

Futura Medical plc

# Annual Report and Accounts 2021

# Welcome to the Futura Medical

### Annual Report 2021

### WHAT WE DO

Futura Medical is a pharmaceutical company developing innovative products based on our proprietary, transdermal technology DermaSys<sup>®</sup>.

for the prescription and consumer

health and pain relief. Development and value creation whilst seeking to minimise

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 long-term value creation potential in a large market where there is an unmet need for new treatment options. In a Phase 3 clinical trial MED3000 achieved statistically significant and clinically important improvements in ED over baseline (before treatment). In 2021 MED3000 received its MDR EU Quality Management Certificate for the placing on the market of a Class 2B medical device ("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"). A confirmatory Phase 3 clinical trial is also underway in preparation for a regulatory filing in the US by the end of Q3 2022.



#### **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 longterm strategy is to expand the product pipeline based on DermaSys®. We are currently exploring opportunities with cannabidiol in CBD100. Our products are underpinned by strong IP, usually specific to each product.



Read more about DermaSys® on page 4

#### **CLINICAL DEVELOPMENT OF TREATMENTS** FOR 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 SDG** goals on page 38

#### **DE-RISKED STRATEGY WHICH FOCUSES ON RAPID ROUTES TO MARKET**

Our lead product has already received CE mark approval which will provide in many non-EU countries a "fast-track" approval. Confirmation has also been received on the remaining clinical trial requirements expected for US approval which will complete in Q3 2022. This means that there is a lower development risk and shorter regulatory pathway to monetisation of our products in many countries.



Read more about **our** strategy on page 20

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.



Read more about **our** partnerships on page 28

#### 6 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 recently strengthened the Board's business and commercial expertise as Futura moves into the next phase of MED3000's commercialisation.



Read more about governance at Futura on page 50

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### Highlights

### MED3000 – EUROPE AND US REGULATORY

- In April 2021, the Company received its MDR EU Quality Management Certificate for placing MED3000 on the market as a Class 2B medical device also known as European "CE mark approval".
  - Futura's breakthrough, topical gel formulation MED3000, will be the first pan-European topical treatment for erectile dysfunction ("ED") available without the need of a doctor's prescription ("OTC").
- The US Food and Drug Administration ("FDA") agreed that an application could be made for MED3000 as a medical device for ED treatment, with a De Novo classification. A number of productive and positive presubmission meetings with FDA followed during 2021 to discuss existing Phase 3 clinical data, pathway to OTC status and any additional clinical and non-clinical requirements:
  - In March 2021 an agreement was reached between FDA and Futura on the detailed clinical study design (protocol) for a small supplemental clinical trial (known as "FM71").
  - In August 2021 the FDA confirmed that to enable OTC classification a non-clinical, "Human Factors" study would need to take place to test the ability of subjects to self-diagnose their ED, correctly select the product based on label information and test their ability to correctly use the product without supervision of a doctor. The FDA asked for a minimum of 15 subjects to complete the study.
  - On 14 September 2021 the first patient was enrolled in the FM71 confirmatory clinical study. Patient recruitment was completed at the end of 2021 and the study remains on track for US filing by the end of Q3 2022.
  - In December 2021 Futura announced successful completion of the Human Factors study, with 32 subjects entering the study. Results supported the regulatory submission for OTC designation and will enable Futura to finalise the OTC product label for a US filing expected to be made after FM71 has completed.
  - US marketing authorisation remains on track for potential approval of MED3000 in Ql 2023.

### MED3000 – COMMERCIAL AND MANUFACTURING

- Joint collaboration agreement for China and South East ("SE") Asia with 50/50 share of profits signed in March 2021. Initial submissions have been made to the Chinese National Medical Products Association ("NMPA") initially for determination of the regulatory classification of MED3000 in what is expected to be a three-year regulatory process.
- In August 2021 Futura entered into a licensing agreement with m8 Pharmaceuticals, Inc ("m8"), a specialty biopharmaceutical company focused on commercialisation in Latin America, for the rights to exclusively develop and commercialise the Company's MED3000, in the key ED markets of Brazil and Mexico.
- ► In September 2021 Futura signed a licensing agreement with Labatec Pharma ("Labatec"), a Swiss-based specialty pharma company with expertise in commercialisation in Europe and the Middle East and North Africa ("MENA") region for exclusive rights to commercialise MED3000 in the Gulf Co-operation ("GCC") region, Jordan, Lebanon and Iraq.
- MED3000 manufacturing capabilities expanded in August 2021 with the addition of a new third party, FDA, EMA and UK approved manufacturer and extended shelf life to three years, as Futura strengthens resources in the build up towards initial product launches over the next year.

### POST PERIOD END HIGHLIGHTS

- Entered into a period of exclusivity with an, as yet, unnamed party regarding a potential agreement for the EU and UK marketing rights for MED3000.
- In March 2022 Futura signed a commercial licensing agreement for MED3000 in South Korea with A. Menarini Korea Limited, a subsidiary of Italy-based, multinational specialty pharma company Menarini Group.
- In April 2022, the Company received UKCA mark approval following an application in March 2022 to the UK Notified Body for MED3000 as a Class 2A medical device. This is required before end of June 2023 to replace the CE mark approval which currently covers the UK according to Brexit legislation.



### **BOARD UPDATES**

- In October 2021 management strengthened the Company's Board with additional commercial expertise with the appointment of two Non-Executive Directors, Jeff Needham and Andrew Unitt as Futura moves into the next phase of MED3000's commercialisation.
- Jonathan Freeman stepped down as Senior Independent Non-Executive Director on 31 December 2021 having been on the Board of Futura since the IPO in 2003.

### **FINANCIAL HIGHLIGHTS**

- In May 2021 the Company conducted a £12.00 million (gross) fundraise including retail offer.
- ► £4.96 million net loss in the period (31 December 2020: net loss £2.41 million).
- Cash resources of £10.37 million at 31 December 2021 (31 December 2020: £1.02 million).
- Current cash runway extends beyond initial MED3000 launches expected over the next year and expected US regulatory approval in 2023, assuming no contributions from milestone payments or other revenues.

### DermaSys<sup>®</sup> 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<sup>®</sup>.

#### 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 ("API") and Generally Recognized As Safe ("GRAS") 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.



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

and permeation

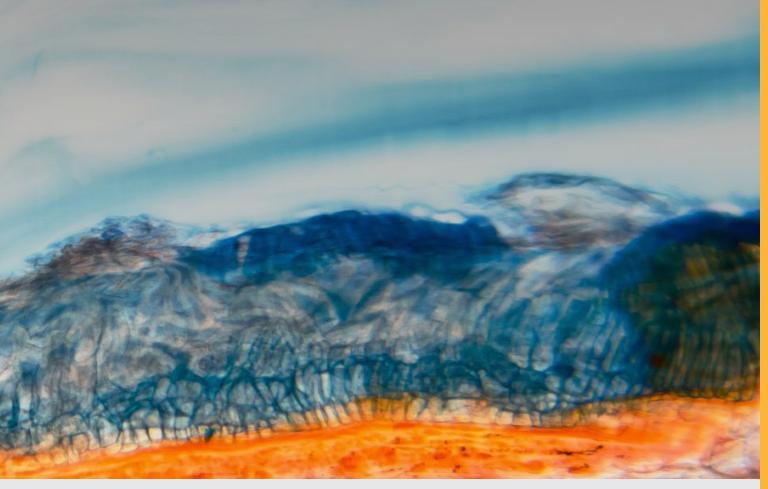
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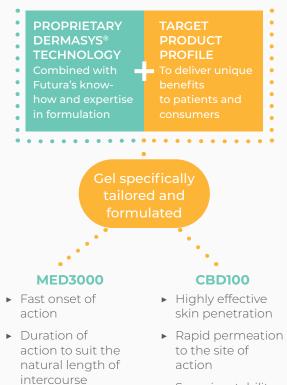
### DERMASYS® AND THE PROCESS BEHIND OUR UNIQUE FORMULATIONS

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

DermaSys<sup>®</sup> 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 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.

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, effective penetration for enhanced therapeutic benefits with fast, effective and long-lasting action.

### DermaSys® process



Superior stability

Excellent safety

profile

### **Products and Pipeline**

Futura Medical is developing innovative products for two large markets, sexual health and pain. We have products in late-stage development, with MED3000 and CBD100 being the lead products.

### GLOBAL TRENDS OUR PRODUCTS ADDRESS

### Ageing populations

Population ageing is a global phenomenon with virtually every country in the world experiencing growth in the size and proportion of older people in their population. Globally, the share of the population aged 65 years or over increased from six per cent in 1990 to nine per cent in 2019<sup>1</sup>. Age is a main factor for the incidence of erectile dysfunction as well as local pain.

### 2 Increasing prosperity

According to a Brookings Institute report, as of 2016, 3.2 billion people globally are considered middle class and it is estimated this number will increase by 140 million annually. In developed countries people in their older years have fewer financial commitments and therefore more disposable income.

### <sup>3</sup> Increased quality of life

With an increasing prosperity and increasing life expectancy, patients and consumers have high expectations to lead a full, active and enjoyable life well into their later years.

### Increasing overall patient demand

With more disposable income and higher expectations from patients towards their sexual health and the desire to lead a full, active and enjoyable lifestyle, we anticipate that overall patient demand and spending will increase.

### OUR MARKET CATEGORIES



### **Sexual Health**

Lead product MED3000 is a unique and highly differentiated easy to use topical gel for erectile dysfunction ("ED") which has been approved as a medical device in the EU and has Phase 3 clinical data demonstrating highly statistically significant and clinically important improvement across all ED patient severities with potential over the counter peak sales of over US\$ 650 million<sup>2</sup>.



### Cannabidiol

CBD100 may be able to provide rapid and targeted 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 with a particular focus on local or regional treatment, such as pain relief. In recent years there has been significant interest in cannabidiol as more data is emerging on its potential benefits with the market forecast to grow to US\$ 15 billion by 2028<sup>3</sup>.

- 1. World Population Ageing 2019 report, United Nations.
- 2. Previous market research conducted by Ipsos Group as an over the counter product on MED2005 showed potential peak sales of US\$660 million. Whilst MED3000 is a slightly different proposition as it has a different mode of action, it offers the same benefits and therefore the Group believes that the market potential is similar.
- 3. Report by Reports and Data, 2021.

### OUR PRODUCT PIPELINE

MED3000	pipeline stage		
	Development	Regulatory	Distribution agreements
EU		MED3000 approved as a medical device in the EU after receiving its MDR EU Quality Management Certificate as a Class 2B medical device ("CE mark approval"). Post-Brexit UKCA mark approval received in April 2022.*	
MENA	<b>S</b>	Supporting Labatec with their regulatory dossiers and submissions which have already commenced.	Licensing deal signed with Labatec
Brazil/ Mexico		Supporting m8 with their regulatory dossiers. Dossiers being prepared for submission in 2022.	Licensing deal signed with m8
Asia	Discussions being held with the Chinese regulator ("NMPA") to clarify scope of clinical work.	In a number of additional South East Asian markets supporting Co-High with regulatory dossiers and submissions.	Licensing deal signed with Co-High
US	Successful completion of Human Factors study to support OTC designation Headline clinical data Q3 2022 Phase 3 FM71 study underway and on track for submission to the FDA by the end of Q3 2022	<b>Regulatory submission by end of Q3 2022</b> Clear regulatory pathway as a medical device with OTC designation in the US.	

\* 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. The UKCA mark will be needed from 1 July 2023 and in the meantime the EU CE mark is valid in the UK. We received UKCA mark approval in April 2022, well ahead of the deadline.

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.		
TIB200	Topical ibuprofen pain relief gel	Partnering discussions ongoing.		

### SPOTLIGHT

Our lead product, MED3000 was approved in April 2021 as a medical device in the EU and will be the first clinically proven, pan-European OTC topical treatment for erectile dysfunction available without a doctor's prescription.

MED3000 is a unique and highly differentiated, easy to use topical gel for erectile dysfunction with a rapid speed of onset which has Phase 3 clinical data demonstrating highly statistically significant and clinically important improvement across all ED patient severities. Licensing deals have been signed for key regions worldwide with launches expected over the next year.



Futura has developed an illustrative pack and branding that licensing partners can select to use at their discretion.

### Chairman's Statement

### Evolving towards commercialisation from a position of strength"

JOHN CLARKE Non-Executive Chairman

2021 was a landmark year for Futura Medical with its lead product MED3000 gaining EU approval as a clinically proven treatment for erectile dysfunction ("ED") available without the need of a doctor's prescription and rapidly transforming from a solely R&D focused operation into a high growth, commercial-stage Company poised for sustainable long-term revenues. The MED3000 regulatory approval was an exceptional achievement for the Company especially when you consider it was achieved against the backdrop of a global pandemic.

In June 2021, we completed a £12 million fundraise which was supported by our key existing shareholders as well as new shareholders. Importantly, this enables the Company to complete the remaining clinical development activities expected to be required by the FDA to gain approval in the US. The US is the largest potential market by value over the counter ("OTC") with all the wellknown oral treatments such as Viagra® and Cialis® requiring a doctor's prescription. The fundraise also strengthened our balance sheet ahead of partnering discussions.

Our commercialisation strategy continues to be to engage with licensing or distribution partners who have extensive local knowledge of their markets, experience of building brands within the pharmaceutical and OTC sector as well as a strong commitment and belief in MED3000. During 2021, we concluded partnering arrangements in China and South East Asia, Latin America, South Korea and the Gulf region including Jordan, Lebanon and Iraq. Our intentions for US commercialisation are to successfully complete data requirements for the US and submit for US approval before progressing US commercial options.

We continue to bring new skills and experience to our already highly skilled Board. A great deal of thought and focus was placed on expanding the Company's commercial and business expertise with a particular focus on the US. Futura strengthened the Board with the appointment of two Non-Executive Directors, Jeff Needham and Andrew Unitt. Both bring OTC market expertise and exceptional skills in strategic development and business management which will further enhance our ambition and focus on building a global brand and distribution network to accelerate Company growth.

Jeff, who joined the Board in October 2021 brings a wealth of knowledge and experience to the Board having been at Perrigo Company plc, the US-based manufacturer and marketer of consumer healthcare products, for 36 years, and a board director of the Consumer Healthcare Products Association (US) for 11 years. Andrew, who joined the Board on 1 January 2022, 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. Andrew will chair the Audit Committee as Jonathan Freeman's successor, following Jonathan stepping down at the end of 2021.

I would like to take this opportunity to thank Jonathan for his wise counsel and his huge contribution over the years. He has been a highly valued and appreciated member of the Board and the Board is unanimous in thanking him for all his efforts.

The COVID-19 pandemic continued through 2021 and I would like to thank all of Futura's employees for their dedication, hard work and commitment during several lockdowns and for successfully working from home when required in the last twelve months. Finally, I would like to thank our shareholders for their continued support and belief in our strategy for making a commercial success of MED3000.

#### JOHN CLARKE Non-Executive Chairman

### Chief Executive's Review

### Poised for growth and sustainable long-term revenues"

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.

To date we have not seen a material impact as the Company is used to operating as a semivirtual business and we have adapted very well to a remote and flexible working model. As the pandemic hopefully reaches its endemic phase we plan to make suitable adjustments to the working environment.

The clinical study FM71 is fully recruited and underway and thus far any disruption as a result of COVID-19 has been minimal.

2021 has been a year of transformational progress and momentum for Futura as the Company achieved major milestones in terms of first regulatory approval for our lead product, MED3000, as an approved erectile dysfunction treatment ("ED") and completion of a number of commercial MED3000 licensing deals as we continue to build a global distribution platform.

The Company received CE mark approval from the European regulator for MED3000 in April 2021. The product is a breakthrough, fast-acting topical gel formulation for the treatment of ED. MED3000 now has the potential to become the first globally available, clinically proven, over the counter ("OTC") treatment option available to the 1 in 5 men<sup>1</sup> that suffer from a variety of severities of ED worldwide, a market that has seen little innovation in the last two decades.

The Company is now preparing for first product launches over the next year and 2023, not just in Europe but also countries where recognition of the CE mark may allow "fast-track" review, importantly making a highly differentiated treatment option accessible and available to ED sufferers without a doctor's prescription. In line with this, recognising how crucial disciplined supply is, we have recruited key quality, manufacturing and supply talent, and are scaling up production to ensure continuity and certainty of supply for launches and future international sales growth.

The US remains the largest market opportunity globally for ED treatments OTC and we are making steady progress towards completing our US Food and Drug Administration ("FDA") regulatory submission for MED3000 and continue to target filing for approval by the end of Q3 2022. We were pleased to announce completion of patient recruitment for our FM71 study (a confirmatory study stipulated by the FDA) at the end of 2021 and reported in December 2021 that the "Human Factors" study was successfully completed, with results able to support the regulatory submission for OTC designation as well as allowing us to finalise the OTC product label for the US filing.

The Board and its commercial advisers believe that post-US-submission with launches underway in other regions is an optimal, key, de-risked inflection point at which to focus on US commercial discussions in earnest to explore all options to capture long-term value and cashflow for shareholders.

2021 also saw the Company begin to execute upon its strategic plan to leverage commercialisation globally with a network of licensing and distribution partners with brand building strength, healthcare credibility and infrastructure and marketing expertise, choosing partners for the development and commercialisation of MED3000 in major markets for ED. In 2021 this covered China, South East Asia, Latin America and the Gulf region in deals structured to capture significant long-term value.

In 2022 to-date we have signed an agreement covering South Korea bringing the total number of MED3000 commercial deals to four, and we have also entered into a period of exclusivity with an, as yet, unnamed party regarding a potential agreement for the EU and UK marketing rights for MED3000, although there can be no guarantee that an agreement can be successfully reached at this stage.

## Chief Executive's Review

A further announcement will be made as appropriate.

We look forward to further updates for shareholders during what we believe will continue to be an exciting 2022 for Futura as we prepare for initial launches of MED3000, further commercial agreements and target US regulatory filing by the end of Q3 2022.

### **OPERATIONAL REVIEW**

Futura's strategy is to leverage its proprietary and tailored DermaSys® transdermal delivery technology to bring innovative products to market in sexual health and pain, bringing new treatment options to patients particularly in areas of significant unmet need. The Company is accumulating critical knowhow, particularly in new market segments of sexual health, including OTC treatments for ED, that it aims to leverage commercially as it continues to build a brand franchise around MED3000 and achieve sustainable revenue growth.

