### Research and development ("R&D")

Expenditure incurred on the development of internally generated products is capitalised if it can be demonstrated that:

- ▶ it is technically feasible to develop the product for it to be sold;
- ▶ adequate resources are available to complete the development;
- ▶ there is an intention to complete and sell the product;
- ▶ the Group is able to out-license or sell the product;
- ▶ sale of the product will generate future economic benefits; and
- expenditure on the project can be measured reliably.

Capitalised development costs, including patents and trademarks, are amortised over the periods in which the Group expects to benefit from selling the products developed. The amortisation expense is included in R&D costs recognised in the Consolidated Statement of Comprehensive Income. The useful life and the value of the capitalised development cost are assessed for indicators of impairment at least annually. The value is written down immediately if impairment has occurred and the unimpaired cost amortised over the remaining useful life.

The Directors consider that the criteria to capitalise development expenditure are not yet met for any of its products as they have either not yet been approved or commercially launched in at least one major market therefore commercial feasibility of the product is not yet certain.

Development expenditure, not satisfying the above criteria, and expenditure on the research phase of internal projects are included in R&D costs recognised in the Consolidated Statement of Comprehensive Income as incurred.

## 2. ACCOUNTING POLICIES (CONTINUED)

### 2.7 PLANT AND EQUIPMENT

Plant and equipment is initially recognised at cost, and subsequently at cost less accumulated depreciation and any accumulated impairment losses. Cost includes expenditure that is directly attributable to the acquisition of the items. Depreciation is charged to the Consolidated Statement of Comprehensive Income at rates calculated to write off the cost, less estimated residual value, of each asset on a straight-line basis over their estimated useful lives.

- Computer equipment
   2 5 years straight-line
- ► Furniture and fittings 3 10 years straight-line

The assets' residual values and useful lives are determined by the Directors and reviewed and adjusted, if appropriate, at each Consolidated Statement of Financial Position date.

### **2.8 IMPAIRMENT OF NON-FINANCIAL ASSETS**

An impairment review is carried out for assets being amortised or depreciated when a change in market conditions and other circumstances indicate that the carrying value may not be recoverable. The recoverable amount is the higher of an asset's fair value less costs to sell and value-in-use. For the purpose of assessing impairment, assets are grouped at the lowest levels for which there are separately identifiable cash flows.

### 2.9 CLASSIFICATION OF FINANCIAL INSTRUMENTS ISSUED BY THE GROUP

In accordance with the requirements of IAS 32, financial instruments issued by the Group are treated as equity only to the extent that they meet the following two conditions:

- they include no contractual obligations upon the Company to deliver cash or other financial assets or to exchange financial assets or financial liabilities with another party under conditions that are potentially unfavourable to the Company; and
- where the instrument will or may be settled in the Company's own equity instruments, it is either a non-derivative that includes no obligation to deliver a variable number of the Company's own equity instruments or is a derivative that will be settled by the Company's exchanging a fixed amount of cash or other financial assets for a fixed number of its own equity instruments.

### **2.10 FINANCIAL INSTRUMENTS**

### i) Recognition and initial measurement

At the year-end, the Group had no financial assets or liabilities designated at fair value through the Consolidated Statement of Comprehensive Income (2021: £nil). Trade receivables and debt securities are initially recognised when they are originated. All other financial assets and liabilities are initially recognised when the Group becomes a party to the contractual provisions in the instrument. A financial asset (unless it is a trade receivable without a significant financing component) or a financial liability is initially measured at fair value plus, for items not measured at fair value through profit and loss ("FVTPL"), transaction costs that are directly attributable to its acquisition or issue. A trade receivable without a significant financing component is measured at the transaction price.

#### ii) Classification and subsequent measurement *Financial assets*

On initial recognition a financial instrument is classified as measured at amortised cost, fair value through other comprehensive income ("FVOCI") or FVTPL. Financial assets are not reclassified subsequent to their initial recognition unless the Group changes its business model for managing financial assets.

A financial asset is measured at amortised cost if it meets both the following conditions and is not designated as FVTPL:

- ▶ it is held within a business model whose objective is to hold assets to collect contractual cash flows; and
- its contractual terms give rise on a specified date to cash flows that are solely the payment of principal and interest on the principal outstanding.

A debt investment is measured at FVOCI if it meets both the following conditions and is not designated as FVTPL:

- it is held within a business model whose objective is achieved by both collecting contractual cash flows and selling financial assets; and
- its contractual terms give rise on specified dates to cash flows that are solely payments of principal and interest on the principal amount outstanding.

for the year ended 31 December 2022

### 2. ACCOUNTING POLICIES (CONTINUED)

### 2.10 FINANCIAL INSTRUMENTS (CONTINUED)

On initial recognition of an equity investment that is not held for trading the Group may irrevocably elect to present subsequent changes in the investment's fair value in OCI. This election is made on an investment by investment basis.

Financial assets at amortised cost are subsequently measured at amortised cost using the effective interest method. The amortised cost is reduced by impairment losses.

### Financial liabilities

Financial liabilities are classified as measured at amortised cost or FVTPL. A financial liability is classified as FVTPL if it is held for trading, it is a derivative or it is designated as such on initial recognition. Other financial liabilities are subsequently measured at amortised cost using the effective interest method. Interest expense is recognised in profit or loss. At the year-end, the Group had no financial assets or liabilities designated at FVOCI (2021: £nil).

#### iii) Derecognition Financial assets

The Group derecognises a financial asset when the contractual rights to the cash flows from the financial asset expire, or it transfers the rights to receive the contractual cash flows in a transaction in which substantially all the risks and rewards of ownership of the financial asset are transferred or in which the Group neither transfers nor retains substantially all of the risks and rewards of ownership and it does not retain control of the financial asset.

### Financial liabilities

The Group derecognises a financial liability when the contractual obligations are discharged or cancelled, or expire. The Group also derecognises a financial liability when its terms are modified and the cash flows of the modified liability are substantially different, in which case a new financial liability based on the modified terms is recognised at fair value. On derecognition of a financial liability, the difference between the carrying amount extinguished and the consideration paid is recognised in profit or loss.