#### DERMASYS<sup>®</sup> – OUR 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 gel 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 BREAKTHROUGH, FAST-ACTING TOPICAL GEL FORMULATION WITH THE POTENTIAL TO BECOME THE FIRST GLOBALLY AVAILABLE, CLINICALLY PROVEN, OTC TREATMENT FOR ED

MED3000 is a formulation of the proprietary technology DermaSys®, for the treatment of ED. MED3000 has the potential to be a highly differentiated product by addressing significant unmet needs, across all patient severities in the multi-billion dollar ED market<sup>2</sup>, which include rapid speed of onset enabling spontaneity for both partners, significant clinical benefits alongside excellent safety and low side effects and no interactions with alcohol or food as well as providing a potential treatment option for patients contraindicated from using existing ED therapies.

The prevalence of ED disrupts the lives of at least 1 in 5 men globally<sup>1</sup>, with around 23 million men suffering ED in the US and 20 million men in the UK, France, Italy, Spain and Germany<sup>3</sup>. Whereas there has been little innovation in ED treatments for nearly two decades and many patients continue to suffer dissatisfaction with existing treatments, the market continues to evolve especially within the US with the advent of subscription services such as For Hims and Go Roman, and also in the UK with Numan, which offer a branded concierge service for ED prescription medicines online. These subscription services charge a monthly subscription fee, typically in the region of US\$50 in return for a doctor's consultation and ten generic 50mg sildenafil tablets per month. This increased affordability of around US\$5 per tablet (to the end user) is driving volumes especially in the US which have increased by 85% between 2018 and 2020<sup>2</sup>.

Studies have shown MED3000 to be an effective treatment for ED with an excellent safety profile. MED3000 has a unique evaporative mode of action which the Company believes stimulates nerve endings in the glans penis to cause an erection. MED3000 helps men get an erection within 10 minutes, substantially faster than on-demand oral tablet phosphodiesterase-5 inhibitors ("PDE5i's"), with significant benefits for spontaneous rather than pre-planned sexual intercourse.

Futura's objective of OTC status as a clinically proven treatment for ED for MED3000, particularly in the US, continues to be a top priority given the potential this offers with the difficulties that PDE5i's seem to be encountering in most major markets to get approval for switch from prescription to OTC status. Most recently 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.

#### MED3000 – APPROVED AS THE FIRST PAN-EUROPEAN TOPICAL TREATMENT FOR ED AVAILABLE WITH OTC STATUS

Futura's breakthrough, fast-acting topical gel formulation MED3000, is the first clinically proven, pan-European topical treatment for adult men with ED available without a doctor's prescription. In April 2021 the Company announced that it received its MDR EU Quality Management Certificate for the placing on the market of a Class 2B medical device known as MED3000 ("CE mark approval").

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.

- 1. EMA, Withdrawal assessment report for Viagra, 2008
- 2. IQVIA IMS Health, 2020

<sup>3. 2021</sup> 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.

Due to post-Brexit arrangements, the EU CE mark can be used to market the product in Great Britain until 30 June 2023 by which time a specific UKCA mark has to be obtained. In anticipation of this Futura filed for a UKCA mark for MED3000 as a Class 2A medical device and received approval in April 2022.

#### US – THE LARGEST POTENTIAL OTC ED MARKET GLOBALLY

In 2020, the FDA agreed that an application may be made for MED3000 as a medical device for ED treatment, with a De Novo classification. This was followed by a number of productive and positive presubmission meetings with the FDA during 2020 and 2021 to discuss existing Phase 3 clinical data, pathway to OTC status and any additional clinical and nonclinical requirements.

In August 2021 Futura agreed with FDA the design of a "Human Factors" study to achieve OTC classification. Successful completion of the Human Factors study was announced in December 2021, with 32 subjects recruited. It was demonstrated that individuals are able to correctly self-diagnose ED and to make correct self-selection decisions by considering their own health history and the instructions for use and warnings on the label. Overall, there was a very high degree of comprehension of the label and leaflet to increase confidence that the product will be used appropriately in an OTC setting. These results therefore support the regulatory submission for OTC designation and will enable Futura to finalise the OTC product label for a US filing.

### FM71 – US confirmatory clinical study design

In March 2021 Futura announced that it received official minutes from the FDA agreeing the design for a confirmatory clinical trial. FM71 is a Phase 3, 24-week multicentre, comparative, randomised, open-label, home use, parallel group study in 100 subjects with mild, moderate or severe ED. Co-primary endpoints were agreed with FDA as significant improvement with MED3000 from baseline (pre-treatment) ED, and ensuring that the change from baseline is clinically important defined as at least a 4-unit change on the internationally recognised IIEF-EF scale. Secondary endpoints include FDA agreed criteria to support fast-acting claims, a key product differentiator. Tadalafil 5mg is also included in the study to provide exploratory endpoints and inform FDA of the relative benefit and risk of MED3000 versus a currently marketed product.

FM71 was fully recruited by the end of December 2021 using subjects from Eastern Europe and the US. Timelines remain on track to enable planned US regulatory submission by the end of Q3 2022, and for targeting potential US FDA granting De Novo and OTC classification for marketing authorisation in Q1 2023.

#### MED3000 COMMERCIALISATION

2021 saw the Company enter into several commercial licensing deals in major markets for ED.

In March 2021 Futura announced investment into the Company and joint collaboration with Co-High Investment Management Limited ("Co-High") and certain subsidiaries of Atlantis Group to commercialise MED3000 in China and South East Asia.

Futura also announced in August 2021 that it had entered into a licensing agreement with m8 Pharmaceuticals to commercialise MED3000 in Brazil and Mexico, swiftly followed in September by a licensing agreement with Labatec Pharma ("Labatec") for exclusive rights to commercialise MED3000 in the Gulf region, Jordan, Lebanon and Iraq.

In early 2022 Futura entered into its fourth licensing agreement with A. Menarini to commercialise MED3000 in South Korea.

Futura is establishing a network of licensing and distribution partners with strength in brand building, pharmaceutical credibility and regional infrastructure and marketing expertise for longterm distribution of MED3000 across the globe. With multiple commercial agreements to date Futura now has a strong and expanding distribution platform in place for regions outside the key US market. The Board's US commercialisation strategy is to successfully complete data requirements for the US and submit for US approval before progressing US commercial options which is also expected to be reinforced by validation of initial product launches in other countries. Nevertheless Futura has already received a number of inquiries regarding commercialisation opportunities for MED3000 in the US and the Board and its advisers are keeping an open mind on the best options in order to maximise long-term value and sustainable revenues whilst minimising risk for Futura's shareholders.

### China and South East Asia – Co-High

In March 2021 Futura entered into £1.5 million convertible debt and £0.5 million of warrants financing transactions with HT Riverwood Multi-Growth Fund ("Riverwood"), a fund managed by Atlantis Investment Management Limited ("Atlantis"), which provided the Company with £2 million in cash. These financial instruments were respectively converted and exercised by Riverwood in March and April 2021 and there are no further amounts outstanding to Riverwood from Futura.

Atlantis is a 100% owned subsidiary of the Atlantis Group and Co-High is a 60% owned subsidiary of the Atlantis Group. Ms Yang Liu, now Atlantis' Chairperson and Chief Investment Officer, acquired the Atlantis Group in 2009.

### Chief Executive's Review

Additionally, Futura entered into a licensing agreement with Pride Century Ventures, a special purpose vehicle owned by Co-High for the rights to exclusively develop and commercialise the Company's topical, gel-based ED treatment MED3000, in China and South East Asia (the "Region"). Co-High will provide funding currently estimated to be up to £4 million for the expected remaining R&D work required to gain approval of MED3000 throughout the Region. Futura will be entitled to 50% of profits from the commercialisation of MED3000 within the Region including any profits derived from local partner agreements within the Region.

Atlantis is a leading international asset management company with a focus on the Greater China Region and South East Asia. Co-High is a specialist private equity company in the Greater China region and invests in and collaborates with some of the world's most promising companies which are believed to be poised to enter a hypergrowth phase. Healthcare investment and collaboration is targeted at companies with a clear scientific edge who are working to solve the major unmet medical needs of the Greater China region.

Under the terms of the agreement, Futura and Co-High will work together to develop and commercialise MED3000 as a clinically proven OTC treatment for ED throughout South East Asia.

Discussions are being held with the Chinese regulator, the National Medical Products Administration, to clarify the scope of clinical work required to gain approval in China and initial submissions have been made to determine whether MED3000 will be designated a medical device or drug. Current expectations are that a Chinese clinical trial will be required to establish safety as well as efficacy in Chinese men. The Chinese regulatory process is currently expected to take up to three years, inclusive of the likely time required to conduct a local clinical trial although more accurate timings can only be given once designation is complete.

Brazil and Mexico – m8 Pharmaceuticals

In August 2021 Futura entered into a licensing agreement for MED3000 with m8 Pharmaceuticals, Inc ("m8"), a specialty biopharmaceutical company focused on commercialisation in Latin America, for the rights to exclusively develop and commercialise MED3000, in Brazil and Mexico.

Under the terms of the agreement Futura and m8 will work together to gain marketing authorisation and commercialise MED3000 as a clinically proven treatment for ED available OTC 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. Futura will receive payments on all sales of MED3000 from m8, and up to four milestone payments totalling US\$8.5 million based on cumulative sales volumes within the initial term.

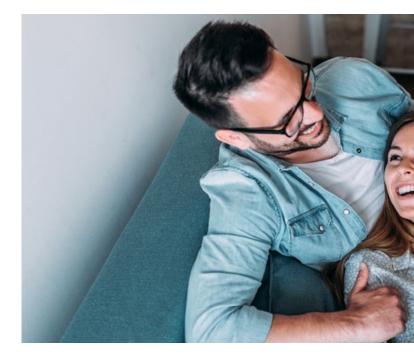
### Gulf Co-operation Council ("GCC") region and Middle East – Labatec

In September 2021 Futura entered into a licensing agreement with Labatec Pharma ("Labatec"), a Swiss-based specialty pharma company focused on commercialisation in Europe and the Middle East and North Africa ("MENA") regions, for the rights to exclusively commercialise MED3000 in the GCC region as well as Jordan, Lebanon and Iraq.

Futura is eligible to receive initial upfront payments, as well as undisclosed milestone payments based on regulatory approval. Labatec will pay an agreed price to Futura for the manufacture and supply of MED3000 by Futura's Contract Manufacturing Organisation ("CMO"), plus royalties on all sales. Labatec is responsible for all local MED3000 development and regulatory costs as well as all launch and marketing expenses. The initial licence agreement term is for eight years with the ability to extend for successive two-year terms by mutual consent.

### South Korea – A. Menarini Korea Ltd

In March 2022 Futura announced a licensing agreement with A. Menarini Korea Limited ("Menarini") for the rights to exclusively commercialise MED3000 for the treatment of ED in South Korea. A.Menarini Korea Ltd is a wholly owned subsidiary of the Italian-based specialty pharma company Menarini Group. Menarini Group is the world's largest Italian biopharmaceutical company



with a heritage of over 135 years and over 17,500 employees in more than 140 countries. Menarini Korea possesses the capability to successfully register, launch and commercialise brands in the market, with key strengths in therapeutic areas such as cardiovascular, hemato-oncology/pain, men's health, consumer health, and specialty/orphan diseases and is a trusted medicines supplier in the region that is ideally placed to market retail products, with local teams that have a deep understanding and experience of the South Korean market.

Futura is eligible to receive initial undisclosed upfront payments and under agreement terms, will support Menarini to gain marketing authorisation and commercialise MED3000 for ED in South Korea. 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 required. Futura will provide reasonable technical support for product development and commercialisation and provide manufactured product from Futura's CMO at an agreed price.

#### MANUFACTURING

Futura's team has been significantly strengthened with key recruitment in both supply and manufacturing expertise and additional quality management as the Company moves from R&D to commercial production and supply for its main product. MED3000 manufacturing scale up and production capacity to meet projected demand is progressing well. We are cognisant that good supply discipline is crucial and are also continuing to work on optimising cost of goods.

In August 2021, the Company announced the addition of a new, US FDA, EMA and UK approved contract manufacturer as Futura works towards initial launches of MED3000 over the next year.



Currently, Futura's approved contract manufacturing facilities are located in the UK as well as the EU. The Company is actively exploring additional manufacturing sites, including in the US, to support continuity of supply for future international sales growth as well as the logistical challenges of intermarket sales. Submissions for further regulatory approvals of MED3000 outside Europe have already started through Futura's partners and manufacturing scale up and validation is well advanced as we move towards manufacturing launch supplies.

Futura now has an approved shelf life for MED3000 of three years across all temperature zones an important feature for markets such as the Middle East where ambient temperatures and humidity are much higher than within the UK.

#### PATENTS

An initial UK patent was filed in December 2019 around MED3000's clinically significant and novel findings shown in FM57 followed by further supplementary UK filings to establish a priority date prior to a Patent Cooperation Treaty ("PCT") and certain non-PCT patent applications in late 2020. The PCT currently has 153 contracting countries where the Company can seek patent protection claiming priority from an original application such as the UK. An application to the European Patent Office was also made in August 2021 for examination and further national applications in line with normal PCT filing procedure will be made in Q2 2022 in those countries considered necessary to protect the commercial interests of MED3000. If national applications are successful this will provide patent protection until 2040.

#### TPRIOO – TOPICAL NON-STEROIDAL ANTI-INFLAMMATORY FOR THE TREATMENT OF PAIN AND INFLAMMATION ASSOCIATED WITH SPRAINS, STRAINS, BRUISES AND SOFT TISSUE RHEUMATISM

TPR100 is partnered for manufacturing and distribution in the UK with Thornton and Ross, one of the UK's largest consumer healthcare companies and a subsidiary of STADA AG.

Following the Medicines and Healthcare products Regulatory Agency's ("MHRA") request for a Phase 3 study to support the improved skin permeation and potential potency of TPR100 including potential superior efficacy claims, Futura has determined that the feasibility of a clinical study that would satisfy the Phase 3 requirements for both UK and US marketing approval will require a US distribution partner prior to the commencement of any Phase 3 programme. The project is currently on hold as the Company focuses its resources on its leading asset, MED3000.

#### CBD100 - FUTURA'S ADVANCED, PROPRIETARY DERMASYS® FORMULATION FOR TRANSDERMAL DELIVERY OF CANNABIDIOL

CBD100 is part of a joint venture collaboration with CBDerma Technology Limited aiming to explore the application of Futura's advanced proprietary transdermal drug delivery technology, DermaSys® for delivery of cannabidiol.

### Chief Executive's Review

CBDerma Technology is a company that was established and funded to specifically exploit the therapeutic potential of cannabis. Cannabidiol is a major component of the cannabis plant and is generally regarded as non-addictive and nonpsychoactive, making it ideal for consideration as a topically delivered molecule for local or regional (nonsystemic) use. The market for cannabidiol products is growing rapidly. A 2021 report by Reports and Data forecasts that the market for cannabidiol products is forecast to grow from US\$3 billion in 2020 to US\$15 billion by 2028, at a Compound Annual Growth Rate of 22.6%, during the forecast period. The market is primarily driven by the increase in the usage of cannabidiol in medical applications and consumer products such as supplements, beverages and skin care cosmetics.

Futura's extensive DermaSys® cannabidiol formulation work has demonstrated highly efficient penetration of cannabidiol into and through the skin, superior to an established, marketed, comparator product. Additionally, cannabidiol is known to be unstable with many common excipients. CBD100 was specially formulated to minimise this issue and has shown encouraging early stability work, which is expected to ensure potency is retained during shelflife. This work resulted in robust intellectual property filings covering various unique aspects of the CBD100 gel formulation.

As the medical and consumer applications of cannabidiol become more and more accepted and the regulatory environment becomes ever clearer a gel that has been formulated using strict pharmaceutical development principles with strong delivery characteristics, stability and high quality continues to be a very attractive commercial proposition when compared to current market incumbents in either cosmetic or more traditional pharmaceutical markets for cannabidiol such as pain and inflammation. Both options are being examined.

Whilst Futura's resources are focused on key asset MED3000, the Company has received interest in CBD100 and continues to explore commercial opportunities for the product with discussions progressing and further validation work being conducted both internally and externally by a potential partner to validate the power of the DermaSys<sup>®</sup> technology which may result in a commercial agreement and we intend to update shareholders in due course.

#### **RESEARCH AND DEVELOPMENT**

Futura is committed to delivering long-term and sustainable value to the Company allowing a long-lasting growth franchise to be built around MED3000 and other 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 an OTC product treating ED. Futura intends, in due course, to commission further in-market research, especially for the US, to identify commercially attractive product line extension opportunities.

### OUTLOOK

The fundraise in May 2021 was pivotal in terms of strengthening the Company's finances and commercial negotiating positions and so the last year has seen Futura achieve considerable milestones both in the evolution of the Company as it approaches a sustainable revenue stream and in terms of bringing closer the availability of MED3000 to men with ED where treatments that meet their needs are lacking. This includes CE mark approval for Europe and the UK as an ED treatment for adult men without the need for a doctor's prescription and multiple commercial licensing deals in large markets for ED in regions such as China and South East Asia, Latin American, the Middle East and South Korea. The Company has also entered into a period of exclusivity with an, as yet, unnamed party regarding a potential agreement for the EU and UK marketing rights for MED3000, although there can be no guarantee that an agreement can be successfully reached at this stage.

Going forward we will continue to gear up manufacturing and supply in line with expected demand ready for first product launches over the next year, having strengthened the Company's team of direct employees and directors in terms of global commercial, quality, manufacturing and supply experience as well as gain manufacturing regulatory approvals through regional partners to support international expansion beyond 2022.

We are also firmly focused on the US regulatory pathway for MED3000 with the US confirmatory FM71 clinical trial well underway having fully enrolled patients towards the end of 2021 and the short, non-clinical, "Human Factors" study successfully completed to support US OTC designation. Everything is on track for planned MED3000 regulatory dossier submission in the US by the end of Q3 2022 and a potential marketing authorisation in Q1 2023. The US remains the largest potential OTC market for ED and OTC status would be a first in the US. as it is for the majority of countries within the EU, providing ED sufferers with an accessible, new treatment option, for their ED. We look forward to reporting on these important inflection points to shareholders as the year progresses and Futura gathers increasing momentum as it transitions to commercial operations to capture the value of MED3000.

#### JAMES BARDER Chief Executive

### Marketplace – Erectile Dysfunction

One in five men suffer from erectile dysfunction worldwide<sup>1</sup>. Erectile dysfunction ("ED") is closely linked to age and a number of co-morbidities associated with obesity such as diabetes and heart disease with the incidence of erectile dysfunction expected to increase to 322 million worldwide by 2025<sup>2</sup>.

Both severity and prevalence of ED increase with age, a factor of great consequence given the ageing of the population and rising levels of obesity and diabetes in many countries. ED can result from organic or psychological causes and is increasingly affecting younger men who can also suffer from performance anxiety due to social pressure and false expectations from easy online access to pornography. ED can lead to low selfesteem, lack of confidence and depression. The detrimental impact on partners and relationships is well documented and acknowledged by the medical community. The discovery and approval of the PDE5i's to treat ED over 20 years ago (such as Viagra® and Cialis®) not only revolutionised available treatments for men with ED but also dramatically raised awareness amongst the general public of this significant problem.

### Ш

### Erectile dysfunction affects around 50% of men between 40 and 70 years old<sup>3</sup>"

The approval of PDE5i's over 20 years ago has transformed the treatment of ED, nevertheless whilst highly efficacious for many patients, oral PDE5i's have several adverse effects as well as potentially significant drug-drug interactions in the target population. The most commonly reported adverse events include headache, flushing, dyspepsia, nasal congestion and impaired vision. They are contraindicated for use with a number of medications such as nitrates, anti-hypertensives and alpha blockers. They generally take significant time to work requiring the patient to anticipate or pre-plan for sexual intercourse. Viagra® for example only starts to work in 30-60 minutes. For these reasons many men and their partners are dissatisfied with PDE5i's and it has been estimated that almost 50% discontinue use after one year4. In most countries oral PDE5i's are only available as a prescription only product which presents too high a barrier to men seeking treatment requiring an inconvenient and often expensive consultation with a doctor regarding a condition often perceived as highly embarrassing.

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ED is increasingly affecting younger men with the prevalence of ED in young men being as high as 30%<sup>5</sup>"

### ED SUFFERERS' UNMET NEEDS

There has been little effective innovation in nearly two decades for the treatment of ED. Today, there remains a significant unmet clinical need for those men wanting easy access to a fast-acting treatment that can give greater spontaneity and can form part of sexual foreplay thereby offering enhanced intimacy. ED sufferers are also looking for a product with a more favourable side effects profile which can be used safely with some of their other medications and which they are comfortable using over a period of years. Crucially they are looking for a treatment which could be available without a doctor's prescription normalising their condition and removing the financial and practical barriers to treatment for men with ED and their partners.



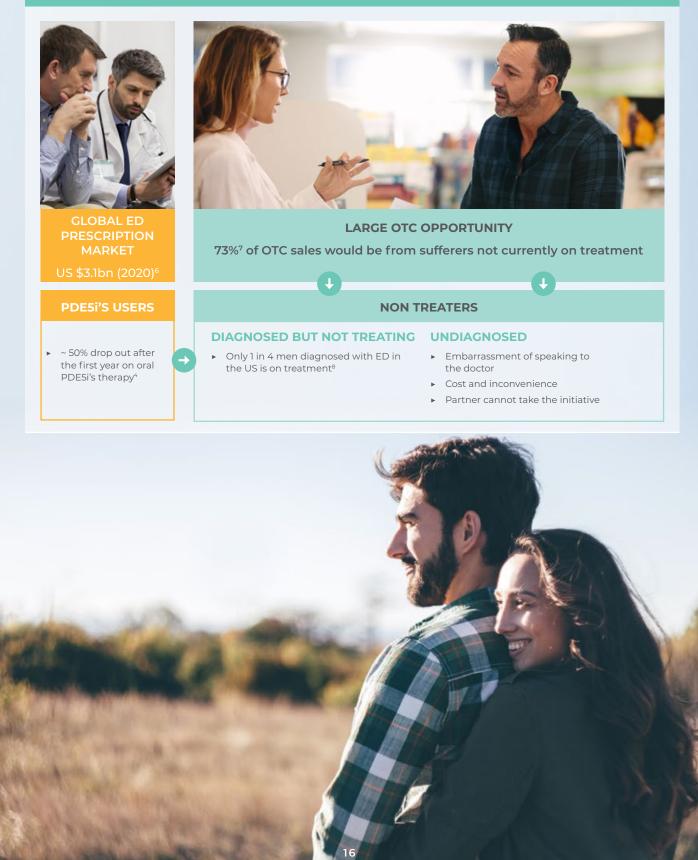
- 1. EMA, Withdrawal assessment report for Viagra, 2008
- 2. McKinlay JB. Int J Impot Res. 2000; 12 (suppl 4): S6-S11
- 3. Feldman HA et al. J Urol 1994; 151: 54 61
- 4. Corona G., "First-generation phosphodiesterase type 5 inhibitors dropout: a comprehensive review and meta- analysis", Andrology, 2016, 4, 1002–1009
- 5. Nguyen Sex Med Rev. 2017 Oct, vol 5, 508-520
- 6. IQVIA data 2020, volumes in the US have increased by 85% between 2018 and 2020  $\,$
- 7. Previous market research conducted by Ipsos Group as an over the counter product on MED2005 showed potential peak sales of US\$660 million. Whilst MED3000 is a slightly different proposition as it has a different mode of action, it offers the same benefits and therefore the Group believes that the market potential is similar.
- 8. Frederick L., "Undertreatment of erectile dysfunction: claims analysis of 6.2 million patients", J Sex Med, 2014, Oct, (10):2546-53.

### Marketplace – Erectile Dysfunction

### THE MARKET OPPORTUNITY FOR MED3000

Availability without a doctor's consultation or prescription opens up a large market with unmet needs

MOST MEN WITH ED ARE NOT ON TREATMENT DUE TO BARRIERS TO ACCESS





### US MARKET DYNAMICS

The ED prescription market is considered a mature market. However, substantial numbers of ED sufferers remain untreated. In the US, three out of four men diagnosed with ED are not on treatment<sup>8</sup>. Following the expiry of patents covering the oral PDE5i's the cost of medication has reduced significantly although the cost of access to these prescription treatments with the requirement of a doctor's consultation remains high. Although the value of the US prescription ED market has reduced, volumes have almost doubled from 2018 to 2020<sup>6</sup>, highlighting the strong continued demand. The embarrassment, inconvenience and particularly in the US the cost of a doctor's visit represent significant barriers to diagnosis and treatment. Many men will also have significant out-of-pocket costs as most health insurance schemes including Medicare and Medicaid do not cover prescriptions for ED.

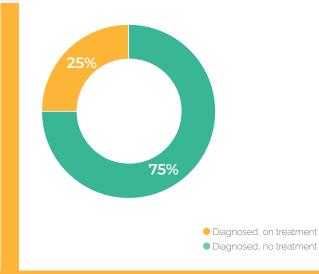
The market continues to evolve with the increase of telemedicine offering a paid for subscription service for ED prescriptions online. The advent of the COVID-19 pandemic has accelerated a growing trend towards online healthcare in general. Consumer demand for telemedicine is forecast to represent 60% of the prescription market revenues by 2024 up from 5% in 2019<sup>9</sup>. ED is the second most common condition for direct to consumer telemedicine representing one in five visits<sup>10</sup>. Following the price erosion of the PDE5i's in the US, the out-of-pocket costs from a doctor's consultation become one of the most important financial aspects of the pharmaceutical treatment of ED. This is the reason why internet pharmacies

and telemedicine companies attempt to include counselling and prescribing as part of their services to subscribers. Subscription services such as For Hims and Roman, offer a branded concierge service for ED prescription medicines online. They offer a monthly subscription fee, typically in the region of US\$50 in return for a doctor's consultation and ten generic 50mg sildenafil tablets per month.

The removal of the barriers to accessing prescription ED treatments, such as the oral PDE5i's, as well as the costs normally associated with a doctor's consultation makes MED3000, once approved as an OTC clinically proven treatment for ED, a significant commercial opportunity.

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### 3 out of 4 men diagnosed with ED in the US are not on treatment<sup>8</sup>"



nning with Consumers Post Covid-19" October 29, 2020

### Our Business Model

### **KEY RESOURCES**

### HOW WE CREATE VALUE

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Our resources and operating model as a semi-virtual company has enabled us to manage well during the COVID-19 pandemic.

#### People

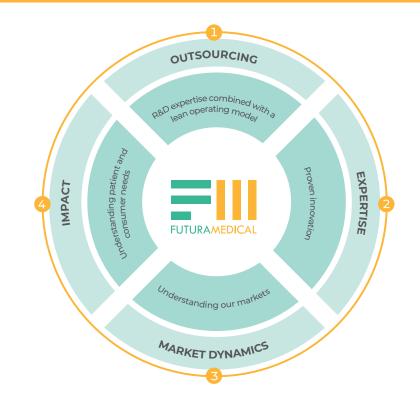
- Highly experienced and motivated team focused on innovative solutions
- Team of 30 consultants used for their specialist knowledge and leadership in the field
- Strong results driven culture and teamwork

### 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 coordinate the outsourcing of key activities with a range of experienced consultants and highly regarded subcontractors and manufacturers.

#### **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 meet the demands behind the current market dynamics driving chronic disease such as ageing populations, obesity, stress and anxiety which, combined with increasing prosperity and expectations from patients and consumers for a high quality and enjoyable life, lead to increased demand. 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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### FUTURA IS EVOLVING TO MEET THE NEXT PHASE OF ITS GROWTH AND READYING FOR THE **COMMERCIALISATION OF MED3000 DEVELOPING ITS BUILDING A** CDEATING DISTRIBUTION INFRASTRUCTURE A STRONG NETWORK AND RPAND AROUND THE MANUFACTURING **IDENTITY** WORLD CAPABILITIES **MED3000**

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

### **Commercialising our products**

With the approval in the EU of MED3000 as a Class 2B medical device available without a prescription and with a clear US regulatory pathway to approval as an OTC medical device in the US, we have and continue to focus our efforts on finding the best commercial options and partners. We are focused on 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.

A number of licensing deals have been signed in 2021 and 2022, part of our plans to build a 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**

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 with a potential of over US\$650 million<sup>1</sup> from over the counter sales alone. This is being achieved by gaining regulatory approval as an effective clinically proven treatment for erectile dysfunction and building a strong global network of licensing and distribution partners.

Previous market research conducted by Ipsos Group as an over the counter product on MED2005 showed potential peak sales as an over the counter product of US\$660 million. Whilst MED3000 is a slightly different proposition as it has a different mode of action, it offers the same benefits and therefore the Group believes that the market potential is similar.

## 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.



### 2021 PRIORITIES AND PERFORMANCE

- 1 Approval in the EU of MED3000 as a medical device by the Notified Body.
  - A number of constructive meetings took place with the FDA to confirm the requirements of a further Phase 3 clinical study FM71 which commenced in September 2021.
    - Agreements signed in China and South East Asia, the Middle East and Brazil/Mexico.
- 4 Manufacturing and internal capabilities strengthened to prepare for the commercialisation and supply of MED3000.
- 5 The approval of MED3000 as a Class 2B medical device in the EU means that MED3000 will be the first pan-European topical treatment for ED available without the need of a doctor's prescription.
- The Company has been developing its capabilities, infrastructure and expertise to supply and support our new commercial partners around the world. This has included an extension of shelf life from two to three years.

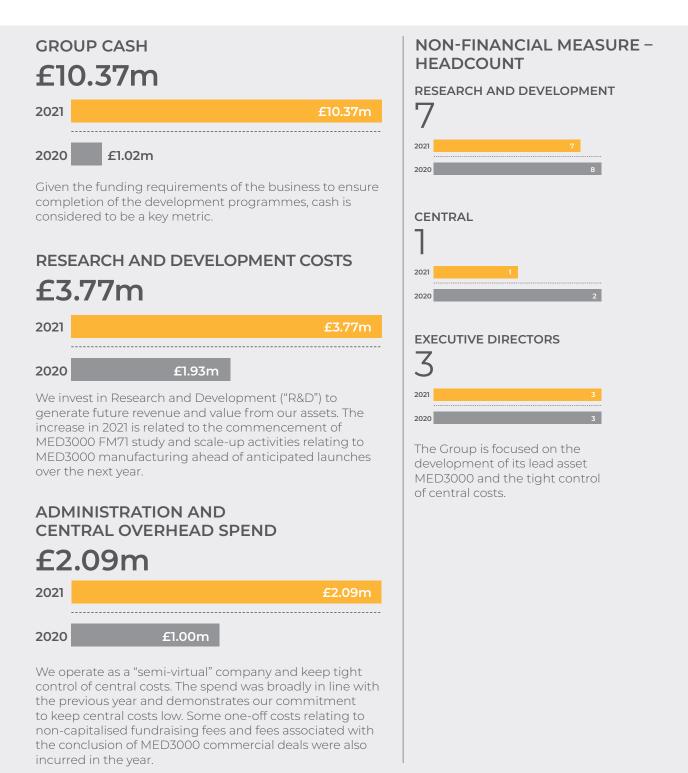
### 2022 FOCUS

- Completion of Phase 3 study FM71 and submission to the FDA as an OTC medical device by the end of Q3 2022.
- Sign further agreements for key markets and countries worldwide. Focus on building a strong global network of licensing and distribution partners and on building a strong brand identity for MED3000.
- Support our commercial partners in their own submissions to local regulatory bodies and in some instances additional clinical studies which will be paid for in all instances by our commercial partners.
- Continue to expand on our quality, supply chain, manufacturing and commercial capabilities to supply and support our commercial partners in their launches.
  - Ensure ED sufferers can have access to MED3000 as quickly as possible and continue to develop CBD100.

### **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.



### Product Review – MED3000

### MED3000 – A BREAKTHROUGH TOPICAL GEL FOR THE TREATMENT OF ERECTILE DYSFUNCTION

MED3000 is a treatment applied directly to the glans or head of the penis for 15 seconds. Because it is a gel it means that men with erectile dysfunction ("ED") or their partners can apply it as part of foreplay. It is fast-acting with 60% of men noticing an erection within 10 minutes and easy to use helping to restore spontaneity and intimacy in the relationship. MED3000 works rapidly to help achieve and maintain an erection whilst offering an excellent safety profile. In 2021, MED3000 received its MDR EU Quality Management Certificate for the placing on the market of a Class 2B medical device ("CE mark approval") and will be the first pan-European topical treatment for erectile dysfunction available without the need of a doctor's prescription with the potential to be the first clinically proven treatment available over the counter in the US, with potential global peak sales of over US\$650 million<sup>1</sup>.

### KOL ENGAGEMENT PROGRAMME

Futura has engaged in an outreach programme to increase awareness in the ED medical community of the development and potential benefits that our topical treatment could bring to ED sufferers. Two advisory boards (US and Europe) comprising world renowned urologists and researchers in erectile dysfunction have been formed and convene as needed to review data, share information and obtain feedback regarding the programmes. The COVID-19 pandemic has hampered our programme of face to face interactions at Conferences but we continue to be committed to our KOL engagement programme for 2022 and beyond. There has been growing interest from leading Key Opinion Leaders in our topical product because it offers a novel and unique treatment and additional armoury in their therapy options to address their patients' needs.

 Previous market research conducted by Ipsos Group as an over the counter product on MED2005 showed potential peak sales of US\$660 million. Whilst MED3000 is a slightly different proposition as it has a different mode of action, it offers the same benefits and therefore the Group believes that the market potential is similar.

### WHAT KEY OPINION LEADERS ARE SAYING ABOUT OUR INNOVATIVE TREATMENT FOR ERECTILE DYSFUNCTION MED3000

The efficacy of MED3000 is remarkable and approaches the efficacy of current first line therapy but with significantly lower adverse events. With topical application, it will be of particular appeal to mild to moderate ED patients who want a fast onset of action. Lack of drug interactions with prescription products will enable the product to be used with other medications such as nitrates and other cardiovascular drugs. It can also be used in conjunction with other ED efficacy for patients. As such the product will be of great interest to the medical community."

### PROFESSOR DAVID RALPH Consultant Urologist

St. Peter's Andrology Centre & Institute of Urology, UCLH, London Past President of the European Society of Sexual Medicine

In my humble opinion and as an expert in the field of erectile dysfunction management, I am very supportive of MED3000 and do believe that it offers an important and valid addition to the armamentarium of treatments we can offer our patients for erectile dysfunction."

### PROFESSOR ARTHUR BURNETT

Johns Hopkins University School of Medicine, Baltimore, US MD, MBA, FACS, Patrick C Walsh Distinguished Professor of Urology Past President of the Sexual Medicine Society of North America

### MED3000 – DEVELOPMENT AND CLINICAL STUDY

MED3000 is a unique and exciting development in the field of erectile function. It is a topical gel applied to the glans (head) of the penis using the DermaSys® technology. MED3000 has been shown to be effective in a large Phase 3 study and is fastacting with 60% of men noting an erection within 10 minutes. The incidence of side-effects is very low and its drug-free formulation means that adverse interactions with drug products are unlikely. A confirmatory clinical study FM71 is underway as part of the regulatory dossier required for the FDA submission.

### MED3000 – FM57 PHASE 3 CLINICAL TRIAL

FM57 was a Phase 3 clinical trial involving 1,000 patients across approximately 60 centres across nine Central and Eastern European countries. FM57 was a dose ranging, randomised, doubleblind, placebo-controlled, home use, parallel group clinical trial. FM57 was designed to investigate the efficacy and safety of a range of topically applied gels using IIEF-EF and SEP 2 and 3 as co-primary clinical endpoints in mild, moderate and severe ED patients.

MED3000 achieved positive results, with a striking consistency in being highly significantly statistically superior to baseline for all three co-primary endpoints (using validated and globally accepted measurement tools), as well as being statistically significant in each separate cohort of severity (mild, moderate and severe). At one, two and three months' treatment time points highly statistically superior improvement over baseline was achieved.

MED3000 begins to work immediately in some patients, with 60% of patients seeing onset of their erection within 10 minutes of application, substantially faster than on demand oral tablets with significant benefits for spontaneous rather than pre-planned sexual intercourse.

Safety and tolerability data were also highly positive, with no serious adverse events recorded in any patient, or their female partner, with a highly favourable overall side effect profile across all doses against baseline.