### **2.11 TAXATION**

Income tax is recognised or provided at amounts expected to be recovered or to be paid using the tax rates and tax laws that have been enacted or substantively enacted at the Consolidated Statement of Financial Position date. R&D tax credits are recognised on an accruals basis and are included as an income tax credit under current assets.

Deferred tax assets and liabilities are recognised where the carrying amount of an asset or liability on the Consolidated Statement of Financial Position date differs from its tax base, except for differences arising on:

- the initial recognition of an asset or liability in a transaction which is not a business combination and which at the time of the transaction affects neither accounting profit nor taxable profit; and
- investments in subsidiaries and jointly controlled entities where the Group is able to control the timing of the reversal of the difference and it is probable that the difference will not reverse in the foreseeable future.

Recognition of deferred tax assets is restricted to those instances where it is probable that taxable profits will be available against which the difference can be utilised.

The amount of the asset or liability is determined using tax rates that have been enacted or substantively enacted by the Consolidated Statement of Financial Position date and are expected to apply when the deferred tax liabilities/(assets) are settled/(recovered). Deferred tax balances are not discounted.

Deferred tax assets and liabilities are offset when the Group has a legally enforceable right to offset current tax assets and liabilities and the deferred tax assets and liabilities relate to taxes levied by the same tax authority on either:

- ▶ the same taxable group company; or
- different group entities which intend to settle current tax assets and liabilities on a net basis, or to realise the assets and settle the liabilities simultaneously, on each future period in which significant amounts of deferred tax assets or liabilities are expected to be settled or recovered.

## 2. ACCOUNTING POLICIES (CONTINUED)

### 2.12 FOREIGN CURRENCY TRANSLATION

Foreign currency transactions are translated into the functional currency using the exchange rates prevailing at the dates of the transactions. Foreign exchange gains and losses resulting from the settlement of such transactions and from the translation at period end exchange rates of monetary assets and liabilities denominated in foreign currencies are recognised in the Consolidated Statement of Comprehensive Income in the period in which they arise.

### **2.13 EMPLOYEE BENEFITS**

### Defined contribution plans

The Group provides retirement benefits to all employees who wish to participate in defined contribution pension schemes. The assets of these schemes are held separately from those of the Group in independently administered funds. Contributions made by the Group are charged to the Consolidated Statement of Comprehensive Income in the period in which they become payable.

### Accrued holiday pay

Provision is made at each Consolidated Statement of Financial Position date for holidays accrued but not taken, at applicable rates of salary. The expected cost of compensated short-term absence (holidays) is charged to the Consolidated Statement of Comprehensive Income on an accruals basis.

### Share-based payment transactions

The Group operates an annual equity-settled share-based compensation plan. For all share options awarded to employees, and others providing similar services, the fair value of the share options at the date of grant is charged to the Consolidated Statement of Comprehensive Income over the vesting period. Non-market vesting conditions are taken into account by adjusting the number of equity instruments expected to vest at each Consolidated Statement of Financial Position date so that, ultimately, the cumulative amount recognised over the vesting period is based on the number of share options are modified before they vest, the change in the fair value of the share options, measured immediately before and after the modification, is also charged to the Consolidated Statement of Comprehensive Income over the remaining vesting period. The proceeds received when share options are exercised, net of any directly attributable transaction costs, are credited to share capital (nominal value) and the remaining balance to share premium. All employee share option holders enter into an HM Revenue & Customs joint election to transfer the employers' National Insurance contribution potential liability to the employee, therefore no Group asset or liability arises.

### Long-term incentive plan

The Group operates a long-term incentive plan ("LTIP") for all staff and Directors. The quantum of any awards receivable will depend on the Group achieving set milestones and the share price at the time relative to targets set in advance. The Group plan is intended to be settled in equity with cash settlement possible at the discretion of the Board. For all LTIP share options awarded to employees, and others providing similar services, the fair value of the share options at the date of grant is charged to the Consolidated Statement of Comprehensive Income over the vesting period. Non-market vesting conditions are taken into account by adjusting the number of equity instruments expected to vest at each Consolidated Statement of Financial Position date so that, ultimately, the cumulative amount recognised over the vesting period is based on the number of share options that eventually vest. If the terms and conditions of share options are modified before they vest, the change in the fair value of the share options, measured immediately before and after the modification, is also charged to the Consolidated Statement of Comprehensive Income over the remaining vesting period. The proceeds received when share options are exercised, net of any directly attributable transaction costs, are credited to share capital (nominal value) and any remaining balance to share premium. All employee share option holders enter into an HM Revenue & Customs joint election to transfer the employers' National Insurance contribution potential liability to the employee, therefore no Group asset or liability arises.

### 2.14 FINANCE INCOME

Interest income is recognised on a time-proportion basis using the effective interest rate method.

for the year ended 31 December 2022

## 2. ACCOUNTING POLICIES (CONTINUED)

### 2.15 CONVERTIBLE LOAN NOTES

The component of the convertible notes issued by the Group which exhibits the characteristics of a financial liability is recognised as a liability in the Consolidated Statement of Financial Position, net of transaction costs.

On the issue of the convertible notes the fair value of the liability component is determined using a market rate for an equivalent non-convertible bond and this amount is recorded as a non-current liability measured at amortised cost until extinguished on conversion or redemption. The increase in the liability due to the passage of time is recognised as a finance cost. The remainder of the proceeds are allocated to the conversion option that is recognised and included in shareholders equity as an other reserve, net of transaction costs. The carrying amount of the conversion option is not remeasured in the subsequent years. The corresponding interest on convertible notes is expensed to profit or loss.

### 2.16 OTHER RESERVES

On initial recognition of the convertible loan notes the consideration received for issuing the notes was split between the equity and liability components in accordance with IAS 32 'Financial Instruments: Presentation'. This other reserve represents the equity component of the convertible loan notes.

### 2.17 CASH AND CASH EQUIVALENTS

Cash and cash equivalents are basic financial assets and comprise of cash in hand, which are readily available and with original maturity of three months or less.

### 3. ESTIMATES AND JUDGEMENTS

In the application of the Group's accounting policies, which are described in Note 2, Management is required to make judgements, estimates and assumptions about the carrying amounts of assets and liabilities that are not readily apparent from other sources.

The significant judgements and estimates made in relation to the financial statements are:

### SHARE-BASED PAYMENTS

The Group operates an equity-settled share-based compensation plan for employee (and consultant) services to be received and the corresponding increases in equity are measured by reference to the fair value of the equity instruments as at the date of grant. The fair value determination is based on the principles of the Black–Scholes model which uses an input of volatility based on historical data. Historical volatility may not be indicative of future volatility, yet the Directors judge this to be the most appropriate method of calculation. Given the share option expense of £671,852 (2021: £181,822), the volatility methodology used is not expected to have a material impact on these financial statements. Details of the fair value calculation for options granted during the year, including other inputs into the Black–Scholes model, are disclosed in Note 16.

### VALUATION OF CONVERTIBLE LOAN NOTES

The fair value of the liability component of the convertible loan notes issued in 2021 was calculated using the prevailing market interest rate for a similar non-convertible instrument being 10%. No convertible loan notes were issued in 2022.

### **VALUATION OF WARRANTS**

No warrant instruments were issued in 2022. Warrant instruments issued in 2021 were measured at fair value using the Black–Scholes model. The following inputs were used for the model:

Share price	16.5p
Warrant exercise price	22.0p
Expected life of warrant	l year
Volatility	105.08%
Dividend yield	0%
Risk-free interest rate	0.14%
Fair value	5.23p

## 3. ESTIMATES AND JUDGEMENTS (CONTINUED)

### CONVERSION OF CONVERTIBLE LOAN NOTES AND WARRANT INSTRUMENTS

The Group issued a new convertible loan note and warrants on 4 March 2021. In accordance with the Group's accounting policy as detailed in Note 2, the liability and equity components of the instruments were calculated at fair value as detailed in Note 17. These instruments were converted in April 2021 and converted to equity. Management has concluded that the £1,184,227 liability converted to equity at its liquidated sum of £1,500,000 resulting in an increase in retained losses of £315,773 with a corresponding increase in share premium. On conversion, the warrant reserve and other reserve amounting to £315,773 created on the issue of the two instruments also reverse therefore decreasing retained losses by the same amount.

There were no warrants or convertible loan notes issued in 2022.

### **R&D TAX CREDITS**

The current tax receivable as disclosed in Note 8 represents an R&D tax credit based on an advance claim with HMRC. The final receivable is subject to the correct application of complex R&D rules and HMRC approval. Historically, claims have been successful and the Group expects the current year to be successful too.

### **R&D COSTS**

Management is required to make a judgement about certainty of commercial success of its products. No Research and Development costs have been capitalised in the current or prior period and further details can be found in Note 2.6.

### FAIR VALUE OF DERIVATIVE INSTRUMENTS

Where the fair value of derivative instruments recorded in the Consolidated Statement of Financial Position cannot be derived from active markets, their fair value is determined using valuation techniques. The inputs to these models are taken from observable markets where possible. Where this is not feasible, a degree of judgement is required in establishing fair values. The judgements include considerations of inputs such as volatility. Details of the fair value calculation for warrants granted during the year, if any, including other inputs into the Black–Scholes model, are disclosed in Note 17.

There are no significant estimates which are expected to lead to material adjustments in the next accounting period.

## 4. FINANCIAL RISK

### **4.1 FINANCIAL RISK FACTORS**

The Group's activities expose it to a variety of financial risks: market risk (including foreign exchange rate risk, cash flow interest rate risk and fair value interest rate risk); credit risk and liquidity risk. It is Group policy not to enter into speculative positions using complex financial instruments.

### (i) Market risk

### Foreign exchange rate risk

The Group primarily enters into supplier contracts which are to be settled in sterling. However, some contracts involve other currencies including the US Dollar and the Euro. The Group may use forward exchange contracts as an economic hedge against currency risk, where cash flow can be judged with reasonable certainty. There were no open forward contracts as at 31 December 2022 or at 31 December 2021.

for the year ended 31 December 2022

### 4. FINANCIAL RISK (CONTINUED)

## 4.1 FINANCIAL RISK FACTORS (CONTINUED)

At 31 December 2022, the Group held balances of the following denominated currencies:

	:	Year ended 31 December 2022 £	Year ended 31 December 2021 £
GBP	£	3,589,876	9,163,871
EUR	€	139,167	19,514
USD	\$	377,427	1,608,363

The majority of operating costs are denominated in Sterling although certain expenditures were payable in Euros and US Dollars. At 31 December 2022 the Group had trade payables denominated in a foreign currency totalling £149,189 (31 December 2021: £751,499).

### Cash flow interest rate risk and fair value interest rate risk

The Group's interest rate risk arises from short-term money market deposits.

### (ii) Credit risk

Credit risk arises from cash and cash equivalents and money market deposits as well as credit exposure in relation to outstanding receivables. The exposure relating to outstanding receivables is immaterial and the carrying amount of cash balances is as follows:

	31 December 2022 £	31 December 2021 £
Cash at bank and in hand	4,026,112	10,372,571
Sterling short-term money market funds	-	-
	4,026,112	10,372,571

The Directors consider the Group's exposure to credit risk to be acceptable and normal for a similar entity at its stage in development.

### (iii) Liquidity risk

The Group's approach to managing liquidity is to ensure that, as far as possible, it will always have sufficient liquidity to meet its liabilities when due, under both normal and stressed conditions, without incurring losses or risking damage to the Group's reputation.

The following are the remaining contractual maturities of financial liabilities at the reporting date. The amounts are gross and undiscounted.

31 December 2022	Carrying amount £	2 months or less £	2 – 12 months £	More than 1 year £
Trade and other payables	1,320,958	1,320,958	_	_
Contract liability	432,151	-	322,716	109,435
	1,753,109	1,320,958	322,716	109,435

## 4. FINANCIAL RISK (CONTINUED)

## 4.1 FINANCIAL RISK FACTORS (CONTINUED)

31 December 2021	Carrying amount £	2 months or less £	2 – 12 months £	More than 1 year £
Trade and other payables	1,968,749	1,968,749	-	-
Contract liability	109,435	-	109,435	_
	2,078,184	1,968,749	109,435	_

The Group manages all of its external bank accounts centrally and in accordance with defined treasury policies. The policies include a minimum acceptable credit rating of relationship bank accounts and financial transaction authority limits. Any material change to the Group's principal bank facility requires Board approval.