### Product Review – MED3000

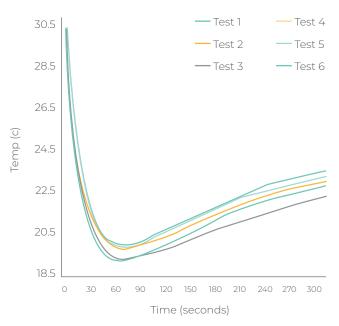
### MED3000 – FM71 PHASE 3 CLINICAL TRIAL FOR US REGULATORY DOSSIER

In March 2021 Futura received the official minutes from the FDA agreeing the design for a confirmatory clinical trial. FM71 is a Phase 3, 24-week multicentre, comparative, randomised, open-label, home use, parallel group study in 100 subjects with mild, moderate or severe ED. Co-primary endpoints were agreed with FDA as significant improvement with MED3000 from baseline (pre-treatment) ED, and ensuring that the change from baseline is clinically important, defined as at least a 4-unit change on the internationally recognised IIEF-EF scale. Secondary endpoints include FDA agreed criteria to support fast-acting claims, a key product differentiator. Tadalafil 5mg is also included in the study to provide exploratory endpoints and inform FDA of the relative benefit and risk of MED3000 versus a currently marketed product. FM71 was fully recruited by the end of December 2021 using subjects from Eastern Europe and the US. Timelines remain on track to enable planned US regulatory submission by the end of Q3 2022, and for targeting US FDA granting De Novo and OTC classification for marketing authorisation in Q1 2023.

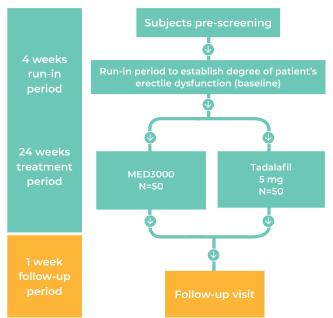


### MED3000 MECHANISM OF ACTION – HOW DERMASYS® WORKS TO TREAT ERECTILE DYSFUNCTION

MED3000 works through a unique mode of action. MED3000's combination of volatile solvent components creates an evaporative action that stimulates nerve sensors in the highly innervated glans penis by a cooling and recovery warming effect, rapidly leading to smooth muscle relaxation, tumescence and erection as shown on the diagram below.



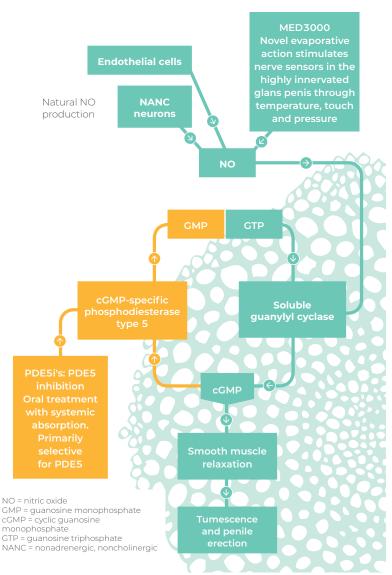
The glans penis is very highly innervated and there are sensors which are reactive to a range of physical sensations, including touch, pressure and temperature. Futura conducted further research and analysis which demonstrated the mode of



### FM71 CLINICAL TRIAL STUDY DESIGN



### MED3000 MECHANISM OF ACTION





action for MED3000 as shown in the graph. 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.

### A YEAR OF GREAT REGULATORY PROGRESS WITH THE APPROVAL OF MED3000 IN THE EU AND DOSSIER SUBMISSION EXPECTED IN 2022 IN THE US

MED3000 was approved in the EU in April 2021 after receiving its MDR EU Quality Management Certificate for placing on the market as a Class 2B medical device also known as European "CE mark approval". A Class 2B approval is by definition an approval allowing marketing of MED3000 as a non-prescription treatment across the European Union. With the CE mark certificate, this also paves the way for faster approval in many countries around the world including the Middle East, Africa, Far East and Latin America who allow "fast-track" review based on their recognition of the EU CE mark. The CE marking is also recognised in Great Britain until 30 June 2023 and Futura submitted an application for the new post-Brexit UKCA mark, which was received in April 2022<sup>2</sup>. This will be a streamlined administrative process since the UK application can bridge to the EU approval. We are also supporting our distribution partners with their regulatory dossiers and submissions have already commenced.

In 2020, the FDA agreed that an application may be made for MED3000 as a medical device for the treatment of ED, with a De Novo classification. This was followed by a number of productive and positive pre-submission meetings with the FDA during 2020 and 2021 to discuss existing Phase 3 clinical data, pathway to OTC status and any additional clinical and non-clinical requirements.

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.

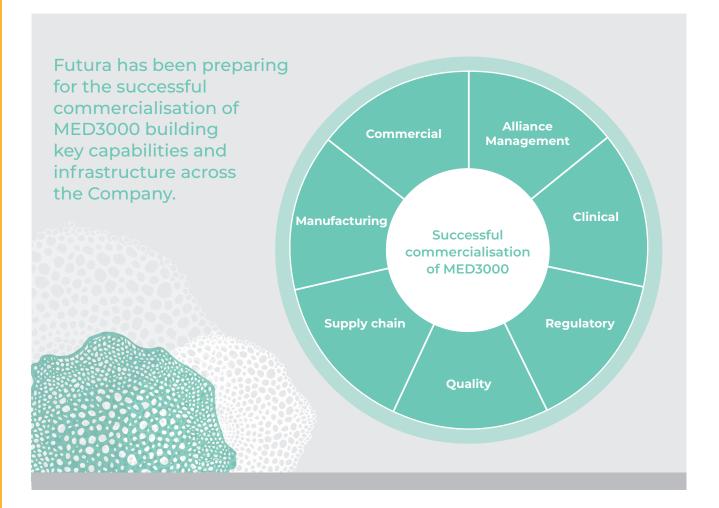
### Product Review – MED3000

In August 2021 Futura agreed with the FDA the design of a "Human Factors" study to achieve OTC classification. Successful completion of the Human Factors study was announced in December 2021, with 32 subjects recruited. It was demonstrated that individuals are able to correctly self-diagnose ED and to make correct self-selection decisions by considering their own health history and the instructions for use and warnings on the label. Overall, there was a very high degree of comprehension of the label and leaflet to increase confidence that the product will be used appropriately in an OTC setting. These results therefore support the regulatory submission for OTC designation and will enable Futura to finalise the OTC product label for a US filing.

### FUTURA READYING FOR COMMERCIAL SUCCESS

2021 has been a year of substantial effort to prepare the Company for the next phase in its growth, the commercialisation of MED3000, with the strengthening of its infrastructure and expertise, particularly in quality, supply chain and manufacturing, all key capabilities necessary to successfully supply and support our commercial partners around the world. In particular Futura has recruited a new Head of Quality and a new Head of Alliance Partnerships and Supply, both highly experienced and knowledgeable in their fields as well as having appointed two highly experienced new independent Non-Executive Directors to the Board.

Scale-up of manufacturing and production capacity to meet projected demand continues to progress well as Futura works towards initial launches of MED3000 over the next year. MED3000 manufacturing capabilities were expanded in August 2021 with the addition of a new third party, FDA, EMA and UK approved manufacturer as Futura strengthens resources to ensure continuity of supply and geographic expansion in the build up towards commercial launches. Futura is also focused on increasing the flexibility in the supply chain with a recently approved extension from a two to a three year shelf life. This three year shelf life will cover all global zones, meaning MED3000 will have a three year shelf life across the world even in very hot and humid countries such as the Middle East region.





### **SUPPLY CHAIN**

The role of the Supply Chain function at Futura is to ensure that MED3000 transitions smoothly from development to commercial supply. At the heart of this is the responsibility for all operational activities and the implementation of processes and procedures to deal with artwork generation and approval, customer service, order fulfilment and risk management. A key part of this function will be the management of Futura Medical's Contract Manufacturers and the development of sales and operations planning functions, coupled with forecasting and long-term capacity planning. Third-party distributor customer service levels, manufacturing cost of goods, and efficiencies are a particular focus. In 2021 the focus has been on developing a detailed commercial forecasting model and implementing changes to address supply chain risk management and artwork approvals in preparation for MED3000 launches in multiple countries.

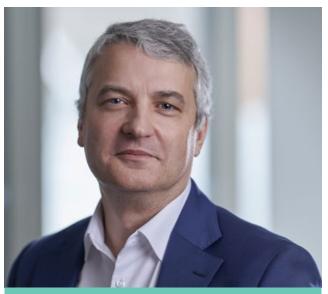
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In 2022, the Supply Chain function's focus will be on expanding existing processes and implementing procedures to support full commercialisation of MED3000 across multiple markets whilst engaging with Futura's distributors to finalise MED3000 artwork, sales forecasts and launch plans to refine our planning and commercial model. Throughout the year, Supply Chain will continue to identify savings opportunities to improve efficiency and manage cost of goods."

#### **GRAHAM SMITH**

Head of Alliance Partnerships and Supply

Over 30 years' experience in commercial operations and supply chain management in the pharmaceutical and medical devices industry.



### QUALITY

The main role of Quality at Futura Medical is to be accountable for the Quality Management System ("QMS"). This is the set of procedures that we follow to conduct our product development and commercial supply activities (such as device design, risk management, supplier approval, product release, legal manufacturer duties and post-launch safety review).

Having a QMS certified, and audited annually, to a recognised international standard is a central part of the approval of MED3000 in Europe which, in turn, supports the ability for us to supply and distribute MED3000 in countries around the world. We also provide independent oversight of activities to ensure that they are being conducted in compliance with the procedures as well as identifying areas of opportunity to improve compliance, make efficient use of Futura Medical's resources or to streamline procedures where possible.

### 

For 2022, the focus for the Quality function will be to support the ability to supply product to Futura's distributors by maintaining our QMS certification; support the continued supply of product in the UK after Brexit by obtaining certification of our QMS against the new UK Regulation; ensure that the QMS is ready for the start of commercial supply and ensure that the QMS is adapted to meet local market requirements to support geographic expansion plans."

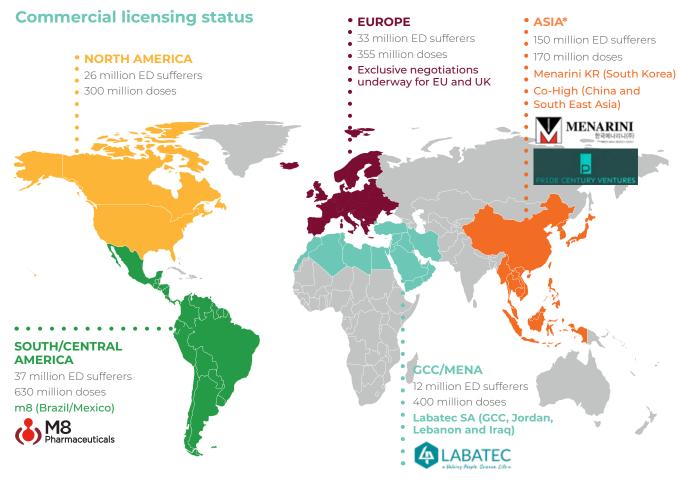
### **KEVIN LANGRIDGE**

Head of Quality

Over 30 years' experience in quality covering R&D and commercial supply operations at GSK Consumer Healthcare.

### Product Review – MED3000

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



\*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.

### COMMERCIALISATION OF MED3000 PROGRESSING WITH DEALS SIGNED IN KEY TERRITORIES WORLDWIDE

We are executing upon our strategic plans to leverage commercialisation globally with a network of licensing and distribution partners with brand building strength, healthcare credibility, regional infrastructure and marketing expertise for longterm distribution of MED3000 across the globe. Just as importantly we have chosen partners who have demonstrated their enthusiasm for MED3000 and for whom its success will be meaningful whilst being firmly focused on our goal of delivering long-term and sustainable value to the Company. Over the past twelve months the Company has entered into several commercial licensing deals in large markets for ED in regions such as China and South East Asia, South Korea, Latin America and the Middle East.

In March 2021, Futura entered into a joint collaboration agreement for China and South East (SE) Asia with 50/50 share of profits with Co-High, via a licensing agreement with Pride Century Ventures, a special purpose vehicle owned by Co-High Investment Management Limited ("Co-High"). Discussions are being held with the Chinese regulator, the National Medical Products Administration, to clarify the scope of clinical work required to gain approval in China and initial submissions have been made to determine whether MED3000 will be designated a medical device or drug. Current expectations are that a Chinese clinical trial will be required to establish safety as well as efficacy in Chinese men which is likely to take up to two years such that the regulatory process could take up to three years overall. Expected additional R&D costs of up to £4 million are being fully met by our partner. In a number of additional SE Asian markets Futura and Co-High are also working on nearer term regulatory submissions although the priority remains approval in the largest Asian market, China.

We are delighted to license Futura's MED3000 for the GCC and other Middle Eastern countries. We feel that there is significant market potential in the region for MED3000 as a trusted, branded medicine for enhancing erectile performance, optimally through pharmacy sales and are confident of generating significant value and long-term sustainable growth for both Futura and Labatec with this innovative, clinically proven product."

#### FAISAL DARWAZEH Chief Executive Officer, Labatec Pharma SA

In August 2021 Futura entered into a licensing agreement with m8 Pharmaceuticals, Inc ("m8"), a specialty biopharmaceutical company focused on commercialisation in Latin America, for the rights to exclusively develop and commercialise MED3000 in Brazil and Mexico. Under the terms of the agreement Futura and m8 will work together to gain marketing authorisation and commercialise MED3000 as a clinically proven treatment for ED available OTC 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. Futura will receive payments on all sales of MED3000 from m8, and up to four milestone payments totalling US\$8.5 million based on cumulative sales volumes within the initial term.

In September 2021 Futura signed a licensing agreement with Labatec Pharma ("Labatec"), a Swissbased specialty pharma company with expertise in commercialisation in Europe and the Middle East and North Africa ("MENA") region for exclusive rights to commercialise MED3000 in the Gulf Cooperation region, Jordan, Lebanon and Iraq. Futura is eligible to receive initial upfront payments, as well as undisclosed milestone payments based on regulatory approval.

Labatec will pay an agreed price to Futura for the manufacture and supply of MED3000 by Futura's contract manufacturer, plus royalties on all sales. Labatec is responsible for all local MED3000 development and regulatory costs as well as all launch and marketing expenses. The initial licence agreement term is for eight years with the ability to extend for successive two-year terms by mutual consent. In March 2022 Futura announced a licensing agreement with A. Menarini Korea Limited ("Menarini") for the rights to exclusively commercialise MED3000 for the treatment of ED in South Korea. A. Menarini Korea Ltd is a wholly owned subsidiary of the Italian-based specialty pharma company Menarini Group. Menarini Group is the world's largest Italian biopharmaceutical company with a heritage of over 135 years and over 17,500 employees in more than 140 countries. Menarini is a trusted medicines supplier in the region that is ideally placed to market retail products, with local teams that have a deep understanding and experience of the South Korean market.

Futura is eligible to receive initial undisclosed upfront payments and under agreement terms will support Menarini to gain marketing authorisation and commercialise MED3000 for ED in South Korea. 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 required. Futura will provide reasonable technical support for product development and commercialisation and provide manufactured product from Futura's contract manufacturer at an agreed price.

Futura has also entered into a period of exclusivity with an, as yet, unnamed party regarding a potential agreement for the EU and UK marketing rights for MED3000.

### Product Review – MED3000

### FOCUS ON BUILDING A STRONG BRAND IDENTITY

Futura has been developing a potential brand identity for MED3000 based on the Eroxon® proposition in order to support the delivery of longterm and sustainable value to the Company. Futura's distributors will be able to use the Eroxon® brand name at their discretion to build awareness and brand equity. As part of building the commercial proposition for MED3000 and supporting its launch in countries around the world, Futura has developed materials for partners including an illustrative pack and various communication tools such as a website and presentation materials which licensing partners can select to use at their discretion, which Futura hopes will be adopted by as many of its commercial partners as possible depending on local trademark and regulatory constraints.

To support MED3000's unique proposition, Futura commissioned an extensive strategic review of its Intellectual Property which was conducted by independent pharmaceutical patent specialists retained by Futura.

An initial UK patent was filed in December 2019 around MED3000's clinically significant and novel findings shown in FM57 followed by further supplementary UK filings to establish a priority date prior to a Patent Cooperation Treaty ("PCT") and certain non-PCT patent applications in late 2020. The PCT currently has 153 contracting countries where the Company can seek patent protection claiming priority from an original application such as the UK. An application to the European Patent Office was also made in August 2021 for examination and further national applications in line with normal PCT filing procedure will be made in Q2 2022 in those countries considered necessary to protect the commercial interests of MED3000. If national applications are successful this will provide patent protection until 2040.



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Futura has developed an illustrative pack and branding that licensing partners can select to use at their discretion."

JAMES BARDER Chief Executive



### Product Review – Other Products

### CBD100 – DERMASYS® FOR THE DELIVERY OF CANNABIDIOL

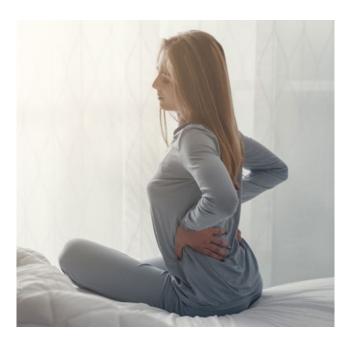
Futura announced a joint venture collaboration with CBDerma Technology Limited in 2019 to explore the application of Futura's advanced proprietary transdermal technology, DermaSys® for the delivery of cannabidiol.

Derived from both the Hemp and Marijuana plants, cannabidiol is one of the 113 cannabinoid compounds found within the cannabis family. Cannabidiol has no effect on one's consciousness or lucidity. It is generally regarded as non-addictive and non-psychoactive, making it ideal for consideration as a topically delivered molecule for local or regional (non-systemic) use.

### MARKET 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 particularly pain and epilepsy but also in a range of other conditions including skin conditions, multiple sclerosis, migraines, arthritis and cancer side effects.

While still in its infancy, the consumer cannabidiol market has rapidly developed over the past five years and is widely anticipated to further increase in scale. Cannabidiol products are now commonplace across supermarkets, pharmacies, beauty and convenience stores in many parts of the world, and a significant percentage of the general population has at least heard of this cannabinoid. As medical cannabis access schemes have been rapidly adopted across the globe, awareness and interest in cannabidiol has risen as a result. In combination with scientific research, this has created a generalised sentiment that cannabis is beneficial in a large subsection of consumers and has led to the growth of a significant wellness and consumer market for cannabidiol products.



However, products are often questionable in quality with little thought given to the amount of cannabidiol actually contained in the product in respect of the intended bioavailability other than to be able to say 'contains cannabidiol'. Regulatory and compliance issues have deterred large FMCG companies from moving rapidly into the space, and those which have, have often taken cautious steps by introducing hemp seed oil rather than cannabidiol in their products. However, this is likely to change once there is sufficient regulatory clarity, with positive recent developments in both the US and Europe.