### **4.2 CAPITAL RISK MANAGEMENT**

The Group's objectives when managing capital is to safeguard its ability to continue as a going concern, so that it can provide returns for shareholders and benefits for other stakeholders. The Group does not yet have significant recurring revenues and has mainly financed its operations through the issue of new shares and management of working capital. The Group's capital resources are managed to ensure it has resources available to invest in operational activities designed to generate future income. These resources were represented by £4,026,112 of cash at bank as at 31 December 2022 (31 December 2021: £10,372,571).

## 5. SEGMENT REPORTING

The Group is focused on the development and commercialisation of MED3000 and therefore operates as one segment. During the year, no revenue was recognised.

## 6. OPERATING LOSS

Operating loss is stated after charging:	Year ended 31 December 2022 £	Year ended 31 December 2021 £
Depreciation of plant and equipment (Note 10)	24,734	19,808
Loss on disposal of plant and equipment	585	125
Short-term leases: property	120,881	116,194
Gain on foreign exchange	98,923	39,664

The fees of the Group's Auditor Grant Thornton UK LLP for services provided are analysed below:

Audit services	Year ended 31 December 2022 £	Year ended 31 December 2021 £
Parent Company	51,237	58,612
Subsidiaries	15,420	17,505
Other non-audit services		
iXBRL tagging	2,000	1,133
Total fees	68,657	77,250

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## 7. STAFF NUMBERS AND COSTS

The average number of persons (including all Executive and excluding Non-Executive Directors) employed by the Group during the year, analysed by category, was as follows:

		Year ended 31 December 2021
R&D staff	7	7
Finance and Administration staff	2	1
Executive Directors	3	3
	12	11

The aggregate payroll costs of these persons were as follows:

	Year ended 31 December 2022 £	Year ended 31 December 2021 £
Wages and salaries	2,150,346	1,730,007
Social security costs	274,083	243,125
Other pension and insurance benefits costs	153,384	151,912
Total cash-settled remuneration	2,577,813	2,125,044
Share-based payment remuneration charge	671,852	181,822
Total remuneration	3,249,665	2,306,866

All employees of the Group are employed by Futura Medical Developments Limited.

Directors' remuneration	Year ended 31 December 2022 £	Year ended 31 December 2021 £
Wages and salaries	1,166,078	1,040,075
Other pension and other benefit costs	26,591	22,776
Share-based payment remuneration charge	313,867	97,503
Social security costs	143,503	142,846
Total remuneration	1,650,039	1,303,200

In 2022 there was one Director whose share options were exercised under the Group share option schemes and a gain of £37,975 was realised (2021: £nil). In respect of the highest paid Director the realised gain was £37,975 (2021: £nil).

In 2022 there were no Directors (2021: no Directors) who participated in a private money purchase defined contribution pension scheme. Emoluments for individual Directors are disclosed within the Remuneration Committee Report.

The Directors consider that there are no Key Management Personnel other than the Directors.

## 7. STAFF NUMBERS AND COSTS (CONTINUED)

Remuneration on the previous page includes the following amounts in respect of the highest paid Director:

	Year ended 31 December 2022 £	Year ended 31 December 2021 £
Wages and salaries	390,898	353,341
Employer pension contributions and other benefits	6,186	3,517
Share-based payment remuneration charge	100,119	37,501
Social security costs	60,144	56,388
Total remuneration	557,347	450,747

## 8. TAXATION

## **8.1 CURRENT TAX**

	Year ended 31 December 2022 £	Year ended 31 December 2021 £
UK corporation tax credit on loss on ordinary activities	1,024,994	908,600
- The tay assessed for the year was lower than the LIK corporation tay rate (2021: low	or) The differe	ncos aro

The tax assessed for the year was lower than the UK corporation tax rate (2021: lower). The differences are explained below:

	Year ended 31 December 2022 £	Year ended 31 December 2021 £
Loss on ordinary activities before tax	6,871,489	5,866,311
Loss on ordinary activities at an average standard rate of corporation tax in the UK of 19% (2021: 19%)	1,305,583	1,114,599
Expenses not deductible for tax purposes	(247)	(124)
Unrecognised deferred tax	(122,999)	(37,824)
Unutilised tax losses	(624,175)	(616,719)
Share scheme deduction	25,793	58,780
Loss surrendered for refund	(318,101)	(282,562)
Additional relief for R&D claims	759,140	674,326
UK corporation tax credit	1,024,994	910,476
Adjustment to tax charge relating to prior period	-	(1,876)
UK corporation tax credit reported in the Consolidated Statement of Comprehensive Income	1,024,994	908,600

for the year ended 31 December 2022

### 8. TAXATION (CONTINUED)

### 8.1 CURRENT TAX (CONTINUED)

The Group has tax losses of approximately £38,980,404 (2021: £35,694,575) available for offset against future taxable profits.

The corporation tax credit for the year represents research and development tax credits of £1,024,994 (2021: £910,476), arising from the surrender of losses (rather than carrying forward to future years) of £7,068,921 (2021: £6,279,145) at 14.5%, under HMRC's small and medium size enterprise scheme. The taxable loss for the year is in excess of the accounting loss for various reasons, principally the additional deductions given for tax purposes on research and development expenditure.

A claim under the large company Research and Development Expenditure Credit ("RDEC") scheme resulted in a refund of £nil (2021: £nil).

### **8.2 DEFERRED TAX**

Deferred tax assets amounting to £10,484,989 (2021: £9,502,702) have not been recognised due to it not being probable that taxable profits will be available against which these deductible temporary differences can be utilised. An increase in the main rate of UK corporation tax from 19% to 25% from 1 April 2023 was substantively enacted during the year ended 31 December 2021. As a result, the opening asset not recognised is stated at 19% but the unrecognised asset at 31 December 2022 has been calculated assuming a prevailing rate when the timing differences reverse of 25%. The unrecognised asset comprises of:

	Year ended 31 December 2022 £	Year ended 31 December 2021 £
Depreciation differential versus capital allowances	(6,800)	(9,576)
Other short-term timing differences	746,688	588,004
Unutilised tax losses	9,745,101	8,823,644
	10,484,989	9,502,072

## 9. LOSS PER SHARE

The calculation of basic and diluted earnings per share ("EPS") is based on the following data:

	2022	2021
Loss for the purposes of basic EPS and diluted EPS (£)	5,846,495	4,957,711
Weighted average of ordinary shares for purposes of basic and diluted EPS (number)	287,478,055	271,046,179
Loss per share basic and diluted (pence)	2.03	1.83

Diluted EPS is calculated in the same way as basic EPS but also with reference to reflect the dilutive effect of share options in existence at the year-end which were 6,583,800 (2021: 6,646,800). The diluted loss per share is identical to the basic loss per share, as potential dilutive shares are not treated as dilutive since they would reduce the loss per share.
# 10. PLANT AND EQUIPMENT

Cost	Compute Equipmen		Total £
At 1 January 2022	545,27	0 65,321	610,591
Additions	740,69	7 –	740,697
Disposals	(2,11-		(2,114)
At 31 December 2022	1,283,85	3 65,321	1,349,174
Depreciation			
At 1 January 2022	108,88	4 59,050	167,934
Eliminated on disposals	(1,52	9) –	(1,529)
Charge for year	24,73	4 –	24,734
At 31 December 2022	132,08	9 59,050	191,139
Net book value			
At 31 December 2022	1,151,764	4 6,271	1,158,035
At 31 December 2021	436,38	6 6,271	442,657

Cost	Computer Equipment £	Furniture and Fittings £	Total £
At 1 January 2021	127,709	63,285	190,994
Additions	417,561	2,161	419,722
Disposals		(125)	(125)
At 31 December 2021	545,270	65,321	610,591
Depreciation			
At 1 January 2021	90,339	57,787	148,126
Charge for year	18,545	1,263	19,808
At 31 December 2021	108,884	59,050	167,934
Net book value			
At 31 December 2021	436,386	6,271	442,657
At 31 December 2020	37,370	5,498	42,868

All fixed assets of the Group are held in Futura Medical Developments Limited.

# **11. FINANCIAL INSTRUMENTS BY CATEGORY**

The accounting policies for financial instruments have been applied to the line items below:

Assets as per Consolidated Statement of Financial Position Loans and receivables at amortised cost	31 December 2022 £	31 December 2021 £
Trade and other receivables (Note 12)	70,114	7,547
Cash and cash equivalents (Note 13)	4,026,112	10,372,571
Total financial assets at amortised cost	4,096,226	10,380,118

# Notes to the Consolidated Financial Statements

for the year ended 31 December 2022

# 11. FINANCIAL INSTRUMENTS BY CATEGORY (CONTINUED)

	31 December	31 December
	2022	2021
Liabilities as per Consolidated Statement of Financial Position at amortised cost	£	£
Trade and other payables (Note 14)	1,753,109	981,392
Total financial liabilities at amortised cost	1,753,109	981,392

The Directors consider that there is no material difference between the carrying values of financial assets and liabilities, and their fair value.

# 12. TRADE AND OTHER RECEIVABLES

Amounts receivable within one year:	31 December 2022 £	31 December 2021 £
Trade receivables	70,114	7,547
Other receivables	-	-
Financial assets (Note 11)	70,114	7,547
Prepayments	195,570	71,709
	265,684	79,256

Trade and other receivables do not contain any impaired assets. The Group does not hold any collateral as security and the maximum exposure to credit risk at the Consolidated Statement of Financial Position date is the fair value of each class of receivable.

# 13. CASH AND CASH EQUIVALENTS

	31 December	31 December
	2022	2021
	£	£
Cash at bank and in hand	4,026,112	10,372,571
	4,026,112	10,372,571

# 14. TRADE AND OTHER PAYABLES

	31 December 2022 £	31 December 2021 £
Trade payables	316,181	981,392
Social security and other taxes	145,092	281,766
Contract liability	432,151	109,435
Accrued expenses	859,685	705,591
	1,753,109	2,078,184

# 15. SHARE CAPITAL

	31 December	31 December	31 December	31 December
	2022	2021	2022	2021
Allotted, called up and fully paid	Number	Number	£	£
Ordinary shares of 0.2 pence each	288,046,527	287,150,971	576,093	574,302

The number of issued ordinary shares as at 1 January 2021 was 245,626,926. During the year ended 31 December 2021, the Company issued shares of 0.2 pence with each ordinary share carrying the right to one vote as follows:

Month	Reason For Issue	Gross Consideration £	Shares Issued Number
March 2021	Exercise of share options at 7.5 pence per share	30,600	425,000
April 2021	Exercise of warrants at 22 pence per share	500,000	2,272,727
April 2021	Non-Executive Director award at 12.24 pence per share	21,581	176,318
April 2021	Convertible loan conversion at 20 pence per share	1,500,000	7,500,000
April 2021	Exercise of share options at 30 pence per share	75,000	250,000
April 2021	Exercise of share options at 30.5 pence per share	140,300	460,000
April 2021	Exercise of share options at 7.5 pence per share	27,000	360,000
June 2021	Placing and Primarybid Offer	12,000,000	30,000,000
November 2021	Exercise of share options at 31 pence per share	24,800	80,000
		14,319,281	41,524,045

The number of issued ordinary shares as at 1 January 2022 was 287,150,971. During the year ended 31 December 2022, the Company issued shares of 0.2 pence with each ordinary share carrying the right to one vote as follows:

Month	Reason For Issue	Gross Consideration £	Shares Issued Number
January 2022	Non–Executive Director award at 15 pence per share	21,834	145,556
September 202	22 Exercise of share options at 30 pence per share	75,000	250,000
September 202	22 Exercise of share options at 7.5 pence per share	18,750	250,000
September 202	22 Exercise of share options at 31 pence per share	46,500	150,000
November 202	2 Exercise of share options at 7.5 pence per share	7,500	100,000
		169,584	895,556

# Notes to the Consolidated Financial Statements

for the year ended 31 December 2022

### **16. SHARE OPTIONS**

At 31 December 2022, the number of ordinary shares of 0.2 pence each subject to share options granted under the Company's Approved and Unapproved Share Option Schemes were:

Exercise Period	Exercise Price per Share Pence	At 1 January 2022 Number	Options Exercised Number	Options Lapsed Number	Options Granted Number	At 31 December 2022 Number
1 October 2017 – 30 September 2022	30.00	350,000	(250,000)	(100,000)	-	-
1 October 2018 – 30 September 2023	57.50	730,000	-	(50,000)	-	680,000
1 October 2019 – 30 September 2024	30.50	500,000	-	_	-	500,000
1 October 2020 – 30 September 2025	7.50	850,000	(350,000)	_	-	500,000
1 October 2021 – 30 September 2026	31.00	1,140,000	(150,000)	(50,000)	-	940,000
1 October 2022 – 30 September 2027	15.50	1,308,000	-	_	-	1,308,000
1 October 2023 – 30 September 2028	37.90	1,588,800	-	_	-	1,588,800
1 October 2023 – 30 September 2028	29.50	_	-	_	100,000	100,000
1 October 2025 – 30 September 2030	45.00	_	_	_	967,000	967,000
7 January 2023 – 6 January 2033	0.02	_		_	4,444,940	4,444,940
		6,466,800	(750,000)	(200,000)	5,511,940	11,028,740

On 14 September 2022 share options over 967,000 new ordinary shares were granted to employees (including Executive Directors) at a price of 45p. The options have a three-year vesting period and the exercise period for these options is 1 October 2025 to 30 September 2030.

On 7 December 2022 share options over 4,444,940 new ordinary shares were granted to employees (including Executive and Non-Executive Directors) at a price of 0.02p per share. The options granted will vest 25% immediately with a further 25% vesting annually following the date of grant.

The share options outstanding at 31 December 2022 represented 3.84% of the issued share capital as at that date (2021: 2.25%) and would generate additional funds of £2,142,884 (2021: £1,899,295) if fully exercised. The weighted average remaining life of the share options outstanding at 31 December 2022 was 81 months (2021: 55 months) with a weighted average remaining exercise price of 19.43 pence (2021: 29.36 pence).

The share options exercisable at 31 December 2022 totalled 5,039,235 (2022: 3,570,000) with an average exercise price of 21.34 pence (2021: 31.0 pence) and would have generated additional funds of £1,075,373 (2021: £1,094,400) if fully exercised.

The Group's share option scheme rules apply to 11,028,740 of the share options outstanding at 31 December 2022 (31 December 2021: 6,466,800) and include a rule regarding forfeiture of unexercised share options upon the cessation of employment (except in specific circumstances).

Options have historically been issued to advisers under the unapproved scheme. Such options generally vest immediately and are exercisable between one and two years after grant. There were 247,416 share options outstanding to advisers at 31 December 2022 (31 December 2021: 100,000).

There were no market vesting conditions within the terms of the grant of the share options.

The Black–Scholes formula is the option pricing model applied to the grants of all share options made in respect of calculating the fair value of the share options.

# 16. SHARE OPTIONS (CONTINUED)

### SHARE-BASED PAYMENTS

		LTIP A	ward				
	Tranche 1	Tranche 2	Tranche 3	Tranche 4			
Grant date	07 Dec 2022	07 Dec 2022	07 Dec 2022	07 Dec 2022	21 Sep 2022	02 Jun 2022	05 Oct 2021
Number of shares under option	1,111,235	1,111,235	1,111,235	1,111,235	967,000	100,000	1,654,000
Vesting period ends	Dec 22	Dec 23	Dec 24	Dec 25	Oct 25	Oct 23	Oct 23
Share price as at date of grant	44.60p	44.60p	44.60p	44.60p	44.80p	29.50p	37.90p
Option exercise price	0.2p	0.2p	0.2p	0.2p	45.00 p	29.50p	37.90p
Expected volatility	<b>96.49</b> %	<b>96.49</b> %	<b>96.49</b> %	<b>96.49</b> %	100.62%	<b>113.72</b> %	121.14%
Dividend yield	0%	0%	0%	0%	0%	0%	0%
Risk-free investment rate	<b>3.29</b> %	3.25%	<b>3.12</b> %	3.24%	3.05%	1.98%	0.75%
Exercisable from/to	Dec 22- Dec 30	Dec 23- Dec 30	Dec 24- Dec 30	Dec 25- Dec 30	Oct 25- Sep 30	Oct 23- Sep 28	Oct 23- Sep 28
Expected life of options (years)	0.25	1.25	2.25	3.25	3	3	3
Fair value per share at grant date	39.94p	39.95p	39.95p	39.96p	26.53p	16.5p	25.26p

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# 17. CONVERTIBLE LOAN NOTES AND WARRANT INSTRUMENT

There were no convertible loan notes or warrant instruments issued in 2022. The balance of the warrant reserve is related to a warrant instrument issued in January 2020, as part of a wider share issue to raise funds under a subscription agreement. The Company issued 10,937,500 warrants at a ratio of one warrant for every two ordinary shares subscribed in respect of the Subscription. The warrants are exercisable until the fifth anniversary of their issue at a price of 40 pence per ordinary share and have not yet been exercised.

On 4 March 2021, the Company created one hundred £15,000 unsecured convertible loan notes ("Notes"). The Notes attract an interest rate of 2% per annum payable annually following an initial interest-free period of 180 days. The noteholder shall be entitled, at any time within 36 months of the date of the instrument ("Maturity Date"), to serve a conversion notice on the Company to convert all or some only of the outstanding Notes into fully paid ordinary shares at a conversion price of 20 pence per share. To the extent the Notes are not converted at the Maturity Date, the outstanding principal amount of the Notes, together with any accrued interest, is redeemable.

In addition, 2,272,727 warrants ("Warrants") were issued to the noteholder to subscribe to ordinary shares exercisable within 48 months of issue at a conversion price of 22 pence taking the total number of warrants in issue to 13,210,227. The Warrants were valued using the Black–Scholes model.

The initial value of the debt component of the Notes was calculated as £1,184,227. The cash flows attached to the Notes up to the Maturity Date were calculated and discounted at an appropriate venture debt rate of 10%. The fair value of the Warrants was calculated at £118,864 and the residual value of the equity component of the Notes was calculated as £196,909.

On 1 April 2021, the noteholder exercised the Warrants in full at an exercise price of 22 pence and was issued with 2,272,727 ordinary shares. On 15 April 2021, the noteholder converted the loan notes in full and was issued with 7,500,000 ordinary shares.