### CANNABIDIOL'S MARKET POTENTIAL

The market for cannabidiol products is growing rapidly. A 2021 report by Reports and Data forecasts that the market for cannabidiol products is forecast to grow from US\$3 billion in 2020 to US\$15 billion by 2028, at a Compound Annual Growth Rate of 22.6% during the forecast period. The market is primarily driven by the increase in the usage of cannabidiol in medical applications, supplements, beverages and skin care.

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 one-quarter and one-fifth of the total European market are made up of the topicals market.

Awareness of cannabidiol and market penetration are increasing and vary by region, in large part depending on the regulatory framework of the country. Consumer surveys from New Frontier Data suggest that usage rates are lowest in France, Spain and Portugal, all three of which have restrictions of some kind on cannabidiol in their national markets. Awareness of cannabidiol is highest in the UK at 78% and lowest in France at 36%. Consumption of cannabidiol also varies greatly by country in Europe from 7% in France to 33% in Austria.

### DERMASYS<sup>®</sup> CANNABIDIOL FORMULATION

DermaSys<sup>®</sup> 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. It is a versatile and bespoke technology that we are currently seeking to tailor and adapt for the specific requirements of cannabidiol. We are seeking to develop our formulation to pharmaceutical standards in order that any future product could potentially be sold as a cosmetic or potential pharmaceutical product although, in the case of the latter, it is likely to require significant clinical development. As part of a robust formulation process using strict pharmaceutical development principles, Futura has carried out extensive DermaSvs<sup>®</sup> cannabidiol formulation work and initial in vitro tests on human epidermis. The studies demonstrate highly efficient penetration

### Product Review – Other Products

### AWARENESS AND MARKET PENETRATION OF CANNABIDIOL

	/Switzerland Austria	UK/Ireland	Italy	France	Germany	Spain/ Portugal
Have heard of cannabidiol	69%	78%	52%	36%	49%	44%
Have consumed cannabidiol	33%	14%	11%	7%	14%	10%

Source: New Frontier data

of cannabidiol into and through the skin, superior to an established, marketed, comparator product. Additionally, cannabidiol is believed to be unstable with many common excipients. The DermaSys® cannabidiol gel was specially formulated to minimise this issue and early stability work is showing encouraging results, which is expected to ensure potency is retained during the shelf-life. This work resulted in intellectual property patent applications being submitted covering various unique aspects of the CBD100 gel formulation.

### DEVELOPMENT JOINT VENTURE WITH CBDERMA TECHNOLOGY

CBDerma Technology is a company that has been established and funded to specifically exploit the therapeutic potential of cannabis. The company's management, backers and advisers have extensive knowledge, expertise and investments in plant derived product manufacturing.

As part of the agreement, Futura is developing and optimising a DermaSys® cannabidiol formulation and has conducted early ex vivo 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.

Futura continues to believe that as the medical and consumer applications of cannabidiol become more widely accepted from both a regulatory and consumer perspective a gel that has been formulated using strict pharmaceutical development principles with strong delivery characteristics, stability and high quality will be an attractive commercial proposition. Whilst Futura's resources are focused on key asset MED3000, the Company has received interest in CBD100 and continues to explore commercial opportunities for the product with discussions progressing and further validation work being conducted both internally and externally by a potential partner to validate the power of the DermaSys® technology.

### TPR100 – A DICLOFENAC 1.86% PAIN RELIEF GEL TARGETING PAIN AND INFLAMMATION

#### 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 marketleading 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 launch.

# **Financial Review**

### 

Strengthened balance sheet enabling robust progress towards commercialisation"

ANGELA HILDRETH Finance Director and Chief Operating Office



As outlined in the Chairman's Statement and Chief Executive's Review, during the year Futura focused its financial resources on MED3000, its fast-acting topical 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 March 2021, the Company concluded a funding transaction which resulted in £1.50 million received upon the issuance of convertible loan notes and in April 2021 the Company received an additional £0.50 million following the exercise of warrants by HT Riverwood Fund (part of the Atlantis Group).

In April 2021 the Company was notified that MED3000 had been approved as a Class 2B medical device in Europe and the FDA confirmed that a further, smaller, supplementary study was required for approval in the US. Following a Placing and Retail Offer in June 2021, securing gross proceeds of £12.00 million, this supplementary study (FM71) commenced in July 2021 with recruitment completing in December 2021 and headline data followed by US regulatory submission expected by the end of Q3 2022.

### REVENUE

The Company continued to focus its financial and human resources on late stage clinical development of its fast-acting topical treatment for ED and on accelerating progress towards achieving a significant, continuous revenue stream within a few years. No revenue was recognised in the period.

### RESEARCH AND DEVELOPMENT COSTS

Research and Development ("R&D") costs for the period ended 31 December 2021 were £3.77 million, compared to £1.93 million for the period ended 31 December 2020. The increase of £1.84 million is reflective of the commencement and recruitment of the FM71 study and focus on manufacturing scale-up activities ahead of anticipated MED3000 launches.

### ADMINISTRATIVE COSTS

Administrative costs were £2.09 million for the period ended 31 December 2021 compared to £1.00 million for the period ended 31 December 2020. This is an increase on the prior year and partly driven by higher costs associated with expansion of the team and resources relating to commercial, manufacturing and supply chain in readiness for launching MED3000 over the next year. In addition there were some oneoff costs incurred relating to fundraising costs and fees associated with negotiating and concluding commercial arrangements for MED3000.

### TAX

It is expected that an R&D tax credit of £0.91 million will be claimed in respect of 2021 and the cash refund is expected to be received mid-2022 from HMRC.

### LOSS PER SHARE

The basic loss per share for 2021 was 1.83p (2020: 0.99p). Details of the loss per share calculations are provided in Note 10 to the consolidated financial statements.

### CASH BALANCE

The cash balance at the end of 2021 was £10.37 million (2020: £1.02 million). Cash burn during the year was £4.39 million (2020: £6.77 million) primarily in relation to the start and execution of the FM71 clinical study, manufacturing scale-up activities associated with MED3000 and other one-off costs associated with fundraising and the conclusion of commercial agreements with MED3000 licensing and distribution partners.

Current cash runway extends beyond initial MED3000 launches expected over the next year and expected US regulatory approval in 2023, assuming no contributions from milestone payments or other revenues.

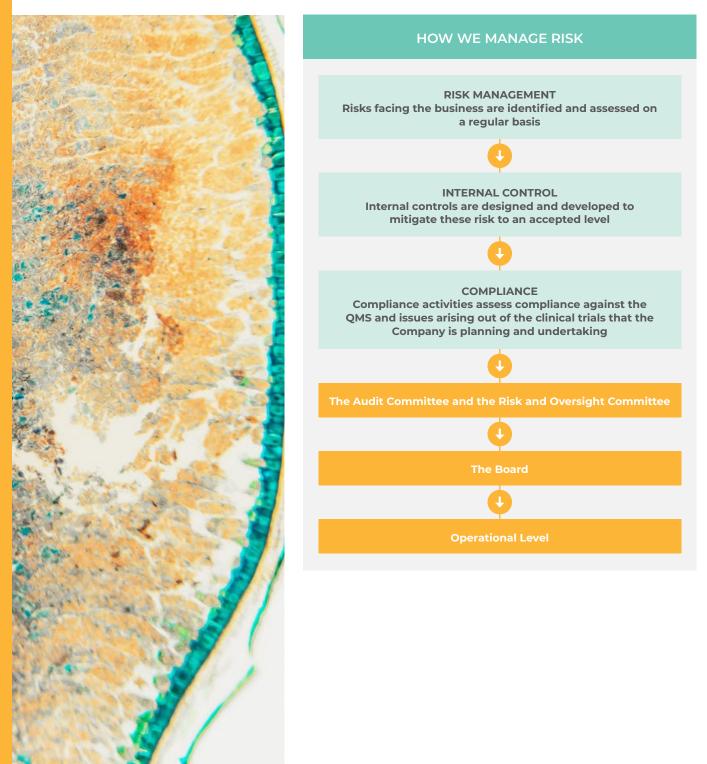
ANGELA HILDRETH Finance Director and Chief Operating Officer

There was no capitalisation of R&D costs in 2021.

# 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		Mitigation
Clinical development and regulatory 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. The regulatory pathway for our treatment for erectile dysfunction MED3000 has been significantly de-risked with data generated from the Phase 3 study FM57 and the CE mark approval of MED3000 as a Class 2B medical device in the EU providing a greater level of confidence of success. The FM71 study commenced in July 2021 and recruitment was completed on time in December 2021. The outline design of this study, protocol and endpoints were agreed with FDA through a series of pre-submission meetings which are offered by FDA to help improve the quality of subsequent submissions, shorten total review times and facilitate the development process for new devices.
Commercial risk	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 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 2021, the Company entered into a number of licensing and distribution agreements covering China and South East Asia, the Middle East and Brazil/Mexico.

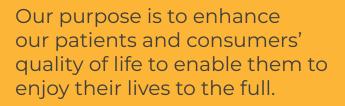
# Key Risks and Mitigation

Risk		Mitigation
Financial risk	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.	Futura is focusing its financial resources on its lead asset MED3000. The Group successfully completed a fundraising exercise in May 2021 raising £12.00 million gross to fund the product through to US regulatory approval. The Company also received £1.50 million in March 2021, issuing convertible loan notes and £0.50 million in April 2021 following the exercise of warrants by HT Riverwood Fund.
		The Group also entered into commercial agreements relating to MED3000 with launches anticipated over the next year.
		The Group places considerable emphasis on communication with existing shareholders and potential investors, to maximise the chances of successful future fundraising.
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 and its ability to compete effectively with other companies depend, amongst other things, on its ability to obtain and maintain patents sufficiently broad in	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.
	During the year, the Group filed for examination with the European Patent Office for MED3000 and also within the GCC region and will be seeking to file PCT national applications during 2022. Whilst the Group is confident that the patents will be granted, it cannot guarantee this will be the case.	
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 risks have also been identified by the Group and will be kept under review as the situations develop and any potential impact becomes clearer.

Risk		Mitigation
Impact of Brexit	The full impact of the UK having left the EU is still uncertain.	The impact of Brexit has been considered and the following has been assessed and concluded that there will be minimal to no impact.
		• <b>Regulatory strategy</b> The EU Notified Body has confirmed that the UK will be included in the approval until 2023. The Company applied for a UKCA mark in the meantime and this was received in April 2022, well before the current CE mark approval coverage of the UK expires on 30 June 2023.
		<ul> <li>Patent protection         Both the UK and the European Patent Office are         members of the Patent Cooperation Treaty and therefore         we believe Brexit will have limited impact on patent         prosecutions or filings.     </li> </ul>
		Some uncertainty still remains around the full impact of Brexit and we will continue to monitor relationships with regulatory bodies such as the EU Notified Body and the European Patent Office as new information is provided.
Impact of COVID-19	The full impact of the COVID-19 pandemic remains uncertain.	The impact of COVID-19 is thankfully diminishing and the Directors do not believe that Futura will be significantly impacted during 2022. This is based on the following assessments:
		<ul> <li>Operational activities</li> <li>As a semi-virtual organisation, our employees are already used to effectively working remotely, flexibly and alongside our valued and skilled network of consultants and sub-contractors. Contingency plans are in place to draw upon this capacity should we experience any issues with employees being unable to perform their duties as a result of illness.</li> </ul>
		<ul> <li>The FM71 clinical study is now fully recruited across Eastern Europe and the US and has not been materially affected by the pandemic.</li> </ul>
		<ul> <li>There is a possibility that COVID-19 may impact on the timelines with Regulators. The US Regulator has not yet advised of any delays to its timelines. We will keep this under review.</li> </ul>
		<ul> <li>COVID-19 impact in general seems to be reduced given the positive response to the UK vaccination programme and the symptoms of COVID-19 now becoming less severe for most patients who contract it.</li> </ul>

# 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.

Good governance enables investment, innovation and sustainable growth. Our approach to sustainability 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:

#### GOOD HEALTH AND WELL-BEING

- We are developing medical products that are optimised for clinical efficacy, safety, mode of administration and patient 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.

#### 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 this research with the medical community to enhance scientific research.



# **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. However, the Board also acknowledges that in light of the COVID-19 pandemic, face to face engagement in 2021 remained challenging.

# 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

#### **Our stakeholders' concerns**

The Board naturally considers its shareholders to be key stakeholders of the Company and is focused upon delivering long-term value for their benefit.



#### How we engage

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. As a result of the COVID-19 pandemic, we were unable to hold any Investor or R&D Seminars and the AGM was held by telephone conference. The Company has ensured that regular webcasts and interviews have been posted to the Investor section of the website to compensate for the lack of face to face engagement and as the pandemic restrictions subside, we hope to be able to return to hosting events and face to face AGMs.

#### Impact review post engagement

The results of this investor engagement are reported to the Board to help inform our strategy and communications.

# EMPLOYEES

#### Our stakeholders' concerns

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.



#### How we engage

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.

#### Impact review post engagement

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. These actions were consistent with the Board's commitment to investing in and responsibly rewarding employees as they deliver the Company's strategy.

# PATIENTS AND SUFFERERS

#### Our stakeholders' concerns

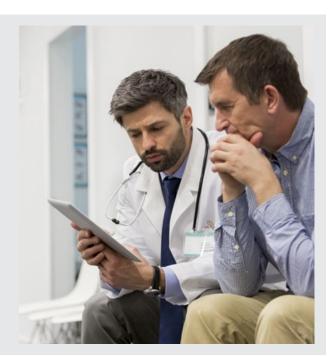
The patients our therapies are designed to treat are at the heart of why we do it. Our purpose is clear, "to enhance our patients and consumers' quality of life to enable them to enjoy their lives to the full".

#### How we engage

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.

#### Impact review post engagement

We are focused on bringing innovative products to market where there are unmet patient needs with existing treatments. We look forward to bringing MED3000 our treatment for erectile dysfunction to sufferers across the world.



# DEVELOPMENT PARTNERS, MANUFACTURERS AND SUPPLIERS

#### Our stakeholders' concerns

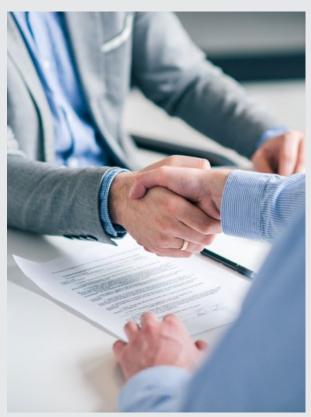
Our development partners, manufacturers and suppliers want to work in a collaborative way that allows them to plan work and become part of the team.

#### How we engage

As a semi-virtual company, Futura relies upon its relationships with external service providers, consultants and sub-contractors 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 long-term relationships.

#### Impact review post engagement

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.



# Our Stakeholders

#### REGULATORS

#### **Our stakeholders' concerns**

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. Key agencies for Futura include the Medicines and Healthcare products Regulatory Agency ("MHRA"; UK), the US Food and Drug Administration ("FDA"), the European Medicines Agency ("EMA" European Union) and the Notified Bodies in the European Union.

#### How we engage

Futura works proactively and collaboratively with regulators through the pre-submission and submission process with an open and constructive dialogue which enables Futura to optimise its clinical development programme.

#### Impact review post engagement

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.



### **COMMERCIAL PARTNERS**

#### Our stakeholders' concerns

The Board keeps itself aware of changes in the industry by fostering existing relationships and through extensive networking. 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.

#### How we engage

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.

#### Impact review post engagement

The Company has signed several 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.



# Governance

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# **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



JAMES BARDER Chief Executive



ANGELA HILDRETH

Finance Director, Chief Operating Officer and Company Secretary



#### KEN JAMES

Executive Director and Head of R&D

#### **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, Kind Consumer Holdings Limited 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.

#### Brings to the Board

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

#### **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 Investment Management 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 insurance and finance including firms he founded.

#### Brings to the Board

Over 25 years of experience in setting up, managing and running companies.

#### 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.

#### **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 US.

#### Brings to the Board

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



### JEFF NEEDHAM

(joined 8 October 2021) 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 US) and Senior Vice President at Perrigo Company Plc, the US-based manufacturer and marketer of consumer healthcare products, and a board director of the 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

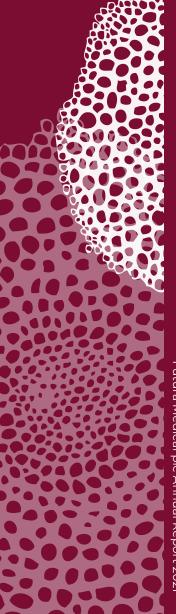
Over 20 years of experience as a Finance Director in a wide range of industries with strong financial experience and OTC market expertise.



#### JONATHAN FREEMAN

(stepped down 31 December 2021) Senior Independent Non-Executive Director

Jonathan Freeman was a Senior Independent Non-Executive Director. He chaired the Audit Committee and the Remuneration Committee and was also a member of the Nominations Committee.



# **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 Jonathan Freeman until 31 December 2021 when Jeff Needham took over the position. Since 2018, 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 two Remuneration Committee meetings during 2021.

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.

There are four main elements of the remuneration package for Executive Directors and staff.

#### BASIC SALARIES AND BENEFITS IN KIND

Basic salaries are recommended to the Board by the Remuneration Committee, taking into account the performance of the individual and the rates for similar positions in comparable companies. Benefits in kind comprising death in service cover and private medical insurance are available to all staff and Executive Directors. Benefits in kind are nonpensionable.

# SHARE OPTIONS AND OTHER SHARE-BASED INCENTIVES

The Group operates approved and unapproved share option schemes for the Executive Directors and other employees to motivate those individuals through equity participation. Unapproved share options are also sometimes granted to key consultants. Exercise of share options under the schemes is subject to specified exercise periods and compliance with the AIM Rules. 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 Remuneration Committee considers that the best alignment of employee interests with those of its shareholders is through the continued use of incentives for performance through the award of share options or other share-based arrangements.

The Group operates a Long-Term Incentive Plan ("LTIP"). The quantum of any awards receivable by the staff and all Directors will depend on achieving set Group performance milestones and the share price at the time relative to targets set in advance. As a guide, if all of the approved milestones are achieved at the share price targets over the next 48 months and if the Group exercised its discretion to settle the awards in equity then the additional shares issued would be equivalent to no more than 5% of the fully diluted share capital as at 31 December 2021.

#### BONUS SCHEME

Bonuses are granted on a discretionary basis and linked to performance objectives set by the Remuneration Committee at the end of each calendar year in order to quantify the bonus that has been achieved by each individual within the scheme.

#### PENSION CONTRIBUTIONS

The Group pays a defined contribution to the pension scheme of Executive Directors and other employees. The individual pension schemes are private and their assets are held separately from those of the Group.

Salaries and benefits are reviewed in December to cover the following calendar year. The timing of the review enables the Group's performance over the preceding financial year and the strategy for the forthcoming year to be considered.

#### 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 2021 was settled in January 2022 by the issue of 145,556 shares at 14.97 pence per share. The 2022 award has been determined at 37.36 pence per share and the Non-Executive Directors will accrue these shares over 2022 and receive them, or such lower number as have accrued if they leave the Group earlier, in January 2023.

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.

### DIRECTORS' EMOLUMENTS

The emoluments of the Directors, who represent the key management personnel were as follows, in 2021:

Year ended 31 December 2021

							_
	Salary & Directors' Fees £	Bonus £	Share Awards £	Benefits In Kind £	Pension £	Total £	Year ended 31 December 2020 £
James Barder	242,556	110,785	-	3,517	-	356,858	309,310
Ken James	179,299	87,967	-	-	-	267,266	248,224
Angela Hildreth	180,000	90,000	-	1,259	18,000	289,259	240,295
Non-Executive Directors							
John Clarke	66,334	-	26,999	-	-	93,333	91,504
Jeff Needham	9,375	-	-	-	-	9,375	-
Jonathan Freeman	37,765	-	8,995	-	-	46,760	45,844
Totals	715,329	288,752	35,994	4,776	18,000	1,062,851	935,177

The above fees and emoluments exclude reimbursed expenditure incurred in the conduct of Group business. There were no settlements under the LTIP in 2021 (2020: £nil).



# **Remuneration Committee Report**

# DIRECTORS' INTERESTS IN SHARES

	31 Decem	ber 2021	31 Decem	per 2020
	Beneficial Interests	Non- beneficial Interests	Beneficial Interests	Non- beneficial Interests
John Clarke	642,542	_	512,788	_
James Barder	1,093,472	117,500	1,093,472	117,500
Jonathan Freeman	222,282	-	175,718	_
Ken James	299,581	-	299,581	_
Angela Hildreth	142,857	-	142,857	_
Totals	2,400,734	117,500	2,224,416	117,500

### DIRECTORS' INTERESTS IN SHARE OPTIONS

The Board uses share options to align Executive 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 Executive Directors were as follows:

	<b>31 December 2021</b> 31 Decem		31 Decem	nber 2020
	Options Held	Share-based Payment Expense	Options Held	Share-based Payment Expense
James Barder	1,880,000	37,501	1,800,000	26,993
Ken James	1,304,000	30,001	1,040,000	21,594
Angela Hildreth	904,000	30,001	640,000	21,594
Totals	4,088,000	97,503	3,480,000	70,181



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 below:

	Grant Date	Number Awarded	Exercise Price/ Share	Earliest Exercise Date	Expiry Date
James Barder	13 January 2017	124,348	57.50 pence	1 October 2018	
James Barder	19 November 2018	250,000	7.50 pence	1 October 2020	30 September 2025
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
Totals		2,722,670	-		

# DIRECTORS' INTERESTS IN LONG-TERM INCENTIVE PLAN

The performance milestones, which are non-market related milestones, were not met in 2021 and therefore no charge was recognised in the period. Assuming that each remaining Group performance milestone is met, at the target share price and before the next target date ends, and if the awards were to be equity-settled then the number of shares that could be awarded, before tax, will be capped at 5% of the fully diluted share capital with individual awards to be determined.

The Directors consider that until a milestone has been met it is not appropriate to recognise a share-based remuneration charge in the Consolidated Statement of Comprehensive Income in respect of the LTIP.

#### JEFF NEEDHAM Chairman of the Remuneration Committee

# Corporate Governance Statement

The Board is committed to building long-term shareholder value in an open and ethical manner."

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 2021. I am responsible for leading the Board so as to ensure that the Group has in place the strategy, people and structure to deliver value to shareholders and other stakeholders of the Group as a whole over the medium to long-term, supported by a corporate culture based on sound ethical values and behaviour, as more fully explained in the Corporate Governance Report on the following pages. Angela Hildreth in her capacity of Company Secretary, has responsibility for ensuring the Group has appropriate corporate governance standards in place and that these requirements are followed and applied within the Group as a whole.

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. We continue to evaluate how we govern the Group on an ongoing basis, working for the best long-term interests of our shareholders in an open, transparent and ethical manner. The Board considers that this framework can grow with the Company, yet it is considered premature to plan for an evolution of the governance framework at this stage. If the Company undertakes significant transactions that would lead to growth, then the Board will consider the implication of this on the corporate governance structure at that point in time.

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 51 to 55 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 25 April 2022



# **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.

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 with interests in both prescription ("Rx") and OTC products. If resources permit, the Group may choose to advance a product 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 34 to 37 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 when 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 40 to 42.

# 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 2021 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 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 34 to 37 of our Strategic Report.

# **Corporate Governance 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 56.

#### 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. As COVID-19 restrictions were lifted in the second half of the year, the Board met three times in person and the other meetings were held by video conference. 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 statement.

Director	Board	Audit Committee	Remuneration Committee	Nominations Committee
John Clarke	6/6	2/2	2/2	1/1
Jonathan Freeman	6/6	2/2	2/2	1/1
James Barder	6/6			
Angela Hildreth	6/6			
Ken James	6/6			
Jeff Needham	2/2		1/1	

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.

#### 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 balance.

In 2021, Futura strengthened the Company's Board with the appointment of two Non-Executive Directors, Jeff Needham and Andrew Unitt as announced in October 2021, expanding the Company's Board with business expertise and commercial acumen, particularly in the US as Futura moves into the next phase of MED3000's development. Both bring OTC market expertise and exceptional skills in strategic development and business management which will further enhance our ambition and focus on building a global brand and distribution network to accelerate Company growth towards long-term, sustainable revenues. Jeff Needham brings a wealth of knowledge and experience to the Board having been at Perrigo Company plc, the US-based manufacturer and marketer of consumer healthcare products, for 36 years, and a board director of the Consumer Healthcare Products Association (US) for 11 years. Andrew Unitt, who joined the Board on 1 January 2022, 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.

Director	Pharma/ OTC sector	Financial	General management	Other public company (Board level)
John Clarke	$\checkmark$		$\checkmark$	1
Jonathan Freeman <sup>1</sup>	$\checkmark$	$\checkmark$	$\checkmark$	1
Jeff Needham <sup>2</sup>	1		$\checkmark$	1
Andrew Unitt <sup>3</sup>	$\checkmark$	$\checkmark$	$\checkmark$	$\checkmark$
James Barder	$\checkmark$	$\checkmark$	$\checkmark$	$\checkmark$
Angela Hildreth	$\checkmark$	$\checkmark$	$\checkmark$	$\checkmark$
Ken James	$\checkmark$		$\checkmark$	

1. Jonathan Freeman appointment ended 31 December 2021

2. Jeff Needham appointment commenced 8 October 2021

3. Andrew Unitt appointment commenced 1 January 2022

### **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 December 2021 in the form of peer appraisal, questionnaires 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 Non-Executive Director Jonathan Freeman and will be led by Andrew Unitt following his departure.

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 vear is measured.

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

# **Corporate Governance Report**

# **PRINCIPLE 8**

# CORPORATE CULTURE

The Board recognises that their 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 to 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 day-to-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 the 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. 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 1020 Eskdale Road, Winnersh, Wokingham, RG41 5TS 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 46 to 49.

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, but at least once per year, 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. Unfortunately, due to the COVID-19 pandemic during 2021, it was not possible to hold events as we normally would.

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 25 April 2022



# Directors' Report

# DIRECTORS

The Directors during the year were:

John Clarke	Non-Executive Chairman
James Barder	Chief Executive Officer
Jonathan Freeman	Non-Executive Director <sup>1</sup>
Jeff Needham	Non-Executive Director <sup>2</sup>
Andrew Unitt	Non-Executive Director <sup>3</sup>
Ken James	Head of R&D/Executive Director
Angela Hildreth	Finance Director/Chief Operating Officer

1. Appointment ended 31 December 2021

2. Appointment commenced 8 October 2021

3. 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 1 to 42 provides a review of the business, including the Group's trading for the year ended 31 December 2021, 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 European Union. 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 (2020: £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 46 to 49. 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 46 to 49.

# 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 2021 the Group's expenditure on R&D was £3,774,269 (2020: £1,927,658).

### 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.

# 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.

#### 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 40. A consideration of the Company's relationship with wider stakeholders, including suppliers and commercial partners, is disclosed in the Stakeholders section on pages 40 to 42.

# SUBSEQUENT EVENTS

In QI 2022 the Company entered into a period of exclusivity with an, as yet, unnamed party regarding a potential agreement for the EU and UK marketing rights for MED3000.

In March 2022 Futura signed a commercial licensing agreement for MED3000 in South Korea with A. Menarini Korea Limited, a subsidiary of Italy-based, multinational specialty pharma company Menarini Group.

In April 2022, the Company received UKCA mark approval following an application in March 2022 to the UK Notified Body for MED3000 as a Class 2A medical device. This was required before the end of June 2023 to replace the CE mark approval which currently covers the UK according to Brexit legislation.

# SIGNIFICANT INTERESTS

On 31 March 2022 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	26.90%
TAdams	8.08%
WT Lamb Investments Limited	5.23%
RA Lamb	3.71%

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 International Financial Reporting Standards as adopted by the European Union (IFRSs as adopted by the EU) 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 EU;
- 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.

# **Directors' Report**

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. 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 25 April 2022



# 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 two meetings held in the year and matters discussed were as follows:

#### APRIL 2021

Presentation of 2020 Audit Report (see 2020 Annual Report for 2020 Audit Report)

Review of 2020 audit performance

#### DECEMBER 2021

Handover from Jonathan Freeman to Andrew Unitt

Review of audit planning including audit risk areas for the year ended 2021

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 licence agreements to commercialise MED3000 in Latin America and the Middle East, future potential agreements covering 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, further regulatory approval is required within those

regions and where regulatory approval is granted, commercial agreements are not yet in place. The Committee concluded 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 product sales that were not included within the cashflow forecasts and could further extend the cash runway. On this basis the Committee concluded that it was appropriate to prepare the 2021 financial statements on the going concern basis.

### **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 their 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 their work for the year ended 31 December 2021 is included within the Independent Auditor's Report on pages 61 to 68. Grant Thornton were 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

# Financial Statements

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# Independent Auditor's Report

to the Members of Futura Medical plc

#### OPINION

#### OUR OPINION ON THE GROUP FINANCIAL STATEMENTS IS UNMODIFIED

We have audited the group financial statements of Futura Medical Plc for the year ended 31 December 2021, 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 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 UK-adopted international accounting standards.

In our opinion, the group financial statements:

- give a true and fair view of the state of the group's affairs as at 31 December 2021 and of its loss for the year then ended;
- ► have been properly prepared in accordance with UK-adopted international accounting standards; and
- ▶ 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 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.

#### CONCLUSIONS RELATING TO GOING CONCERN

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 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 to cease 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 2023 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 feasibility of securing new revenue contracts and the likely timing and quantum of outlay of expenditure and challenging management where necessary;
- assessing the impact of not achieving expected revenue and evaluating the impact if no revenue was generated. We considered whether the assumptions are consistent with our understanding of the business and other audit work undertaken;
- assessing the accuracy of management's past forecasting by comparing management's future forecasts modelled in the prior year to the actual results for the current 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; and
- assessing the adequacy of related disclosures within the annual report and accounts.

# Independent Auditor's Report

to the Members of Futura Medical plc

In our evaluation of the directors' conclusions, we considered the inherent risks associated with the company's business model including effects arising from macro-economic uncertainties such as Brexit and Covid-19, we assessed and challenged the reasonableness of estimates made by the directors and the related disclosures and analysed how those risks might affect the company's financial resources or ability to continue operations over the going concern period.

Based on the work we have performed, we have not identified any material uncertainties relating to events or conditions that, individually or collectively, may cast significant doubt on the group's ability to continue as a going concern for a period of at least twelve months from when the financial statements are authorised for issue.

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.

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 group 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**

#### TREATMENT OF CONVERTIBLE LOAN NOTE AND WARRANTS

We identified the treatment of convertible loan note and warrants as one of the most significant assessed risks of material misstatement due to error.

During the year a £1.5m convertible loan note and warrants were issued and converted to equity, with total proceeds received from the warrants exercised of £0.5m.

The convertible loan note and warrants are accounted for in accordance with International Accounting Standards (IAS) 32 'Financial instruments: Presentation'. The process for determining the accounting treatment and classification of these financial instruments is complex and requires significant management judgement to be applied including bifurcation the total proceeds received from the transaction between the separate financial instruments issued.

#### RELEVANT DISCLOSURES IN THE ANNUAL REPORT AND ACCOUNTS 2021

- Financial statements: Note 2.3, Note 3 and Note 19.
- Audit committee report.

#### HOW OUR SCOPE ADDRESSED THE MATTER

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

- obtaining an understanding and assessing the design and implementation of the group's processes and relevant controls relating to: identification of related contracts and determining the appropriate classification as debt or equity;
- obtaining an understanding of management's assessment of the most appropriate classification and accounting treatment in accordance with the requirements of IAS 32;
- comparing the accounting policy applied to the requirements of IAS 32;
- assessing the key assumptions used by management in determining the appropriate classification, reading the agreements and comparing the key assumptions to the clauses included in the contracts;
- recalculating an expected value of the warrant reserve, by using an appropriate option-pricing model and comparing this to the amount calculated by management;
- recalculating an expected value of the bifurcation of the total proceeds received and comparing this to the amount calculated by management; and
- examining the disclosures made in the financial statements with respect to significant estimates and judgements made around the conclusion of the classification and valuation of the instruments issued and agreeing these to the requirements of IAS 32.

#### **OUR RESULTS**

Based on our audit work, we are satisfied that the assumptions made in management's assessment of the accounting treatment is in accordance with IAS 32 and that the disclosure given in Note 19 is in accordance with the underlying transactions that occurred during the year.

# Independent Auditor's Report

to the Members of Futura Medical plc

### 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				
MATERIALITY FOR FINANCIAL STATEMENTS AS A WHOLE	We define materiality as the magnitude of misstatement in the financial statements that, individually or in the aggregate, could reasonably be expected to influence the economic decisions of the users of these financial statements. We use materiality in determining the nature, timing and extent of our audit work.				
Materiality threshold	£287,000, which is 4.9% of the group's loss before tax for the year.				
Significant judgements made by auditor in determining materiality	In determining materiality, we made the following significant judgements:				
	<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>				
	Materiality for the current year is higher than the level that we determined for the year ended 31 December 2020 to reflect the increase in the group's loss before tax during the year.				
PERFORMANCE MATERIALITY USED TO DRIVE THE EXTENT OF OUR TESTING	We set performance materiality at an amount less than materiality for the financial statements as a whole to reduce to an appropriately low level the probability that the aggregate of uncorrected and undetected misstatements exceeds materiality for the financial statements as a whole.				
Performance materiality threshold	£200,900, which is 70% of financial statement materiality.				
Significant judgements made by auditor	In determining performance materiality, we made the following significant judgements:				
in determining 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 risk assessment and consideration of the group's control environment.</li> </ul>				
SPECIFIC MATERIALITY	We determine specific materiality for one or more particular classes of transactions, account balances or disclosures for which misstatements of lesser amounts than materiality for the financial statements as a whole could reasonably be expected to influence the economic decisions of users taken on the basis of the financial statements.				
Specific materiality	We determined a lower level of specific materiality for the following areas:				
	<ul> <li>directors' remuneration; and</li> </ul>				
	<ul> <li>related party transactions.</li> </ul>				
COMMUNICATION OF MISSTATEMENTS TO THE AUDIT COMMITTEE	We determine a threshold for reporting unadjusted differences to the audit committee.				
Threshold for communication	£14,400 and misstatements below that threshold that, in our view, warrant reporting on qualitative grounds.				

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

#### OVERALL MATERIALITY



# 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

- Evaluating the group's internal control environment and documenting our understanding of controls relevant to the audit.
- Performing process walkthroughs and documenting, and assessing, 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.

TFPUM: Tolerance for potential uncorrected

FSM: Financial statements materiality

PM: Performance materiality

misstatements

#### 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 performed analytical procedures at group level on the financial statements of Futura Medical Healthcare Limited;
- We identified the treatment of convertible loan note and warrants as key audit matter relating to the group, and the procedures performed in respect of this has been included in the key audit matters section of our report. This key audit matter was addressed by full-scope audit procedures.

#### PERFORMANCE OF OUR AUDIT

- The year-end audit was conducted remotely due to Covid-19 restrictions and social distancing requirements. 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 based on the above strategy.

#### 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.

# Independent Auditor's Report

to the Members of Futura Medical plc

### 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 group financial statements are prepared is consistent with the group 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 its 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:

- 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, the directors are responsible for the preparation of the group 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 group financial statements that are free from material misstatement, whether due to fraud or error.

In preparing the group financial statements, the directors are responsible for assessing the group'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 to cease operations, or have no realistic alternative but to do so.

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

Our objectives are to obtain reasonable assurance about whether the group 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 group 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.

OTHER MATTER

We have reported separately on the parent company financial statements of Futura Medical Plc for the year ended 31 December 2021. That report includes details of the parent company key audit matters; how we applied the concept of materiality in planning and performing our audit; and an overview of the scope of our audit.

#### 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 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 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 group's 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.

# Independent Auditor's Report

to the Members of Futura Medical plc

- ► We 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.
- ► 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.
- 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.

# 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

25 April 2022

# Consolidated Statement of Comprehensive Income

for the year ended 31 December 2021

	Notes	Year ended 31 December 2021 £	Year ended 31 December 2020 £
Revenue	2.4	-	_
Research and development costs		(3,774,269)	(1,927,658)
Administrative costs		(2,092,042)	(1,000,736)
Operating loss	6	(5,866,311)	(2,928,394)
Finance income	8	-	924
Loss before tax		(5,866,311)	(2,927,470)
Taxation recoverable	9	908,600	519,093
Loss for the year being total comprehensive loss attributable to owners of the Parent Company		(4,957,711)	(2,408,377)
Basic and diluted loss per share (pence)	10	(1.83)	(0.99)

All amounts relate to continuing activities.

The Notes on pages 73 to 92 form part of these consolidated financial statements.