# Notes to the Consolidated Financial Statements

for the year ended 31 December 2022

# 17. CONVERTIBLE LOAN NOTES AND WARRANT INSTRUMENT (CONTINUED)

The Warrants have been measured using the relative fair value method and fair value has been calculated using the Black–Scholes method using the following inputs:

Inputs to warrant pricing model	31 December 2022	31 December 2021
Grant date	-	4 March
Number of warrants	-	2,272,727
Share price as at date of grant	-	16.50 pence
Warrant conversion price	-	22 pence
Expected life of warrants	-	l year
Expected volatility	-	105.8%
Dividend yield: no dividends assumed	-	0%
Risk-free rate	-	0.41% p.a

### **18. PENSION COSTS**

The pension charge represents contributions payable by the Group to independently administered funds which during the year ended 31 December 2022 amounted to £153,383 (2021: £135,670). Pension contributions payable in arrears at 31 December 2022, included in accrued expenses at the relevant Consolidated Statement of Financial Position date, totalled £11,325 (2021: £32,299).

# **19. COMMITMENTS**

At 31 December 2022 the Group had operating short-term lease commitments in respect of property leases cancellable on one month's notice of £10,365 (2021: £9,963).

#### **20. INVESTMENTS**

During 2021 the Group entered into a collaboration agreement with Pride Century Ventures Limited ("Pride"). A special purpose vehicle ("SPV") was set up for the purpose of conducting the activities under the collaboration agreement. On the basis that the Group was entitled to voting rights on a steering committee which directs principally all of the relevant activities of the SPV, Management has concluded the Group has significant influence over the SPV. In line with the Group's accounting policies and the requirements of IAS 28 'Investments in Associates and Joint Ventures', the SPV was initially recognised at cost. Management has concluded that the initial cost of investment was £nil (Note 3).

#### **21. RELATED PARTY TRANSACTIONS**

Related parties, as defined by IAS 24 'Related Party Disclosures', are the wholly owned subsidiary companies, Futura Medical Developments Limited, Futura Consumer Healthcare Limited and the Board. Transactions between the Company and the wholly owned subsidiary companies have been eliminated on consolidation and are not disclosed.

#### **KEY MANAGEMENT COMPENSATION**

The Directors represent the key management personnel. Details of their compensation and share options are given in Note 7 and within the Remuneration Committee Report.

# Parent Company Balance Sheet

as at 31 December 2022

Company No. 04206001

	Notes	As at 31 December 2022 £	As at 31 December 2021 £
Fixed assets			
Investment	2	65,244,565	58,427,010
Current assets			
Debtors – due within one year	3	12,812	10,764
Total debtors		12,812	10,764
Cash at bank and in hand		2,090,384	8,773,622
		2,103,196	8,784,386
Creditors: amounts falling due within one year	4	(149,633)	(210,934)
Net current assets		1,953,563	8,573,452
Net assets		67,198,128	67,000,462
Capital and reserves			
Called up share capital	5	576,093	574,302
Share premium account		66,545,796	66,378,003
Warrant reserve		165,868	165,868
Profit and loss account		(89,629)	(117,711)
Shareholders' funds		67,198,128	67,000,462

The loss in respect of the Company for the year was £643,770 (2021: £741,665). The Parent Company financial statements were approved and authorised for issue by the Board on 4 April 2023.

The Notes on pages 79 to 81 form part of these Parent Company financial statements.

By order of the Board

JAMES BARDER Chief Executive

# Parent Company Statement of Changes in Equity

for the year ended 31 December 2022

	Note	Share Capital £	Share Premium £	Warrant Reserves £	Other Reserves £	Retained Losses £	Total Equity £
At 1 January 2021		491,254	52,814,090	165,868	_	442,132	53,913,344
Total comprehensive loss for the year		_	_	_	_	(741,665)	(741,665)
Share-based payment		-	_	-	_	181,822	181,822
Shares issued during the year	5	63,503	11,661,978	-	_	_	11,725,481
Convertible loan and warrants issue		_	_	_	118,864	196,909	315,773
Conversion and exercise of warrant and loan		19,545	1,901,935	_	(118,864)	(196,909)	1,605,707
Transactions with owners		83,048	13,563,913	-	_	181,822	13,828,783
At 31 December 2021		574,302	66,378,003	165,868	-	(117,711)	67,000,462
Total comprehensive loss for the year		_	_	_	_	(643,770)	(643,770)
Share-based payment		-	_	-	_	671,852	671,852
Shares issued during the year	5	1,791	167,793		_	_	169,584
Transactions with owners		1,791	167,793	_	_	671,852	841,436
At 31 December 2022		576,093	66,545,796	165,868	_	(89,629)	67,198,128

Share premium represents amounts subscribed for share capital in excess of nominal value, less the related costs of share issues.

Warrants issued are held as a separate 'warrant reserve' within equity. The warrant reserve will be transferred to retained earnings on exercise or lapse, as it is treated as distributable profit from the point of issue.

Profit and loss account represents the cumulative net profit recognised. The total comprehensive loss for the year represents the total recognised income and expense for the year.

The Notes on pages 79 to 81 form part of these Parent Company financial statements.

# Notes to the Parent Company Financial Statements

for the year ended 31 December 2022

# **1. ACCOUNTING POLICIES**

The Parent Company financial statements have been prepared on a going concern basis and under the historical cost convention and have been prepared and approved by the Directors in accordance with Financial Reporting Standard 101 'Reduced Disclosure Framework' ("FRS 101"). The principal accounting policies applied in the preparation of the financial information and where advantage of the FRS 101 disclosure exemptions have been taken are set out below. These policies have been consistently applied to all years presented, unless otherwise stated.

The Parent Company financial statements presented are in sterling.

As a Consolidated Statement of Comprehensive Income is published, no separate statement of comprehensive income for the Parent Company has been included in these financial statements, as permitted by section 408 of the Companies Act 2006. The loss in respect of the Company for the year was £643,770 (2021: £741,665). The remuneration of the Directors of the Company is disclosed in Note 7 to the consolidated financial statements. Auditor's remuneration is disclosed in Note 6 to the consolidated financial statements.