# Consolidated Statement of Changes In Equity

for the year ended 31 December 2021

	Notes	Share Capital £	Share Premium £	Merger Reserve £	Other Reserves £	Retained Losses £	Total Equity £
At 1 January 2020		409,321	50,002,990	1,152,165	-	(51,510,824)	53,652
Total comprehensive loss for the year		_	_	_	_	(2,408,377)	(2,408,377)
Share-based payment	17	-	_	—	-	149,364	149,364
Shares issued during the year	16	81,933	2,811,100	_	165,868		3,058,901
Transactions with owners		81,933	2,811,100	-	165,868	149,364	3,208,265
At 31 December 2020		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	17	-	_	-	-	181,822	181,822
Shares issued during the year	16	63,503	11,661,978	-	-	_	11,725,481
Convertible loan notes and warrants	18	_	_	_	118,864	196,909	315,773
Convertible loan notes conversion and warrant exercise	18	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	1,152,165	165,868	(58,545,726)	9,724,612

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 73 to 92 form part of these consolidated financial statements.

## Consolidated Statement of Financial Position

as at 31 December 2021

		As at 31 December 2021	As at 31 December 2020
	Notes	£	£
Assets			
Non-current assets			
Plant and equipment	11	442,657	42,869
Total non-current assets		442,657	42,869
Current assets			
Trade and other receivables	13	79,256	39,790
Current tax asset	9	908,312	518,805
Cash and cash equivalents	14	10,372,571	1,018,601
Total current assets		11,360,139	1,577,196
Liabilities Current liabilities			
Trade and other payables	15	(2,078,184)	(766,525)
Total liabilities		(2,078,184)	(766,525)
Total net assets		9,724,612	853,540
Capital and reserves attributable to owners of the Parent Company			
Share capital	16	574,302	491,254
Share premium		66,378,003	52,814,090
Merger reserve		1,152,165	1,152,165
Other reserves		165,868	165,868
Retained losses		(58,545,726)	(53,769,837)
Total equity		9,724,612	853,540

The consolidated financial statements were approved and authorised for issue by the Board on 25 April 2022.

The Notes on pages 73 to 92 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 2021

	Notes	Year ended 31 December 2021 £	Year ended 31 December 2020 £
Cash flows from operating activities			
Loss before tax		(5,866,311)	(2,927,470)
Adjustments for:			
Depreciation	11	19,808	25,008
Loss on disposal of fixed assets		125	-
Finance income	8	_	(924)
Share-based payment charge	17	181,822	149,364
Cash flows used in operating activities before changes in working capital		(5,664,556)	(2,754,022)
Decrease in inventories		_	7,780
(Increase)/decrease in trade and other receivables		(39,466)	61,401
(Decrease)/increase in trade and other payables	15	1,311,659	(4,080,996)
Cash used in operations		(4,392,363)	(6,765,837)
Income tax received		519,093	2,222,482
Net cash used in operating activities		(3,873,270)	(4,543,355)
Cash flows from investing activities			
Purchase of plant and equipment	11	(419,722)	(8,371)
Interest received		-	924
Cash used in investing activities		(419,722)	(7,447)
Cash flows from financing activities			
Issue of ordinary shares	16	14,319,281	3,270,534
Expenses paid in connection with share issue		(672,319)	(211,632)
Cash generated by financing activities		13,646,962	3,058,902
Increase/(decrease) in cash and cash equivalents		9,353,970	(1,491,900)
Cash and cash equivalents at beginning of year		1,018,601	2,510,501
Cash and cash equivalents at end of year	14	10,372,571	1,018,601

The Notes on pages 73 to 92 form part of these consolidated financial statements.

for the year ended 31 December 2021

## **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 2021.

The consolidated financial statements of the Company and the Group for the year ended 31 December 2021 were authorised for issue by the Board of Directors on 25 April 2022.

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

Notwithstanding a loss for the year ended 31 December 2021 of £4,957,711 the financial statements have been prepared on a going concern basis which the Directors consider to be appropriate for the following reasons. The Board has considered the applicability of the going concern basis in the preparation of the financial statements. This included the review of internal budgets and financial results and a review of cash flow forecasts for the 12 months' period following the date of signing the financial statements. Under current business plans, the Group's cash resources will extend beyond April 2023 (at least 12 months from the date of signing the financial statements).

The Directors have considered scenarios in which commercial launches of MED3000 are delayed compared to base case forecasts. In these circumstances, mitigating actions such as reduction of discretionary research and development costs or selling and marketing expenditure could be taken to preserve cash but that in any event, any significant impact would occur outside of the forecasted period.

The Directors also have a reasonable expectation that the Group will also be able to generate additional revenue streams through entering into further strategic collaborations for the commercialisation of MED3000 in the EU and rest of the world following the conclusion of commercial agreements relating to MED3000 within the Middle East and North Africa, Latin America, China, South East Asia and South Korea with the US expected to follow.

Based on the above factors the Directors believe that it remains appropriate to prepare the financial statements on a going concern basis.

#### 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 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.

for the year ended 31 December 2021

### 2. ACCOUNTING POLICIES (CONTINUED)

#### 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 milestones 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 2021, our customers were 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.

#### **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.

## 2. ACCOUNTING POLICIES (CONTINUED)

### 2.5 LEASED ASSETS (CONTINUED)

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 IT equipment. 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 but not exceeding five years. 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 reduced 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.

#### 2.7 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.

for the year ended 31 December 2021

### 2. ACCOUNTING POLICIES (CONTINUED)

#### 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 (2020: £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.

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.

## 2. ACCOUNTING POLICIES (CONTINUED)

#### 2.10 FINANCIAL INSTRUMENTS (CONTINUED)

#### 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 (2020: £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 de-recognises 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 de-recognition 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.

for the year ended 31 December 2021

### 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 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 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. There was no charge recognised in the year as the milestones and targets were not met.

#### 2.14 FINANCE INCOME

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

#### 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. ACCOUNTING POLICIES (CONTINUED)

#### 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.

## 3. CRITICAL ACCOUNTING JUDGEMENTS, ASSUMPTIONS AND ESTIMATES

The preparation of the consolidated financial statements in conformity with IFRS requires management to make certain estimates, assumptions and judgements that affect the application of accounting policies and the reported amounts of assets and liabilities and the reported amounts of income and expenses in the year. Critical accounting estimates, assumptions and judgements are continually evaluated by the Directors based on available information and experience. As the use of estimates is inherent in financial reporting, actual results could differ from these estimates. No significant estimates were identified during the year. Other estimates are disclosed below.

#### **3.1 ESTIMATES AND ASSUMPTIONS**

#### 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 £181,822 (2020: £149,364), 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 17.

#### Valuation of convertible loan notes

The fair value of the liability component of the convertible loan notes was calculated using the prevailing market interest rate for a similar non-convertible instrument being 10%.

#### Valuation of warrants

Warrant instruments were measured at fair value using Black-Scholes model. The following inputs were used for the model:

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

for the year ended 31 December 2021

## 3. CRITICAL ACCOUNTING JUDGEMENTS, ASSUMPTIONS AND

**ESTIMATES** (CONTINUED)

### **3.2 JUDGEMENTS**

#### 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 18. 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 reverses therefore decreasing retaining losses by the same amount.

#### Deferred tax recognition

The determination of probable future profits, against which the Group's deferred tax profits can be offset, requires judgement. To date no deferred tax assets have been recognised.

#### R&D tax credits

The current tax receivable as disclosed in Note 9, 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 are required to make a judgement about certainty of commercial success of their 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 judgment 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, including other inputs into the Black-Scholes model, are disclosed in Note 18.

## 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 2021 or at 31 December 2020.

### 4. FINANCIAL RISK (CONTINUED

#### 4.1 FINANCIAL RISK FACTORS (CONTINUED)

At 31 December 2021, the Group held balances of the following denominated currency:

		Year ended 31 December 2021 £	Year ended 31 December 2020 £
GBP	£	9,163,871	941,818
EUR	€	19,514	7,072
USD	\$	1,608,363	96,127

The majority of operating costs are denominated in Sterling although certain expenditures were payable in Euros and US Dollars. At 31 December 2021 the Group had trade payables denominated in a foreign currency totalling £751,499 (31 December 2020: £34,217).

#### 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 2021 £	31 December 2020 £
Cash at bank and in hand	10,372,571	644,729
Sterling short-term money market funds	-	373,872
	10,372,571	1,018,601

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.

	Carrying amount £	2 months or less £	2 – 12 months £	More than 1 year £
31 December 2021				
Trade and other payables	2,078,184	2,078,184	_	_
Deposit liability	109,435	_	109,435	-
	2,187,619	2,078,184	109,435	-

for the year ended 31 December 2021

### 4. FINANCIAL RISK (CONTINUED)

### 4.1 FINANCIAL RISK FACTORS (CONTINUED)

	Carrying amount £	2 months or less £	2 – 12 months £	More than 1 year £
31 December 2020				
Trade and other payables	766,525	766,525	-	-

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 policy is to maintain a strong capital base. 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 £10,372,571 of cash at bank as at 31 December 2021 (31 December 2020: £1,018,601) and short-term money market funds £nil (2020: 373,872).

## 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 2021 £	Year ended 31 December 2020 £
Depreciation of plant and equipment (Note 11)	19,808	25,008
Loss on disposal of plant and equipment	125	-
Short-term leases: property	116,194	116,714
Gain on foreign exchange	39,664	18,840

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

Audit services	Year ended 31 December 2021 £	Year ended 31 December 2020 £
Parent Company	58,612	43,500
Subsidiaries	17,505	7,500
Tax services		
Parent Company	-	-
Subsidiaries	-	-
Other non-audit services		
iXBRL Tagging	1,133	1,000
Total fees	77,250	52,000

## 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 2020
R&D staff	7	8
Finance and Administration staff	1	2
Executive Directors	3	3
	11	13

The aggregate payroll costs of these persons were as follows:

	Year ended 31 December 2021 £	Year ended 31 December 2020 £
Wages and salaries	1,730,007	1,598,473
Social security costs	243,125	154,829
Other pension and insurance benefits costs	151,912	163,910
Total cash-settled emoluments	2,125,044	1,917,212
Share-based payment remuneration charge	181,822	149,364
Total emoluments	2,306,866	2,066,576

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

Directors' emoluments	Year ended 31 December 2021 £	Year ended 31 December 2020 £
Aggregate emoluments	1,040,075	912,209
Other pension and other benefit costs	22,776	22,968
Subtotal per Remuneration Report	1,062,851	935,177
Share-based payment remuneration charge	97,503	47,866
Employer's national insurance charge	142,846	77,222
Total emoluments	1,303,200	1,060,265

In 2021 there were no Directors whose share options were exercised under the Group share option schemes and no gain was realised (2020: £nil). In respect of the highest paid Director the realised gain was £nil (2020: £nil).

In 2021 there were no Directors (2020: 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.

for the year ended 31 December 2021

## 7. STAFF NUMBERS AND COSTS (CONTINUED)

Emoluments on the previous page include the following amounts in respect of the highest paid Director:

	Year ended 31 December 2021 £	Year ended 31 December 2020 £
Aggregate emoluments	353,341	306,658
Employer pension contributions and other benefits	3,517	2,652
Subtotal per Remuneration Report	356,858	309,310
Share-based payment remuneration charge	37,501	18,410
Employer's national insurance charge	56,388	32,266
Total emoluments	450,747	359,986

## 8. FINANCE INCOME

Interest receivable in 2021 on treasury funds was £nil (2020: £924).

## 9. TAXATION

### 9.1 CURRENT TAX

	Year ended	Year ended
31	l December	31 December
	2021	2020
	£	£
UK corporation tax credit on loss on ordinary activities	908,600	519,093

The tax assessed for the year was lower than the UK corporation tax rate (2020: lower). The differences are explained below:

	Year ended 31 December 2021 £	Year ended 31 December 2020 £
Loss on ordinary activities before tax	5,866,311	2,927,470
Loss on ordinary activities at an average standard rate of corporation tax in the UK of 19% (2020: 19%)	1,114,599	556,220
Expenses not deductible for tax purposes	(124)	(6)
Unrecognised deferred tax	(37,824)	(37,213)
Unutilised tax losses	(616,719)	(224,744)
Share scheme deduction	58,780	-
R&D expenditure credit	-	(1,036)
Loss surrendered for refund	(282,562)	(159,728)
Additional relief for R&D claims	674,326	381,186
UK corporation tax credit	910,476	514,679
Adjustment to tax charge relating to prior period	(1,876)	(288)
R&D expenditure credit re 2020	-	4,474
R&D expenditure credit re 2021	-	-
UK corporation tax credit reported in the Consolidated Statement of Comprehensive Income	908,600	518,805

### 9. TAXATION (CONTINUED)

#### 9.1 CURRENT TAX (CONTINUED)

The Group has tax losses of approximately £35,694,575 (2020: £32,448,687) available for offset against future taxable profits.

The corporation tax credit for the year represents research and development tax credits of £910,476 (2020: £514,679), arising from the surrender of losses (rather than carrying forward to future years) of £6,279,145 (2020: £3,549,507) 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 (2020: £4,414).

#### 9.2 DEFERRED TAX

Deferred tax assets amounting to £9,502,702 (2020: £6,575,569) 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. As a result, the opening asset not recognised is stated at 19% but the unrecognised asset at 31 December 2021 has been calculated assuming a prevailing rate when the timing differences reverse of 25% (2020: 19%). The unrecognised asset comprises of:

	Year ended 31 December 2021 £	Year ended 31 December 2020 £
Depreciation differential versus capital allowances	(9,576)	(496)
Other short-term timing differences	588,004	410,814
Unutilised tax losses	8,823,644	6,165,251
	9,502,072	6,575,569

### **10. LOSS PER SHARE**

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

	2021	2020
Loss for the purposes of basic EPS and diluted EPS (£)	4,957,711	2,408,376
Weighted average of ordinary shares for purposes of basic and diluted EPS (number)	271,046,179	243,721,303
Loss per share basic and diluted (pence)	1.83	0.99

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 6,642,800 (2020: 7,295,000). 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.

for the year ended 31 December 2021

## 11. PLANT AND EQUIPMENT

	Computer	Furniture	
Cost	Equipment £	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

Cost	Computer Equipment £	Furniture and Fittings £	Total £
At 1 January 2020	119,338	63,285	182,623
Additions	8,371	_	8,371
At 31 December 2020	127,709	63,285	190,994
Depreciation			
At 1 January 2020	66,745	56,373	123,118
Charge for year	23,594	1,414	25,008
At 31 December 2020	90,339	57,787	148,126
Net book value			
At 31 December 2020	37,370	5,498	42,868
At 31 December 2019	52,593	6,912	59,505

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

## 12. 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 2021 £	31 December 2020 £
Trade and other receivables (Note 13)	7,547	16,067
Cash and cash equivalents (Note 14)	10,372,571	1,018,601
Total financial assets at amortised cost	10,380,118	1,034,668

## 12. FINANCIAL INSTRUMENTS BY CATEGORY (CONTINUED)

	31 December	31 December
	2021	2020
Liabilities as per Consolidated Statement of Financial Position at amortised cost	£	£
Trade and other payables (Note 15)	981,392	182,900
Total financial liabilities at amortised cost	981,392	182,900

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

## 13. TRADE AND OTHER RECEIVABLES

Amounts receivable within one year:	31 December 2021 £	31 December 2020 £
Trade receivables	7,547	5,627
Other receivables	-	10,440
Financial assets (Note 12)	7,547	16,067
Prepayments	71,709	23,723
	79,256	39,790

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.

## 14. CASH AND CASH EQUIVALENTS

	31 December 2021 £	31 December 2020 £
Cash at bank and in hand	10,372,571	644,729
Sterling short-term money market funds	-	373,872
	10,372,571	1,018,601

## **15. TRADE AND OTHER PAYABLES**

	31 December 2021 £	31 December 2020 £
Trade payables	981,392	182,900
Social security and other taxes	281,766	64,092
Deposit liability	109,435	-
Accrued expenses	705,591	519,533
	2,078,184	766,525

The increase in payables is reflective of the increased activity relating to research and development activities in comparison to the prior year.

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## 16. SHARE CAPITAL

Authorised	31 December	31 December	31 December	31 December
	2021	2020	2021	2020
	Number	Number	£	£
Ordinary shares of 0.2 pence each	500,000,000	500,000,000	1,000,000	1,000,000
Allotted, called up and fully paid	31 December	31 December	31 December	31 December
	2021	2020	2021	2020
	Number	Number	£	£
Ordinary shares of 0.2 pence each	287,150,971	245,626,926	574,302	491,254

The number of issued ordinary shares as at 1 January 2020 was 204,660,267. During the year ended 31 December 2020, 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 2020	Non-Executive Director Share Award	20,534	341,659
January 2020	Subscription and PrimaryBid Offer	3,250,000	40,625,000
		3,270,534	40,966,659

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

## **17. SHARE OPTIONS**

At 31 December 2021, 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 2021 Number	Options Exercised Number	Options Lapsed Number	Options Granted Number	At 31 December 2021 Number
1 October 2016 – 30 September 2021	51.75	480,000	_	(480,000)	-	-
1 October 2017 – 30 September 2022	30.00	600,000	(250,000)	-	-	350,000
1 October 2018 – 30 September 2023	57.50	810,000	_	(80,000)	-	730,000
1 October 2019 – 30 September 2024	30.50	990,000	(460,000)	(30,000)	-	500,000
1 October 2020 – 30 September 2025	7.50	1,240,000	(360,000)	(30,000)	-	850,000
7 January 2020 – 6 January 2029	7.20	212,500	(212,500)	-	-	_
31 August 2020 – 6 January 2029	7.20	212,500	(212,500)	-	-	_
1 October 2021 – 30 September 2026	31.00	1,250,000	(80,000)	(30,000)	-	1,140,000
1 October 2022 – 30 September 2027	15.50	1,500,000	-	(192,000)	-	1,308,000
1 October 2023 – 30 September 2028	37.90			(66,000)	1,654,800	1,588,800
		7,295,000	(1,575,000)	(908,000)	1,654,800	6,466,800

On 5 October 2021 share options over 1,654,800 new ordinary shares were granted to employees (including Executive Directors) at a price of 37.90p. The options have a two-year vesting period and the exercise period for these options is 1 October 2023 to 30 September 2028.

The share options outstanding at 31 December 2021 represented 2.25% of the issued share capital as at that date (2020: 2.97%) and would generate additional funds of £1,899,295 (2020: £1,939,700) if fully exercised. The weighted average remaining life of the share options outstanding at 31 December 2021 was 55 months (2020: 56 months) with a weighted average remaining exercise price of 29.36 pence (2020: 29.04 pence).