#### **DISCLOSURE EXEMPTIONS ADOPTED**

In preparing these financial statements the Company has taken advantage of all disclosure exemptions conferred by FRS 101. Therefore, these financial statements do not include:

- ▶ certain comparative information as otherwise required by UK endorsed IFRS;
- financial instrument disclosures;
- ▶ certain disclosures regarding the Company's capital;
- ► a statement of cash flows;
- ▶ the effect of future accounting standards not yet adopted;
- ▶ the disclosure of the remuneration of key management personnel;
- disclosure of related party transactions with other wholly owned members of the Group; and
- disclosure of impairment of assets.

#### **NON-DERIVATIVE FINANCIAL INSTRUMENTS**

Non-derivative financial instruments comprise investments in equity, trade and other debtors, cash and cash equivalents and trade and other creditors.

#### TRADE AND OTHER DEBTORS

Trade and other debtors are recognised initially at fair value. Subsequent to initial recognition they are measured at amortised cost using the effective interest method, less any impairment losses.

#### TRADE AND OTHER CREDITORS

Trade and other creditors are recognised initially at fair value. Subsequent to initial recognition they are measured at amortised cost using the effective interest method.

#### **CASH AND CASH EQUIVALENTS**

Cash and cash equivalents comprise cash balances and treasury fund units.

#### SHARE-BASED EMPLOYEE REMUNERATION

The Company has no employees but does issue shares to satisfy share option awards made by its subsidiary company Futura Medical Developments Limited.

The grant date fair value of share-based payments awards granted to employees is recognised as an increase in the investment, with a corresponding increase in equity, over the period in which the employees become unconditionally entitled to the awards. The fair value of the awards granted is measured using the Black–Scholes model, taking into account the terms and conditions upon which the awards are granted.

# Notes to the Parent Company Financial Statements

for the year ended 31 December 2022

### 1. ACCOUNTING POLICIES (CONTINUED)

#### TAXATION

Tax on the profit or loss for the year comprises current and deferred tax. Tax is recognised in the profit and loss account except to the extent that it relates to items recognised directly in equity or other comprehensive income, in which case it is recognised directly in equity or other comprehensive income.

Current tax is the expected tax payable or receivable on the taxable profit or loss for the year, using tax rates enacted or substantively enacted at the balance sheet date, and any adjustment to tax payable in respect of previous years.

A deferred tax asset is recognised only to the extent that it is probable that future taxable profits will be available against which the temporary difference can be utilised.

### 2. INVESTMENT IN SUBSIDIARY

The investment represents 100% of the issued ordinary £1 shares in the subsidiary undertaking Futura Medical Developments Limited whose registered address is: 40 Occam Road, Guildford, Surrey GU2 7YG. The principal activity of the Company is the research and development of pharmaceutical drugs and medical devices and their commercial exploitation. The investment is stated at cost plus amounts capitalised in respect of the intercompany receivable. The results of the subsidiary are included in the consolidated financial statements. The Company capitalises intercompany balances with its subsidiaries at each month-end (creating an investment in subsidiaries) up to the point where it believes the subsidiary is in a position to repay any balances within the next 12 months. Capitalised balances are reviewed for impairment annually. It was concluded that there was no impairment required.

	£
At 1 January 2021	53,616,120
Additions in the year	4,810,890
At 31 December 2021	58,427,010
Additions in the year	6,817,555
At 31 December 2022	65,244,565

Futura Medical Developments Limited owns 100% of the issued ordinary £1 shares of Futura Consumer Healthcare Limited whose registered address is: 40 Occam Road, Guildford, Surrey GU2 7YG. The principal activity of Futura Consumer Healthcare Limited is the commercial exploitation and branding of pharmaceutical drugs and medical devices developed by Futura Medical Developments Limited. This is an indirect investment and Futura Consumer Healthcare Limited has been dormant since the start of 2018.

# 3. DEBTORS

	31 December 2022	31 December 2021
	£	£
Amounts receivable within one year: prepayments	12,812	10,764

### 4. CREDITORS: AMOUNTS FALLING DUE WITHIN ONE YEAR

	31 December 2022	31 December 2021
Trade creditors	80,318	£ 95,200
Accruals	69,315	115,734
	149,633	210,934

# 5. CALLED UP SHARE CAPITAL

	31 December 2022	31 December 2021	31 December 2022	31 December 2021
Allotted, called up and fully paid	Number	Number	£	£
Ordinary shares of 0.2 pence each	288,046,527	287,150,971	576,093	574,302

Details of shares issued by the Company in the year and details of share options outstanding are given in Notes 15 and 16 to the consolidated financial statements.

# 6. RELATED PARTY TRANSACTIONS

The Company has taken the exemption in line with FRS 101 not to disclose related party transactions between wholly owned subsidiaries.

# **Company Information**

#### COMPANY NUMBER

04206001

### DIRECTORS

John Clarke James Barder Angela Hildreth Ken James Jeff Needham Andrew Unitt Non-Executive Chairman Chief Executive Officer Finance Director and Chief Operating Officer Executive Director Non-Executive Director Non-Executive Director¹

#### COMMITTEE MEMBERS SERVING THROUGHOUT THE YEAR WERE:

#### AUDIT COMMITTEE

Andrew Unitt John Clarke

# SECRETARY AND REGISTERED OFFICE

Angela Hildreth Futura Medical plc Surrey Technology Centre 40 Occam Road Guildford Surrey GU2 7YG

### NOMINATED ADVISER AND BROKER

Liberum Capital Limited 25 Ropemaker Street London EC2Y 9LY

# PRINCIPAL BANKER

HSBC Bank 12A North Street Guildford GU1 4AF REMUNERATION

**COMMITTEE** Jeff Needham John Clarke Andrew Unitt

# AUDITOR

Grant Thornton UK LLP First Floor 20 Valpy Street Reading Berkshire RG1 1AR

# NOMINATIONS COMMITTEE

John Clarke Andrew Unitt

# REGISTRAR

Link Group Unit 10 Central Square 29 Wellington Street Leeds LS1 4DL

# PATENT ATTORNEY

Withers & Rogers LLP 2 London Bridge Road London SEI 9RA

# PUBLIC RELATIONS ADVISER

Optimum Strategic Communications 10 Devonshire Square London EC2M 4YP

1. Appointment commenced 1 January 2022



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