The share options exercisable at 31 December 2021 totalled 3,570,000 (2020: 4,545,000) with an average exercise price of 31 pence (2020: 26.04 pence) and would have generated additional funds of £1,094,400 (2020: £1,319,700) if fully exercised.

The Group's share option scheme rules apply to 6,620,000 of the share options outstanding at 31 December 2021 (31 December 2020: 6,720,000) 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 100,000 share options outstanding to advisers at 31 December 2021 (31 December 2020: 575,000).

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.

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## 17. SHARE OPTIONS (CONTINUED)

### SHARE-BASED PAYMENTS

Inputs to share option pricing model	31 December 2021	31 December 2020
Grant date	5 October	21 September
Number of shares under option	1,654,000	1,500,000
Share price as at date of grant	37.90 pence	14.72 pence
Option exercise price	37.90 pence	15.5 pence
Expected life of options: based on previous exercise history	3 years	3 years
Expected volatility: based on median fluctuations over 3 years	121.14%	104.96%
Dividend yield: no dividends assumed	0%	0%
Risk-free rate: yield on 3-year treasury stock as at date of grant	0.75%p.a.	0.05%p.a.
Outputs generated from share option pricing model	31 December 2021	31 December 2020

Outputs generated from share option pricing model	2021	2020
Fair value per share under option	25.26p	9.24p
Total expected charge over the vesting period	£418,002	£138,600

Recognised in Consolidated Statement of Comprehensive Income	31 December 2021 £	31 December 2020 £
The share-based remuneration charge comprises:		
Share-based payments – employees	48,646	19,104
Share-based payments – consultants	-	-
Share-based payments	48,646	19,104

The total expense recognised for the year arising from share-based payments is as follows:

	31 December 2021	31 December 2020
	£	£
Group equity-settled share-based payment expense	181,822	149,364

## 18. CONVERTIBLE LOAN NOTES AND WARRANT INSTRUMENT

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 £0.20 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 £0.22 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 £0.22 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.

On 20 January 2020, Futura Medical plc issued a warrant instrument 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. 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:

	31	
Inputs to warrant pricing model	December 2021	31 December 2020
Grant date	4 March	21 January
Number of warrants	2,272,727	10,937,500
Share price as at date of grant	16.50 pence	12.75 pence
Warrant conversion price	22 pence	40 pence
Expected life of warrants	1 Year	5 years
Expected volatility	105.8%	81.56%
Dividend yield: no dividends assumed	0%	0%
Risk-free rate	0.41% p.a	0.44% p.a.

## **19. PENSION COSTS**

The pension charge represents contributions payable by the Group to independently administered funds which during the year ended 31 December 2021 amounted to £135,670 (2020: £128,161). Pension contributions payable in arrears at 31 December 2021, included in accrued expenses at the relevant Consolidated Statement of Financial Position date, totalled £32,299 (2020: £18,948).

for the year ended 31 December 2021

## 20. COMMITMENTS

At 31 December 2021 the Group had operating lease commitments in respect of property leases cancellable on one month's notice of £9,963 (2020: £9,802).

## **21. INVESTMENTS**

During the year 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 have 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 have concluded that the initial cost of investment was £nil (Note 3.2).

## 22. 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.

# Independent Auditor's Report

to the Members of Futura Medical plc (Parent Company)

### OPINION

## OUR OPINION ON THE PARENT COMPANY FINANCIAL STATEMENTS IS UNMODIFIED

We have audited the parent company financial statements of Futura Medical Plc for the year ended 31 December 2021, which comprise 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 United Kingdom Accounting Standards, including Financial Reporting Standard 101 'Reduced Disclosure Framework' (United Kingdom Generally Accepted Accounting Practice).

In our opinion, the parent company financial statements:

- ▶ give a true and fair view of the state of the parent company's affairs as at 31 December 2021;
- have been properly prepared in accordance with United Kingdom Generally Accepted Accounting Practice; and
- ▶ 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 parent company financial statements' section of our report. We are independent of the parent company in accordance with the ethical requirements that are relevant to our audit of the parent company 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.

## CONCLUSIONS RELATING TO GOING CONCERN

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 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 parent company to cease to continue as a going concern. Our evaluation of the directors' assessment of the parent company'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 2023. The parent company is not a trading company and is reliant on the support of the group to be able to continue as a going concern. Our assessment of the group's ability to continue as a going concern included 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 feasibility of securing new revenue contracts and the likely timing and quantum of outlay of expenditure and challenging management where necessary;
- assessing the impact of not achieving expected revenue and evaluating the impact if no revenue was generated. We considered whether the assumptions are consistent with our understanding of the business and other audit work undertaken;
- assessing the accuracy of management's past forecasting by comparing management's future forecasts modelled in the prior year to the actual results for the current 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; and
- assessing the adequacy of related disclosures within the annual report and accounts.

## Independent Auditor's Report

to the Members of Futura Medical plc (Parent Company)

In our evaluation of the directors' conclusions, we considered the inherent risks associated with the company's business model including effects arising from macro-economic uncertainties such as Brexit and Covid-19, we assessed and challenged the reasonableness of estimates made by the directors and the related disclosures and analysed how those risks might affect the company's financial resources or ability to continue operations over the going concern period.

Based on the work we have performed, we have not identified any material uncertainties relating to events or conditions that, individually or collectively, may cast significant doubt on the parent company's ability to continue as a going concern for a period of at least twelve months from when the financial statements are authorised for issue.

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.

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

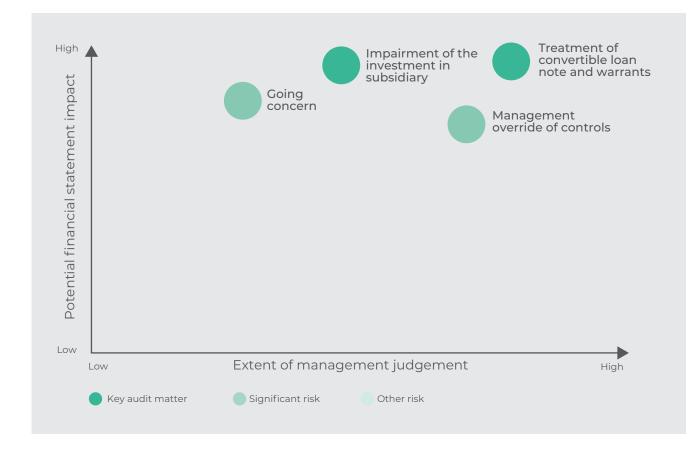


## **KEY AUDIT MATTERS**

Key audit matters are those matters that, in our professional judgement, were of most significance in our audit of the parent company 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 parent company 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.





## Independent Auditor's Report

to the Members of Futura Medical plc (Parent Company)

#### **KEY AUDIT MATTER**

## TREATMENT OF CONVERTIBLE LOAN NOTE AND WARRANTS

We identified the treatment of convertible loan note and warrants as one of the most significant assessed risks of material misstatement due to error.

During the year a £1.5m convertible loan note and warrants were issued and converted to equity, with total proceeds received from the warrants exercised of £0.5m.

The convertible loan note and warrants are accounted for in accordance with International Accounting Standards (IAS) 32 'Financial instruments: Presentation'. The process for determining the accounting treatment and classification of these financial instruments is complex and requires significant management judgement to be applied including bifurcation the total proceeds received from the transaction between the separate financial instruments issued.

#### HOW OUR SCOPE ADDRESSED THE MATTER

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

- obtaining an understanding and assessing the design and implementation of the group's processes and relevant controls relating to: identification of related contracts and determining the appropriate classification as debt or equity;
- obtaining an understanding of management's assessment of the most appropriate classification and accounting treatment in accordance with the requirements of IAS 32;
- comparing the accounting policy applied to the requirements of IAS 32;
- assessing the key assumptions used by management in determining the appropriate classification, reading the agreements and comparing the key assumptions to the clauses included in the contracts;
- recalculating an expected value of the warrant reserve, by using an appropriate option-pricing model and comparing this to the amount calculated by management;
- recalculating an expected value of the bifurcation of the total proceeds received and comparing this to the amount calculated by management; and
- examining the disclosures made in the financial statements with respect to significant estimates and judgements made around the conclusion of the classification and valuation of the instruments issued and agreeing these to the requirements of IAS 32.

### RELEVANT DISCLOSURES IN THE ANNUAL REPORT AND ACCOUNTS 2021

- Financial statements: Note 2.3, Note 3 and Note 19 of the consolidated financial statements.
- Audit committee report.

#### **OUR RESULTS**

Based on our audit work, we are satisfied that the assumptions made in management's assessment of the accounting treatment is in accordance with IAS 32 and that the disclosure given in Note 19 is in accordance with the underlying transactions that occurred during the year.

#### **KEY AUDIT MATTER**

## 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 2021 was £58.4m. 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.

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.

#### HOW OUR SCOPE ADDRESSED THE MATTER

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. In prior years an internal auditor expert was used to assist in the impairment assessment. We confirmed that in the current year there had been no significant changes in the objectives of the group, nor any significant changes in the target industry of the MED3000 medical device. 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.
- corroborating the key inputs used in support of the key underlying assumptions to relevant supporting documentation;
- 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
- 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'

#### **OUR RESULTS**

Based on our work we concluded that management's judgement that no impairment was required as at 31 December 2021 was reasonable.

## Financial statements: Note 2Audit committee report.

**RELEVANT DISCLOSURES IN THE** 

**ANNUAL REPORT AND ACCOUNTS 2021** 

## Independent Auditor's Report

to the Members of Futura Medical plc (Parent Company)

### 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.

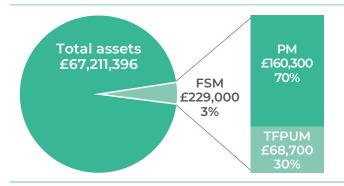
Materiality was determined as follows:

### MATERIALITY MEASURE PARENT COMPANY

MATERIALITY FOR FINANCIAL STATEMENTS AS A WHOLE	We define materiality as the magnitude of misstatement in the financial statements that, individually or in the aggregate, could reasonably be expected to influence the economic decisions of the users of these financial statements. We use materiality in determining the nature, timing and extent of our audit work.				
Materiality threshold	£229,000, which represents 0.3% of total assets.				
Significant judgements	In determining materiality, we made the following significant judgements:				
made by auditor in determining materiality	<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>				
	<ul> <li>This has been restricted to be lower than group materiality as it is a component of the group.</li> </ul>				
	Materiality for the current year is higher than the level that we determined for the year ended 31 December 2020 to reflect the increase in group materiality.				
PERFORMANCE MATERIALITY USED TO DRIVE THE EXTENT OF OUR TESTING	We set performance materiality at an amount less than materiality for the financial statements as a whole to reduce to an appropriately low level the probability that the aggregate of uncorrected and undetected misstatements exceeds materiality for the financial statements as a whole.				
Performance materiality threshold	£160,300, which is 70% of financial statement materiality.				
Significant judgements made by auditor in	In determining performance materiality, we made the following significant judgements:				
determining performance materiality	<ul> <li>our experience with auditing the financial statements in previous years including the number of misstatements identified; and</li> </ul>				
	• our risk assessment and consideration of the company's control environment.				
SPECIFIC MATERIALITY	We determine specific materiality for one or more particular classes of transactions, account balances or disclosures for which misstatements of lesser amounts than materiality for the financial statements as a whole could reasonably be expected to influence the economic decisions of users taken on the basis of the financial statements.				
Specific materiality	We determined a lower level of specific materiality for the following areas:				
	<ul> <li>directors' remuneration; and</li> </ul>				
	<ul> <li>related party transactions.</li> </ul>				
COMMUNICATION OF MISSTATEMENTS TO THE AUDIT COMMITTEE	We determine a threshold for reporting unadjusted differences to the audit committee.				
Threshold for communication	£11,500 and misstatements below that threshold that, in our view, warrant reporting on qualitative grounds.				

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

#### **OVERALL MATERIALITY**



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 parent company's business and in particular matters related to:

## UNDERSTANDING THE PARENT COMPANY, ITS ENVIRONMENT, INCLUDING CONTROLS

Evaluating the parent company's internal control environment, documenting controls relevant to the audit and performing process walkthroughs and documenting, and assessing, the relevant controls covering the Key Audit Matters and certain other risks in the financial reporting system identified as part of our risk assessment.

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

➤ We identified the treatment of convertible loan note and warrants and impairment of investment in the subsidiary as key audit matters relating to the parent company, and the procedures performed in respect of this has been included in the key audit matters section of our report.

#### PERFORMANCE OF OUR AUDIT

► The year-end audit was conducted remotely due to Covid-19 restrictions and social distancing requirements. This was supported through the use of software collaboration platforms for the secure and timely delivery of requested audit evidence.

#### 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, 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 parent company financial statements, our responsibility is to read the other information and, in doing so, consider whether the other information is materially inconsistent with the parent company 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 parent company 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.

## Independent Auditor's Report

to the Members of Futura Medical plc (Parent Company)

## 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 parent company financial statements are prepared is consistent with the parent company 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 parent company and its 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, the directors are responsible for the preparation of the parent company 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 parent company financial statements that are free from material misstatement, whether due to fraud or error.

In preparing the parent company financial

statements, the directors are responsible for assessing the 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 parent company or to cease operations, or have no realistic alternative but to do so.

### AUDITOR'S RESPONSIBILITIES FOR THE AUDIT OF THE PARENT COMPANY FINANCIAL STATEMENTS

Our objectives are to obtain reasonable assurance about whether the parent company 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 parent company financial statements.

A further description of our responsibilities for the audit of the parent company 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 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 and United Kingdom Generally Accepted Accounting Practice, together with the QCA Corporate Governance Code and the AIM Rules for Companies. We obtained an understanding of how the Futura Medical Plc 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 parent company's 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;

- We 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 parent company operate; and
  - understanding of the legal and regulatory requirements specific to the parent company.

### OTHER MATTER

We have reported separately on the group financial statements of Futura Medical Plc for the year ended 31 December 2021. That report includes details of the group key audit matters; how we applied the concept of materiality in planning and performing our audit; and an overview of the scope of our audit.

## 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

25 April 2022

## Parent Company Balance Sheet

As at 31 December 2021

Company No. 04206001

		As at 31 December 2021		
	Notes	£	£	
Fixed assets				
Investment	2	58,427,010	53,616,120	
Current assets				
Debtors – due within one year	3	10,764	9,934	
Total debtors		10,764	9,934	
Cash at bank and in hand		8,773,622	410,417	
		8,784,386	420,351	
Creditors: amounts falling due within one year	4	(210,934)	(123,127)	
Net current assets		8,573,452	297,224	
Net assets		67,000,462	53,913,344	
Capital and reserves				
Called up share capital	5	574,302	491,254	
Share premium account		66,378,003	52,814,090	
Warrant reserve		165,868	165,868	
Profit and loss account		(117,711)	442,132	
Shareholders' funds		67,000,462	53,913,344	

The loss in respect of the Company for the year was £741,665 (2020: £385,969). The Parent Company financial statements were approved and authorised for issue by the Board on 25 April 2022.

The Notes on pages 104 to 106 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 2021

	Note	Share Capital £	Share Premium £	Other Reserves £	Retained Losses £	Total Equity £
At 1 January 2020		409,321	50,002,990	-	678,737	51,091,048
Total comprehensive loss for the year		-	_	_	(385,969)	(385,969)
Share-based payment		_	_	_	149,364	149,364
Shares issued during the year	5	81,933	2,811,100	165,868	-	3,058,901
Transactions with owners		81,933	2,811,100	165,868	149,364	3,208,265
At 31 December 2020		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 notes and warrants		_	_	118,864	196,909	315,773
Convertible loan note conversion and warrant exercise		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

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 104 to 106 form part of these Parent Company financial statements.

## Notes to the Parent Company Financial Statements

## **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 £741,665 (2020: £385,969). 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 EU 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.

## 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 monthend (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. This conclusion requires judgement and if regulatory approval of MED3000 in the US is rejected, this could result in material impairment.

	£
At 1 January 2020	50,178,526
Additions in the year	3,437,594
At 31 December 2020	53,616,120
Additions in the year	4,810,890
At 31 December 2021	58,427,010

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 2021 £	31 December 2020 £
Amounts receivable within one year: prepayments	10,764	9,934

## Notes to the Parent Company Financial Statements

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

	31 December 2021	31 December 2020
Tur de eus ditesse	±	£
Trade creditors	95,200	· · · · ·
Accruals	115,734	56,915
	210,934	123,127

## 5. CALLED UP SHARE CAPITAL

Authorised	31 December	31 December	31 December	31 December
	2021	2020	2021	2020
	Number	Number	£	£
Ordinary shares of 0.2 pence each	500,000,000	500,000,000	1,000,000	1,000,000
Allotted, called up and fully paid	31 December	31 December	31 December	31 December
	2021	2020	2021	2020
	Number	Number	£	£
Ordinary shares of 0.2 pence each	287,150,971	245,626,926	574,302	491,254

Details of shares issued by the Company in the year and details of share options outstanding are given in Notes 16 and 17 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 Jonathan Freeman

Non-Executive Chairman Chief Executive Officer Finance Director and Chief Operating Officer Executive Director Non-Executive Director<sup>1</sup> Non-Executive Director<sup>2</sup>

### COMMITTEE MEMBERS SERVING THROUGHOUT THE YEAR WERE:

#### AUDIT COMMITTEE

Jonathan Freeman John Clarke

### SECRETARY AND **REGISTERED OFFICE**

Angela Hildreth Futura Medical plc Surrey Technology Centre 40 Occam Road Guildford Surrev GU27YG

### NOMINATED ADVISER AND BROKER

Liberum Capital Limited 25 Ropemaker Street London EC2Y 9LY

## **PRINCIPAL BANKER**

HSBC Bank 12A North Street Guildford GUI 4AF

## REMUNERATION COMMITTEE

Jonathan Freeman John Clarke Jeff Needham

### AUDITOR

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

PATENT ATTORNEY

Withers & Rogers LLP 2 London Bridge Road

London

SE19RA

### NOMINATIONS COMMITTEE

John Clarke Jonathan Freeman

## REGISTRAR

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

### **PUBLIC RELATIONS ADVISER**

Optimum Strategic Communications 8 Devonshire Square Spitalfields London EC2M 4PL

1. Appointed 8 October 2021

2. Appointment ended 31 December 2021



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